
Rediscovering the Value of Intellectual Property Rights

*How Brazil's Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth **

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Abstract

The industrializing economy of Brazil possesses many favorable competencies and capabilities owing to its cultural diversity, its growing technological know-how, and its expanding entrepreneurial class. It also boasts a number of intellectual property-rich companies in the life sciences and information and communication technology sectors whose capacity for innovation has yet to be exploited. Brazil, however, suffers from a deficit in core human capital and lacks a market-friendly enabling environment that incorporates strong intellectual property right protections. These deficiencies have largely

prevented Brazil from developing the cutting-edge indigenous know-how and commercial innovations that could dramatically improve Brazil's future scientific, technological and economic growth prospects.

Unable to resolve its national dilemma itself, the Government of Brazil, has worked alongside numerous developing countries and activist civil society organizations within multiple international fora to promote a new global knowledge paradigm. Such paradigm discounts the value of private intellectual property rights in promoting innovation, and calls for scientific and technology-based knowledge and information, and the commercialized products and processes derived from it, to become, as a matter of international law, universally accessible, open source', and essentially free of charge' to emerging and developing economies, i.e., public international goods'.

The following article documents Brazil's efforts and then disputes the various rationales advanced by proponents of this new anti-private intellectual property paradigm. It emphasizes how patents and trade secrets are forms of exclusive private property which are entitled to legal protection as inalienable constitutional, civil and human rights. It also shows how patents and trade secrets are economically valuable assets that are important to both foreign and domestic investors, especially, knowledge and technology-rich internationally-focused companies, and explains why the Government of Brazil should aggressively seek to protect them. This article, furthermore, analyzes numerous studies that collectively describe how the establishment of a market-friendly enabling environment that includes strong enforcement of intellectual property rights will enable Brazil to attract the research and development-related foreign direct investment and technology transfers, and to realize numerous other incidental spillover benefits, that will dramatically improve its domestic industries, enhance its educational and health systems and satisfy its national innovation needs.

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I. INTRODUCTION - BRAZIL MUST CHOOSE THE RIGHT PATH: INNOVATION vs. OPPORTUNISM

The Purpose of this White Paper

The purpose of this article is to reintroduce the notion of private property rights into the current global debate about the utility of intellectual property (IP) in promoting scientific and technological invention and innovation.¹ This article argues that, if the Government of Brazil reexamined the elements of and rationale underlying the international recognition of private property rights, including intellectual property rights (IPRs) (i.e., patents, trade secrets, copyrights, etc.) it would see how it could dramatically improve Brazil's future scientific, technological, and economic prospects. This article also argues that, based on the successes experienced in other countries that have rediscovered the value of intellectual property rights, the Brazilian government would inevitably be able to promote the indigenous innovation, domestic entrepreneurship, foreign direct investment, and R&D-related technology transfers necessary to catapult Brazil to national and international advancement.

This article, furthermore, explains how, by choosing to proceed down the opportunistic open source'/ universal access path of development, which eschews the concept of private property, including privately held IPRs, in favor of plentiful and cheap public knowledge, Brazil risks the success of its own IP-rich domestic industries. These include mostly small and medium-sized enterprises, many of which rely on know-how and innovation to survive and flourish. In addition, this article explains how governmental failure to strike the right balance between private and public property rights when designing a national innovation system can actually jeopardize the very public goods - knowledge, technology, human health, environmental protection and poverty alleviation (i.e., economic freedom^{2 3 4} as well as political freedom) - that open source/universal access methods cannot possibly provide.

Moreover, this article describes the significant and indispensable role that private IPRs and innovation have played in the history of national industrialization and development. It also cites the important distinctions between the individual-centric (American) and state-centric (Europe-Japan-China-India) innovation systems that Brazil must consider as it reevaluates its policy options. Although there is historical precedent upon which Brazil apparently relies to justify its opportunistic IP behavior, the previous international order that fostered such conduct no longer exists, and the former protagonist nations themselves have since been in the process of politically and economically evolving. Indeed, the more respectful of private property rights and law-abiding emerging and developing economies in Asia, Latin America and the Middle East have become, the greater the prosperity and access to healthcare and knowledge their citizens have enjoyed.

Brazil Promotes a New Global Paradigm that Favors IP Opportunism

The Brazilian Government has undertaken a number of provocative activities internationally within intergovernmental fora to challenge the established global system that protects exclusive private property rights, including intellectual property rights (IPRs), championed by the developed nations of the Organization of Economic Cooperation and Development (OECD). These fora include the WTO, WHO, WIPO, UNCHR, UNDP, UNEP and UNESCO.^{5*} There, Brazil has assumed a leading role in helping to promote a new global paradigm that calls for the current high technology, knowledge and information-based digital era to become universally accessible, open source, and essentially free of charge to developing countries – i.e., public international goods. Brazil, along with a growing chorus of developing nations, activists and self-proclaimed new social and environmental thinkers, has alleged that such an IPR-counter paradigm is consistent with an expansive notion of sustainable development (SD).^{6 7} Brazil has opportunistically defined itself, for these purposes, as a developing country.

Sustainable development,⁸ as defined in this context, is premised on the need to secure continuous international science and technology IP transfers⁹ at concession rate prices.¹⁰ Anti-market, anti-private property and anti-WTO advocates, and increasingly, American internationalists, believe that this is necessary in order to prevent the emergence of extreme economic, scientific, technological and social disparities and popular backlashes against globalization that will likely threaten international peace and security.^{11 12 13 14 15} These advocates also claim that such actions are called for within the Millennium Development Agenda goals so that developing countries

may liberate themselves from endemic poverty and ultimately achieve economic and social parity with the developed world.¹⁶ In other words, 'sustainable development', a concept originally articulated almost twenty years ago, has since been effectively hijacked and shaped, by politically astute social, health and environmental activists and socialist-minded government bureaucrats, into a *negative* anti-development, anti-market, anti-private property and anti-WTO doctrine, largely modeled after the European welfare state.¹⁷ Many such individuals have long been able to influence policymaking in Europe and the United Nations, even without fully understanding science, technology, economics or trade.¹⁸

However, recent research has shown how the pursuit of such a negative paradigm of sustainable development actually harms rather than helps developing country prospects for scientific, technological and economic advancement.¹⁹ And, prior research, as well, performed by famous French author and historian Alexis de Tocqueville, recognized how exclusive private property ownership in 19th century America held a positive and taming influence over the dark forces of revolution and war which had then plagued continental Europe.²⁰

Evidently, the Government of Brazil has been influenced and encouraged by the populist campaigns waged by developing nation governments and utopian-minded social and environmental activist groups (the modern-day revolutionaries') that are aimed at (intended to ingratiate) the common people' - the underprivileged (poverty-stricken) masses. Comprised of mostly political and economic socialists, activist nongovernmental organizations (NGOs), and anti-private property and anti-free market academics,^{21 22 23} these groups are well skilled in manipulating public opinion and the organs of the United

Nations to promote an alternative global framework that minimizes private property ownership rights and the role of neo-liberal economics'. Brazilian politicians are also, to some extent, observing the current political debates within the U.S. over patent system reform^{24 25 26 27} and concerning the utility of the current regulatory framework by which hi-tech industries commercialize U.S. federally funded university-based R&D.^{28 29 30} Their goal is to exploit these debates in order to undermine exclusive U.S. private property rights both domestically *and* abroad.^{31*32 33}
^{34**}Unfortunately, these crosscurrents have generated more policy conflict than consensus among the various expert groups within the Government of Brazil. One may even speculate that this lack of consensus has emboldened Brazil's ruling party to promote a culture of political and economic opportunism within Brazil - intended to mask internal Brazilian systemic deficiencies - that has now transcended national boundaries.³⁵

Brazil's Innovation Conundrum

The industrializing economy of Brazil possesses many favorable competencies and capabilities owing to its cultural diversity, its growing technological know-how, and its expanding entrepreneurial class. As with any new global power, Brazil has its own national interests at heart when it participates in the international arena and seeks to influence international policymaking. Yet, it also speaks increasingly for the member nations of the developing world from which it has largely emerged. This is as much an honor as it is a serious responsibility.

Brazil is a country rich in entrepreneurial spirit, economic growth opportunities, and natural resources. However, it lacks the core human capital^{36 37 38}(to invent) *and* a market-friendly enabling environment that incorporates strong

IPRs (market-based incentives to innovate), and this has largely impaired its ability to develop the indigenous know-how *and* the commercial innovations³⁹ that will maintain and improve Brazil's international economic and technological competitiveness during the twenty-first century.⁴⁰ This deficit in human capital, namely, education,⁴¹ has presented Brazil with a major challenge as it endeavors to become a world power in its own right and a spokesperson for the developing world. Brazil also has other unsustainable domestic spending priorities that compromise its national healthcare and knowledge dissemination policies. It has become increasingly apparent that, in order to remedy its internal problems, Brazil has helped to design an updated new international economic order⁴² for all developing economies.

The Government of Brazil has recently focused on two key policy areas - global information technology and global health to help promote the public international good of global knowledge. It has articulated a national and international position concerning each of these areas that speaks at one-and-the-same time about the benefits to society of creating scientific and technological know-how and innovation, and about the need to make that know-how universal and accessible to all at least cost. However, within its own borders, the Brazilian government has been unable to identify the mechanism that will enable it to convert Brazil's indigenous know-how into a form that may be used as a sustainable engine of national and international economic growth.

To remedy its national knowledge deficit, the Government of Brazil recently enacted a national technical innovation law. Its objective is to promote public-private collaborations for basic research and development and product/process commercialization between Brazil's well-

recognized public research institutes and universities and the various sectors of Brazilian industry, especially its entrepreneurs. Unfortunately, the new Brazilian innovation law does not incorporate the key elements of the successful U.S. innovation system based on the Bayh-Dole Act of 1980. Instead, it borrows from prior failed state-centric innovation models. Most importantly, there does not appear to be a legal and economic mechanism to transfer, on an *exclusive* basis, the knowledge generated as the result of public, private, or public-private R&D collaboration efforts, to private companies for the purpose of market commercialization. There is also no evidence that the know-how, once transferred to and transformed by Brazilian companies into useful products and service innovations, and the associated revenue streams, would be considered *exclusive private property* deserving of protection under Brazilian domestic law.

Private Property and the Established International Order

Clearly, the age-old tension between what is and should be private versus public property (i.e., as concerns both tangible assets and intangible know-how) and how governments should protect and regulate each, is central to Brazil's current dilemma. Political debates over property rights continue to arise in numerous countries throughout the world.⁴³ Such debates have taken place, for example, in China,^{44 45 46} India, France,^{47 48 49 50 51 52 53} Finland, Norway and Sweden,^{54 55} the EU,⁵⁶ and the US.⁵⁷ Typically, they result from objections raised by ex-communists, newly reconstituted socialists⁵⁸, environmental extremists, trade protectionists, and/or health care and open-source technology activists whom are dissatisfied with their lack of economic success, influence or opportunities.⁵⁹ Their prescribed antidote is to reverse the process of globalization, and to secure, at both the

national and international levels, greater public welfare benefits at the expense of private interests – i.e., they favor a stated public policy of societal parity over societal progress.⁶⁰ In some countries, including Brazil, such groups have exacerbated the division between these two forms of property ownership, and have called for the imposition of more regulation, both nationally and internationally, to redefine and limit how science, technology and industrial (IP) know-how should be generated, accessed and utilized.⁶¹

Obviously, each nation possesses the sovereign right to choose how to balance these two types of property ownership, including transcendental human knowledge and creativity. However, that right is subject to the well established international principles of law, economics and politics (the ‘international order’) institutionalized⁶² by the Bretton Woods System – the International Monetary Fund, the World Bank, General Agreement on Tariffs and Trade (1948 and 1994) and World Trade Organization (WTO), and the United Nations System (UN). The international order was conceived following World War II, and has since, been successfully maintained by the United States and other OECD members. Its primary objective continues to be the preservation of international peace and security through economic liberalization and trade.

While this order may have some objectionable features, as has been pointed out, time and again, by the nations of Europe, and increasingly by Brazil and Argentina as they speak up on behalf of the developing world it can, nevertheless, be argued that it has been, and continues to be, an overwhelming success. It has created the greatest sustained engine of international economic growth and prosperity, improved human health and education, and technological innovation the world has ever known.⁶³ As

complex and elaborate as it has become, this order has remained, nonetheless, flexible enough to permit provisional derogations upon demonstration of genuine national needs and exigencies. Most notable among these, are the issues of abject poverty, and the potentially serious, health (epidemic and pandemic) and environmental risks that are determined, as a matter of empirical science, to result from technological advancement. In each of these situations, government policymakers employ principles of equity and risk management to govern the development, use and deployment of innovations and technologies, as circumscribed by legal, scientific, and economic frameworks designed to balance societal and individual interests.⁶⁴

As noted, the established international order and the institutions⁶⁵ that support it are strongly rooted in the recognition and protection of strong private property rights, adherence to the rule of law, benchmarked objective science and economic cost-benefit analysis, and continuous incentive-based technological innovation. Together, these principles have reinforced the universally accepted proposition that private property, economic growth, industrialization, innovation and trade are good things in themselves and must be promoted and preserved.

The fundamental purpose of property rights, and their fundamental accomplishment, is that they eliminate destructive competition for control of economic resources. ***Well-defined and well-protected property rights replace competition by violence with competition by peaceful means*** (emphasis added).⁶⁶

This result is not only desirable, but also essential, because these mechanisms also constitute perhaps the only remedy to the poverty, ill health and environmental degradation that pervades developing nations and threatens peace.

Poverty, not trade, is the underlying cause of worker exploitation and environmental degradation in developing countries. These social ills are symptoms of a disease for which trade is the cure, not the cause. In the long run, the single best way to encourage developing countries to enforce workers' rights and protect the environment is to transform them into middle-income countries. Freer trade is an important mechanism through which the United States can assist in alleviating global poverty, because it provides an engine for economic growth in the developing world. Trade increases economic growth in developing countries; growth reduces poverty and its concomitant social ills.

Trade expansion directly and indirectly promotes democratic values by pushing countries toward policies that are compatible with democracy. ***For free trade to yield the greatest economic gain, governments must acquire a healthy respect for economic freedom, the rule of law, and well-defined property rights.*** These attributes are prerequisites of a functioning liberal democracy. *Trade also contributes to greater income growth in poorer countries.*

*By increasing economic growth, trade liberalization facilitates democratization, as wealthy countries are more likely to have stable democratic regimes. Among political scientists, it is a truism that freer trade, combined with international organizations and democratic institutions, reduces violent interstate conflict. **Some studies go further, arguing that it is economic freedom itself that reduces the likelihood of war** (emphasis added).⁶⁷*

A basic definition of property can help to elucidate the relationship between persons and things.

It determines the rights that persons have in things. Typically, the existence of such rights is predicated on two factors: (1) whether the person has sufficient ability to control possession, use, and transferability of the thing; and (2) whether the underlying policies of the law are furthered by bestowing property rights on the thing. When a person has the unrestricted right to possess, use, and transfer a thing, it is granted property status and the person is the owner of the thing. When a person has no rights of possession, use, and alienation, the thing is denied property status, and it becomes part of the public domain. If the right to possess, use, and transfer a thing is within these two extremes, the determination of whether to grant or withhold property status must be based on what will further the

underlying policies of the relevant body of law. This conclusion is supported by the numerous things that are granted property status despite the existence of limitations and restrictions on the possession, use, or transferability of the thing.
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Property is described rather broadly for this purpose. It includes tangible natural assets and resources, especially raw land and converted real estate, as well as, manmade structures and personal assets. Each type of tangible property can be properly managed for both private *and* public benefit, given the right incentives.

In addition, property also has increasingly encompassed intangible human know-how, ideas and creativity (intellectual property) that can and inevitably do lead to inventions and incremental *and* breakthrough innovations that benefit both individuals AND society.⁶⁹

There are two basic underlying policies of intellectual property law. The first is to secure for the public the benefits of intellectual property. *Granting property status to ideas provides an incentive for innovators to develop new ideas by giving the innovator the right to control use of the idea. As a result, the public will gain the benefit of the idea because economic motives will spur the innovator to share it with the public.* The second policy underlying intellectual property law is to regulate and manage competition. Innovators should be entitled to monetary gain from their ideas. Nevertheless, the control of ideas is inimical to a free society

because it may allow monopolization of ideas. Therefore, *intellectual property law attempts to regulate or manage competition by granting or withholding property status*. Thus regulation strikes a balance between rewarding a person for intellectual achievement and the societal importance of maintaining marketplace competition. ***The granting of property status to ideas is consistent with the basic definition of property*** (emphasis added).⁷⁰

An individual's right to own and enjoy real and personal property, including intellectual property (IP), and the inventions and innovations derived from it, to the exclusion of all others, has had historical, moral and philosophical significance both before^{71 72} and after the development of 18th century English common law.⁷³ Since that time, the U.S. Constitution and its accompanying Bill of Rights have recognized such a right in property as one of the most fundamental, inalienable and liberating of all *natural and civil rights* guaranteed to U.S. citizens.^{74 75 76*} Since 1948, this right has also been recognized and defined as a fundamental and inalienable *human right*.⁷⁷ In addition, since 1992, the Constitution of the independent and sovereign Republic of Mongolia, within its Chapter 2 entitled Human Rights and Freedoms and Article 16 entitled Citizens' Rights, expressly provides for the protection of exclusive private property rights, including patents and copyrights.⁷⁸

The Brazilian Government has undertaken a number of provocative acts nationally and internationally that jeopardize this fundamental right, each of which strongly

signals an intention to indirectly take foreign (including U.S.) patents and trade secrets for Brazilian public use without just compensation'. Both the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)^{79 80} and the World Intellectual Property Organization (WIPO)⁸¹ Agreement recognize and protect exclusive individual private property rights, as do the Universal Declaration of Human Rights and other international instruments.^{82 83 84 85}

Exclusive Private Property Rights are Essential for Innovation

One of the key features of private property is its exclusive nature.

A property right is the *exclusive* authority to determine how a resource is used, whether that resource is owned by government or by individuals... Private property rights have two other attributes in addition to determining the use of a resource. One is the *exclusive* right to the services of the resource... That is the right to the services of the resources (the rent)... Finally, a private property right includes the right to delegate, rent, or sell any portion of the rights by exchange or gift *at whatever price the owner determines* (provided someone is willing to pay that price)... Thus, the three basic elements of private property are (1) *exclusivity* of rights to the choice of use of a resource, (2) *exclusivity* of rights to the services of a resource, and (3) rights to exchange the resource at

mutually agreeable terms
(emphasis added).⁸⁶

Ideas that can be exclusively possessed, used, and transferred by a person are granted property status. Once control of an idea is lost to the public, property status ends. The concept of novelty has been developed to determine whether a person has control of an idea. If a person develops a new idea that is not generally known, the idea is novel and potentially subject to property status. This result is consistent with the basic definition of property because it recognizes that an idea that is both new and not generally known can be controlled by its creator. Likewise, an idea which is not new or is generally known cannot be controlled by an individual; hence, it is not appropriate subject matter for property status (emphasis added).⁸⁷

There is now growing recognition, due to the leading work of Latin American economist Hernando De Soto, that exclusive private tangible real property ownership is fundamental to the operation of capitalism. In addition, there is also a greater understanding of how real property's formal recognition and protection in law can bring many intangible economic and societal benefits (economic as well as political freedom) to developing country citizens – i.e., once land and improvements thereto have been legally titled, registered, collateralized and exchanged and enforced in courts of law.⁸⁸ According to Dr. De Soto,

We were told that there is something about the Latin American culture that is not compatible with capitalism. We don't see that... it's not that poor, post-communist countries don't have the assets to make capitalism flourish... [rather, it]... is that such countries have yet to establish and normalize the invisible network of laws that turns assets from dead into liquid capital.^{89 90}

Given the success of Dr. De Soto's Latin American real property title registration and enforcement program, developing country citizens should expect even greater economic and social benefits to flow from formal government recognition, and enforcement in law of personal intangible (intellectual) property ownership. In other words, the premise underlying Hernando De Soto's work with real property is equally applicable and analogous to intellectual property. At least one legal expert agrees with this position.

De Soto's argument largely focuses on real property, but it applies to intellectual property with equal force. A vast amount of intellectual capital in the developing world is underdeveloped.⁹¹

This is especially important if developing countries are to emerge from poverty during the fast-paced science, technology, and information-based age in which we now live.

Unlike tangible property which tends to be finite as to size and use (what economists refer to as rival goods),

however, intangible property, such as ideas, expressions and know-how, has no such boundaries. Intangible property, comprised of ideas, especially know-how, is essentially limitless - limited only by human imagination and the ability of national and international policymakers to understand, embrace, and harness it for individual and societal ends. Since know-how, which economists now refer to as a non-rival good,⁹² has already become, in many ways, the new global engine of future scientific, technological, and economic growth, it should be managed prudently.

The World Bank's recently released *Doing Business 2007* report⁹³ seems to corroborate Dr. De Soto's thesis and experience. With respect to Brazil, in particular, it found that Registering property in many Brazilian states is difficult in comparison with the rest of Latin America. In the 12 states and the Federal District, an entrepreneur spends on average 61 days and 3.5% of the property value to register property.⁹⁴ According to the Bank's accompanying *Doing Business in Brazil 2007* report, these and other statistical indicators led the Bank to rank Brazil 17[th] out of 22 countries in Latin America... This poor showing foreshadowed Brazil's less than stellar performance in the Bank's overall global ease of doing business rankings: 121 out of 175 countries evaluated - i.e., Brazil was only in the 31st percentile.⁹⁵

Given the conceptual parallels between real property and intangible property registrations, and the actual findings of Dr. De Soto and the World Bank concerning the relationship between business' economic performance and the cost and efficiency of government real property registration systems, one must conclude that Brazil's inefficient real property registration system is a *negative* harbinger of its IP registration system. Indeed, this white

paper discusses, in later sections, how various technological, economic and social problems have flowed from Brazil's troubled IP registration and protection/enforcement systems.

Experts agree that there is nothing to prevent the Government of Brazil and its local industries from creating and commercializing their own indigenous know-how. However, Brazil must first accept that there is a more efficient and socially appealing way to do so – through recognition and vigorous enforcement of IPRs. Brazilian citizens are, certainly, not any less inventive than those living in OECD countries, and consequently, the Brazilian government should not adopt policies that assume that they are.

If people seem to be more inventive in the United States or Europe or Japan, it is not an accident. It is not because of genes or schooling or intelligence or fate. Implementation of the intellectual property system is critical because of the habit of mind which is fostered in the population. Human ingenuity and creativity are not dispersed unevenly across the globe. Those talents are present in every country. In some, unfortunately, the enabling infrastructure of effective intellectual property protection is missing.⁹⁶

Arguably, the current (albeit imperfect) U.S. intellectual property rights framework that covers patents, copyrights and trademarks memorializes the most successful balance thus far struck between private and public intangible property rights. Many of its key features are contained

within the provisions of the W T O 's T R I P S A g r e e m e n t and the WIPO Agreement. TRIPS, however, also borrowed certain of its language from the competing frameworks of other countries, including the member states of the European Union and other OECD members, which incorporate a number of civil society championed flexibilities. At the very least, both the U.S. and the EU frameworks recognize society's need to foster individual as well as collective experimentation and discovery, as a matter of human nature and societal necessity. Moreover, they each acknowledge that significant emotional and economic costs will be incurred and capital, technological, and human resources expended incident to the innovation process, which not all people are willing or able to bear.

The U.S. and EU frameworks, however, have tended to diverge according to the extent that they reward inventors and innovators for the investment risks they have undertaken, and this tension is now being felt at the WTO and other international fora. In exchange for bearing such risks, the U.S. IPR system, in particular, rewards inventors, innovators and their financial sponsors and co-venturers with a temporary market monopoly (exclusivity).^{97 98} Such an incentive is designed to allow them to not only recoup their out-of-pocket costs for basic research, but also to recoup their costs and profit from the commercialization of their inventions, for a limited legally protected period of time. It is understood, that the fruits of their labors will diffuse throughout and benefit society overall as the innovations they have created become incorporated and embedded bit, by bit, into everyday products, services and activities, that will eventually serve as the seeds of tomorrow's new inventions.

The EU and its member states, however, have embraced a less private property-centric approach to rewarding

innovation, and that has had an increasingly negative impact on the innovation potential of European pharmaceuticals, biotechnology,⁹⁹ computer software, and information and communication technology sectors. For example, Europe's relatively weaker^{100 101} but more expensive^{102 103} IPR protections circumscribed by *civil law* notions of 'ordre public', equity and morality,^{104 105} freedom of expression and human rights,¹⁰⁶ overly restrictive regulatory policies, and mandatory price caps, more or less, favor public interests over private interests, and this has had a serious chilling effect on national and regional innovation and competitiveness. In addition, such policies have strengthened the political influence of national socialist parties and civil society activist organizations, which have increasingly demanded institutionalization of what were once purely academic notions (open source and universal access information technology and health care). In response to these growing anti-private property and anti-free market movements, a growing number of European-based multinational companies have shifted their research and development facilities and innovation activities to other nations with laws more favorable to and protective of private property. The U.S. has been the primary beneficiary of such capital flows.^{107 108} Predictably, the European Commission has responded by urgently reforming its regional and global policies concerning R&D investment and innovation in order to stem industry flight and the accompanying brain drain.

The Government of Brazil has observed these negative European developments, and it is aware that America's lead in innovation and technology development has continued to provide its industries and citizens with a significant competitive advantage over their international counterparts. Yet, Brazil continues to embrace and promote

policies that threaten the individual private property rights of both foreign *and* domestic investors, in the hope of securing illusory state benefits.¹⁰⁹ Of particular concern, is the Brazilian government's adoption of the populist doctrines of 'free and open source' (FOS) and universal access as national policy.

Brazil Must Choose the Right Path

These external and internal forces have arguably led the Brazilian government to challenge the carefully negotiated international trade rules found within the TRIPS Agreement that it, along with other WTO members, previously agreed to uphold. They have also led the Government of Brazil to threaten the exclusive private property holdings of the very same internationally focused companies that, along with Brazilian domestic small and medium-sized businesses, develop and produce the technologies and know-how upon which Brazil now depends for its present and future innovation and welfare. And, it is doing so believing that it is in compliance with the WTO TRIPS Agreement and the WIPO Agreement. According to at least one expert, however, it is not only what Brazil *says* it is doing concerning IPRs, as evidenced by its IPR legislation, that counts; rather, it is also how the investment community perceives what Brazil is *actually* doing, as measured by its IPR enforcement.

... [S]ome in Brazil express the view that basically the country has a good intellectual property system ... This view is plausible because it is common to assess protection in terms of specific statutory provisions. This misses the importance of overall marketplace effect as the critical test of an intellectual property

system. The test of whether protection is weak or not is determined by the net marketplace effect of the interrelated parts of an entire system. *More precisely, it is determined by people's decisions made in reaction to the system. A lack of confidence in the system is a primary indicator of weakness* (emphasis added).¹¹⁰

If the Brazilian government's conduct continues without reevaluation, it will dampen foreign and Brazilian industry enthusiasm for investment in research and development, discourage international and Brazilian commercialization of technological innovations, undermine the established international order and thus extinguish any future opportunity for Brazil and its industries to secure economic growth based on technological advancement.¹¹¹ Americans and other OECD country citizens also stand to lose from Brazil's persistent efforts to undermine the existing global IPR regime. At the very least, America's ability to continue functioning as the engine of global scientific and technological innovation and economic growth will be significantly jeopardized,¹¹² and, its long-held advantages in international trade and innovation and the GDP and living standards of its citizens will likely be significantly reduced.¹¹³ Indeed, one recent economic study estimates that,

the current value of the intellectual property that embodies... U.S. ideas... from computer software and musical recordings to patented pharmaceuticals and information technologies... is worth between \$5 trillion and \$5.5 trillion, equivalent to about 45 percent of U.S. GDP

and greater than the GDP of any
other nation in the world.^{114 115}

Brazil is clearly at a crossroads. As an emerging economy and an aspiring regional^{116 117} and global¹¹⁸ power possessing great potential, it is obliged to exercise prudence and responsibility in its international affairs. It has the option of following the proven path towards innovation and economic growth, or of riding populist appeals down the slippery slope of IP opportunism. It is time for the Brazilian government to transcend its IP identity crisis and evolve - to choose the right path for the benefit of both its citizens and the world, before it is too late.

II. BRAZIL CHALLENGES THE ESTABLISHED GLOBAL IPR FRAMEWORK

A. BRAZIL ACTIVELY ENGAGES IN REGIME SHIFTING TO REFORM INTERNATIONAL IP LAW

The Notion of Regime-Shifting

Brazil and other developing countries that have become dissatisfied with the WTO TRIPS Agreement and the American capitalist economic model of risk and reward¹¹⁹ which serves as the basis for the current international intellectual property framework, are now employing, with the assistance of a well funded global civil society (activist NGOs), a strategy known as regime shifting¹¹⁹. International environmental and human rights activists enamored of the socialist model of sustainable development have already used this strategy successfully in other venues.¹¹⁹ NGOs, for one, have proposed to curtail intellectual property

rights in one international forum after another, whether or not IP was the main issue: the WTO, WIPO, UNESCO's proposed Convention on Cultural Diversity, the UN's World Summit for the Information Society, the WHO, and others.¹²⁰ Brazil et al. have engaged in regime shifting despite the overall mutual and balanced concessions they agreed to and the specific IPR-related bargains they reached previously at the Uruguay Round of trade negotiations leading to the consummation of the WTO Agreements. And they are doing so under the guise of 'harmonizing' international law.

These protagonists hope to reform WTO law from within *and* to develop simultaneously new customary international law norms beyond the WTO regime that can eventually swallow up the general principles, norms, and rules that comprise the corpus of WTO IP law. In other words, if the international community of nations permits regime shifting to occur, the temporary and provisional exceptions and derogations (e.g., compulsory licensing) to the general rule of strong intellectual property right protection made expressly available in the TRIPS Agreement will ultimately overtake and subsume the general rule.^{121 122 123 124*} This would result in the establishment of a new treaty-based presumption *against* the adoption of strong international IP protections, along with a reversal of the burden of proof to show harm – from the party challenging IP protections to the party defending them. Thus, higher standards of [IP] protection... [would] only [be allowed] when it is clearly necessary... and where the benefits outweigh the costs of protection.¹²⁵ Arguably, the ostensible public health and knowledge goals that Brazil and other nations, such as Argentina, assert as being the primary motivation behind such regime shifting, are likely overshadowed by their more ambitious but less transparent economic and trade policy (protectionist) objectives. More importantly,

however, opportunistic activities like these further challenge international confidence in the foundations of GATT-WTO law, increase transaction costs, raise international political and economic tensions and only weaken the resolve of nations to pursue international trade, scientific and technological advancement to eradicate poverty and to maintain international peace and security – the original goal of the Bretton-Woods system.^{126 127}

According to one international law expert, IPR regime shifting has essentially entailed the

shift[ing of] negotiations and hard and soft lawmaking initiatives [from the TRIPS Agreement] to four [other] international legal regimes – those governing biodiversity, plant genetic resources, public health and human rights – whose institutions, actors, and subject matter mandates are more closely aligned with these countries' interests. Within these four regimes, developing countries are questioning established legal prescriptions and generating new principles, norms, and rules of intellectual property protection for states and private parties to follow. Intellectual property regime shifting thus heralds the rise of a more complex international environment in which seemingly settled treaty bargains are contested and new dynamics of lawmaking and dispute settlement must be considered.¹²⁸

He explains, furthermore that, regimes are broader than specific treaties or organizations... [and]... reflect[] the

fact that states (and, increasingly, non-state actors) can cooperate without creating formal institutions or legally binding commitments.¹²⁹

Substantively speaking, regimes consist of principles, norms and rules. In the context of IPRs,

The principles... include recognition of state-created private property in abstract intangible objects that embody human innovation and creativity and the need to protect that property from unauthorized exploitation across national borders. The norms... include an obligation for states to create legal monopolies (in the form of exclusive rights controlled by private parties) that generate incentives for human innovation and creativity and to allow foreign creators and inventors to market their products in different national jurisdictions on equal footing with local creators and inventors... [The]... rules encompass the specific prescriptions and proscriptions by which these principles and norms are given effect, such as the most favored nation and national treatment rules, specific exclusive rights and minimum standards of protection, and coordinated procedural mechanisms or priority rules.¹³⁰

International regimes also have an institutional component. They consist of the cooperative arrangements states use to create principles, norms and rules, and can range from highly structured intergovernmental organizations with

staffs, facilities and budgets to informal networks of government officials who exchange information and coordinate national policies with each other.¹³¹

Regime rules often flow from power politics and reflect the national interests of stronger and more influential states. Yet, power alone does not determine how international regimes subsequently evolve. Intergovernmental organizations and international institutions have played an increasing role in limiting the actions of stronger and more influential states. This has afforded weaker states and non-state actors greater latitude to influence the development of principles, norms and rules.¹³² Consequently, the distributions of power among different nations present at the inception of a given regime are not likely to serve as a good predictor of how that regime will later evolve.¹³³

Indeed, relatively weaker states such as Brazil, may lead other less developed countries, together with non-state actors (i.e., nongovernmental organizations (NGOs), activists, etc.) to deliberately alter the status quo ante by moving treaty negotiations, lawmaking initiatives or standard setting activities from one international venue to another through a process known as ‘forum shopping’. For example,

A powerful state unable to realize its objectives through treaty negotiations may shift to domestic lawmaking and enact rules with extraterritorial effects that have much of the same effect. Similarly, states may operate in multiple domestic and international for a, moving back and forth between venues... or pursuing parallel lawmaking agendas simultaneously.¹³⁴

Alternatively, or in addition thereto, weaker states and non-state actors may endeavor to alter the substantive principles, norms and rules of a particular regime by generating counter-regime norms – binding treaty rules and non-binding soft law standards that seek to alter the prevailing legal landscape.¹³⁵

Disadvantaged actors may articulate counter-regime norms that only incrementally modify existing rules but leave uncontested the broader principles from which these rules emanate. A state or an NGO might, for example, object to treaty obligations that require recognition of specific types of patentable subject matter or that narrow exceptions or limitations to a patentee's exclusive rights without questioning the broader goals that a patent system serves. *In other instances, counter-regime norms may be revolutionary rather than evolutionary, posing more fundamental challenges to underlying principles.* [States and non-state actors that] question the economic and social benefits of granting intellectual property rights to foreign creators and inventors are asserting norms that fall into this latter category (emphasis added).¹³⁶

States and non-state actors may affect change through proposals or amendments within the regime whose principles, norms, and rules they are challenging, or they may decide to shift to a different regime altogether in the event they encounter significant resistance. This decision

usually entails a comparative analysis of the participating states and their level of influence, the lawmaking methods, the monitoring and dispute settlement procedures, and the relative roles of intergovernmental institutions and nongovernmental organizations.¹³⁷ Since many of the same state and non-state actors may participate in multiple regimes simultaneously, once-distinct regimes have grown interdependent over time, and regimes no longer focus singularly on isolated well-defined issues, regime shifting has become anything but an orderly process. To the contrary, it has become more difficult to ascertain a given regime's boundaries, and thus, to decide whether to shift regimes at all.¹³⁸

IPR Regime Shifting from TRIPS to UNHRC and WHO

The WHO, an intergovernmental organization, has been responsible for creating principles, norms, and rules concerning the subject of public health. Its norm building activities have focused during the past thirty years on pharmaceuticals. It introduced the concept of 'essential drugs' and urged its member nations to adopt national drug policies'. The WHO first became concerned with intellectual property rights during 1996. This followed the enactment of the WTO TRIPS Agreement, which imposed expanded obligations on states to protect pharmaceutical patents.¹³⁹ Since that time, it has produced several resolutions and a guidebook that recommends to developing countries how to exploit the flexibilities contained within the TRIPS Agreement.

Since 1996, WHO has closely monitored the implementation of TRIPS, advising WHO member states on ways to achieve their national health goals by making use of so-called 'safeguards' already in

TRIPS that grant flexibility to balance intellectual property protection against public health objectives. *Brazil*¹⁴⁰, South Africa, and Zimbabwe, together with public health NGOs... were *the principal catalysts for WHO's critical review of TRIPS*.

The review commenced... with a resolution request[ing] a report on the work of the WTO with respect to national drug policies and essential drugs and ma[de] recommendations for collaboration between WHO and WTO, as appropriate.' This resolution led to the publication in 1998 of a WHO-sponsored guide to the public health consequences of TRIPS. *The guide recommended that states make use of flexibilities already contained in TRIPS – including its transition periods, parallel importation rules, and compulsory licensing provisions – to minimize the effects of pharmaceutical patents on limiting the availability of essential drugs*. It also advocated that developing countries establish a joint position vis-à-vis these hotly debated questions' (emphasis added).¹⁴¹

Although the U.S. and EU objected to the guidebook's language and were unsuccessful in thwarting its publication, they were, nevertheless, able to delete certain inflammatory language within a subsequent 1999 WHO General Assembly resolution. Prior to their efforts, the language had highlighted the negative impact of new world trade agreements on... the issues of access to and

prices of pharmaceuticals in developing countries and urged states to ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies.¹⁴²

However, they could not prevent Brazil and other developing nations from later shepherding such language into a controversial 2001 UN human rights resolution (2000/7)¹⁴³ for strategic regime-shifting purposes.¹⁴⁴ That resolution declared that, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement and international human rights law, and sought to establish the primacy of human rights obligations over economic policies and agreements' (i.e., property rights). To this end, it called upon NGOs¹⁴⁵, governments and a host of intergovernmental organizations, including the WHO, the UNDP and the UNEP, to undertake a critical examination of TRIPS.¹⁴⁶

Developed countries, particularly those in the European Community, opposed ceding to the WHO competence to review health-related intellectual property issues. However, they later softened their position as the HIV/AIDS crisis worsened. This position reversal later proved very costly, as the WHO adopted an approach that has since been skeptical of intellectual property rights, though somewhat less critical than the more aggressive approach adopted by those UN human rights bodies in which Brazil actively participated.

The WHO approach has also set forth suggestions on how states may reconcile competing WTO/WHO regime objectives.¹⁴⁷

A March 2001 bulletin explains the essential elements of WHO policy. The bulletin accepts that

patents create necessary incentives for the development of new drugs, *but* questions whether those incentives are adequate to ensure investment in medicines needed by the poor. *With respect to pharmaceutical patents, the bulletin emphasizes that essential drugs are different than other commodities*, and it advocates the use of TRIPS-compliant mechanisms¹⁴⁸ to lower drug prices and increase their availability. These mechanisms include the full spectrum of safeguards¹⁴⁸ that TRIPS makes available, including patent eligibility standards which reflect public health concerns¹⁴⁸, legislation authorizing compulsory licensing [and] exceptions to exclusive rights,¹⁴⁸ extension of TRIPS transition periods, and the parallel importation of a patented drug from countries where it is sold more cheaply¹⁴⁸. Finally, the bulletin recommends against implementing TRIPS-plus intellectual property protection standards (such as standards more stringent than those mandated by TRIPS) and urges governments to monitor the implementation of TRIPS to formulate comprehensive proposals for reviewing the treaty in the future (emphasis added).

During May 2003, the WHO adopted a resolution recommending the creation of a new body to evaluate the impact of intellectual property protections on the development of new drugs and to issue a report analyzing its findings. This analysis was to have focused on intellectual property rights, innovation, public health, and

the appropriate funding and incentive mechanisms deemed necessary to promote the development of new drugs and other products that were disproportionately required by developing countries. The resolution also urged all members to reaffirm that public health interests are *paramount* in both health and pharmaceutical policies¹⁴⁹ and to consider whenever necessary adapting national legislation in order to use to the full the flexibilities contained in [TRIPS]¹⁵⁰ (emphasis added). Brazil was the lead developing country in this effort, arguing that, access to new medicines must not be impeded by patent protection¹⁵⁰.

One international law expert believes that the efforts made by Brazil and other developing countries to expand the scope of the WHO's jurisdiction to include health *and* intellectual property issues did not reflect an attempt to roll back IPR protections. He contends, rather, that they were intended to heighten member governments' recognition of the flexibilities already inherent within the TRIPS Agreement.

These events reveal that developing states and public health NGOs have used the WHO not as a forum for rolling back intellectual property protection standards, but rather as a venue for advocating the use of flexibilities already embedded within TRIPS... [T]his approach to reconciling the public health and intellectual property regimes strongly influenced the negotiating strategy adopted by developing states seeking to reaffirm their right to invoke TRIPS safeguards when confronted by public health crises. The result was the Public Health Declaration

adopted by WTO members as part
of the launch of the Doha round of
trade negotiations...¹⁵¹

The problem with this expert's analysis, however, is that Brazil and its fellow complainants have not stopped there. Contrary to his assertion, it would seem that Brazil and developing countries are most definitely seeking to roll-back intellectual property protection anyway they can!¹⁵²

During May 2004, for example, they proposed and adopted another WHO resolution which took account of and expanded upon the prior 2003 resolution noted above. It urged members states as a matter of priority... to consider whenever necessary to adapt legislation in order to use to the full the flexibilities contained in the [TRIPS Agreement and]...to encourage that bilateral trade agreements [an allusion to U.S. TRIPS-plus' FTA provisions] take into account the flexibilities in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement on Public Health.¹⁵³

Furthermore, during January 2006, the governments of Kenya and Brazil were finally able to secure the ear of the WHO Executive Board, which set forth for consideration a new proposed resolution¹⁵⁴ emphasizing the primacy of human rights obligations over economic policies and agreements' (i.e., property rights). In other words, Brazil was ultimately successful in shifting regimes – moving the prior 2001 resolution it had advanced within the UN Human Rights Sub-commission on the Promotion and Protection of Human Rights and Intellectual Property Rights, into the WHO.

Three very questionable assumptions underlie the draft resolution's many points. First, IPRs are not necessary to

promote innovation since most drug approvals are for medicines that do not provide incremental benefits over existing ones.¹⁵⁵ Second, IPRs are [only] one of several important tools to promote innovation, creativity and the transfer of technology... Third, a proper balance [must be provided] between IPRs and the public domain and IP rules... need to [be]... implement[ed] in a manner that is consistent with the fundamental right of every human being to the enjoyment of the highest attainable standard of health and the promotion of follow-on innovation.¹⁵⁶

The draft resolution sought to change substantially the model of financing research and development for new essential medicines, and to limit the role that intellectual property rights would ultimately serve in such activities. The draft resolution also made reference to all four of the prior intellectual property right-related resolutions¹⁵⁷ noted previously, and called for the consideration of alternative simplified systems for protection of intellectual property ‘which may provide greater incentives for research and development efforts and investments than the current system.’^{158 159 160 161}

The alternative simplified IP systems referred to within this draft resolution are likely borrowed ‘from the utopian archetypes provided by anti-free market, anti-IP HIV/AIDS activists,^{162 163*} who, as a matter of ideology,¹⁶⁴ advocate the abandonment of drug patents in favor of a more government-centralized and state socialized system of R&D and healthcare¹⁶⁵ requiring a massive redistribution of global wealth. They call for,

Radically altering the intellectual property rights environment for new drugs. *The scheme eliminates patent protection for pharmaceuticals* so that new drugs

are sold at generic prices immediately after regulatory marketing approval. R&D is financed via a tax or tax-like mechanism that is required to raise predetermined amounts at the national level. The national global R&D budgets are determined according to a [proposed medical R&D] treaty^{166 167 168} and are a fixed percentage of a nation's Gross Domestic Product (GDP) (emphasis added).¹⁶⁹

Anti-private property and anti-free market academics and politicians, as well, have weighed in with their own alternatives.

*On innovation grounds, pharmaceutical patents are unnecessary in low income populations, since such markets cannot do much to support global pharmaceutical profits. The public health needs of low income populations require patented drugs to be made produced at the marginal cost of production, without R&D cost recovery. Nonrival access to pharmaceutical knowledge achieves both goals simultaneously (emphasis added).*¹⁷⁰

In addition, the activist community has submitted still, other alternatives. They include,

1) A proposal.. for a mandatory employer-based research fee to be distributed through intermediaries to researchers (Love/Nader 2003);

2) A proposal for zero-cost compulsory licensing patents, in which the patent holder is compensated based on the rated quality of life improvement generated by the drug, and the extent of its use (Hollis 2004); 3) A proposal for an auction system in which the government purchases most drug patents and places them in the public domain (Kremer 1998). [Hay and Zammit (2002) suggest a variant of the Kremer auction system, in which only patents that are especially important for public health (e.g. an AIDS vaccine) are put up for auction and bought by the government. Under this system, many drug patents would remain privately held, with drugs sold in the same manner as they are now]; and 4) A proposal to finance pharmaceutical research through a set of competing publicly supported research centers (Kucinich 2004);¹⁷¹ and 5) (Love/Nader 2005) A proposal to establish a ... Medical Innovation Prize Fund... a[n] evidenced-based system ... that would provide huge rewards for the development of new drugs...¹⁷²

Suffice it to say, that the academics who have promoted these alternatives are anything but objective with respect to private property rights and the current patent and R&D systems.¹⁷³ In fact, at least one such academic has proposed a legislative amendment to the U.S. Bayh-Dole Act¹⁷⁴ that would impose a public interest limitation on intellectual property rights created as the result of federally funded basic research and development. In addition, he has

suggested that the U.S. government surrender national sovereignty to the W H O : delegate power to the W H O or some equivalent [international] organization to issue a compulsory license... on behalf of the patent holder to relevant generic manufacturers to produce... drug[s] ... [in] recogni[tion of the] right of access to essential medicines...¹⁷⁵

Within this menu of multiple, murky, mystifying, and myopic options, lay two discernible certainties. First, no matter which of these idyllic alternatives is ultimately selected, the private property of OECD nation citizen-owners, especially in the U.S., are likely to be sacrificed without their consent for the ostensible (illusory) benefit of serving the global public interest'. This is precisely the end-result sought by anti-globalization activists who have painstakingly erected the opaque international process that is now unfolding.

Recent television and written media focusing on the issue of HIV/AIDS^{176 177} conveyed this message in a less than candid and transparent manner. Beginning with a discussion of this devastating disease, recent television programming then implored individuals and corporations, as a matter of morality, human decency and social responsibility, to take all necessary actions, in addition to undertaking acts of philanthropy and underwriting taxpayer-funded government aid, to eradicate HIV/AIDS internationally, no matter the cost. Through use of such an approach, this programming had effectively bypassed private property and economic concerns. As a result, an unsuspecting public was unaware they had been denied an open and informed debate that would have revealed the many other debilitating global diseases and charitable causes for which additional funding and subsidization, and future private property sacrifices would be required, even

those beyond the realm of healthcare.¹⁷⁸ Neither the media nor the activists and politicians were willing to publicize this kind of information, especially within the U.S., because of the serious negative political ramifications it would likely have – i.e., on the 2006 and 2008 federal and state elections.

The second certainty is that any one of these alternatives will likely be prohibitively expensive, from both an individual and a societal perspective. OECD nations, including the U.S., are likely to be the ones who will subsidize the health care costs of developing country governments and citizens. Presumably, this subsidization will occur with *all* OECD members paying their fair share, but this is highly doubtful. Given the extent of pharmaceutical price controls currently imposed in countries such as, Australia, Canada, Japan, and the member states of the European Union, some of which are extremely proud of their social welfare systems, however, Americans are likely to bear most of these costs, especially in the near term.¹⁷⁹ Although U.S. taxpayers, individually¹⁸⁰ and collectively,¹⁸¹ continue to fund the world's largest HIV/AIDS relief programs for the benefit of stricken developing country citizens, these additional higher costs are likely to assume the form of significantly increased U.S. official development assistance, bilateral technical assistance and international financial assistance, larger national and international tax levies,¹⁸² and, higher U.S. drug cost. And, this does not even include the higher medical diagnostic and insurance costs that U.S. citizens are also likely to pay if life sciences and information technology companies are compelled to donate their products and know-how.

These certainties notwithstanding, the WHO Commission on Intellectual Property and Innovation and Public Health

(CIPRH) has continued its relentless assault on the WTO's intellectual property framework, mainly against patents and trade secrets, within a newly released April 2006 report.¹⁸³ The report opens with the following bold conclusions:

Intellectual property rights are important, but as a means not an end... We know they are considered a necessary incentive in developed countries where there is both a good technological and scientific infrastructure and a supporting market for new health care products. But they can do little to stimulate innovation... in developing country markets... Other incentive and financing mechanisms to stimulate research and development of new products are equally necessary, along with complimentary measures to promote access (emphasis added).
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It then premises its conclusions on several assumptions that seemingly betray a preconceived anti-patent/private property ideology¹⁸⁵ ¹⁸⁶ shared by several of the Commission's developing country members.

[T]he report recognizes [that] patents are irrelevant for the development of the products needed to address the diseases prevailing in developing countries... The extension of pharmaceutical patent protection to developing countries, mandated by the TRIPS Agreement, can do very little to prompt the development of such products, while it generates costs in terms of

reduced access to the outputs of innovation. Where patents exist and are enforceable, medicines can be unaffordable for governments and patients in developing countries (emphasis added).¹⁸⁷

A more critical review of the WHO report's assumptions and conclusions reveals a broader anti-private property and anti-market agenda¹⁸⁸ similar to that advanced by Brazil and Argentina¹⁸⁹ in other international fora:

... [M]arket mechanisms and incentives, as well as allocative decisions of companies, lead to insufficient investment in R&D specifically directed to the needs of developing countries. Because the market fails to induce adequate investment in products needed in developing countries, it is necessary that other measures be put in place to promote relevant innovation (emphasis added).¹⁹⁰

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At least two of the Commission's ten members criticized the report's assumptions and conclusions as lacking substantiation,¹⁹² while a third disputed the main conclusion, that patent reform was necessary at all.¹⁹³

Furthermore, the report recommends the development of an alternative international open source¹⁹⁴/ universal access cycle of innovation model to replace the current US linear innovation model.¹⁹⁵ It justifies this in terms of morality,¹⁹⁶ and fairness (i.e., educational reciprocity)¹⁹⁷, and by reference to the human right to health*¹⁹⁸ (as expressed within the UN International Covenant on Economic, Social and Cultural Rights - CESCR¹⁹⁹). The report also portrays

the right to health, for political purposes,²⁰⁰ as being in conflict with, and having primacy over, economic rights such as private property rights - IPRs.^{201 202 203} Although the report fails to successfully make this case, its conclusions have, nevertheless, been promoted by some media,²⁰⁴ and elevated within a recent draft WHO CIPIH resolution to the level of a proposed global strategy and plan of action. That action plan calls for a newly established WHO intergovernmental working group to develop a proposed set of international guidelines/standards, that can later be formalized into an international R&D and innovation treaty.^{205 206 207}

Based on Brazil's proposed additions to this resolution, there can no longer be any doubt as to its true purpose(s). In addition to facilitating international norm building', the resolution aims to: 1) Confirm for all time that WTO Members must, consistent with a broad reading of the Doha Declaration,²⁰⁸ interpret and implement the TRIPS Agreement in a manner supportive of their right to protect public health and, in particular, to promote medicines for all ; and 2) Initiate consultations on the possibility of elaborating a framework convention on research, development and innovation in public health .²⁰⁹ The Swiss chair of a World Health Assembly drafting group had even proposed to merge the CIPIH resolution with the prior Brazil-Kenya resolution (that called for alternatives to the current international I/P-patent framework) to accelerate commencement of this initiative.²¹⁰ As the result of intense activist, Brazilian government and media pressure, the WHO ultimately adopted, at the May 2006 World Health Assembly meeting,²¹¹ a somewhat modified form of the CIPIH resolution calling for soft' rather than mandatory' norm-building. Despite this softer' language, however, it is clear that the activists still intend to press for development and adoption of a binding treaty in the longer term.²¹²

Both the WHO report and the subsequent resolution clearly fail to substantiate (prove) the need for IP reform. First, as a matter of logic, there is *no* such conflict between human rights and private property rights.

Private property rights do not conflict with human rights. They are human rights. Private property rights are the rights of humans to use specified goods and to exchange them. Any restraint on private property rights shifts the balance of power from impersonal attributes toward personal attributes and toward behavior that political authorities approve. That is a fundamental reason for preference of a system of strong private property rights: private property rights protect individual liberty (em phasis added).²¹³

Second, as a matter of human rights law, Article 17 of the Universal Declaration of Human Rights, upon which the CESCR is based, expressly states that: 1. *Everyone has the right to own property alone as well as in association with others.* 2. *No one shall be arbitrarily deprived of his property* (em phasis added).²¹⁴ In fact, various other provisions within this seminal document, when read together with Article 17,²¹⁵ as well as, with certain provisions of the CESCR,²¹⁶ support the conclusion that there exists *no* hierarchy at all among the various types of human rights, whether health, education, or economic-related.²¹⁷

Third, it is highly likely that the extraordinary emphasis placed by these documents on healthcare as a fundamental human right, has more to do with other non-IPR-related

issues. These include: 1) The need to establish a minimal international standard of human healthcare to which all persons are entitled and all developing country governments must adhere (especially those susceptible to corruption, mismanagement and/or poor governance – i.e., those that systematically violate human rights... [or] failed states that are chronically incapable of meeting the basic security needs of their own populations^{218 219}); 2) The need to define international aid requirements and related UN and member state foreign aid programs and budgets; and 3) The need to provide empirical evidence that healthy populations are indeed more productive and wealthy,²²⁰ to justify increased international health care aid.

Fourth, a close inspection of the WHO report reveals that developing country governments and activist groups have actually sought to appropriate, for public use and benefit, and at less than fair market value, the very same flawed ‘U.S. scientific and technological innovation process and successfully (derived/) commercialized medicines, vaccines, medical treatments, and biomedical innovations²²¹ which they have criticized all along.²²²

Fifth, factors other than foreign IPRs are largely to blame for the poor healthcare and access to medicines suffered generally by middle income and developing country citizens, and these have mostly to do with misplaced government priorities, policy failures, and/or corruption.²²³ With respect to Brazil, at least one recent study (2003) found that import tariffs and federal and state taxes have increased the drug prices paid by Brazilian patients more than 82 percent above the prices charged by pharmaceutical manufacturers.²²⁴ In addition, it is well known that, the Brazilian government’s failure to adequately address its urgent national public health care, education, pension and physical infrastructure needs, is due considerably to its

rampant corruption scandals (poor governance)²²⁵ and its misplaced fiscal priorities, which include very costly (hundreds of millions of dollars) but unnecessary international image-enhancing space programs.²²⁶ As noted above, reputable studies have shown how sustained national spending on public health care improves a middle income or developing country's long-term economic, technological and social productivity and attracts badly needed domestic *as well as* foreign investment.²²⁷

Brazil's IPR Regime Shifting 'Recognized by WHO and Latin America

It is not difficult to conclude that Brazil has been encouraged to continue its regime-shifting activities by UN officials. During September 2005, Dr. Bernard Fabre-Teste, the WHO adviser for disease in the Western Pacific region, made a bold pronouncement. He said that he supported developing countries' right to circumvent national patent laws protecting the property rights of foreign HIV/AIDS drug manufacturers in order to provide citizens with the public health care they deserve. He believed that this could be accomplished either through aggressive use of the flexibilities contained within the WTO TRIPS Agreement, or through the taking of other unilateral actions, including the importation of generic copies of AIDS drugs from third countries, such as India, China and Vietnam. Although Fabre-Teste did not include Brazil within this group of countries, he did refer to Brazil's successful threats of compulsory licensing and patent abrogation against U.S. and European HIV/AIDS drug manufacturers that resulted in significantly reduced medication prices. Apparently, the WHO and Fabre-Teste agree with the Brazilian government that, This kind of decision is really a sign of political commitment [to] public health.²²⁸

In addition, WHO officials, together with officials from the Pan-American Health Organization (PAHO), the Brazilian Health Ministry and several Brazilian research centers/universities, have collectively authored a report highlighting the importance of having refocused and shifted the debate about IPRs and health care, at both the national and international levels, from the WTO to the WHO.²²⁹

Consequently, all developing countries, including Brazil, now have the WHO's blessing to directly or indirectly produce generic copies of any patented drugs they believe are required, without first obtaining the consent of, or paying 'just compensation' to, the patent holder, all in the name of promoting the public interest – i.e., open source/ universal access to health. Perhaps this is why a regional bloc of 19 Latin American and Caribbean nations confidently executed an agreement during January 2006, to act collectively in an effort to reduce the price of HIV/AIDS drugs.

According to World Trade Organization rules, countries can issue licenses to disregard patent rights after negotiating with the patent owners and paying them adequate compensation. *Governments that declare a public health emergency [however,] can skip the negotiating* (emphasis added).^{230 231}

Judging from the WHO CIPIH's recent April 2006 report, the international recognition and approbation that the Brazilian government has thus far received for its national efforts in minimizing life science company patent protection, seemingly extends *also* to Brazil's national

policy towards clinical test data and trade secrets. Brazil²³² remains one of two emerging economies with a growing generic drug (manufacturing) sector (the other is India²³³) that, along with Egypt,²³⁴ has thus far refused to both enact *and* implement WTO/TRIPS-consistent national legislation recognizing the exclusivity of undisclosed *health-related* clinical test data and trade secrets. Pharmaceutical and biotech companies typically submit this data to safety orientated regulators to secure pre-market authorization to commercialize their products.

In fact, the WHO CIPH has once again transcended WTO jurisdictional and national sovereignty lines by opining as to the correct meaning of the WTO/TRIPS data protection/exclusivity provisions. In fact, the WHO has denied that any such property right exists at all!

*Article 39.3, unlike the case of patents, does not require the provision of specific forms of rights. But it does oblige Members to protect undisclosed test or other data against unfair commercial use. It does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data, except where unfair (dishonest) commercial practices are involved. The TRIPS Agreement does not refer to any period of data protection, nor does it refer to data exclusivity*²³⁵ (emphasis added).

Interestingly, at least one of the WHO report's authors, a lawyer from Argentina, has articulated for international

consumption a series of arguments to justify this interpretation.²³⁶ Unfortunately, they are far from apolitical.

Most troubling of all, there appears to be a concerted international effort under way to reinterpret and expand the focus and scope of WHO core competencies and functions beyond, even, the WHO constitution's original mandate.²³⁷ Currently lacking the necessary WHO membership consensus to promote the supranational global governance of healthcare,²³⁸ the WHO, the Government of Brazil, and the NGOs they support have embarked on the lesser global mission of employing the concept of shared sovereignty.²³⁹ ²⁴⁰ In their view, however, the notion of shared sovereignty should seek to promote public international goods at the expense of nationally sanctioned private property rights.

[N]ation states [that] are sharing rather than giving up sovereignty [must define]... the special functions for which international collective action is essential... The first type of essential function transcends the sovereignty of any one nation state, and therefore makes up the core of international health cooperation. *These functions address problems of the global commons*,[] ***in which individual decisions based on property rights are made ineffective*** by the fact that use of resources cannot be contained within boundaries... The two core functions to address these problems are the *promotion of international public goods* and the *surveillance and control of international externalities*... Four such goods are crucial: *research and development*, particularly

regarding problems of global importance when knowledge would benefit all or most nations;[] *information and databases* that can facilitate a sustained process of shared learning across countries; harmonised norms and standards for national use and, more importantly perhaps, for *regulation of the growing number of international transactions*; and consensus-building on health policy, which can help *mobilise political will within each country...* (em phasis added).²⁴¹

Thus, there can be no doubt that the Brazilian government has long played a leading role in the international effort to weaken exclusive individual private property rights.²⁴²

If all of this were not yet enough (overkill), the Health Ministers of Brazil and other Latin American countries very recently issued their own public anti-private property declaration at the 59th World Health Assembly.²⁴³ This declaration essentially reaffirms the prior calls made in the UNHCR and the WHO for the subjugation of exclusive private intellectual property rights to the right to access to medicines and critical raw materials, which is deemed integral to the allegedly more primary and basic human right to health. It also asserts that it is the sovereign duty and obligation of every government to ensure the fulfillment of such right. In order to satisfy this responsibility, the declaration expressly commits Brazil et al. to utilize every conceivable option, exception, derogation and/or exclusion to providing exclusive private patent, trade secret or other IP protection to pharmaceutical products, devices, therapeutic methods (services), and

natural flora, notwithstanding TRIPS and bilateral free trade agreement provisions to the contrary.^{244 245 246 247}

The extent to which private property rights will be sacrificed in the future to satisfy public health needs will soon be tested. Revised international health (global governance) regulations adopted previously by the 58th (2005) World Health Assembly,²⁴⁸ and intended principally to address the threat of global pandemics,²⁴⁹ will enter into force on June 1, 2007.²⁵⁰ These regulations are supposed to be binding on WHO Member States that either do not reject them outright, or do so only in part, pursuant to the treaty's reservation procedures.²⁵¹ It is especially significant that member state governments will be obliged to notify the WHO about, and *the WHO* will be charged with helping them to determine, the existence of a public health emergency of international concern.²⁵² Article 31(b) of the TRIPS Agreement utilizes similar terminology (national emergency).²⁵³ While the regulations require the performance of a science-based assessment of the public health risks posed by a particular communicable or non-communicable disease before government action is taken, they do not appear to address the issue of private property rights.

IPR Shifting from WTO to UNEP/CBD

Brazil is also assisting developing nations and global environmental activists to re-characterize the recognition and protection of private property/IPRs as potential violations of international environmental law, unless the international IPR framework is fundamentally changed. Brazil et al. demanded the changes during a series of recent negotiations that have taken place between the parties to the UN Environment Program (UNEP) Convention on Biological Diversity (CBD).²⁵⁴ The changes would run

contrary to the established law of the WTO/TRIPS and WIPO Agreements. The CBD's objective is to conserve biological diversity, to promote the sustainable use of genetic resources, and to ensure the fair and equitable sharing of all benefits flowing from their use.²⁵⁵

The Government of Brazil has worked with other nations to exploit broad language within the treaty text according IPR protection for genetic resources residing in developing countries. Apparently, these governments have discovered the inherent value of IPRs, at least, on a national ownership level, and now aim to secure it for themselves against the otherwise legitimate interests of private third party developed country companies. IPR-related²⁵⁶ CBD negotiations have concerned two primary issues: 1) protecting the traditional [public] knowledge of indigenous communities; and 2) advocating that intellectual property rights applicants should disclose the country of origin of the [public] genetic resources or traditional knowledge, which form the basis of their application.²⁵⁷ Yet, the TRIPS Agreement requires neither,²⁵⁸ while the CBD text focuses considerably on the issue of access.²⁵⁹

During early 2005, Brazil and other CBD Parties²⁶⁰ proposed the creation of a new international IPR treaty that sanctions the nationalization of biodiversity and any derivative IP. It calls for

Tighter patent rules to prevent their biological resources being misappropriated and to ensure that benefits arising from their use are shared fairly. The proposal would require users of biological resources to first seek informed consent of the country of origin, and to ensure that the origin of the

resources were disclosed in patent applications... Their [ostensible] chief concern [was] biopiracy²⁶¹ whereby biological resources could be appropriated by foreign researchers and used to develop new, patent-protected products, without benefits being returned to the country of origin.²⁶²

A proposed treaty would, if adopted as a final text, most likely become a Protocol to the UN Convention on Biological Diversity.

Brazil and other like-minded nations have opposed the leading alternative to the changes they demand – a market-based approach that involves execution of individual private agreements governing access to and use of genetic resources.²⁶³ They reason that the market approach would require them to police their own biodiversity, and that this entails significant economic costs. However, there are likely other explanations for their refusal to embrace it. In particular, they prefer to establish a global (regulatory) convention that would permit them to control how products *derived from* their biological resources can be used by other governments and non-state actors, which would, consequently, provide them with *economic benefits* to which they would not otherwise be entitled under TRIPS if such products failed to meet commonly accepted patentability requirements.²⁶⁴ In effect,

Even after a patent has been granted for an invention using genetic material, the country from which the material was sourced would have the right to determine how products based on a patented

invention from it would be used.²⁶⁵

[A] draft convention which Ethiopia, speaking for the African countries, along with India *and Brazil* want negotiated into a full convention... [w]ould ensure that]... [e]very transfer of a genetic resource between parties would be recorded and authenticated. The approval of the owner of a genetic resource would be required before it or its derivative could be used in research. The reasoning was this would require companies to negotiate with every owner when a patent was granted *and presumably for a share of the profits* (emphasis added).²⁶⁶

According to at least one commentator, there is also a *political* dimension to this proposal. And, it is clearly anti-patent, anti-private property, anti-free market, and anti-WTO.

Klaus Topfler, the [former] head of the United Nations Environment Programme underlined ... the political message which lies behind the idea of the new convention... in his message to the Bangkok conference. *Patent represented private monopolies' which should be subject to **community ownership***. Is this an anti-private property message? Martin Khor is no fan of private property. He is a longstanding critic of business and a leading campaigner against the World Trade Organisation, a venerable free market body. One of

his avowed goals is to diminish the effectiveness and authority of the WTO at large and its agreement on intellectual property (emphasis added).²⁶⁷

For each of these reasons, it may be appropriate to perceive Brazil et al.'s continuous efforts to push (putsch) this proposal forward as a neo-Marxist attempt to nationalize (take for public use) natural resources for the benefit of the state, irrespective of the costs to both foreign and domestic individual inventors and private investors.²⁶⁸ In fact, at least one study has likened an ABS patent to a national research and development tax (an indirect regulatory taking) that would likely reduce R & D investment in the biotechnology and pharmaceutical sectors by 50 percent and 20 percent respectively.²⁶⁹

Cynicism aside, the Government of Brazil has taken its participation in the CBD process very seriously. It was largely responsible for the progress that took place during the recent mid-February 2006 CBD Working Group meeting in Granada, Spain. Brazil was instrumental in helping to craft a draft ABS convention text (International Regime on Access and Benefit Sharing)²⁷⁰, which was then passed on to the CBD Conference of the Parties (COP) for consideration at their subsequent meeting, held in Curitiba, Brazil, during late March 2006.²⁷¹

Brazil has been taking the lead in insisting that the international regime must provide for compliance with national access and benefit sharing legislation, and require the disclosure of country of origin or source, evidence of prior informed consent, and evidence of fair and equitable benefit sharing in

IPR applications. Compliance and enforcement of prior informed consent and mutually agreed terms for granting access are priorities for developing countries... *Brazil supported a certificate* of legal provenance of genetic resources, derivatives and traditional knowledge issued by the country of origin, in accordance with nationally defined requirements, internationally recognized by the international ABS regime (emphasis added).²⁷²

Brazil played a key role and proposed text to ensure the primacy of the CBD, reiterating that since CBD provisions are negatively affected by intellectual property rules, this is an appropriate forum to tackle them '... *Brazil and Ethiopia's proposal to include derivatives products and associated traditional knowledge*' are in brackets.²⁷³

At least until April 2006, there appeared to exist sufficient developed country government and industry opposition to the draft ABS convention text introduced in Curitiba to temporarily place it on ice until 2010, and away from the TRIPS Agreement.²⁷⁴ However, the ground, apparently, had already begun to shift before that meeting, as the result of heightened activist concern about the negotiation of new bilateral free trade agreements alleged to be in conflict with the CBD.²⁷⁵ The TRIPS Council's February 2006 review of the CBD-TRIPS relationship also did not help matters any.²⁷⁶

Indeed, this dynamic changed further during May and June 2006, due to the concerted efforts of the Governments of Brazil, India and Norway and the good offices of the WTO Director General,^{277 278} to promote harmonization between CBD and TRIPS. On May 29, 2006, approximately two weeks before the next scheduled TRIPS Council meeting (June 12-15) was to take place,²⁷⁹ Brazil and India proposed an amendment to the TRIPS Agreement, (Article 29 *bis*), that was supported by a number of developing countries. That amendment, if adopted, would require introduction into the TRIPS Agreement of a mandatory requirement for the disclosure of origin of biological resources and/or associated traditional knowledge used in inventions for which intellectual property rights are applied for.²⁸⁰ Thereafter, on June 14, the Government of Norway introduced its own proposed TRIPS amendment that supports and is largely consistent with the Brazil-India proposal.^{281 282 283} While Brazil and India warmly welcomed the Norwegian proposal, they were not as receptive to the thoughtful proposal submitted by the Japanese government at roughly the same time.²⁸⁴

Arguably, Brazil's ABS draft treaty and proposed TRIPS amendment amount to nothing more than a national governmental grab for private industry royalties in the absence of the means to convert genetic resources and traditional knowledge into legally recognizable property rights (i.e., patentable subject matter) from which market relevant (commercial) innovations can be derived. They represent nothing less than patent opportunism cloaked in international harmonization and development language.²⁸⁵

B. BRAZIL ACTIVELY PROMOTES A NEW INTERNATIONAL PARADIGM OF „OPEN SOURCE / „UNIVERSAL ACCESS TO KNOWLEDGE (A2K)

Open Source Methods (OSM)

Brazil and a group of similar-minded developing nations known as the Friends of Development,²⁸⁶ are also advancing a new paradigm of open source methods in international fora to accelerate the process of regime shifting. Although these protagonists did not invent open source methods, they immediately recognized their value for their own interests. Unfortunately, some experts from OECD market economies promote such ideas as well.

The Open Source approach towards intellectual property rights has been broadly described within a recent pamphlet authored by the former Head of Policy in UK Prime Minister Tony Blair's Office, who is now the Director of a London-based NGO. Both he and the organization he works for are known for their socialist leanings.²⁸⁷ These advocates contend that open source methods are designed to operate as a gift rather than a market economy. And, although such methods were originally applied to computer software,²⁸⁸ they are now being extended nationally and internationally to other industry sectors that have nothing at all to do with software, namely biosciences and pharmaceuticals.²⁸⁹ Indeed, in their view, open source methods are almost the opposite of traditional intellectual property systems like patents and copyrights which seek to keep knowledge to the creators and people they choose to sell the knowledge to.²⁹⁰

Not surprisingly, the new model has fueled intense controversy and struggle, with new dividing lines in business as some (like IBM) partially side with the open source movement against Microsoft.^{291 292}

²⁹³Even on the geopolitical scale

*there appear to be countries falling broadly into the 'for' and 'against' camps. **These contests over ownership and intellectual property** look set to have a profound influence on how our economies will innovate and operate in the next few decades* (emphasis added).²⁹⁴

European, Brazilian and South African advocates have argued that there exists a sound theoretical basis for the idea of 'open business' models, whether applied either to copyrights or to patents.

[New York University] Professor Yochai Benkler's text, Coase's Penguin ... discusses from the theoretical point of view the emergence of the so-called commons-based peer production models ... [T]he examples mentioned by Benkler in his text are, nevertheless, limited, being circumscribed to free software, the wikipedia and a couple others. This is one of the objectives of the Open Business project.²⁹⁵ To provide numerous other substantial examples that can demonstrate the economic viability of businesses where the content is distributed openly.²⁹⁶

Some of these advocates have successfully persuaded their governments to act on it. During May 2005, for example, the Government of France, with an apparent nod from other European nations,^{297*} announced its intention to establish and support a legal framework under its bilateral science and technology agreement with China that ensures the

sustainable development of ObjectWeb... an open source [software platform]... as a major process for Sino-European collaboration.²⁹⁸

Apparently, certain American business executives, scientists and academics, as well, have taken a fancy to open source methods. Representing open source methods as supportive of intellectual capital rather than intellectual property²⁹⁹, they have aggressively promoted open source methods as a new global knowledge paradigm in the information *and* health sectors.³⁰⁰ In fact, during July 2003, open source activists, scientists and academics comprised part of an international group that drafted a letter to the Director General of the WIPO requesting that the WIPO seriously consider its promotion of such methods *in lieu of* intellectual property right protections.³⁰¹

Indeed, the growing open source movement these groups are leading endeavors to utilize new legal tools, utilitarian economic arguments, a sense of professional elitism, and moral suasion to justify the application of an open source/universal access model to information and communication technologies as well as to biotechnology, pharmaceuticals, and medical technology.³⁰²

The means by which the open source movement is fighting isn't by eliminating intellectual property. Rather, it is by a form of legal jujitsu that turns the opponent's strength against itself. The movement uses radical intellectual property licenses, sometimes called 'copyleft' (an antidote to copyright), to ensure that the open-source technology remains non-proprietary and free. The lesson for the life sciences is that

just as the information technology sector had to go through a rough period of transition to figure out workable models of sharing intellectual property - an evolution that is still ongoing - so too must biotechnology. The process is incremental, and probably inevitable.^{303 304}

The open source movement encompasses the classical economists' spirit of decentralization that is considered essential to progress, with a relatively new conception of enlightened community-interest. [L]egal theorist Yochai Benkler... *considers open source processes as [] peer-based, **non-capitalist modes of production** that [are] likely to expand well beyond software design. There are even moral imperatives facing the biotechnology industry that propel it in this direction, namely, the aim to improve and preserve life, which doesn't exist in information technology. At the same time, the professional culture of the life sciences and information technology share an acknowledged desire to change the world (emphasis added).*³⁰⁵

While it is easy to see why developing country governments would gravitate towards and seek to exploit any available opportunity to acquire free and open source software,³⁰⁶ it should be noted that there is actually more than one model of FOSS to choose from. This raises several important questions: Which of the two primary

FOSS licensing models does the Government of Brazil and the FoD seek to establish as the new international IP paradigm – the GNU General Public License (GPL), or the Berkeley Software Distribution License (BSD)?³⁰⁷ How do they intend to apply their preferred model to the health care sector? And, is this same model favored by European governments and industry, and by American companies?

Pursuant to the GPL model, software authors who otherwise possess exclusive private property rights (copyrights) in their expressed creations (i.e., rights to exclusive use, reproduction and distribution), expressly waive those rights, including the right to profit from them, when contributing their work to the software collective. They willingly surrender their rights in exchange for the right to receive attribution, as a matter of contract. They then leverage that resulting legal contract right to compel future authors/creators of derivative works to waive their otherwise exclusive private property rights. This ensures that they, too, will *not* profit from their creations. As a result, the software standard remains open indefinitely, with the effect of forcing more code into the open community. GPL adherents refer to this restriction as a copyleft as opposed to a copyright, and it serves to remove the software from public domain.³⁰⁸

The GPL binds the recipient of open source software to a set of restrictions governing the ongoing licensing of the open source software... A recipient's modifications of the original software become subject automatically to the GPL, which means the recipient cannot restrict access to the source code of the new and improved version. Further, if the GPL-covered

software is combined with any other software (including that which is considered to be proprietary), then the combination must be treated as 'open' under the GPL, *including that which had been proprietary* (emphasis added).³⁰⁹

IBM has embraced a version of Linux... available under the GPL, which is designed *to eliminate closed source software* (emphasis added).³¹⁰

Despite the appeal of such a model, especially to those who lack the technical know-how or the financial means to create their own software platforms, the GPL license has serious shortcomings. The resulting negative 'contract right, given its broad scope and indefinite duration, arguably constitutes an undue, and perhaps, total' future restraint on the alienation of private property, which common law courts have often invalidated. Newly formed and existing small and medium-sized hi-tech businesses, in particular, would economically suffer as the result of such restrictions if they serve to discourage venture capitalists from investing in their companies. Furthermore, from a litigation perspective, the GPL license is arguably nothing more than a 'house of cards' waiting to fall. Were any single member of the collective to violate the terms of this communal contract, it is likely to trigger a domino of copyright infringements along the entire chain of creations, and thus, a potential litigation 'free-for-all' amongst its members.^{311 312}

According to two legal experts, the GPL license essentially requires a business model centered around programming and support services to generate profit, rather than one based on the software product itself or on

its derivatives.³¹³ However, once a company reduces such services to a uniform and repeatable process, thereby commoditizing them, then a company's cost of developing them and the price they may charge clients for providing them will likely drop significantly. Since competitors' prices for rendering the same or similar services will also fall, it will likely lower the barriers to entry into the marketplace segment, and make it more difficult for such services companies to establish their individual niches and earn a reasonable profit. It will likely also place a severe downward pressure on the salaries and fees paid to in-house and outside consultants that work for the services providers.^{314*}

Pursuant to the Berkeley Software Distribution license (BSD) model,³¹⁵ on the other hand, businesses can legally build upon free software to create proprietary software. This means that, the BSD License allows proprietary commercial use; thus, proprietary commercial products can safely incorporate software released under the license without fear of reprisal. In addition, authors of any works based on and/or derived from the free software can release those works under their own proprietary licenses.³¹⁶

Legal experts have noted how 'open source purists' (GPL supporters) object to the BSD License: open source purists believe the BSD license is detrimental to the open source initiative because it does not require users of BSD-licensed software to openly release their modifications.³¹⁷ They object, in other words, because the Berkeley copyright poses no restrictions on private or commercial use of the software and imposes only simple and uniform requirements for maintaining copyright notices in redistributed versions and crediting the originator of the material only in advertising.³¹⁸ BSD supporters refer to

their model as ‘copyleft’ – between copyleft and copyright.

It would seem that established software companies are increasingly embracing the BSD model. For example, the Macintosh Operating System is, based partially on BSD-licensed code.³¹⁹ ³²⁰Some Microsoft products, as well, appear to contain kernels of BSD code.³²¹ And, IBM recently licensed some of its software under BSD.³²²

Unfortunately, with the support of a few large first-mover ICT companies,³²³ the movement has more stridently challenged those within industry³²⁴ and the scientific community³²⁵ that continue to maintain the traditional closed-loop proprietary view. That view has held that open source models negate the very incentive for industry to invest in the kinds of research and development that are needed to achieve incremental and breakthrough innovations that may then be shared with the developing world. Given the lower 4th quarter 2005 and forecasted 1st quarter 2006 expected revenues recently reported by at least two of these first-mover companies, however,³²⁶ one must seriously question the authenticity of their motivations for migrating to commoditized open source methods,³²⁷ ³²⁸ as well as, the economic viability of the open source business model itself.³²⁹ ³³⁰

Apparently, Brazil has been successful in advocating on behalf of the open source movement partly because it has not clearly identified the model it is pursuing and has failed to distinguish itself accordingly. Also, the movement, Brazil included, has embraced the Machiavellian tactic of ‘divide and conquer’ to pit the leaders of different governments and different industries against one another.³³¹

³³²And some companies, together with governments, in

turn, have employed this doctrine for protectionist purposes.³³³

Brazil's Efforts to Nationalize Open Source Methods

The Brazilian government has obviously observed and been monitoring this unfolding debate, and has chosen to embrace the notion of open source with abandon. According to one Brazilian expert, the Government of Brazil has undertaken a series of popular initiatives at the national and international levels aimed at promoting free and open source (FOS) business methods³³⁴ that, admittedly, imply a political risk to Brazil. The risk to which this expert obliquely refers is that the U.S. government may consider the FOS model that Brazil has adopted³³⁵ to be another new form of disguised trade protectionism.³³⁶ And this, he suggests, may be punishable by withdrawal of Brazil's U.S. GSP status and/or subject to challenge and retaliatory sanctions at the WTO.³³⁷

Brazil's Minister of Culture has explained the current Brazilian government's populist rationale for pushing open source methods.

[T]he fundamentalists of absolute property control' - corporations and governments alike - stand in the way of the digital world's promises of cultural democracy and even economic growth. They promise instead a society where every piece of information can be locked up tight, every use of information (fair or not) must be authorized, and every consumer of information is a pay-per-use tenant farmer, begging the master's leave to so much as access his own hard drive. But Gil has no doubt that the

fundamentalists will fail. A world opened up by communications cannot remain closed up in a feudal vision of property... No country, not the US, not Europe, can stand in the way of it. It's a global trend. It's part of the very process of civilization. It's the semantic abundance of the modern world, of the postmodern world - and there's no use resisting it (em phasis added).³³⁸

It is the opinion of many within the Brazilian government that, the evolving national and international paradigm of open source methods can and should be broadened far beyond the realm of *copyrighted* content-rich music, films and computer software to also include *patented* healthcare products and technologies, as well as, other scientific and technological know-how. A recent article appearing within Wired Magazine discusses the evolving scope and rationale of this expansion effort.

Brazil, in its approach to drug patents, in its support for the free software movement, and in its resistance to Big Content's attempts to shape global information policy, is transforming itself into an open source nation - a proving ground for the proposition that the future of ideas doesn't have to be the program of tightly controlled digital rights now headed our way via Redmond, Hollywood, and Washington, DC.

In a world divided into the content-rich and the content-poor, it's increasingly clear to those on the losing side of the divide that the

*traditional means of addressing the imbalance - piracy - is a stopgap solution at best. Sooner or later some country was bound to square off with the IP [E]mpire and be the first to insist, as a matter of state policy and national identity, on an alternative (em phasis added).*³³⁹

This article notes how the doctrine of open source methods was as central to Brazil's cultural past, as it will be to Brazil's economic/technological future.³⁴⁰

*The prime directive of [Brazil's]... federal Institute for Information Technology is to promote the adoption of free software throughout the government and ultimately the nation. Ministries and schools are migrating their offices to open source systems. And within the government's digital inclusion' programs - aimed at bringing computer access to the 80 percent of Brazilians who have none - GNU/Linux is the rule... We're not just discussing one product as opposed to another here - Ford versus Fiat,' says Sérgio Amadeu da Silveira, the institute's director. We're talking about different models of development' (em phasis added).*³⁴¹

While Brazil initially became interested in expanding open source business methods from software to healthcare during the Cardoso administration,³⁴² ³⁴³ the Lula administration was largely responsible for developing open source' into a mantra. During the Spring of 2005, for example, Brazil declared that it possessed the moral and

legal authority, under both national and international law, to take ‘HIV/AIDS drugs from its U.S. owners (patent-holders) *without* just compensation‘ because the issue of health care is a matter of public interest‘ (i.e., public use‘).³⁴⁴

In other words, the standard articulated by the Brazilian government to justify a taking‘ of private property without just compensation‘ was that of meeting the necessary requirements to guarantee the *sustainability* of the government’s National STD/AIDS Program‘ (i.e., a public use‘). Obviously, Brazil was in over its head *financially*, and relied on the derogations (flexibilities) provided for in the TRIPS Agreement and within its own national law to bail itself out. The Brazilian government, however, had actually been suffering from an *economic* emergency‘ or urgency‘ triggered by its own profligate spending. It had *not* experienced, as the TRIPS Agreement envisions and provides for, and what most health activists described, as a *health* emergency‘ or urgency‘.

Arguably, it is better to address economic emergencies or urgencies of the kind experienced by Brazil or any other emerging economy through balance of payment borrowings or project-related financings obtained from official international development and sovereign lending institutions, official *export finance*-promotion vehicles, or from private banks, or even private aid. By contrast, health emergencies or urgencies of the type experienced by impoverished least developed countries, such as those from sub-Saharan Africa, with respect to HIV/AIDS, malaria and tuberculosis deserve different treatment. For example, they are likely to benefit more from the dispensation of official development aid, bilateral intergovernmental aid packages and private aid grants, as have been generously provided by the U.S. government or by U.S. private foundations, though

such aid has not proven to be as transformational as once believed.^{345 346 347}

In addition, Brazil has also likely suffered from a perennial *knowledge* emergency or urgency. This type of human capital deficit is correctable by improving national and local education capabilities, by attracting foreign private direct investment and by voluntarily negotiating arms-length, market-based arrangements (procurement contracts) with the very private industry participants that can help it to acquire such knowledge.³⁴⁸

Brazil still has the option, in the words of Hernando De Soto, to act wisely and choose the other path'. It should *not* mandate through force of law free-of-charge open methods-based technology transfers to national governments underwritten by private industry, as a condition to gaining or retaining market access. This amounts to nothing less than governmental opportunism, which will serve only to enhance Brazil's welfare dependency at the expense of its domestic industries' creativity and innovation. Even more damaging are the Brazilian policies intended to move this debate into the international sphere.

Brazil's Efforts to Internationalize Open Source Methods'

*Brazil is in the forefront of several proposals regarding Intellectual Property, such as embracing free software and creative commons, as well as struggling for the proper balance of patent rights in order to promote access to medicines.*³⁴⁹
(emphasis added).

Evidence strongly suggests that Brazil's efforts to establish open source methods as the international IP paradigm, especially as applied to the life sciences and information and communication technology industries, are intended to seriously impair the significantly higher value of U.S. and other OECD member intellectual property assets (patents) and the related commercial products and processes that incorporate them.

[T]he fact that an open source approach to biotechnology research and development may have the capacity to weaken government (*in particular, US government*) and industry control over the rate and especially the direction of scientific progress in this field is part of its appeal (emphasis added).³⁵⁰

Brazil couches its efforts in nationalistic political terms intended to appeal to the poverty-stricken masses, by emphasizing how the current IPR system provides the OECD nations, including the U.S., with a considerable comparative trade advantage over emerging WTO member economies, including Brazil.

Brazil's President, Luiz Inacio da Silva, is keen to bridge what he perceives to be a huge technology gap between Brazil and more advanced economies, and sees Open Source as an important means of doing so. He appointed Sergio Amadeu, a former economics professor and Open Source enthusiast, to head Brazil's National Information Technology Institute, after taking office last year. Amadeu wants Open Source to permeate government software

usage, educational software usage
and home computer usage
(emphasis added).³⁵¹

Brazilian officials have also used this argument to justify the use of open source methods in connection with copyrights and the arts.

[A s concerns].. the traditional copyright-based cultural industry in B razil.. [t]he num bers dem onstrate that a very small number of artists have been able to be distributed by means of the traditional industry channel. *Only very few Brazilian music CDs are being released every year in the country, in spite of its huge population. Also, Hollywood movies occupy the vast majority of movie-theaters in Brazil, even though the Brazilian production of movies has been steadily grow ing... [T]he traditional industry is failing to provide the appropriate channels for Brazilian culture to emerge and be disseminated. As a result, creativity is moving to the peripheries* (emphasis added).³⁵²

Thus, Brazil and its developing country comrades have sought to impair the value of U.S. IP assets in multiple steps. First, they have tried to persuade diplomats, policymakers, and businesses that the current WTO IP system suffers from serious market and ethical failures. Second, they have cast those failures as a serious threat to developing countries' national sovereignty, cultural identity and ability to benefit equitably from the science and technology transfers to which they believe they are entitled pursuant to the United Nations Millennium Development

Goals. Third, they have strongly recommended (i.e., demanded as a matter of fundamental fairness³⁵³) that the FOS replace this system as the benchmark for internationally harmonized IP rules. Fourth, they have called for significantly increased development aid funding. All of this is intended to secure what they are really after – global redistribution of scientific and technological know-how and the wealth that goes along with it - in the name of sustainable development.

Certainly, Brazil is not the only emerging economy to promote open source methods as a new global intellectual property policy paradigm nationally and at international fora; however, it is the *most vocal*. In fact, Brazil's voice has registered loud and clear with developing countries, especially those located in Latin America.^{353 354} Suffering from even greater knowledge and technology deficits, they have observed Brazil's diplomatic dips and head jolts, and have eagerly fallen in place behind Brazil to form a political samba line³⁵⁵ for the purpose of dancing to what they hope will be a new international genre of open-source music.³⁵⁶

Already the outlines of an international open source alliance - a coalition of the penguin, if you will - have begun to emerge. India, for instance, is mustering a political commitment to free software that [the father of free software himself, Richard] Stallman... has declared second only to Brazil's... Developing nations, poor in IP rights and in the muscle to enforce them, may have a vested interest in the success of the open source paradigm... The rate of technological change now is such that modernization proceeds more

chaotically than ever, *and with every flip of the clock cycle, the whole world's reality looks more and more like Brazil's*: a high-contrast, high-contact confusion of micro-cultures and inequalities. (emphasis added).³⁵⁷

As the following discussion will show, Brazil has promoted the open source counter-IP paradigm in several different international fora.

At the World Summit on the Information Society (WSIS)

The Government of Brazil challenged the international IPR framework during November 16-18, 2005, at the last UN World Summit on the Information Society [WSIS],³⁵⁸ convened by the International Telecommunications Union (ITU), an UN-based international standards body.³⁵⁹ There, it led a bloc of developing countries, including India, South Africa, and China, that sought to prevent the US and its OECD allies from hardening 'the UN's line on intellectual property rights.'³⁶⁰ In particular, it insisted that the final conference document recognize just as strongly the cultural and economic importance of shared knowledge.

To ensure that the concept of open source methods remained in the minds of foreign governments and the media, the Government of Brazil skillfully convened a press conference during the first day of the Summit, at which it announced the execution of a memorandum of understanding (MOU) with the Secretariat of the UN Conference on Trade and Development (UNCTAD). The MOU provided for UN training and education in the use of free and open-source software (FOSS) in an effort to support the promotion of such paradigm in the developing

world.³⁶¹ Apparently, the UNCTAD, for the past several years, has co-chaired a project the goal of which has been to strengthen the analytical and negotiating capacity of developing countries so that they are better able to participate in IPR-related negotiations...^{362 363}

Although Brazil and its allies were ultimately not successful during the Summit (November 16-18, 2005) in defining the scope of intellectual property rights issues within the WSIS Declaration and Plan of Action³⁶⁴, they were nevertheless able to implant the idea of open source methods by inserting indirect but potentially troublesome declaratory language within these documents.

Intellectual Property protection is important to encourage innovation and creativity in the Information Society; similarly, the wide dissemination, diffusion, and sharing of knowledge is important to encourage innovation and creativity. *Facilitating meaningful participation by all in intellectual property issues* and knowledge sharing through full awareness and capacity building is a fundamental part of an inclusive Information Society (emphasis added).³⁶⁵

Governments, and other stakeholders, should establish sustainable multi-purpose community public access points, *providing affordable or free-of-charge access* for their citizens to the various communication resources, notably the Internet. These access points should, to the extent possible, have sufficient capacity to provide assistance to

users, in libraries, educational institutions, public administrations, post offices or other public places, with special emphasis on rural and underserved areas, while respecting intellectual property rights (IPRs) and *encouraging the use of information and sharing of knowledge* (emphasis added).³⁶⁶

Apparently, Brazil had previously been successful, with the assistance of free and open method advocates, in embedding even more damaging language and anti-IPR references within a prior ITU Report on WSIS Stocktaking.³⁶⁷ The obvious purpose was to promote regime shifting through incorporation of norms from less technical and less economically focused international organizations. For example, the WSIS Stocktaking Report refers to the previous efforts of the UN Educational, Scientific and Cultural Organization (UNESCO) to promote open source methods.³⁶⁸ In particular, the WSIS Stocktaking Report refers to the prior efforts (during 2003) of the UN Educational, Scientific and Cultural Organization (UNESCO), led by European interests,³⁶⁹ to promote open source methods to cyberspace within a recommendation focusing on cultural diversity and multilingualism.³⁷⁰

In addition, the WSIS Stocktaking Report refers to efforts previously undertaken by the UN Development Program (UNDP) to promote open source methods. In fact, during the WSIS Summit, there apparently took place a parallel UN Development Program-sponsored seminar on the subject of free and open source software. It discussed how the open source software movement seeks to promote universal human rights and fundamental freedoms discussed in various other UN projects and UN documents.

The United Nations Development Programme/Asia-Pacific Development Information Programme (UNDP-APDIP) hosted a morning workshop on the subject of software for development'... Participants confirmed their belief that communication is a basic human right, and that software plays a key role in enabling that communication. Panelists reminded the audience that the essential values of freedom, equality and solidarity were enshrined in the 2000 UN Millennium Declaration. The principles behind free and open source software (FOSS) are very much the same: they recognize human freedom, and in particular the freedom to use software when you wish, change it when you want, copy it as needed and distribute it to others who might need it. The importance of FOSS in the context of fundamental freedoms must be emphasized, rather than the need to merely provide cheap and powerful software, said speakers. FOSS represents another opportunity for developing countries, and can encourage innovation and adoption of ICT. It helps people to break free from imposed and costly software solutions, and to freely access global communication and information networks. Patent laws should be reformed to support and not discourage innovation, participants said. They called on the United Nations to take a leading role in fostering productive

open source partnerships, to liberate the poor and empower them to use technology for social and economic development (emphasis added).³⁷¹

Socialist-minded governments, including the present Lula Government of Brazil, and civil society activists have become increasingly prolific and adept at non-economic norm-building,³⁷² and at subsequently elevating those norms into soft law³⁷³ standards^{374*} intended to pollute trade and economic fora.³⁷⁵ Thus, if not carefully monitored, these seemingly innocuous statements and declarations could conceivably be modified, combined, expanded and otherwise used with or within other documents to develop an overly broad non-economic framework from which to reconsider the role of intellectual property law in international affairs.

At the World Intellectual Property Organization (WIPO)

... *Brazil* (along with Argentina) was responsible for proposing the so-called Development Agenda at the World Intellectual Property Organization (WIPO), which seeks to discuss the implications of Intellectual Property for development.³⁷⁶

During late August 2004, Brazil, along with Argentina, submitted to the WIPO Secretariat a formal detailed proposal relating to the establishment of a new development agenda within WIPO.

The proposal requested that the WIPO General Assembly consider eight different issues. They include: 1) Adoption

of a high-level declaration on intellectual property and development; 2) Adoption of proposed amendments to the WIPO convention; 3) Inclusion within any WIPO Treaty under negotiation, such as the Substantive Patent Law Treaty, provisions on the transfer of technology, on anticompetitive practices as well as on the safeguarding of public interest flexibilities; 4) Establishment of technical cooperation programs between WIPO and developing countries aimed at strengthening national intellectual property offices (capacity-building); 5) Creation of a Standing Committee on Intellectual Property and the Transfer of Technology, for the consideration of measures to ensure an effective transfer of technology to developing countries and LDCs – one such measure could entail establishment of an international regime that would promote developing country access to the results of publicly funded research in developed countries. Such a regime could take the form of a Treaty on Access to Knowledge and Technology; 6) Organization of a Joint WIPO-WTO-UNCTAD international seminar on intellectual property and development; 7) Wider participation of civil society in WIPO's activities; and 8) Establishment of a Working Group on the Development Agenda to further discuss its implementation.³⁷⁷

The proposed amendments to the WIPO Convention essentially call for each country's stage of development to determine the scope and degree of private intellectual property protections in that country so that IPRs do not impede access to culture and technology.³⁷⁸ According to the proposals,

In order to ensure that development concerns are fully brought into WIPO activities, the Member States may consider the possibility of amending the

Convention Establishing the World Intellectual Property Organization (1967). The amendment would explicitly incorporate the development dimension into WIPO's objectives and functions. Since Article 4 (Functions) of the WIPO Convention relates its Article 3 (Objectives), paragraph (i) of Article 3 of the WIPO Convention could be amended to read as follows: (i) to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization, fully taking into account the development needs of its Member States, particularly developing countries and least-developed countries' (emphasis in original).³⁷⁹

At least one Brazilian government representative who attended the special session noted that the amendments had received strong support from the Friends of Development (FoD).³⁸⁰

The WIPO General Assembly subsequently convened an extraordinary session to consider the multi-part proposal from September 27 to October 5, 2004. It ultimately decided to follow-up with inter-sessional intergovernmental meetings to examine the proposal, as well as additional proposals of Member States.³⁸¹

Shortly following the commencement of the 2004 special session, a group of European socialist-minded open source advocates and civil society activists submitted their own WIPO proposal, otherwise known as the Geneva

Declaration on the Future of WIPO'.³⁸² The declaration demanded that, WIPO abandon its current culture of expanding monopoly privileges without regard to social cost and to instead strike a balance between the public domain and competition on the one hand and the realm of property rights on the other. [It] also expresse[d] strong support for the... Argentina and Brazil... Proposal.³⁸³ It focused on the perceived inequities surrounding access to innovations in, and the scientific and technical know-how underlying, medical, information, and other essential technologies. And, it called for WIPO to ensure universal access to all such knowledge, as a matter of both morality and international law.³⁸⁴ Following the political success of the Geneva Declaration, other European activists have since submitted their own proposals equating these inequities with human rights violations, and calling for a reinterpretation of the WIPO Convention's mandate, consistent with international human rights law.³⁸⁵ The Brazilian and Argentine governments and other NGOs have also called for greater NGO participation in WIPO's enforcement committee.³⁸⁶

It must be remembered that, during the 2005 WIPO General Assembly session (spanning September 26 to October 5, 2005), WIPO member governments had agreed to establish a Provisional Committee (PCDA) that would continue discussions on how to mainstream the proposed 'development agenda' into WIPO's work program.³⁸⁷ The PCDA delivered its first proposal to the WIPO Secretariat during February 2006,³⁸⁸ and a second proposal on June 23, 2006.³⁸⁹ Although the PCDA subsequently met during June 26-30, 2006 to consider these proposals, it was unable to reach agreement on how to proceed,³⁹⁰ thereby leaving the WIPO General Assembly to decide the future of the Development Agenda when it meets again during September 2006.³⁹¹ Apparently, Brazil and Argentina were

largely responsible for the lack of consensus at that meeting. This is not surprising given their severe criticisms of the chair's text, which they argued, disproportionately reflected submissions supported by developed countries... and ... constituted a move to dilute the Development Agenda process.³⁹²

In conclusion, the open source methods' paradigm provides a highway for assembling the anti-private property, anti-IP, anti-free market and anti-globalization troops to mount a prolonged attack against the established international economic and legal order, originally designed to preserve international peace and security. It did this through protection of exclusive private property, including IP, and through preservation of the role of free markets in financing and commercializing scientific and technological knowledge. The open source approach, if adopted as suggested, will fundamentally change, for the worse, the entire international system of research and development, scientific and technological innovation, foreign trade and foreign direct investment. Therefore, OECD governments should immediately undertake efforts to repel such initiatives within each and every international and national forum they are introduced.³⁹³

Brazil's OSM Regime Shifting Has Trade Protectionist Undertones

The Brazilian government's prior record of upholding the private intellectual property rights of foreign companies is far from stellar and this does not bode well for IP-reliant Brazilian companies. To date, Brazil has extolled the virtues of universal, affordable, and open public access' to medicines at the expense of private property rights. Its ostensible objective is to procure well-recognized branded drugs, medical services and medical devices and

technologies at *at-cost or below-cost* prices³⁹⁴ from reputation-vulnerable multinational pharmaceutical and biotechnology companies for national distribution to all Brazilian AIDS victims. The Government of Brazil has secured these prices, time and again, by threatening to invoke Brazil's compulsory licensing provisions or to enact domestic non-patentability laws that rely on an overly broad interpretation of TRIPS provisions and a manufactured public need'. This has provided it with the political capacity to override *any* pharmaceutical patents for public health concerns (interests)', and/or to insist that gross profit margins for licensed patented drugs not exceed 5 percent.

Yet, arguably, for all of the international recognition that its HIV/AIDS universal access to medicines' program has received, including from international financial institutions,³⁹⁵ it appears that Brazil's true policy goals have evolved, and are now more likely trade, politics, and ideology-related than health-related. At least one prior study has revealed that Brazil is likely cloaking its actual intentions with a new form of disguised trade protectionism that has multiple purposes. They include: 1) gaining negotiating leverage at the WTO Doha Round against developed countries on the issue of agricultural subsidies³⁹⁶; 2) exercising its legal option to cross-retaliate against the U.S. if the latter fails to comply with a prior adverse WTO ruling on cotton subsidies; 3) developing a technically proficient and export-capable national generic drug industry that could compete domestically and internationally with China and India, and ultimately secure Brazil's independence from the very international institutions that have supported and assisted it all along;³⁹⁷ and 4) articulating a new international development agenda that gives short shrift to private property (IP) rights – i.e., that converts private goods into public international goods.

In other words, Brazil, an aspiring member of the United Nations Security Council, is arguably seeking a leadership role in international affairs through acts of IP opportunism rather than innovation.³⁹⁸

The Brazilian government's posturing on the world stage, nevertheless, may not reflect a national consensus, as suggested by at least one leading Brazilian industry expert.

The Lula government has operated under a market-seeking consensus'. It has only moved aggressively and with determination when the objective was to open foreign markets. *There is not, however, a government-wide consensus on the opening of the national market.* Promoting exports by financing, visiting places and striking business relationships is easy to agree on. Opening markets to increase competition, quality and integration into the world economy has proven to be quite a different story and the administration has had to spend a lot of political capital mediating between at least two major factions within the government itself – one on either side of the internationalization debate. Brazil needs an efficiency-seeking consensus that is broader and less one-sided if it intends to move forward as a major global player.³⁹⁹

Rather, it may be more indicative of a hard-line, nationalist and populist ideology held by a particular faction of the current socialist government. If this is true, the more moderate forces within the Government of Brazil must act

quickly to contain and minimize any damage already done to long-term diplomatic and Brazilian industry interests before it becomes irreversible.

Ideology has indeed been an important part of Brazil 2004 trade policy. Shunning agreements with the world's (not just Brazil's) most important trading partners has raised suspicion regarding the government's ideological approach to trade, as it *does not seem to reflect either public opinion' or the state of Brazil's industry... The private sector, those with their pockets on the line in the evolving trade drama, is simply not happy with the government's taking important decisions in the absence of comprehensive prior consultations...* It is no secret that the agricultural community feels that the government has been too timid in making concessions in the FTAA and the Mercosur-European Union negotiations, thus rendering it impossible for the major countries to concede on tariffs and other barriers to agriculture.

... The perception that the government is willing and able to continue to act unilaterally, without seeking internal support on matters as sensitive as China, Mercosur or the FTAA is a source of weakness in Brazil's current trade policy regime. The perception that the government will invariably sacrifice trade interests in the presence of even loose support for crucial elements of its geopolitical agenda – such as a possible seat at

the U.N. Security Council or a benevolent leadership in Mercosur – *has undermined the very necessary trust it needs to engage in such high-pitched pursuits. The perception that the government has been arrogant in purporting to know better than those directly involved in trade and trading has done great damage to its image, strategy and the sustainability of its trade policy* (emphasis added).⁴⁰⁰

Consequently, if the U.S. and the OECD nations are to make any progress in securing Brazil's compliance with the TRIPS Agreement, especially as concerns the sensitive issues of compulsory licensing and patent abrogation, they must take into account this indispensable dynamic.

C. BRAZIL'S CHALLENGE OF THE GLOBAL IPR FRAMEWORK AIMS TO „TAKE (REDISTRIBUTE) PRIVATE PROPERTY (ECONOMIC WEALTH) FOR „PUBLIC USE WITHOUT „JUST COMPENSATION

The Government of Brazil might improve its citizens' scientific, technological and economic prospects if it learned more about the role that private property has served in the American system of innovation. The Brazilian government might also better understand why American patent and trade secret holders respond in a hostile fashion to its threats of compulsory licensing or other proposed forms of uncompensated patent or trade secret abrogation.

Property and the U.S. Constitution: Individual vs. Public Rights

In the United States, the individual possesses the inalienable right to invent and create, and to enjoy the fruits of his or her labors (i.e., the private property he or she invents, creates, acquires, earns or converts to use), which is recognized and protected by the U.S. Constitution and its accompanying Bill of Rights. These documents also guarantee the protection of individuals' private property against arbitrary and wanton government interference ostensibly intended to serve the public good. The following two principles, at least, begin to explain this dynamic:

*That all lawful power derives from the people and must be held in check to preserve their freedom is the oldest and most central tenet of American constitutionalism (emphasis added).*⁴⁰¹

*The US system is rooted in the Bill of Rights and the sanctity of the individual. The Constitution of the United States... places great symbolic weight on human rights. It elevates the basic rights of man to supreme constitutional status (emphasis added).*⁴⁰²

Individual Natural Rights Include the Right to Private Property

Several provisions within the WTO TRIPS and WIPO Agreements express the U.S. Constitution's imposed limitations on the sphere of government and its anticipation of individuals' *natural* rights. Included among those rights is the right to own and enjoy private property.

Just as each of the three branches of the federal government was bound to remain within its proper jurisdiction, so the state or federal government as a whole had no power to act outside its rightful jurisdiction *to intrude upon the natural rights' reserved to the people within the private domain... Rights belonging to citizens by virtue of their very citizenship, including personal security, **personal liberty**, and **private property**, would thus be preserved not only by decentralization of power and mutually checking forces... but by rules enforceable in the proper tribunals at the behest of threatened citizens... [T]hey were to be preserved because they comprised the central tenets of the unwritten constitution or social compact among the citizenry upon which the government itself was based. Common law and written constitutions expressed and elaborated these notions, but did not create them ... (emphasis added).*⁴⁰³

The U.S. Constitution instructs us that an individual's property rights must be preserved and protected by *and* from government. Property is not, however, entirely a natural right. The Founders understood that it would need to be further defined in a statute.^{404 405} In support of this proposition, the U.S. Supreme Court, in the case of *Lynch v. Household Finance Corp.*, defined the right to private property as a basic civil right.

[T]he dichotomy between personal liberties and property rights is a false one. Property does not have rights. People have rights. The right to enjoy property without unlawful deprivation, no less than the right to speak or the right to travel, is in truth a personal right, whether the property in question be a welfare check, a home, or a savings account. *In fact, a fundamental interdependence exists between the personal right to liberty and the personal right in property. Neither could have meaning without the other. That rights in property are basic civil rights has long been recognized* (emphasis added).⁴⁰⁶

Patents are Exclusive Private Personal Property

The recognition of a person's exclusive right to his or her discoveries (inventions) is contained within Article I, Section 8, Clause 8, of the U.S. Constitution:

The Congress shall have power... to promote the Progress of Science and useful Arts, *by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries* (emphasis added).⁴⁰⁷

The U.S. Constitution both anticipates *and* recognizes patented discoveries as an intangible form of personal property bearing private and exclusive rights for a temporary period of time. The Founders relied upon this clause of the constitution, as a matter of national policy, to

provide U.S. inventors and creators with an adequate incentive to undertake research and develop innovations.

*Our Founders recognized the importance of patents and copyrights in encouraging research and innovation. In drafting the framework for the United States, they placed into the Constitution in Article I, Section 8, the authority for Congress [t]o promote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.’ For over two centuries our Nation has remained deeply committed to that vision. The Founders understood that a property interest granted to inventors and creators, for a limited period, would create the incentive for innovation **to propel us from a small, agrarian colony into an advanced and prosperous country**... The understanding of the patent system begins with the recognition that patents are a form of property **anticipated by the United States Constitution**...⁴⁰⁸
(emphasis added).*

A patent, in effect, is a right to *temporarily exclude others* from making use, offering for sale, selling, or importing an invention ‘ into the United States,⁴⁰⁹ and has long been recognized as falling within the protection of the Fifth Amendment’s taking clause.⁴¹⁰ Once the statutory conditions for obtaining a patent have been satisfied, only the patent owner or other authorized parties possesses the affirmative right to exercise the patent in the marketplace to derive benefits from it.⁴¹¹

Trade Secrets are Exclusive Private Personal Property

Similar to patents, the right inherent in a trade secret relates to its holder's ability to *temporarily exclude others* from making use, offering for sale, or importing one's otherwise undisclosed invention'.⁴¹² Over twenty years ago, in the decision of *Ruckelshaus v. Monsanto, Co.*,^{413 414} the U.S. Supreme Court recognized that trade secrets also have legal significance deserving of protection. The Court held that, to the extent [a private company] has an interest in its health, safety, and environmental research data cognizable as a trade-secret property right under [state] law, that property right is protected by the Taking Clause of the Fifth Amendment.⁴¹⁵

The Bill of Rights Limits Government Action Against Exclusive Private Property

No person shall... be deprived of life, liberty, or property, without *due process of law*; nor shall *private property* be taken for *public use* without *just compensation* (emphasis added).⁴¹⁶

Property 'refers not simply to the underlying estate but to all the uses that can be made of that estate. James Madison put the point well in his essay on property: [A]s a man is said to have a right to his property, he may be equally said to have a property in his rights.' Take one of those rights – one of those sticks in the bundle of sticks' we call property' and you take

something that belongs to the owner. Under the Fifth Amendment, compensation is due that owner.⁴¹⁷

Federal Government Action – „Just Compensation

The just compensation requirement was added in 1791, as the Fifth Amendment to the U.S. Constitution (a/k/a the Bill of Rights).⁴¹⁸ It effectively limits the powers of the federal government otherwise conferred by Articles I and II of the U.S. Constitution, such as the power of eminent domain (i.e., the federal government's power to take private property for public use).⁴¹⁹

Whether traced to a principle that society simply should not exploit individuals in order to achieve its goals, or to an idea that such exploitation causes too much dissatisfaction from a strictly utilitarian point of view unless it is brought under control, *the just compensation requirement appears to express a limit on government's power to isolate particular individuals for sacrifice to the general good* (emphasis added).⁴²⁰

The broad aim of this requirement is to prevent the federal government from arbitrarily or wantonly sacrificing the rights of individuals for the public good, which, apparently, can occur in several different ways. First, government may deliberately try to redistribute wealth through direct or indirect means. Second, government may try indirectly to reallocate property among citizens by generating a uniformly desired good or by reducing a uniformly disliked

public bad, without otherwise affecting the distribution of wealth. Third, government may act indirectly out of some high sense of morality to forbid a formerly accepted and tolerated use of property.⁴²¹

The U.S. Supreme Court has defined the just compensation requirement as ensuring payment that amounts to full and adequate compensation⁴²² or a full and perfect equivalent for whatever interest in or share of real or personal property has been taken.^{423 424} It also ruled that, the value of the property interest in question shall be determined by refer[ring] to the uses for which the property is suitable, having regard to the existing business and wants of the community, or such as may be reasonably expected in the immediate future.⁴²⁵ In other words, just compensation must reflect the arms-length fair market value of the property, i.e., what a willing buyer would pay a willing seller.⁴²⁶ If circumstances render it difficult to calculate fair market value, or such value is not otherwise ascertainable, then other data must be utilized that will yield a fair compensation that reflects the true economic value of the asset taken.⁴²⁷ A similar standard has applied to patents and codified into federal law.⁴²⁸ Calculating just compensation, nevertheless, remains particularly difficult where direct or indirect government action or threat of action (e.g., the threat of issuance of a compulsory license or enactment of a law that would abrogate patent or trade secrets rights) actually results in an artificial or irregular diminution in the fair market value of such property.^{429*}

The U.S. Supreme Court set forth the rationale underlying the just compensation requirement, in its discussion of the nature of exclusive patent rights, as far back as 1881.

That the government of the United
States when it grants letters-patent
for a new invention or discovery in

the arts, *confers* upon the patentee **an exclusive property** in the patented invention which cannot be appropriated or used by the government itself, without just compensation, ***any more than it can appropriate or use without compensation*** land which has been patented to a private purchaser, we have no doubt. **The Constitution gives to Congress power** to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries, ***which could not be effected if the government had a reserved right to publish such writings or to use such inventions without the consent of the owner.*** Many inventions relate to subjects which can only be properly used by the government, such as explosive shells, rams, and submarine batteries to be attached to armed vessels. ***If it could use such inventions without compensation, the inventors could get no return at all for their discoveries and experiments.*** It has been the general practice, when inventions have been made which are desirable for government use, either for the government to purchase them from the inventors, and use them as secrets of the proper department; or, if a patent is granted, to pay the patentee a fair compensation for their use. ***The United States has no such prerogative as that which is claimed by the sovereigns of***

England, by which it can reserve to itself, either expressly or by implication, a superior dominion and use in that which it grants by letters-patent to those who entitle themselves to such grants. The government of the United States, as well as the citizen, is subject to the Constitution; and when it grants a patent the grantee is entitled to it as a matter of right, and does not receive it, as was originally supposed to be the case in England, as a matter of grace and favor (emphasis added).^{430 431 432}

The due process of law ‘ to which the Fifth Amendment refers relates to both procedural and substantive safeguards guaranteed to individuals against arbitrary governmental actions.

These procedural safeguards have their historical origins in the notion that conditions of personal freedom can be preserved only when there is some institutional check on arbitrary government action... [D]ue process is a restraint on the legislative as well as on the executive and judicial powers of the government, and cannot be so construed as to leave congress... free to make any process due process of law ‘, by its mere will (emphasis added).⁴³³

An individual’s due process rights are deemed to be implicated whenever government action seemingly conflict[s] with substantive individual rights . According to the U.S. Supreme Court, these rights include the right to the preservation and protection of private property, even to a

greater extent than had been afforded by the common and statutory law of England prior to the formation of the United States.⁴³⁴ Procedurally speaking, the due process clause guaranteed, at a minimum, the right to a notice and a hearing prior to deprivation of such a substantive right.⁴³⁵

State and Local Government Action – „T a k i n g s

In 1868, the 14th Amendment to the U.S. Constitution extended the notion of Due Process of Law ‘, and its application to the Fifth Amendment Takings Clause ‘.

[N]or shall any State deprive any person of life, liberty, or *property*, without *due process* of law ...
(emphasis added).⁴³⁶

The U.S. Supreme Court has interpreted the 14th Amendment as requiring the protection, at the State and Local level, of virtually all of the rights guaranteed to individuals by the Bill of Rights at the Federal level. This entails both procedural and substantive rights, including those protected by the Takings ‘ Clause.⁴³⁷

The fifth and fourteenth amendments ‘ due process clauses as interpreted in the Supreme Court ‘s substantive due process analyses have furnished a broad definition of the ‘liberty ‘ that was in turn afforded procedural protection against arbitrary deprivation... In addition, there were protections independently required by fundamental fairness.
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The U.S. Supreme Court recently affirmed the purpose behind the takings clause⁴³⁹ in the very recent case of *Lingle v. Chevron USA, Inc.* According to the Court, the Takings Clause was designed not to limit the governmental interference with property rights per se, but rather to secure compensation in the event of otherwise proper interference amounting to a taking.⁴⁴⁰

Direct and Indirect Takings

The U.S. Supreme Court's takings⁴⁴¹ jurisprudence has addressed the issue of private property takings⁴⁴² mostly in disputes involving states and local municipalities, where it was alleged that real property had been unfairly appropriated without adequate compensation. The Court has held that a taking⁴⁴³ can occur even in the absence of a direct physical appropriation of, or ousting from, private property. If a government regulation deprives an owner of substantially all of the beneficial use, enjoyment, or value of his or her private property, then a taking⁴⁴⁴ is deemed to have occurred. In *Lingle v. Chevron USA, Inc.*, for example, former Justice Sandra Day O'Connor argued that both the permanent physical invasion of private property⁴⁴⁵ and the complete elimination of a property's value⁴⁴⁶, i.e., the total deprivation of [its] beneficial use⁴⁴⁷, are equivalent in that they both eviscerate *the owner's right to exclude others* from entering and using her property⁴⁴⁸. She explained that the Court's historical analysis has generally *focused on the severity of the burden that government imposes indirectly via regulation on private property rights*, rather than on the failure of a regulation to substantially advance⁴⁴⁹ legitimate state interests.^{443 444}

Similarly, the intangible personal property right reflected in a patent or trade secret, to *temporarily exclude others* from making use, offering for sale, selling, or importing one's

invention', is also susceptible to forced appropriation (a taking'), indirectly, by way of regulation, including by eminent domain – i.e., via *compulsory licensing*⁴⁴⁵).⁴⁴⁶ The U.S. Supreme Court has ruled that a regulation which compels the disclosure to third parties of otherwise costly proprietary trade secrets amounts to an unauthorized taking' of valuable intangible private property that can impair, in a substantial manner, the beneficial use and enjoyment of that property.⁴⁴⁷ ⁴⁴⁸ In such case, the Court held that the third party beneficiary was required to pay just compensation' to the information owner.⁴⁴⁹

Takings for Public Use

Another very recent but controversial U.S. Supreme Court decision, *Susette Kelo, et al. v. City of New London*⁴⁵⁰ has temporarily placed the Court's takings' jurisprudence in conflict with itself. It narrowly concerns the legality of a municipality's forced sale (taking') of private real property belonging to one class of individuals (current land owners) for the benefit of a different class of individuals (i.e., for the private use' of future purchasers and lessees of newly constructed dwellings and commercial office space), incident to a municipal economic redevelopment plan.⁴⁵¹ The Court's majority ruled that it was *not* necessary that the replacement property actually be used by the general public' to be considered a legitimate public use'. Rather, all that was required was for the redevelopment to serve a broad public purpose'.

According to the Court's troubled reasoning, a public purpose' would be inferred, if the redevelopment plan either eliminated some undesirable social and economic evils' (e.g., crime, time-consuming, costly data research, etc.), or sought to create some broad public benefit (e.g., a community that is beautiful as well as healthy, spacious as

well as clean, well-balanced as well as carefully patrolled). And, it does not matter whether some private individuals would indirectly benefit at the expense of others, in the process.^{452 453} The *Kelo* Court's logic would also seem to justify environmental legislation or regulations that provide, without sound scientific or economic bases, a preference for (benefit to) certain types of energy and/or industrial-related infrastructure investments at the expense of others, in order to serve a less than clear public purpose. In other words, perhaps, the *Kelo* decision will be employed by anti-private property and environmentalist ideologues to develop and refine a new genre of 'economic blight' and 'environmental blight'-based takings'.⁴⁵⁴

Beyond the influence of the *Kelo* decision on the U.S. law of tangible real and personal property takings, U.S. state and local governments have already begun to rely upon it to propose laws and/or regulations that would allow for the issuance of compulsory licenses to secure lower patented drug prices for the public benefit'.⁴⁵⁵ More importantly, however, it is arguable that this decision will have much broader and serious ramifications *internationally*. For example, foreign governments are likely to rely on the majority's misreading of precedent when considering how to treat intellectual property rights, such as patent, trade secrets, and copyrights privately held by U.S. corporations and individuals operating within their borders. Will the Government of Brazil now be more emboldened to use the threat of a compulsory license to constructively 'take' U.S. HIV/AIDS, and other drug or biomedical technology patents for an ostensible 'public use' that benefits one class of individuals (Brazilian citizens and industries) at the expense of another (U.S. citizens and industries), without paying 'just compensation'?

U.S. Private Property Rights Are Entitled to Constitutional Protection Abroad

The U.S. Supreme Court has held that the U.S. government is not free to act against, and must affirmatively protect, outside of the United States, any and all of the rights guaranteed to U.S. citizens by the U.S. Constitution and the Bill of Rights within the United States. The Fifth Amendment right against the taking of private property for public use without just compensation falls within this obligation.⁴⁵⁶ This has remained the law of the land for over 150 years.^{457 458}

Constitutional Limitations on the Federal Treaty-Making Power

The U.S. federal government's obligation to protect the private property rights held by U.S. citizens outside of US borders against unlawful appropriation also extends to takings' effectuated pursuant to treaties.⁴⁵⁹ While treaties and federal statutes constitute the supreme law of the United States', and are effectively equal to one another in status, they are both *inferior* to the U.S. Constitution and the Bill of Rights. The U.S. Supreme Court recognized this hierarchy almost fifty years ago, in the case of *Reid v. Covert*.⁴⁶⁰

There is nothing in this language [Article VI, Section 1 - the Supremacy Clause] which intimates that treaties do not have to comply with the provisions of the Constitution. Nor is there anything in the debates which accompanied the drafting and ratification of the Constitution⁴⁶¹ which even suggests such a result. It would be manifestly

contrary to the objectives of those who created the Constitution, as well as those who were responsible for the Bill of Rights--let alone alien to our entire constitutional history and tradition--to construe... the treaty provision in... Article VI as permitting the United States to exercise power under an international agreement without observing constitutional prohibitions.^{462 463}

Thus, according to the Court, it is arguable that the President cannot execute and the Congress cannot ratify a treaty with another nation(s) that effectively violates *any* of the individual constitutional rights protections afforded U.S. citizens.

The prohibitions of the Constitution were designed to apply to all branches of the National Government and they cannot be nullified by the Executive or by the Executive and the Senate combined... This Court has regularly and uniformly recognized the supremacy of the Constitution over a treaty.⁴⁶⁴

This limitation on the treaty clause likely prohibits the President, in the exercise of his Article II powers, and the Congress, in the exercise of its Article I powers, from executing and ratifying a treaty the provisions of which do *not* adequately protect U.S. citizens against unauthorized foreign governmental (treaty party) takings of U.S.-owned tangible and intangible private property. At the very least, this suggests that the President and the Congress have the *constitutional obligation* to ensure that all bilateral as well

as multilateral trade and investment agreements require the payment of just compensation' in the event a foreign treaty party government threatens to take *or* actually takes, privately owned patents, trade secrets or copyrights for public use'. Indeed, this is perhaps why the U.S. government has insisted that a takings' clause be included within Article 31 of the TRIPS Agreement,⁴⁶⁵ Chapter 11 of the NAFTA, the recently executed CAFTA, and approximately 2,200 bilateral investment treaties (BITS) it has consummated or is currently negotiating with other nations around the world.^{466 467}

It is apparent that the inclusion of a takings' clause has served to promote cross-border investment and international trade, and to prevent a foreign government's hold-up (i.e., the substantial diminution in the value) of private investments via oppressive regulation⁴⁶⁸ or outright threat of expropriation once considerable upfront costs have already been sunk'.⁴⁶⁹ According to legal commentators, the investor-to-state' provision within NAFTA Chapter 11, defines the term expropriation' rather broadly to include both direct and indirect measures.

NAFTA's Chapter 11 defines expropriation broadly: it includes not only direct measures, such as *nationalizing industries*', but also creeping expropriation' or *regulatory takings*' that arise when governments impose new regulations and restrictions on firms' activities (emphasis added).⁴⁷⁰

They also emphasize that, although a taking' of private property may occur to fulfill a public purpose', the U.S. property owner is still entitled

to receive ‘just compensation’ as payment for his or her economic loss, as a matter of due process.

According to Article 1110, *even if the host's actions are for a public purpose, non-discriminatory, and in accordance with due process, they are still subject to compensation requirements* (emphasis added).⁴⁷¹

While several NAFTA tribunals arrived at the correct legal conclusion in connection with such indirect regulatory takings,⁴⁷² other NAFTA tribunals have, for political and ideological reasons (e.g., environmentalist public pressure), failed to interpret the expropriation clause as broadly as they should have. They have instead provided for a *police powers carve-out* from said definition.⁴⁷³ Such carve-outs have permitted foreign government treaty parties to avoid compensating foreign investors for injuries suffered as the result of oppressive environmental regulations or other actions taken for an ostensible ‘public good’, that are not otherwise deemed discriminatory. In fact, some legal commentators who have grown sympathetic to the ‘environment or health-first’ position of regulatory-minded governments have strongly disputed the extent of Fifth Amendment protections afforded under NAFTA.⁴⁷⁴ They have also supported the future use of this approach by other tribunals called to mediate similar types of regulatory disputes arising under the hundreds of other bilateral and multilateral investment treaties (MITs) entered into by the U.S.^{475 476}

This result is not surprising, considering the support that activist anti-private property NGOs and academics have given to a controversial proposed model international investment agreement. That model agreement would

provide developing country governments with the sovereign right to take indirectly (through regulation) title to foreign-owned intellectual property, such as patents and trade secrets, for a public (health, environment, safety, etc.) purpose, *without* paying just compensation.⁴⁷⁷ Such an agreement only adds to the confusion over the scope of private property rights that has been triggered by these troubled NAFTA decisions and the recent U.S. Supreme Court *Kelo* ruling. It also further encourages emerging and developing economies like Brazil and Argentina to challenge the international IP framework.

It is evident that successive U.S. administrations, despite their divergent views on the scope of private property rights, have made a considerable effort to protect the private property rights of U.S. citizens doing business abroad. They have likely done so by ensuring the inclusion of strong expropriation clauses within the BITS and MITs they have negotiated and ratified, and may have even conducted takings impact assessments^{478 479 480 481 482* 483*} prior to entering into such arrangements.

However, are such efforts enough, from a U.S. constitutional law perspective, to prevent the Government of Brazil and other opportunistic foreign governments from exploiting those divergent views internationally? After all, the Brazilian government has regularly threatened to issue compulsory licenses against and/or to abrogate U.S. private patent and trade secret rights outright (i.e., engages in constructive takings⁴⁷⁸), and this has had the effect of substantially diminishing the value of such IPRs and weakening the negotiating leverage of the IP holders. Furthermore, while the Brazilian government has pursued this approach through exercise of its police power⁴⁷⁹ for the ostensible purpose of benefiting the Brazilian public interest⁴⁸⁰ – i.e., the interests of Brazilian citizens and

companies, it has done so *without* intending to pay U.S. rights holders 'just compensation' for their private property. Is the U.S. government legally obligated to do more than it already has to ensure the protection and enforcement of U.S. private property rights abroad? Must it not guarantee that treaty takings provisions are implemented fully by foreign treaty party governments - i.e., that 'just compensation' (full and adequate economic value) is actually paid to U.S. citizens when a foreign government issues or threatens to issue a compulsory license, or undertakes or threatens to undertake some other form of patent or trade secret abrogation? How is it possible for the Government of Brazil to claim that it is entitled to the private IPRs of U.S. citizens that the U.S. government can neither legally appropriate for itself for a public interest without paying just compensation, nor otherwise abandon at the expense of rights holders? Is this, but, another sign of things yet to come in America?⁴⁸⁴

D. BRAZIL SHOULD NOT RELY UPON THE HISTORY OF INDUSTRIAL OPPORTUNISM TO JUSTIFY ITS CURRENT BEHAVIOR

In some respects, Brazil's exploitation of patents and trade secrets belonging to foreign knowledge-based life sciences and information and communication technology companies is no different from the opportunistic practices of other countries during past industrial eras. However, three critical distinctions deserve emphasis. First, there are now binding multilateral treaties (e.g., the GATT/WTO/WIPO/BIT Agreements) and politically active international institutions to regulate and guide cross-border industry and government policies and practices relating to tariff rates, dumping, subsidies, market access and compliance, investments and intellectual property. Second, there are now time-tested industry and mercantile customs

and industry standards codes in place, which may serve as precedent to determine the shape and direction of evolving industry practices surrounding new hi-technologies. Third, there is now documentary evidence of successful national systems of innovation that recognize and protect exclusive private property rights, including IPRs. In other words, Brazil should not take comfort in the old ways to justify its current bad habits. The world-class countries that previously employed these methods and the prior informal international order upon which they relied have largely since evolved.

Opportunism - Historically Speaking

During the past two hundred years, and particularly, during the prior era of industrialization, businesses and national governments worked separately and/or together to opportunistically acquire the inventions and underlying technologies of their foreign competitors. This occurred primarily for two reasons: to secure national self-preservation and/or to gain a strategic competitive advantage. The following discussion briefly describes some of these practices.

In most cases, there was not much beyond the realm of customary practice or bilateral navigation and cooperation treaties. A well-established and structured legal order circumscribed by international conventions that set universal standards to which all nation state-parties were legally and politically bound simply did not exist. The notion of national comparative advantage governed international commerce and national trade policies were very much protectionist-minded. Each country vied for its own national interests as part of, what was then described, as a zero-sum 'game of trade.

Until the late nineteenth century, European countries, namely, England, France, Spain and the Netherlands held the competitive advantage in international trade through use of various tariff barriers, discriminatory and non-transparent patent regimes and state-centralized industrial development policies. From the late eighteenth through the late nineteenth century, America followed Europe's example by employing its own tariff barriers and discriminatory patent regimes to acquire the technologies and inventions it needed to survive and expand. It shaped its opportunistic patent rules largely after those utilized by their European counterparts.⁴⁸⁵ America's, laws, however, emphasized and focused on individuals' capacity to innovate, and upon the sanctity of private property and free enterprise. Its societal model reflected how the primacy of individual over state' interests could collectively serve and operate as an industrial development policy for the benefit of the nation.

America

According to one scholar of global intellectual property history, following the American Revolution, President George Washington, worked quickly with Congress and Alexander Hamilton, whom he later appointed as the nation's first Treasury Secretary, to reduce America's dependence on other nations based on national security needs. To achieve economic and political self-sufficiency, Alexander Hamilton developed a national innovation system that entailed high tariff barriers, a strong patent system that gave inventors and investors a government-guaranteed right to the exclusive use of their innovations for a fixed period and very favorable immigration policies aimed at encouraging the migration of skilled foreign workers.⁴⁸⁶

As far as U.S. patent law was concerned, the original Patent Act of 1793 protected only American citizens' inventions; foreign inventors were not eligible for patent protection.

Thus, any American could bring a foreign innovation to the [U.S.] and commercialize the idea, all with total legal immunity.⁴⁸⁷ The U.S. Patent Act was first amended in 1800, to permit resident aliens living within the U.S. for two or more years to become eligible to obtain a patent. These aliens, however, were obliged to take an oath that, the ideas they were attempting to patent had not previously been known or used in the [U.S.] or abroad. The Act was amended again in 1832. This time, resident aliens would become eligible for a patent if they agreed to take an oath declaring their intention to become U.S. citizens, and provided they actually worked the patent in the U.S. within a twelve-month period.⁴⁸⁸ The U.S. amended its patent law at least two additional times during the 19th century, in 1836 and 1842, respectively. These changes served as the foundation for the modern system.⁴⁸⁹

Beyond the patent law itself, Hamilton and Congress sought to rapidly industrialize the United States... by whatever means necessary.⁴⁹⁰ This policy effectively encouraged government sanctioned industrial and technological espionage by various individual Americans.⁴⁹¹ [A] succession of presidents, beginning with George Washington, John Adams, Thomas Jefferson and James Madison, authorized this policy.⁴⁹²

Germany

America, however, was not alone in this tradition. Germany engaged in more focused and systematic opportunism during the late nineteenth and early twentieth centuries. Germany's rise during this period entailed use of a new brand of trade protectionism and aggressive patent policies.

It focused on developing innovative science-based manufacturing and processing technologies (e.g., chemical dyes) upon which multiple downstream industries in foreign countries relied, and on the deployment of new combinations of tariff barriers, discriminatory and non-transparent patent regimes, and inaccurate or nondescript patent applications to dominate these industry sectors. It also sanctioned the creation of industry cartels and utilized centralized industrial-military planning to achieve these ends.⁴⁹³ In other words, Germany's policy objective was not merely to secure industrial and developmental self-sufficiency.

Germany's patent laws imposed residency, citizenship and/or work requirements that effectively permitted the German government to deny patents to virtually every foreign chemical maker, and thus block market entry of industry competitors. It also enabled German companies to use illicit means to acquire arguably superior foreign technologies not patented in Germany.⁴⁹⁴ In addition, German companies were encouraged to employ a four-level patent strategy within the U.S. in order to dominate that market as well. They generally refused to license their patented technology to U.S. companies, hired skilled and politically connected counsel to file thousands of U.S. patents, failed to describe their inventions in sufficient detail in patent filings, and bargained for low reciprocal tariffs on dyes in which they had a comparative trade advantage.⁴⁹⁵ This strategy proved extremely successful until the end of the World War II.

Japan

The tightly constructed industrial and economic networks of post-World War II Japan helped to rebuild Japanese society and restore Japan's global competitiveness in a

relatively short time. These policies originally focused on acquiring other countries' advanced technologies to rebuild Japan's manufacturing and technical capacity in order to meet its domestic development needs. They later facilitated the growth of one of the world's greatest manufacturing export platforms. Like England, France and Germany before it, Japan's innovation policy largely relied on aggressive patent protections, nontransparent disclosure mechanisms, protective tariffs and market access barriers. As with Germany, Japan's economic rise depended on a close-knit relationship between industry and government. This effectively resulted in the formation of state-centralized and sanctioned subsidy programs, industry cartels, and patent licensing procedures.⁴⁹⁶

Japanese companies employed a particularly effective sword and shield strategy to weaken the valuable patents of foreign competitors, particularly, U.S. companies, known as state-sponsored patent flooding'. This entailed the filing with the national patent agency of many small nuisance patents closely related to the original foreign patent.⁴⁹⁷ According to one legal expert, these nuisance patents alleged minor or incremental variations or improvements to the basic technology developed by the original patent filer (i.e., the foreign target company). Their purpose and effect was to lock-in the foreign patent filer to such an extent that it could not commercially exploit its own technology in Japan without risk of being subject to costly and time-consuming patent infringement litigation. If successful, the original patent holder would be persuaded to request a license from the patent flooder. While the latter usually agreed to such a request, it would then demand a cross-license in return for use of the target company's technology. In essence, the Japanese company would employ the patent flood to both (offensively) strip away the target company's exclusive rights in its own

cutting-edge technology. It would then (defensively) obtain for itself valuable rights into foreign technology that would have otherwise placed it at a competitive market disadvantage.⁴⁹⁸ Apparently, flooding had become a common and successful practice in Japan because it reflected and was consistent with the national system of 'recognized incrementalism' – progress that comes through the small continuous efforts of many inventors.⁴⁹⁹

Japan also employed other patent practices.⁵⁰⁰ For instance, Japanese authorities regularly delayed foreign patent approvals, limited the scope of foreign patent protection, permitted Japanese rivals to examine and comment on foreign patent applications, and adopted unworkable enforcement mechanisms.⁵⁰¹ Furthermore, Japan entered into a number of strategic alliances with American companies and universities during the 1980's and 1990's, which it then exploited to obtain novel U.S. technologies. This was later corroborated by the National Science Foundation, which report[ed] that [during]... 1985-2000, U.S. and Japanese corporations created 820 such alliances in the fields of information technology, biotechnology, new materials, aerospace and defense, automotive, and chemicals, virtually all of which involved technology transfers to Japan.⁵⁰² These alliances largely arose from a 1985 law that helped to create several U.S. joint research consortia, and that fell under the auspices of the existing U.S.-Japan bilateral science and technology agreement.⁵⁰³ Over time, it had become clear to the U.S. and other participating governments (e.g., the EU), that the programs were being mined by the Japanese government and its industries through undisclosed surrogates to obtain the resulting technologies. The Japanese then used their domestic laws to transfer that technology illegally to nonparticipating Japanese companies.⁵⁰⁴

China

China has employed a perceptibly more attractive multi-level strategy that has enabled it to progress along the economic ladder much more rapidly than its industrial predecessors.⁵⁰⁵ As a result, it has become, for the moment, the 'factory of the world', as well as a future aspiring technology leader.⁵⁰⁶ China's strategy differs markedly from Japan's strategy insofar as, it was necessitated by a simultaneous need for development, skilled labor, technology, and investment.⁵⁰⁷ Although China has utilized practically every device in the opportunist's toolbox,⁵⁰⁸ its conduct has remained more palatable to developed nation industries. Apparently, China has learned to frame its innovation needs in terms acceptable to the marketplace.⁵⁰⁹

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China has largely premised its model of innovation and development on the mechanism of joint venture-based investment. Typically, a foreign investor contributes intellectual property, including manufacturing process know-how and overseas distribution in exchange for a Chinese company's contribution of local manufacturing plant and equipment plus an unlimited supply of low-wage skilled labor. Incremental technology improvements and any new patents, trademarks and copyrights inure to the benefit of the new enterprise. Joint venture-based products are usually subject to export and substantially banned from the domestic Chinese market, which is largely reserved for Chinese state-owned or private enterprises.^{512 513 514} The Chinese government has documented the massive extent of foreign technology transfer that has already occurred. In 2001 alone, the government approved 240,000 joint venture technology transfer contracts, worth approximately \$10 billion, reflecting a 23% increase from the prior year (2000).⁵¹⁵

In addition to recognizing how it could capitalize on its seemingly endless supply of cheap labor, China has also sought to develop indigenous human capital (labor skills) which it deems essential to innovation. The Chinese government obviously knows that intellectual property-based innovation is the key to technological advancement. In this regard, China has employed a global charm offensive⁵¹⁶ that has sought to persuade, lure and sometimes force foreign corporations to locate their most advanced research and development facilities in China. It has also sent its students abroad to advanced western universities to become educated, with the expectation that they will eventually return.⁵¹⁶

In order to keep its factories running and its labor pool content China has sought to control the mass wholesalers and retailers upon which most global end-use consumers depend for their daily purchases. To accomplish this, however, China has had to develop the ability to efficiently: 1) import large quantities of raw materials; 2) build and operate large manufacturing and processing facilities that convert those materials into useable intermediate and/or finished goods; and 3) export large quantities of finished products to consumers. This has required that it quickly learn all about global procurement and distribution systems. Consequently, when a western company decides to move its R & D operations to China to capitalize on China's relatively cheap labor and very well educated knowledge pool, it is unwittingly transferring its next generation of knowledge and innovations there,⁵¹⁷ and helping China to become an independent innovative as well as manufacturing force.^{518 519 520}

India

India, long obscured by the economic shadow cast by China, expressed its self-confidence and ambition at the January 2006 World Economic Forum.⁵²¹ India has come a long way during the past decade following market reforms initiated in 1991, which have finally given rise to significant global investor interest.^{522 523}

However, economists believe that additional reforms are still necessary to improve infrastructure, broaden privatization and expand labor-intensive production. They have also recommended liberalization of inefficient industry sectors, such as retail, banking and insurance. In addition, although India has made some progress in removing trade barriers since it assumed WTO membership, it still retains high import tariffs and has only recently reformed its intellectual property laws so that they ostensibly comply with the TRIPS Agreement. Investors are concerned that unless India increases the pace of its legal and economic reforms, it will slip backward and lose the opportunity that now presents itself to emerge from generations of endemic poverty.⁵²⁴

Indeed, the recent economic rise of India has inevitably led to comparisons with China.⁵²⁵ These comparisons commonly point out that India must continue to adopt and implement policies that do the following; 1) attract foreign direct investment flows; 2) establish local enabling environments that promote rather than restrain the creation and operation of entrepreneurial businesses;⁵²⁶ 3) encourage investment in human capital (education); and 4) result in the development of sound legal and financial institutions. This is required to ensure that indigenous innovation occurs – so that what is labeled *Made in India, China, and Brazil* is actually *Made by India, China and Brazil*. In this regard, [it is agreed that] India has done a better job than China.⁵²⁷

As of January 1, 2005, the Indian government abandoned the prior 1970 Indian Patent Act, which sanctioned the reverse engineering of foreign patents by restricting Indian patents to manufacturing processes rather than to end-products.⁵²⁸ Previous Indian governments apparently did not think twice about using national patent laws to copy drugs and chemicals invented overseas (in the U.S. and Europe) to ensure not only the country's industrial development, but also the expansion of its indigenous technological capabilities.

According to one international IP expert, India justified its prior imposition of protectionist tariff barriers and employment of opportunistic patent rules on the need to ensure indigenous production, and hence, employment. He argues that this was reasonable, in light of India's early stage of economic development and its lack of industrial and technological self-sufficiency. In a country that possessed little indigenous scientific or technological capacity to invent, and contributed little to global markets, he notes how Indian politicians initially believed that their establishment of a strong patent system would benefit only the foreign inventors that made the economic investments, rather than the local population.^{529 530} However, India is a much different country than it was ten, five, three or even one year ago. Consequently, this ideology will likely prove harmful to India's continued evolution as an exporter of high technology products derived from patented inventions. Furthermore, such ideology is also not likely to appeal to modern investors, domestic industry associations and foreign corporate investors, who have become concerned that, unless India evolves more quickly, it may slip back into its old socialist mindset.⁵³¹

Brazil

Within the past year, the Brazilian government has adopted legislation to address the rampant piracy of U.S. *copyrighted* products in the music, film and software industries. It has also established a Council to Combat Piracy and Intellectual Property Crimes, a 99-point national Anti-Piracy Action Plan, stepped of IPR enforcement along its border with Paraguay, and increased its seizure rate of *copyrighted* materials. Prior to these efforts, the Brazilian Congress' Deputies had formed a Commission of Parliamentary Inquiry (CPI) on piracy and amendments to the criminal code.⁵³² No doubt, the Brazilian government has made tremendous progress in stemming such counterfeiting, and it now recognizes that foreign inventor and investor frustration with its latent pirate policy may adversely affect Brazil's standing in international financial markets.

Notwithstanding these efforts, however, U.S. government officials remain concerned that Brazil continues to fall short in providing adequate and effective protection of U.S. IPRs. Despite Brazil's enactment of modern *copyright* legislation, significant challenges to effective copyright enforcement, particularly with respect to optical media and internet piracy, remain. Furthermore, Brazil continues to be one the world's largest markets for technology opportunists, in terms of *patents*.

Brazil's inability to make any significant progress in addressing its acute patent-processing backlog dilemma has partly contributed to this problem. As of January 2005, U.S. industry had estimated Brazil's patent backlog at approximately 47,000 patents, for which industry had paid substantial upfront processing fees.⁵³³ Yet, during January 2006, the U.S. government discovered that Brazil's patent backlog was actually 130,000 patents. Of these, 17,000 are

for pharmaceutical patents, each bearing an upfront \$30,000 filing fee (collective fees of \$510 million have already been paid out), and some have been pending for several years.⁵³⁴

What is more troublesome than this tragic administrative problem, however, is the ideological manner in which Brazil has used this and other hidden governmental failures as an excuse to deny legal protection to foreign private property - IPRs. One such failure concerns the inability of Brazil's health infrastructure to distribute medicines efficiently to rural communities, and to treat effectively those patients whom it can reach. Another such failure concerns Brazil's lack, until very recently, of a national innovation system that supports that which it continues to lack - a national industrial policy. Furthermore, Brazil's ideological reluctance to recognize private IPRs (patents and trade secrets) in the field of life science technologies, despite the existence of national patent and data exclusivity legislation, has ignited international passions in the pharmaceutical and biotechnology industries.⁵³⁵

The Government of Brazil has, with the assistance of anti-private property and anti-free market activists, academics, and bureaucrats, continued to employ opportunistic practices to extort significantly reduced (at-or-below-cost) drug prices from international pharmaceutical companies. If the companies refuse, Brazil then threatens to 'break' (i.e., to 'take') their patents via issuance, or *threat* of issuance, of a compulsory license, which it argues is sanctioned as a permissible flexibility within the WTO TRIPS Agreement. Leading Brazilian scientists are now at the forefront of this policy movement because they recognize how it can contribute to Brazil's national industrial and technological development. For this reason, they have endeavored to help the government of Brazil to

create an artificial legal distinction, in the minds of international regulators and policymakers, between life sciences patents and all other patents.⁵³⁶

Indeed, it is arguable that, like the previous governments of Germany, Japan, and China, and until recently, the government of India, Brazil has used its domestic patent laws, in combination with tariffs and other trade barriers, to mask a hidden state-centralized agenda and ideology of patent opportunism. Brazil has made no secret of its ambitions to develop its generic drug manufacturing capacity to compete with Chinese and Indian producers and distributors for both the third world and developed world markets. It has also been very willing to interpret international trade, environment, health, and human rights laws liberally in order to achieve this objective. As India had done previously, Brazil has spent many years honoring patented processes not patented products, despite the fact that its 1996 Patent Law required recognition and enforcement of both patented products *and* processes. This has permitted Brazil, to reverse engineer many foreign drugs, and then to reconstitute them through application of new synthetic processes, as a completely new entity (molecule) or product susceptible to national patenting. Brazil has proceeded to justify this, as did India, by reference to the extreme economic hardships that it would endure if it were required to pay the higher prices that patents usually demand.^{537 538}

According to one prominent Brazilian scientist and intellectual property expert, IPRs are dispensable and may be wielded as both a shield and a sword by the Brazilian government if, and when, it is convenient and in the national interest to do so.

Intellectual property rights are strategic and fundamental assets for the maintenance and expansion of health policies. As can be noted from the Brazilian experience, the wisdom of developing strategies in the field of international diplomacy associated with strategies for access to medicines and the reduction of prices is capable of making a difference. As IP rights are in constant evolution on the international scene and the Brazilian legal system, certain recommendations are valid. Amongst them are: i) increase general understanding as to the specificity of public health questions in the negotiations for intellectual property; (ii) seek to increase the negotiation capacity (including as a strategy for price reduction); (iii) take full advantage of opportunities and flexibility contained in international agreements; (iv) study the feasibility of incorporating all forms of safeguards (compulsory licen[s]es, parallel imports, Bolar provisions, etc.) into national law; (v) promote the overall consolidation of the National Institute of Industrial Property, especially concerning the technical examination of patent applications; (vi) systematically monitor the grant of patents in the areas of interest (so as to verify, for example, what is or is not of public domain, which are the most active companies, what is about to expire, etc.); (vii) after establishing a determined level of protection,

verify the impact on local industry; and (viii) strengthen the management of intellectual property and technology transfers in research institutions and innovation systems for health (emphasis added).⁵³⁹

Interestingly, some within Brazil's pharmaceutical industry agree. They see the protectionist benefits they may gain from the Brazilian government's emphasis of the *potential health* risks engendered by according unnecessary protection to foreign patents and trade secrets. Actually, the Brazilian Association of Chemical Industries (ABIFINA) recently raised the following *objection* to maintaining a strong protection of foreign patents.

Critical the current part of the empirical constatação that in place of a stimulation to the inventors *the patent more became a mechanism of reserve of market for great companies*, making it difficult the innovation and, that in the form as they have been generated, the documents of clear more hide that they disclose the underlying technology to the invention, frustrando the dissemination objective. A study based on inquiry carried through with more than 1,400 American industrial companies it showed that: - *the majority of the companies, with exception of the ones of the pharmaceutical sector, does not consider patents a mechanism important to guarantee the apropriabilidade of the profits derived from its innovative products* (emphasis added).⁵⁴⁰

Based on this evidence, one may credibly argue that some Brazilian government regulators and domestic companies seek for Brazil to continue its opportunistic acquisition of foreign technologies, which they believe is justified by the need to advance both Brazil's evolving national industrial and innovation agenda and its international economic (trade) interests. Whether the innovation model that the Government of Brazil has ultimately chosen for this purpose resembles any one or more of the strategies previously described, is subject to interpretation.⁵⁴¹

The Government of Brazil should be aware, however, that there already exists a very successful and evolved science and technology (knowledge and information)-based innovation model that has survived the tests of time and experience. That evolved model emphasizes the importance of individual innovation, the sanctity of private property, and the primary role of free markets in both rewarding the efforts and investments of individual inventors and collaborators, and of sharing the know-how in the form of commercially useful products distributed throughout society. It also recognizes the primacy of the individual over the state as a constitutional matter, and acknowledges how individual inventor interests (private goods) when collectively channeled can create a greater public good that serves both national and international interests. The Brazilian government need not resort to industrial and technological opportunism to promote economic growth, if it focuses on acquiring these tools of innovation.⁵⁴²

III. THE TOOLS OF INNOVATION

A. PATENT-BASED INTELLECTUAL PROPERTY IS VALUABLE

Intellectual Property is the Key to Innovation

During 2003, the Multilateral Investment Fund (MIF) of the Inter-American Development Bank (IADB) issued an insightful report analyzing the effectiveness of institutional reform projects it had previously funded during the 1990s to ensure the proper functioning of Latin American markets. These projects identified the protection of private *intellectual property rights* as one of the key factors needed to ensure the competitiveness of firms operating within regional markets.⁵⁴³

*Intellectual property is an asset, and as such, has an economic value. Whoever creates, invents, or designs something can protect that creation by using the legal tools contemplated for that purpose by law. By using those tools, legal recognition of the creative activity can be obtained in the form of an intellectual property right' which allows us to protect what we have created and prevent others from exploiting it without our consent (emphasis added).*⁵⁴⁴

According to the report, some of these projects focused on reforming and modernizing *intellectual property registries* to achieve this objective.

... During the 1990s, most of the... projects in the region aimed to reform and modernize intellectual property registries. They... channel[ed] funds for

buildings, personnel training courses, the introduction of information technologies and software, and dissemination activities... These projects have played an important role given that *intellectual property registries are components in the system*. It is they that are called upon to register patents, trademarks, and industrial designs, analyze applications for new registrations, and keep the records on file (em phasis added).⁵⁴⁵

The report, furthermore, identified innovation as the linchpin and innovation systems as the facilitator of intellectual property creation.

Innovation is essential for creating intellectual property. The two basic factors of understanding innovation are: (i) *the enterprises themselves as creators and administrators of knowledge*; and (ii) *the national innovation system, as the provider of the environment and resources to generate this know-how* (em phasis added).⁵⁴⁶

Moreover, the report cited the economic benefits that would flow from the various productive uses of innovations protected by intellectual property rights. They include improved brand and market differentiation, acquisition and development of valuable economic assets that may be financially leveraged and increased access to new markets through licensing, franchising, etc.^{547 548}

Interestingly, the economic freedom and benefits that can be realized by intellectual property owners that have

officially registered‘ their legally recognized rights and collateralized or otherwise exploited (e.g., licensed franchised) their legally protected assets, are analogous to those benefits thus far realized by individuals who have officially registered their informal claims to real property throughout Latin America. In this regard, the Government of Brazil should carefully study the successful program of Peruvian economist Hernando De Soto. That program has enabled poor people living in various Latin American countries to secure official registration and recognition of informal title (deeds) to land that they had long occupied, and such ownership has helped them to realize significant economic benefits.^{549 550}

Lastly, the IADB report concluded that many of the obstacles faced in promoting the value of intellectual property in Latin America do not stem not from any lack of appreciation by the *private sector* for the *legal* concepts of intellectual property and private property rights in general. Rather, it found that the failure of governments to coordinate with and enhance the ability of (i.e., to enable) local enterprises and academic institutions to develop, convert, and commercialize their know-how has effectively denied them the economic benefits from such ownership.⁵⁵¹

A recent (2005) OECD report concluded that the economic value of patents, especially those secured by knowledge-intensive companies operating within the ICT, pharmaceuticals, and biotech sectors,⁵⁵² has been rapidly rising.

... *The economic value of patents is increasing.* Spurred by increasing competition from low-wage countries, firms in OECD countries are putting more emphasis on innovation and the

creation of intellectual property as a means of generating comparative advantage and are filing a growing number of patents. *Economic studies show an order-of-magnitude increase in the estimated value of patents, although considerable variation remains in the value of individual patents, with a large share of the total value of patent portfolios deriving from a small number of patents. Value is strongly influenced by the novelty of the invention and the availability of alternative routes to the same solution (i.e. inventing around a patent (em phasis added).*⁵⁵³

This study also found that, since the economic value of patents comprised an ever larger share of company market value, successful companies operating within these sectors would need to employ the most prudent and economically efficient means to manage their innovation practices (R&D) and related intellectual property portfolios and to then exploit (commercialize) those assets in the marketplace.

[The economic value of patents]... is highly context-dependent and relates to the ability of a firm to extract the value from its patents through competent management, as well as on the particular market environment facing a patent holder. Differences across sectors are driven by factors such as patent strength, market structure, technology characteristics, company strategies and firm size... Management of

intellectual assets, notably patents, has become a central issue in the knowledge-based economy. An increasing share of the market value of firms appears to derive not from tangible assets as reported in financial statements but from intangible, intellectual assets that firms are attempting to manage more actively. Technology markets, which facilitate the exchange of patented inventions (via sale or licensing), are an important part of the economic infrastructure for exploiting patents and can help improve the efficiency of innovation processes by putting inventions in the hands of those most able to *commercialise* them (emphasis added).⁵⁵⁴

Furthermore, the study noted that while public research institutions have an important role to play in fostering technological innovation that offer significant social and economic benefits, governments at large should restrict their interventions to merely removing obstacles to and facilitating/overseeing the efficient operation of technology markets.

... Public institutions have an important role to play. *While the development and implementation of technology markets is largely a private-sector activity, there is general consensus that governments play an important role in ensuring the efficient operation of markets and competition authorities monitor their functioning and prevent anticompetitive licensing*

behaviour. The creation of markets takes time and governments can help remove obstacles to the development of technology markets to accelerate the process (emphasis added).⁵⁵⁵

Moreover, the study observed that because of growing competition posed by technology-oriented companies from advanced as well as emerging economies, a new global business environment has evolved which engenders higher technology development costs, lower profit margins, shorter product lifecycles, and continuing market demand for new and more specialized technologies. As a result, companies' use of patents has assumed a more central and strategic character in their daily business that varies according to the idiosyncrasies of the industry sector in which they operate.⁵⁵⁶ Thus, industry actors are compelled to rely increasingly on strong patent protections internationally to both defend their most valuable assets and expand their already vulnerable market shares.

In recent years, the globalisation of marketing and manufacturing has brought in stronger competition, lower profit margins and shorter product life cycles. Technology has become more complex, raising the cost of R&D and demanding specialised technology suppliers. As a result, returns to the investments in the development of new products and services are less certain, and *emphasis has shifted away from manufacturing as the key to competitiveness and towards R&D as a source of new ideas* and to build better relationships with customers. As IP protection has

strengthened (especially in the United States), patents and trademarks have become strategic weapons for many businesses. *Companies protect their inventions via patents and build up their patent portfolios for strategic purposes.* Wise management of IPRs through technology marketing and licensing strategies is increasingly seen as a strategic way to generate revenues and profits. *Such changes are leading to an intellectual economy in which IP becomes the basis for value creation for firms, whether through its incorporation into innovation products and services or through its sale in the market place* (emphasis added).⁵⁵⁷

The U.S. Congressional Research Service had drawn similar conclusions regarding the economic utility of patents in a report it released earlier during 2005.⁵⁵⁸ Apparently, the European Commission has done the same.⁵⁵⁹ Also, at least one (2004) study has noted how competition-minded Asia-Pacific-based agro-businesses have increasingly focused on the economic value of establishing strong IPR (i.e., patent) regimes to enhance the protection of their evolving life science technologies – e.g., new plant and animal varieties, biologically based inputs for agriculture, and crop-based nutritional and pharmaceutical goods.⁵⁶⁰

Even the WHO has recognized that protected patents serve multiple functions within society that can result in public as well as private benefits. First, patent protection has an incentive function. It can provide inventors with the necessary incentive to generate intellectual creations for

economic and social gain. Second, patent protection has a transactional function. Protected inputs to a collaborative research endeavor can facilitate [greater] inter-firm R&D collaboration, that can result in the conversion of inventions into marketable products. In addition, protected patents also can facilitate the division of profits among contributors to a given stream of research [which,] in turn, affects the extent of incentives available to successive inventors. Third, patent protection has a disclosure function. A properly prepared patent application can and must publicly disclose all of the technical information concerning the invention, and such information must be described clearly enough to enable a skilled person to reproduce the invention. Fourth, patent protection has a signaling function. Valid ownership of a patent indicates to prospective investors a firm's innovative capabilities, and thereby increases that firm's ability to secure third-party financing, including from venture capitalists.⁵⁶¹

B. EXCLUSIVE TEST DATA AND TRADE SECRETS ARE VALUABLE INTELLECTUAL PROPERTY

The General Case for Protecting Test Data and Trade Secrets

In addition to securing patent protection, life sciences companies rely significantly on their ability to protect, as a separate intellectual property right, the costly know-how or other undisclosed information they have generated, compiled, analyzed, organized and submitted, at their own expense, to government regulators. This usually occurs, subsequent to or in lieu of a patent's issuance, in order to secure commercial marketing approval for the ultimate product.⁵⁶²

There are good public policy reasons for recognizing and protecting such private property rights. First, it results in the development and distribution of new, more specialized, and higher quality drug and medicinal products that can improve the healthcare and enhance the quality of most citizens' lives. Second, it encourages inventors and producers of data and other information to create new incremental innovations that spawn new uses that can ensure continuous future *societal* progress and well-being. Third, it is both equitable and fair for life sciences companies to be able to recoup their economic outlays (return on capital)⁵⁶³ and to earn a reasonable profit to boot (return on sales),⁵⁶⁴ which they can later reinvest in search of new breakthrough and incremental medicines.⁵⁶⁵ Fourth, it attracts greater research and development-related foreign direct investment.⁵⁶⁶

The Economic Underpinnings

Most countries require that innovative drugs undergo lengthy examination procedures to ensure that they are effective and safe for public use before they are granted marketing approval.⁵⁶⁷ Drug innovators (originators) must provide regulators with a great amount of confidential and proprietary information during this examination process, much of it being the result of very costly experiments and clinical trials spanning many years.⁵⁶⁸ Drug innovators are motivated to endure this painful process because they anticipate earning enough revenue and profit once their drug enters the market to recover their considerable investment of time and money. Generic manufacturers, however, typically do not undergo such a timely and costly development process. Nor are generic copies of patented drugs usually subject to such an exhaustive examination before they are granted country-marketing approval. Generic manufacturers need only establish that their

version of the innovative drug is bioequivalent' to the already approved original drug. It is mostly from this discrepancy in cost, time, and effort, and the otherwise undisclosed (secret') know-how generated in the process, that drug innovators hope to derive a competitive advantage in the marketplace.

It is easy to see how allowing a generic applicant to utilize bio-equivalence-related information previously obtained by regulators about an innovative drug during the course of an earlier examination, would be viewed as commercially unfair, especially if it occurs without the drug originator's consent and fair compensation. Arguably, absent the need to conduct its own clinical trials and to produce independent evidence of bioequivalence, a generic drug manufacturer acquires a significant competitive advantage over the drug originator – the ability to obtain fast and cheap marketing approval through other than its own efforts.⁵⁶⁹ An innovative drug is usually accorded a period of exclusivity, to the extent it is protected by patents, and this assists the originator to recoup a portion of the expenditures incurred to undergo many years of *basic* product research and development. These sunk costs, however, are separate and *apart from*, and are incurred usually *before*, the subsequent clinical testing activities, the details of which are ultimately reported in the confidential data submitted to regulators. For this reason, many countries, beginning with the United States, have created a complementary mechanism of data exclusivity' to compensate the originator for the extra time and expense needed to provide safety and efficacy information. Its objective is to eliminate the competitive market advantage that would otherwise inure to the generic manufacturer as the result of using such a fast-lane' approach. In essence, data exclusivity refers to a period during which no third

party applicant can rely on data filed by the original applicant for a marketing authorization.⁵⁷⁰

Data exclusivity provisions usually provide rights holders with a period of exclusive data enjoyment that spans between 5 and 10 years from the date of the drug application's approval. During this period, while generic applicants may seek marketing approval for their generic drug copies, they may *not* rely on, *and* the government employees and officials (i.e., regulators reviewing their application) may *not* rely on, the information drug innovators generated, composed, presented and submitted to the regulatory agency for the original drug's prior examination. Since data exclusivity protects only the information so provided, a generic manufacturer seeking marketing approval is free to provide regulators reviewing its application with information and data originating from *any other* source.

Data exclusivity sometimes has the effect of protecting innovative drugs the underlying patents of which have expired, or for which patent protection is unavailable. In fact, data exclusivity may serve as the sole protection for the innovative drug manufacturer in that case. It can therefore be said that the grant of data exclusivity, like other pharmaceutical regulation and authorization, reflects an attempt[] to protect the investment of companies in their innovations.⁵⁷¹

The Legal Underpinnings

Data exclusivity derives its legal significance as private property from two areas of the common law, which have since been codified into uniform state statutes in the U.S. – namely that of trade secrets and unfair competition.⁵⁷²

Trade Secrets at Common Law

Data exclusivity, by its very nature is, in part, an affirmative common law property right of trade secret'.⁵⁷³ Exclusivity is usually justified if it protects from disclosure and unauthorized use information that the drug originator has developed over considerable time and as a result of significant expenditure which it otherwise made a reasonable effort to keep secret (from public knowledge), and that has, in fact, remained undisclosed (secret') at the time it is submitted to regulators. In other words, the information or clinical testing data for which exclusivity is sought must not already be in the public domain. Typically, such information is not protected by a patent, because a patent requires, as a condition for its issuance, that the applicant publicly disclose (fully and clearly) in its application all technical information about the product or process for which patent protection is sought.⁵⁷⁴

A trade secret is legally defined as anything that gives a competitor an advantage [edge] or head-start that is not in the public domain. It typically includes opportunities that present themselves to a business, involves dedication of substantial time, cost, and effort, and often consists of the knowledge possessed by company executives and key employees.⁵⁷⁵ In other words, the economic value of a trade secret resides in the pecuniary and human outlays (costs) associated with its development, along with the effort expended to prevent its disclosure to others – i.e., to maintain its exclusivity. The nondisclosure of a trade secret is protected for a temporary period against both the acts of commercial competitors AND the acts of government officials if properly designated as such.⁵⁷⁶

Statutory provisions have been enacted that are designed to *prevent unwarranted administrative*

disclosure of trade secrets. Thus, when companies submit license applications for regulatory review, officials at the FDA are prohibited from improperly disclosing confidential information, including trade secrets.⁵⁷⁷

In addition, the U.S. Freedom of Information Act (FOIA) provides trade secrets, including information submitted to the U.S. Food and Drug Administration, with an exemption from public disclosure, even though the underlying policy purpose of the statute is to provide public disclosure.

[I]t is an inextinguishable fact that much of the information that is submitted to the FDA is subject to production under the Freedom of Information Act (FOIA). Although FOIA's underlying policy is public disclosure, trade secrets are protected from disclosure by 5 U.S.C. §552(b)(4) (Exemption 4), in addition to the statutory provisions cited above. *This exemption to FOIA protects trade secrets and commercial or financial information obtained from a person and privileged or confidential* (emphasis in original).⁵⁷⁸

This safe harbor protection, however, is not absolute as it is subject to public interest' exceptions.⁵⁷⁹

Furthermore, the disclosure, divulgence, or making known of commercial trade secrets or any information relating thereto by any federal employee in any manner not authorized by law can constitute a criminal offense punishable by fine and/or imprisonment.⁵⁸⁰

Unfair Competition at Common Law

The character and nature of the affirmative right to data exclusivity is also shaped, in part, by the common law of torts (unlawful wrongs'). Section 757 of the Restatement of Torts First (1939), provided the first broad widely accepted definition of a trade secret: Any formula, pattern, device or compilation of information which is used in one's business, *and which gives him an opportunity to obtain an advantage* over competitors who do not know how to use it (emphasis added).⁵⁸¹ And, this definition can be traced back to the common law right of prospective economic advantage'. In the environment of free and fair competition evolving during the early twentieth century, the unlawful and willful interference with this right gave rise to an action in tort.⁵⁸²

As a matter of law, the burden of proof (i.e., the burden to show causation) is placed upon the plaintiff, who must establish that it is reasonably probable that the lost economic advantage [i.e., an evolving economic interest that has not yet matured] would have been realized but for the defendant's interference. This means, in other words, that it must be reasonably probable that the prospective economic advantage would have been realized but for defendant's interference.⁵⁸³

The right of prospective advantage is based partly on the right to pursue probable opportunities (expectancies) for economic reward without undue interference from others. It is arguable that the ability of an actor to pursue this right to its logical end implies excluding any other actor that might be inclined to interfere with its exercise.

... [I]n a civilized community which recognizes the right of private property among its institutions, the notion is intolerable that a man should be protected by the law in the enjoyment of property once it is acquired, but left unprotected by the law in his effort to acquire it; and that since *a large part of what is most valuable in modern life depends upon probable expectancies* as social and industrial life becomes more complex the courts must do more to discover, define and protect them from undue interference (emphasis added).⁵⁸⁴

In addition, this right is partly based on the privilege of individuals to engage in free competition by all fair and reasonable means⁵⁸⁵ in pursuit of that reward.⁵⁸⁵ The conduct of unfair competition⁵⁸⁶ refers generally to all dishonest or fraudulent rivalry in trade and commerce, but is particularly applied to the practice of endeavoring to substitute one's own goods or products in the markets for those of another.⁵⁸⁶ It also encompasses unfair *methods* of competition.⁵⁸⁷

It can be said that the modern law of unfair competition evolved, at least in part, from the need to protect this right of prospective advantage, since it is intended to resolve the natural conflict between the need for competition in the commercial arena and the opposing need for reasonable restraints on methods of competition.⁵⁸⁸ The tort of unfair competition now includes the tort of misappropriation⁵⁸⁸, which consists of three basic elements: 1) the plaintiff has made a substantial investment of time, effort, and money to create a thing misappropriated; 2) the defendant has

appropriated⁵⁸⁹ the thing at little or no cost; [and] 3) The defendant has injured the plaintiff by the misappropriation.^{590 591}

In effect, any *improper* method used to obtain [misappropriate] a competitor's trade secret is an infringement [of the right of prospective economic advantage] and is subject to injunction and damages (emphasis added).⁵⁹² Section 39 of the Restatement (Third) of Unfair Competition (1995) reinforces this interpretation. It defines a trade secret as any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford *an actual or potential economic advantage* over others (emphasis added). And, it embodies the principles of trade secrecy codified in the Uniform Trade Secret Act (USTA).⁵⁹³ Consequently, The U T S A , as adopted by various states, together with the Restatement (Third) of Unfair Competition §39, provides a basis for companies to obtain equitable and injunctive relief for the appropriation of information that is not necessarily tied to the productive process.^{594 595}

Data Exclusivity (Hatch-Waxman) and Regulatory Non-Disclosure

U.S. law was the first to grant the statutory right of data exclusivity to the life sciences industries, with the passage in 1984 of The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act'.⁵⁹⁶ The Act actually relaxed the level of protection afforded to testing data in the US. Previously, testing data submitted to regulatory agencies had received indefinite protection as trade secrets. Under the Hatch-Waxman Act, applications for approval of *new* drugs receive 5 years of data exclusivity. Applications for the approval of *new*

indications for an existing drug receive 3 years of data exclusivity.⁵⁹⁷ The Hatch Waxman Act established a fundamental trade-off: In exchange for permitting manufacturers of generic copies of patented drugs to gain FDA marketing approval *by relying* on safety and efficacy data from the original manufacturer's [new drug application] NDA, the original manufacturers received a period of *data exclusivity*...^{598 599}

*... A grant of market exclusivity does not depend on the existence of patent protection ... The length of market exclusivity is contingent on whether or not the drug is considered a new 'chemical entity (NCE)...*⁶⁰⁰ If the approved drug is not an NCE, then the FDA may not approve an ANDA for a generic version of the approved drug until three years after the approval date of the pioneer NDA. In contrast, if the approved drug is an NCE, then a would-be generic manufacturer cannot submit an ANDA until five years after the date of the approval of the pioneer NDA. *The effect of this provision is to restrict a potential generic manufacturer from bringing a product to market for five years plus the length of the FDA review of the ANDA* (emphasis added).⁶⁰¹

As noted in a recent report prepared by the Congressional Research Service (CRS),

This market exclusivity only pertains to the new indication and does not prevent the approval of a new pharmaceutical if all the

required clinical studies are performed to support the same changes. *The intent is to encourage ongoing [incremental] innovation on existing pharmaceuticals* (emphasis added).⁶⁰²

A close reading of the congressional report reveals that as a condition to obtaining a term of market exclusivity (whether 5 years or 3 years), either the molecule (chemical entity) must be new ‘ or the indication (e.g., use, formulation, dosage, composition, labeling, etc.) must be new ‘ – i.e., not previously *disclosed* in the public domain. In addition, the Hatch-Waxman Act included another quid pro quo. In exchange for originator companies being forbidden, pursuant to the Bolar Amendment,⁶⁰³ from challenging clinical trials conducted by generic manufacturers on patented drugs prior to their expiration, originators were granted the right to obtain an extension of their patent term to the extent they experienced any delays between patent approval and market authorization.⁶⁰⁴ Apparently, this trade-off had been deemed successful in addressing competing industry interests by the EU Commission and the UK government, each of which proposed adoption of their own Bolar provisions.^{605 606} However, due to EU activist opposition and differences in EU member state statutory interpretation, they have yet to be enacted.⁶⁰⁷

The same CRS report concluded that American society, on balance, has benefited more than the pharmaceutical industry from the Act’s grant of the right to market exclusivity ‘ for drug registration data. As the price of rewarding Americans with the opening up of a vigorous and highly competitive generic drug market that offers low-cost generic substitutes to branded drugs, branded

pharmaceutical companies have suffered considerable market share *and* profitability erosion.^{608 609 610}

Notwithstanding such market erosion, however, recognition of the right to data exclusivity has enabled pharmaceutical companies to protect the large investments in confidential clinical testing and data preparation they have incurred *in addition to, and following after*, an already costly, time-consuming, and perhaps, patent-protected research and development period. Hence, by providing drug originators with temporary data exclusivity, the government has achieved its policy goals: to encourage discovery and development of cutting-edge medicines that are also reasonably profitable in economic terms.

Data Exclusivity and TRIPS

The core concept of data exclusivity became part of the 1994 multinational Agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS Agreement)⁶¹¹, as set forth within Article 39(3):

Members, when *requiring*,⁶¹² as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities,⁶¹³ the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against *unfair commercial use*. *In addition*, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that

the data are protected against *unfair commercial use* (em phasis added).

While there has been much international debate over the meaning of the text within this provision, it is widely agreed that previously undisclosed clinical test and other data is a category of intellectual property with economic value deserving of legal protection.

According to Article 1.2 of the TRIPS Agreement, **the protection of test data is a category of “intellectual property” like patents, copyrights and trademarks.** The structure of Article 39 suggests that the regime for test data has been conceived by the negotiating parties as a *particular* case in the framework of the **protection of „undisclosed information (trade secrets)“**... (Italicized em phasis in original; boldface and underlined emphasis added).⁶¹⁴

Furthermore, it is widely agreed that the subject matter to be protected under Article 39.3 includes undisclosed

... written material which details the results of scientific health and safety testing of drugs and agrochemicals, in relation to human, animal and plant health, impact on the environment and efficacy of use. The provision covers tests and other data that may be required by the authorities. These other data may include, for instance, manufacturing, conservation and packaging methods and conditions, but only to the extent that submission of this

information is *necessary* to obtain marketing approval (emphasis added).⁶¹⁵

In other words, it is well understood that 'Undisclosed information' covers *any* secret information of commercial value, including [1] technical know-how, such as design, process, formula and other technological knowledge often resulting from experience and intellectual ability; [2] data of commercial value, such as marketing plans, customers lists and other business-related information that provides an advantage over competitors; [3] test and other data submitted for the approval of pharmaceutical and chemical products for agriculture (emphasis added).⁶¹⁶

The debate surrounding the IPR of data exclusivity, therefore, largely concerns the extent and scope of legal protection it should be afforded nationally and internationally.⁶¹⁷

IV. ACQUIRING THE TOOLS OF INNOVATION

A. BRAZIL SHOULD ADOPT IPR PROTECTIONS TO ATTRACT FOREIGN DIRECT INVESTMENT

IPR Protections Are Important to Foreign Investors

Due to the significant and growing economic value of patents, it is understandable why developing countries have undertaken considerable efforts to acquire such tools of innovation. One way to do so is through foreign direct investment (FDI). Arguably, FDI flows are even more

important than trade flows in today's rapidly expanding technology and information society.⁶¹⁸

As noted by the World Bank,

what makes FDI especially important is that unlike trade in goods, where developing countries try to glean whatever information they can from the products and services imported or import capital goods that embody modern technology, FDI involves explicit trade in technology...⁶¹⁹

One recent (2005) study identifying secure property rights as a *key* concern of foreign investors,⁶²⁰ examined the impact of developing country institutional efforts to attract FDI. It found a positive correlation between a developing country's adoption of open and transparent domestic capital account control policies and its participation in international treaty regimes (including WTO membership, and preferential trade and bilateral investment agreement participation) on the one hand, and positive FDI flows on the other.

Developing countries can domestically enact policies that are attractive to private foreign investors, or they can employ international strategies, such as entering into international agreements [such as WTO membership, preferential trade agreements and/or bilateral investment treaties] that promote policy orientations seen as reassuring by foreign investors... Each of these provides a

direct or indirect mechanism *for reassuring foreign investors that the country will protect its property rights and allow profitability*. They serve as credible signals to private investors of the government's intentions because, at least for the international agreements, they are costly to renege on (em phasis added).⁶²¹

The study viewed the protection of investor property, including IPRs, as critical to securing such flows, given the substantial, long-term, capital-intensive and immobile nature of the types of investments being made (i.e., plant and equipment and research and development).⁶²² It also admonished foreign investors to be weary about committing significant investments to any one of a number of developing and emerging economies that do not have a well-established property rights regime.^{623 624} The study concluded that developing country membership and participation within international treaty regimes that promoted physical and intellectual property right protections (e.g., TRIPS) was more likely than not to contribute to its ability to secure FDI. This result obtains because such diplomatic engagement *usually* requires complimentary domestic reforms.⁶²⁵ At least one more recent (2006) study seems to have confirmed that U.S. and OECD bilateral investment agreements have stimulated greater FDI flows to developing countries with a high quality of institutions *and strong local property rights* (emphasis added).⁶²⁶

These conclusions were also confirmed within a recent (2005) United Nations study. It found that the setting of minimum IPR standards at the international level via the TRIPS Agreement had been effective in facilitating

domestic reforms that can lead to actual R&D-related FDI flows to certain emerging and developing countries.

[A lthough m any international agreements give special attention to investment in R&D activities...[by focusing on] [k]ey issues [that] relate to the entry and establishment of R&D-related FDI, the treatment of R&D performance requirements (whether by restricting or explicitly permitting them), incentives encouraging investment in R&D activities [etc.]... [m]ost international investment agreements do not have provisions that specifically protect R&D-related FDI; they protect FDI in general... [C onsequently,] *[t]he protection of IPRs at the international level and minimum standards set by international treaties are of particular relevance for R&D related FDI. The most important instrument in this area is the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)* (emphasis added).⁶²⁷

Furthermore, one recent (2005) study has documented how a developing country's adoption of domestic TRIPS-compliant IPR reforms has resulted in increased IP-related foreign corporate manufacturing investments.⁶²⁸ And, another recent (2005) study found that the degree and scope of such investments and technology transfer activities largely depends on the nature of those reforms, i.e., the extent to which they expand/strengthen IPRs.⁶²⁹ This latter study also evaluated the magnitude of the economic impacts in terms of technology transfer. It did this by

measuring the changes in the value of inter-company licensing (royalty) payments and allocations of inter-company R&D expenditures among corporate affiliates.⁶³⁰ The study found that following a developing country's adoption of IPR reforms, the amount of royalty payments made by an affiliate to its parent for the use or sale of transferred technologies, just like the amount of local R&D expenditures the affiliate incurred related to such transferred technology, increased in excess of 30 percent.⁶³¹

And, still another recent (2005) study evaluated the broad welfare implications for developing countries should they decide to protect IPRs consistent with the TRIPS Agreement. It concluded, that based on the positive overall impacts that strengthened IPRs would have upon innovation, market structure and technology transfer, it would be *irrational* for developing countries *not* to adopt IPR protections. In particular, it found that,

*[W]hen technology transfer considerations are accounted for it is **not rational** for governments in these countries to **oppose IPR protection**... In a North-South trade environment, the South sets its IPR policy strategically to manipulate multinationals' decisions on innovation and location... As the Southern government sets the IPR protection level before the Northern firm makes its multinational decision, it can influence this choice by inducing technology transfer or encouraging innovation... Firms can protect their technology by exporting, or risk spillovers by undertaking FDI to avoid tariffs... *In relatively low technology intensive industries, attracting foreign investment as a**

channel of technology transfer is the motive behind protecting IPR. The level of protection is chosen such that exporting is never strictly preferred to FDI by the North. Although the South may desire a lower level of IPR protection to reach its first-best welfare, the Northern firm's credible threat of exporting rather than undertaking FDI restricts the latter to a stricter IPR regime.

... For more R&D intensive industries, innovation as opposed to technology transfer is the key concern for protecting IPR in the South. The South stimulates innovation by tempting the multinational to deter entry by means of substantial R&D efforts. Although the South does not imitate the complex technology to compete with the North, it benefits from the enhanced innovation it induces by protecting the IPR of the Northern multinational. Therefore a rational South would never strictly prefer to violate international IPR, as the optimal level of protection for the South is always very high...[Much to the contrary, a] stringent IPR regime is always optimal for the South as it triggers technology transfer by inducing FDI in less R&D-intensive industries and stimulates innovation by pushing multinationals to deter entry in high-technology sectors (emphasis added).⁶³²

IPR Protections and the Enabling Environment Can Influence Investment Composition

Technology companies may invest in and undertake R&D within developing countries, even in the absence of strong IPR protections, though clearly, strong IPR jurisdictions are preferred. At first glance, this possibility would appear to contradict conventional wisdom. After all, firms have been advised that since poor institutional environments erode the 'appropriable value' of innovations, they should keep their knowledge-intensive activities away from weak IPR regimes. Yet, other factors may be at play.

One early (1993) study involving Brazil and Argentina revealed that, despite the lack of adequate patent protections in those countries, U.S. pharmaceutical companies continued to invest there.⁶³³ It found that such behavior was likely a predatory response from rival companies (competitors), which were eager, in the face of weak patent protection, to move in (by establishing a manufacturing facility) and capitalize on (reproduce) products not protected by patents. Alternatively, as was the case in Turkey, during the early 1960's, U.S. pharmaceutical company FDI increased despite that government's abolishment of product and process patent protection. It was later concluded that other factors had played a larger role in those companies' foreign investment decisions. They included more favorable foreign exchange rates, and lower taxes, regulatory costs, and wage rates, than was then available in the U.S. and other venues.⁶³⁴

Even if a foreign company's decision concerning whether to invest in a given country has already been made, it can still be influenced by the degree of IPR protection afforded. One recent (2006) study⁶³⁵ examined how the level of protection a developing country provides to foreign IPRs

would affect the nature of an MNC's investment in that country. In particular, it focused on two possible scenarios: direct investment via an independent venture (i.e., FDI), and indirect investment through a joint venture (JV) arrangement with a local company. Since joint ventures usually provide local rivals with the opportunity to gain market share at the expense of co-venturers, the study found that the MNC would need to undertake an amount of research & development per dollar invested (R&D intensity) that would both allow itself to benefit economically from the venture and also to compensate the local co-venturer for its market share loss. The study found, incidentally, that this same R&D intensity level would also produce technology spillover benefits for local firms not involved in the JV. Most importantly, the study concluded that, by strengthening its IPR regime consistent with the TRIPS Agreement, a developing country could reduce the losses to the JV caused by local outside firm imitation of JV technology, and facilitate the formation of more JVs that could increase MNC R&D intensity, local spillover benefits, and total developing country firm profits.⁶³⁶

This new study's findings support those of earlier studies. This includes the findings of a (1994) study that surveyed 100 major U.S. firms operating across a spectrum of different industries about their views towards IPR protection and FDI. It found that the level of a developing country's IPR protections would most substantially affect the FDI decisions of high technology, research-intensive industries with products or processes that are relatively easy to imitate.⁶³⁷ In particular, it concluded that these companies would not likely be inclined to invest in countries with weak IPR protections.⁶³⁸ As concerns the composition of their investment, once the decision to invest had already been made, the U.S. high-tech firms

interviewed indicated that their investments would more likely assume the form of sales and distribution outlets or rudimentary production and assembly facilities, than R&D facilities and component or finished goods manufacturing plants. And, if it they were to engage in any technology transfer at all, it would likely be with older rather than newer technologies.⁶³⁹

These conclusions were confirmed by a more recent (1998) study. It, too, recognized how the degree of IPR protection a country provides can influence a foreign company's decision whether and how to invest its IP assets in that country.

[On the one hand,]... stronger IPR protection provides title holders with increased market power and could, at least theoretically, cause firms to actually *divest and reduce* their service to foreign countries... [On the other hand,]... *higher levels of protection* may cause TNCs to *switch their preferred mode of delivery* from foreign production to licensing. [Companies may] *prefer foreign investment over licensing* in the case of *weak protection* because internalized foreign production helps firms to maintain direct control over their proprietary assets.⁶⁴⁰

Alternatively, cautious companies may ultimately decide to invest in developing countries through corporate *affiliates*. In this situation, however, firms are usually more covetous of their technologies and know-how, and less willing to share them with local companies. As a result, there are potentially fewer opportunities to engage in *collective* R&D

at the local level, and thus, much less of a possibility for technology transfer/diffusion and knowledge spillovers to domestic firms.

In effect, the decision of *how* a company decides to use its IP assets within a given developing country boils down to a choice between 'internalizing' (keeping within the corporate group) or 'externalizing' them (outsourcing to third parties). It often also entails a choice between undertaking 'horizontal' (where firms establish plants abroad to produce the same or similar goods for local or regional markets) and 'vertical' FDI (where plants in different countries produce outputs that serve as inputs in other plants). When a company has decided to *internalize* its IP assets but has not decided how (and where) to produce them, the question essentially becomes one of FDI *composition* – i.e., the apportionment or allocation of production resources among firm affiliates.⁶⁴¹

[W]hich portion of a firm's production processes is influenced by IPR protections... [may determine]... how higher levels of protection affect the composition of FDI... [The importance of IPRs regarding the composition of FDI depends to a large extent on whether firms are able to maintain control over their proprietary assets in the absence of legal protection... Foreign firms are less willing to invest in joint ventures with local companies if they risk losing their proprietary assets... [T]he importance of IPRs on the degree of foreign ownership depends on the extent to which the title holder is able to maintain

control over its proprietary assets in
the absence of protection.⁶⁴²

The study found this to be a major issue among knowledge-intensive companies in the chemicals, pharmaceuticals, machinery and electrical equipment product sectors.

... IPR protection [was found] to be more relevant in making decisions related to investment in R&D facilities than in decisions related to FDI in sales and distribution outlets... Companies in the chemical, pharmaceutical, machinery and electrical equipment industries reported that IPRs played a major role in their decisions with respect to investment in joint ventures abroad. In contrast, companies in the transportation equipment, metals, and food industries considered IPR protection to have marginal significance on FDI.⁶⁴³

... We conclude that, although one could argue that almost all FDI stocks and flows are indirectly affected by IPRs protection, the *direct impact* of IPRs protection is likely to be confined to selected FDI stocks and flows (e.g., foreign investment in *pharmaceutical R&D facilities*) (emphasis added).⁶⁴⁴

A subsequent (2000) World Bank study that evaluated how IPR protections affect the composition of FDI also confirmed these observations.

[W]hat makes FDI especially important is that unlike trade in

goods, where developing countries try to glean whatever information they can from the products and services imported or import capital goods that embody modern technology, FDI involves explicit trade in technology... It is well known that multinational firms are concentrated in industries that exhibit a high ratio of R&D relative to sales and a large share of technical and professional workers... By encouraging FDI, developing countries hope not only to import more efficient foreign technologies but also to generate technological spillovers... [i.e.,] the facilitation of technology adoption... for local firms...⁶⁴⁵

... [T]he level of IPR protection in a country... affects the *composition of FDI* in two different ways. First, *[in] industries in which IPRs are crucial (pharmaceuticals for example)*, firms may refrain from investing in countries [with] a weak regime of IPR protection. Second, regardless of the industry in question, multinationals are *less likely to set up manufacturing and R&D facilities in countries with [weak] IPR regimes and more likely to set up sales and marketing ventures, since the latter run no risk of technology leakage...* [Consequently,]... *IPR policy may also affect the mode of technology transfer (licensing, joint ventures, or establishment of wholly owned subsidiaries)* (emphasis added).⁶⁴⁶

Similar conclusions were drawn in a more recent (2004) study in which this same author participated.⁶⁴⁷

Another (2004) study produced analogous findings. It showed that, although most (84%) executives interviewed in an Economist Intelligence Unit survey had generally considered the lack of IPR protections in emerging economies to pose a serious challenge to R&D investment, R&D spending in countries such as Brazil, China, India and Mexico had actually increased. In addition, it found that, the nature of the R&D conducted in such countries often exceeded the level required by local law or for local market use and diffusion.⁶⁴⁸ Apparently, the companies in question had filed thousands of patents with the *U.S.* Patent and Trademark Office based on technologies developed in those countries, in anticipation of pursuing other more lucrative national and global markets.⁶⁴⁹

This study, however, arrived at a different conclusion about *why* a multinational technology company would still decide to invest in those countries. It discovered that, in many such cases, firms relied on the superior ‘*internal*’ linkages within their multinational corporate group to compensate for the inadequacies of governmental institutions.

[T]echnologies developed in countries with weak IPR protection are used more *internally*, and technologies developed by firms with R&D in weak IPR countries show stronger *internal* linkages. The results suggest that firms may use *internal* organizations to substitute for inadequate external institutions. By doing so, they are able to take advantage of the arbitrage opportunities⁶⁵⁰ presented

by the institutional gap across countries (emphasis added).⁶⁵¹

In effect, the study found that the strong, structured, close-knit, and insular culture prevalent within these corporate groups enabled them to cost-effectively build, manage, integrate, and transfer their technology resources internally throughout their global organization, while protecting them from external threats – i.e., imitation and expropriation.

MNEs' ability to conduct R & D in weak IPR countries stems from their efficiency in transferring, integrating, and quickly building on technologies developed in various IPR regimes. By keeping complementary resources well protected, MNEs can actually leverage the institutions in strong IPR countries for their operations worldwide. R&D-intensive MNEs, with their closely interlinked R&D activities worldwide, are in a unique position to arbitrage the difference in factor prices across national borders...⁶⁵²

For example, it found certain practices quite effective in enhancing both the value and protection of their internally derived intellectual property assets (patents), especially where low cost, talented, and underutilized labor in developing countries is plentiful.⁶⁵³

First, such companies compartmentalize or break down their technologies into components to prevent imitation. Second, they disperse the units of knowledge geographically throughout their global organization and make them difficult to convey or otherwise share in standardized form.

[I]mitation [is] discourage[d]... by developing technologies that require complementary knowledge not readily available to imitators. For example, basic research still far from commercialization, or technologies that are firm specific, are usually less attractive to imitators. Second, the acquisition of complementary knowledge is subject to the constraints of geographic distance. It has long been realized that a multinational corporation is a geographically distributed innovation network, with the capacity to assimilate, generate and integrate knowledge on a worldwide basis (Bartlett and Ghoshal 1990). Knowledge that is difficult to codify or teach can be more efficiently transferred within the firm. Therefore, outside firms would have to face much higher costs... [or might even find it] impossible... to obtain complementary knowledge across country borders...⁶⁵⁴

Third, they engage extensively in the practice of patent self-citation, which is a form of internalized knowledge transfer.⁶⁵⁵

I find supportive results that patents developed in weak IPR countries are cited more internally than those developed in other foreign countries. In addition, firms doing R&D in weak IPR countries feature significantly stronger internal linkages among their technologies than those who do not.

The results are consistent with the thought that the internal linkages allow firms to appropriate value from their knowledge even in weak institutional environments.⁶⁵⁶

In sum, the study illustrates how the closely-knit innovation structures of multinational companies serve to immunize them against the potentially harmful viruses that fester in the hostile external environment of weak IPR regimes.

A recent (2005) United Nations study confirms the increasing global rate of *intra-firm* R&D transfers between corporate affiliates operating in developing countries, including Brazil.

[F]oreign affiliates are assuming more important roles in many host countries' R & D activities. Between 1993 and 2002 the R&D expenditure of foreign affiliates worldwide climbed from an estimated \$30 billion to \$67 billion (or from 10% to 16% of global business R&D). Whereas the rise was relatively modest in developed host countries, it was quite significant in developing countries: the share of foreign affiliates in business R&D in the developing world increased from 2% to 18% between 1996 and 2002. The share of R&D by foreign affiliates in different countries varies considerably. *In 2003 foreign affiliates accounted for more than half of all business R&D in Ireland, Hungary and Singapore and about 40% in Australia, **Brazil**...* (emphasis added).⁶⁵⁷

And, it correctly recognizes, as did the previous studies noted above, that MNCs will still invest in R&D activities within developing countries such as Brazil, India and China, even if IPR protections are presently weak or otherwise lacking. This result obtains for several reasons. First, R&D may be conducted in a country to develop products directed at markets of different countries. Second, a technology may be highly firm-specific and thus of limited value to local competitors. Third, R&D may be too far advanced for the host country to exploit, i.e., to copy and use commercially. Fourth, the technology may involve tacit and uncodifiable elements that are difficult for outsiders to imitate without intimate knowledge gained by working with that specific technology.⁶⁵⁸

Thus, an MNC's concern about the level of available IPR protections afforded in a given developing country does not always dominate the reasoning underlying its decision to invest there if, in the totality, there are other significant financial, legal, or economic issues also to consider. In addition, to IPR protection, such considerations would likely include the overall size of the potential market, the regulatory enabling environment, the level of taxation and attractiveness of tax-based incentives, the relative cost of labor, etc.⁶⁵⁹

A multinational corporation is a complex and sprawling organism with multiple operations, functions and theatres of activity. Beyond red-flagging the most urgent of threats posed to the profitability of its particular operations by the foreign institutions with which it interfaces and the market environments within which it is located, it seeks to gain maximum efficiencies in pursuit of profitability. Hence, with respect to each particular threat scenario it encounters, it seeks to retain the flexibility it requires to employ the most feasible alternative available. This, in, no way,

however, detracts from, diminishes, or devalues the worth, importance and relevance of intellectual property rights, such as patents or trade secrets.

B. BRAZIL SHOULD DEVELOP AN EFFICIENT NATIONAL INNOVATION SYSTEM

Generally

Many experts would agree that what Brazil most urgently needs is not creativity, but rather, a well-organized, comprehensive national innovation system capable of harnessing the strengths of private industry. According to one former senior U.S. official, this entails the development of a supportive institutional environment (laws, policies, and culture), capable and efficient organizations, and a positive working relationship (linkages) between industry, the organizations, and the institutional environment.⁶⁶⁰

Brazil already possesses the capacity to innovate, and it appears that the Brazilian government has already committed substantial public monies to create the necessary organizations that generate research and scientific and technical know-how – universities, public research institutes and government-funded laboratories. The Government of Brazil may even have most of the essential laws and institutions in place, with some notable exceptions. But, more importantly, it still lacks the ability to tap the know-how that resides in these organizations, a trusting relationship with Brazilian industry, a reliable track record for implementing its recently adopted IP laws, and a culture or mindset that is conducive to commercializing private innovations.⁶⁶¹

This same expert argues that all of these observations boil down to one critical failure: the lack of a strong patent

framework.⁶⁶² According to a recent (2005) U.S. Foreign Commercial Service market study,

Patents cost too much in terms of time and money... and act as... a disincentive to Brazilian researchers and inventors. Strengthening the patent office would protect and encourage new Brazilian technologies and products. Educating judges in IPR enforcement would reduce copyright piracy that today costs Brazil almost 10 billion dollars in lost tax revenues and 1.5 million jobs.⁶⁶³

Brazil's Emerging National Innovation System

In many ways, the Brazilian legal framework for intellectual property, including patents, has evolved in this direction since 1996^{664 665}. It is currently administered by a number of domestic government agencies – the Ministries of Industry, Culture, Agriculture, Environment, Food and Drug, and the Ministry of External Relations when international issues are involved.⁶⁶⁶ And it has resulted in the use of patents to promote government-funded development of medicines for neglected diseases, particularly, in culture collections, specific projects, teaching and information,⁶⁶⁷ and in agriculture to promote development of bioengineered cultivars.

At least one Brazilian expert, who is both a chemical engineer and a senior researcher at Brazil's well-respected Oswaldo Cruz Foundation (FIOCRUZ),⁶⁶⁸ clearly recognizes how a properly calibrated patent framework can motivate inventors to create commercially relevant innovations that may be exploited directly or licensed to enterprising third

parties capable of exploiting the patent in the marketplace. She also supports the public policy goal achieved through universal disclosure of the substantive contents of the patent, once it has been issued *and only after* the temporary period of exclusivity during which the patent holder and its designated licensee(s) may exploit the patent for commercial purposes has expired. And, she cites the chemical and pharmaceutical industries, in particular, as warranting such a trade-off.

The chemical and pharmaceutical industries appear especially sensible to patenting – *the absence of legal protection inhibits investments in development and trade*. However, it has to be clear that, in spite of providing a greater barrier for mobility, the strategy to prolong the competitive advantage through intellectual property protection mechanisms may fail. Substituting technologies may appear through the disclosure of protected knowledge. The contents of patents are divulged and subject of being used for the improvement of other techniques. This is the proper basis of the patent system. *Although an imperfect instrument, it represents the best solution for the trade-off between providing incentives to the investments and stimulating the process of making the benefits of the new technologies available to society* (emphasis added).⁶⁶⁹

The Difficulties Encountered

Yet, despite these known benefits of a strong patent system, Brazilian IP laws, to date, have had only a limited impact on the ground, i.e., on domestic industry innovation. At least one Brazilian industry expert, who is also the president of the Brazilian subsidiary of a multinational medical device corporation, attributes this problem to technical difficulties. First, a quirk in the language of the 1996 patent law has made it difficult for Brazilian companies to negotiate technology transfer arrangements. Second, the patents as written by Brazilian inventors have been technically deficient or otherwise incomplete, and thus, not susceptible to application *as is* by industry to create commercially relevant products that could generate a reasonable economic return.⁶⁷⁰

In addition, at least one Brazilian trade association (AmCham Brazil) recognizes the indispensability of strong IPR protection to societal and commercial innovation and economic progress in Brazil. It has argued that Brazil's current system of administering patents is inadequate to satisfy Brazil's current and emerging needs, as is the overall legal enabling environment. Its recent analysis emphasizes that,

Intellectual property is a crucial factor for a nation to attain sustainable economic and social development. To improve a country's competitiveness, it is necessary to create a business environment that provides protection to companies' investments and encourages technological creation and qualification. However, the establishment of those conditions depend[s] on the existence of a safe legal system and clear and stable trademarks, patents and copyrights

rules, as well as respect for international intellectual property treaties currently in effect. The National Institute of Industrial Property (INPI – Instituto Nacional da Propriedade Industrial is the federal agency that supervises and assigns industrial property rights in Brazil, promoting technological qualification of companies and research centers, dissemination of knowledge and optimization of investments in research and development activities. According to the INPI, there are currently 40 trademark examiners and 88 patent examiners. This reflects the current critical situation of application accumulation (backlog) that tends to worsen. Considering that an experienced patent examiner is capable to examine about nine applications a month. Therefore one comes to the conclusion that, in the current situation, they can examine at most about 9,500 patent applications per year. Bearing in mind that the number of annual patent application deposits are of about 23,000, one reaches the conclusion that the annual accumulation of processes [a backlog] is of at least [12-]13[years]... A similar situation applies to application examinations for trademark registration, where the case is equally alarming...[a backlog of 10 years] ... The figures show the INPI is far from meeting the Brazilian society's needs (emphasis added).⁶⁷¹

Academic experts have tended to corroborate this account of the problem, citing the very poor operational conditions and the lack of qualified personnel at the INPI as a major reason why limited use [has been made] of the industrial property system in Brazil.⁶⁷²

Despite what may seem poorly conceived and/or executed government policies, the Government of Brazil has, to its credit, endeavored to correct this alarming situation⁶⁷³ since the release of this study and its accompanying recommendations.⁶⁷⁴ And, this was confirmed by the Deputy Chief of Mission of the Brazilian Embassy to the United States earlier this year.⁶⁷⁵

Furthermore, at least one academic expert has attributed the relatively low number of patents filed by Brazilian organizations (as compared to the number filed by foreign applicants) to Brazilian industry's limited technological capabilities.

The participation of Brazilian applicants in the patent filing process is very small, demonstrating a condition of technological frailty. The chief reason resides in the country's limited technological capability. This number could be slightly higher (although not much above the present figure) if there was more attempt to protect inventions on the part of the universities and research institutes. However, due to the extremely low corporate efforts in R&D there is no expectation of significant growth in these numbers.⁶⁷⁶

And, still other Brazilian experts have traced the lack of marketable patents to an ideological reluctance on the part of high-minded academics seeking to promote publishable open source‘ societal knowledge,⁶⁷⁷ to transfer technologies to their more pedestrian‘ proprietary-minded colleagues for commercial purposes.⁶⁷⁸ Also, in the field of agricultural biotechnology, there was previously a significant lack of coordination and linkages, and even distrust between and among industry participants and research institutes.⁶⁷⁹ These negative attitudes may partly explain why, even though Brazil has devoted considerable public resources to create a national research and development platform capable of spawning world-class‘ innovations⁶⁸⁰, those resources have remained mostly underutilized and ineffective, in an economic sense.

In addition, a semi-disguised political/populist aversion to a patent system based on American-style capitalism⁶⁸¹ may also be partly to blame. This can be seen in the field of agricultural biotechnology.

[A lthough] [i]n Brazil, many lines of research and development are already benefiting from the application of biotechnology tools such as marker-assisted plant and animal breeding, genomic mapping of several species, embryo transfer applied to different animal species, genetic resources characterization and conservation, and transgenic products... [there are]... three difficulties that relate to this forum: the lack of regional integration in science, *scientists‘ reluctant acceptance of the free market, and a failure to acknowledge the importance of IPR in modern research* (em phasis added).⁶⁸²

Moreover, there is evidence that the lack of marketable Brazilian patents is somehow related to the Brazilian government's desire to retain the knowledge of cultivars within the public system of national institutes and foundations,⁶⁸³ which effectively serve as repositories of public knowledge. Apparently, during the late 1990's, multinational companies had been steadily acquiring Brazilian biotech companies. This had alarmed the government and Brazilian industry to such an extent (agriculture being the largest industry sector in the country), that they employed a disguised form of trade protectionism to keep the knowledge under Brazilian control. Regretfully, the Government of Brazil has not since fully relinquished its control, and this partly explains why it has failed to recognize patent rights as *exclusive private property rights* in the agbiotech sector.

*Excessive market protection was one of the key elements restricting the pharmaceutical sector development during the 25-year absence of patent protection.*⁶⁸⁴ It was also expected that national firms would build up internal capacity unfettered by property rights. When the Patent Law [1997] [was] passed, private investment by [domestic] pharmaceutical companies [was] expected to increase dramatically. A similar trend [was] observed in the Brazilian seed industry. Following approval of the Cultivar Protection Law and the new Patent Law, *many of the national private breeding programs were... absorbed by multinational corporations. It seems only a matter of time before more*

investment by private industry will take most of the commodity breeding programs away from the government-funded institutions. Effects on the country's agriculture productivity and competitiveness, and the maintenance of investment to produce cultivars adapted to different ecosystems remain to be seen.

... The national seed companies that have not yet been taken over by the multinationals (a trend that is rapidly changing the face of the seed market) feel they are going to lose ground, and that it is only going to get worse with the incoming new genes made available through biotechnology inputs (emphasis added).⁶⁸⁵

This would also largely explain why Brazilian companies have had little incentive to generate scientific and technological know-how alone or as contributing members to public-private collaborations.

If these assumptions are correct, Brazil's innovations have remained essentially trapped within the nation's universities and government funded laboratories and research institutes due to ideological biases *and* international competitiveness concerns, and this has had adverse downstream 'domestic' impacts. Some Brazilian government officials and intellectual property experts have tended to agree. According to at least one minister,

Patents are not contributing to development in Brazil as they might, not because of a lack of R&D and innovation, but due to a

*lack of understanding and use of patents. Industry in Brazil needs to develop their use of the patent system over time. There is not a lot of use or analysis of patent data in Brazil. Universities are not promoting technology transfer and development of basic R&D into marketable products. There is a need to enhance efforts to facilitate domestic use of the benefits of the IP system (emphasis added).*⁶⁸⁶

Another minister has stated it differently: Brazilians get lost between basic research and its transformation into technology, between academic life and the manufacturing system.⁶⁸⁷

In one expert's opinion, the Brazilian government's failure to bridge the gap between academic research and technological innovation (commercialization) is primarily responsible for Brazil's lack of progress.

Nowadays, the Brazilian government recognises the gap between academic research output and technological innovation... *There are, however, difficulties in making the connection between science, technological development and the market. Intellectual property is an inseparable part of this set, constituting essential knowledge to overcome this gap. Legal instruments allowing more consistent and wider protection of research results provide the necessary basis for qualitative and quantitative technological changes. Although having a solid research*

*structure in biotechnology with institutions all over the country, there are little results with global impact (em phasis added).*⁶⁸⁸

The view from outside Brazil is not much different. At least one American bioscientist has described the lack of IP harmony between Brazilian industry and the Government of Brazil as reflecting the two faces of Brazil‘.

*[W]hen it comes to IP, Brazil has a functional private sector but a dysfunctional government ... The private sector is up and running with IP but the government is saying, We have to look at IP in terms of providing greater access to pharmaceuticals and other products‘... The problem is not IP itself; the problem is how to get Brazil to use its enormous private sector, which is very innovative, to create wealth that enables the poor to afford access to drugs, instead of going out and making it difficult for Brazilian companies to compete. [Brazil’s hard line against IP in widely publicized confrontations]... discourages investment and short-changes the private sector. Instead, *Lula needs to explain to the left wing that its best interests lie in increasing the pie by applying new technology that is protected by IP, not by trying to grab a larger share of the pie that exists today. The good news is that the Brazilians have the technological capacity to expand the pie* (em phasis added).*⁶⁸⁹

Such disharmony and lack of understanding also characterizes Brazil's treatment of clinical test data and trade secrets. Brazil first proposed TRIPS-consistent legislation protective of undisclosed test data and other information submitted to government regulators as a condition to obtaining market authorization, back during 2000,⁶⁹⁰ and finally enacted such legislation in December 2002.⁶⁹¹ Yet, even though the law is technically on the books, the Government of Brazil does not appear to be enforcing it. According to the USTR, [u]nauthorized copies of pharmaceutical products continue to receive sanitary registrations that rely on undisclosed tests and other confidential data, although no unauthorized copies have been marketed yet.⁶⁹² Unfortunately, this, too, may be ideologically based.

Despite the... public health sensitive changes, implemented into Brazilian IPR legislation during [1996-2003], *a step back occurred with the enactment of Law # 10.603 on December 17, 2002.* This Law allowed for the protection of undisclosed data submitted by pharmaceutical companies to national regulatory authorities in order to obtain marketing approval for veterinary pharmaceutical products, fertilizers as well as agrottoxics and their components (Brasil, 2002). As discussed... this provision has been included in recent bilateral agreements between US and several developing countries worldwide. *In fact, these agreements constitute part of the US strategy to create more restrictive IPR regimes than those previously established by TRIPS*

Agreement (Jorge, 2004)... this provision, like patent protection, hinders competition. It creates a type of monopoly for medicines, even when they are not under patent protection (emphasis added).⁶⁹³

Hence, one may conclude that the resulting low integration between scientific and industrial [government] policies has rendered a number of Brazilian industries less innovative and technically proficient than they otherwise could have been and need to be to compete effectively in global markets, and consequently, that it has slowed down Brazil's overall technological development. In particular, such policy failure has severely limited the innovative capabilities of the country's health system and provided Brazilian industry with only limited negotiation capacity (especially in the public administration sector in negotiations involving technology transfers and intellectual property rights).⁶⁹⁴ In addition, it has also impaired Brazil's advancement in the rapidly evolving field of biotechnology.

The limited innovative capability of the Brazilian health system constitutes an obstacle to government policies for universal access to health. The dependency on imports for the maintenance of the strategic programmes is a vulnerability that may be potentially aggravated by variations in international financial markets. *In view of the weak technological and industrial policies, the trend is for an increase in the difference between Brazil and countries with an intense production of knowledge*

and products with high aggregate value (emphasis added).⁶⁹⁵

According to one Brazilian scientist and HIV/AIDS specialist, the Brazilian governments' use of financial incentives, including IP such as patents, to attract badly needed qualified research personnel and to promote greater cooperative public-private R&D efforts, should neither be overlooked nor disparaged, even if it is deemed ideologically controversial to some. In his view, the failure to provide intellectual property protections could very well result in an even greater failure to discover medical cures to significant and emergent future health risks.⁶⁹⁶

Brazil's New Innovation Law

Efforts were undertaken recently in Brazil to bridge these ideological and technical gaps. On July 5, 2004, the Brazilian House of Representatives approved a new legal framework the general purpose of which is to provide incentives to increase nation-wide innovative activities that yield new commercialized hi-technology products and processes. This legislation was later signed by President Lula into law on December 2, 2004 (hereinafter referred to as the Technical Innovation Law').^{697 698} The framework is expected... to improve the country's capacity to generate and commercialize technology... to increase the percentage of Brazilian patent applications in the Brazilian National Institute of Industrial Property [INPI] from 30 percent to a figure that reflects the importance of technology and the competitiveness of Brazilian industry...⁶⁹⁹

Brazil's Technical Innovation Law has three express objectives:⁷⁰⁰ 1) To create an enabling environment that facilitates the formation of strategic research and development partnerships between and among universities,

science and technology institutes (STIs⁷⁰¹) and national companies⁷⁰²; 2) To stimulate engagement of STIs in the process and management of innovation⁷⁰³; and 3) To provide companies with economic and legal incentives to innovate.⁷⁰⁴

To promote formation of public-private partnerships, Brazil's STIs shall, for an agreed upon fee, share their laboratories, equipment, instruments and materials with national universities and companies undertaking specific R&D-related innovative projects.⁷⁰⁵ In addition, STIs shall also, for an agreed upon fee, provide staff services to universities and companies involved in such collaborative R&D activities.⁷⁰⁶ The Law also permits individual companies to compensate public institutions to perform specific R&D services on their behalf with respect to a specific innovative product or process.⁷⁰⁷

STIs are charged with the management of the entire innovation system. This includes selecting parties for technology licensing, helping to arrange the terms for exclusive licensing of creations for commercial exploitation, and ensuring that licensed technology is commercially exploited in the public interest in due course.⁷⁰⁸ And, it includes encouraging the consummation of public-private R&D partnership agreements.⁷⁰⁹ STIs shall also oversee and manage the allocation of IPRs (*copyrights*) and overhead and administrative expenses related to IP development, between and among R&D partnership collaborators, in proportion to the know-how and R&D efforts contributed.⁷¹⁰ STIs shall also be responsible for the selection of public researchers who will be paid to participate in innovative activities, depending on their qualifications.⁷¹¹

Furthermore, STIs are responsible for creat[ing] Offices of Technological Innovation ‘... which, among other duties, will be responsible for the management of the technology generated by researchers with special attention to decisions regarding intellectual property and licensing.’⁷¹²

STIs, moreover, are authorized to acquire *patented* innovations developed by individual inventors, to the extent they may contribute to existing STI R&D innovation efforts and/or to the commercialized products of public-private partnerships. They are also charged with negotiate[ing] a share of the benefits resulting from the commercialization of [such invention[s]].⁷¹³

Lastly, STIs, together with promotion agencies,⁷¹⁴ shall encourage the participation of private companies in national innovative R&D activities by offering them financial subsidies. To be eligible to receive such funding, companies must commit to provide a predetermined amount of resources, including personnel, to the R&D venture.⁷¹⁵ Promotion agencies will also target small and micro-firms for special programs.⁷¹⁶

Based on the cursory review noted above, one may draw some tentative conclusions regarding dispensation of IPRs. First, and foremost, this is more a government-centric than a market-centric approach to innovation, administered by government funded agencies and instrumentalities from top to bottom and beginning to end. This means that methods, processes and determinations will be amenable more to the objectives and benchmarks of bureaucrats and their civil servants than to those of industry. Second, there is no indication that the Government of Brazil, acting through its STIs, is either politically willing or legally able to cede to private industry full and clear legal title to *any* invention derived from the R&D activities undertaken by any public-

private collaboration. Furthermore, while division of IPRs is generally to be made in proportion to the resources each party brings to the table, it is highly unlikely that the STIs will, in practice, often relinquish more than a negligible portion of their rights in primary intellectual property to companies, lest they be accused of squandering precious government, and thus, public resources.⁷¹⁷

The most that participating industry members could hope for, then, would be government-funded subsidies, and use of STI facilities (STI's) and personnel (scientists, research etc.). On a lesser note, Brazilian companies would also be entitled to a government-determined share in any collaborative R&D project *derivative IP* they have subsequently developed and commercialized, alone or with assistance from private universities. This economic interest would seem to extend beyond the ordinary royalty owed by derivative patent holders to the joint owners of a primary patent, where the primary patent holders (i.e., the joint collaborators) are not involved at all in the commercialization of the relevant know-how. It is well known that the costs of commercialization can, and often do, comprise most of the investment in the entire innovative undertaking.⁷¹⁸ This is borne out by the continual use of the term 'licensing' throughout the statute, which seems to cover the profits earned by the commercialization of know-how.⁷¹⁹ Even IP contributed by industry inventors to an R&D public-private partnership are subject to economic profit-sharing with the Government of Brazil.⁷²⁰ And, it is only in this latter case that the legal right of 'patent' rather than 'copyright' is used or referred to.⁷²¹

This leads curious minds to question whether the Government of Brazil is setting the groundwork for the complete migration of the nation to GPL-style open

source‘ or creative commons‘ open-content licenses for *all* science and technology innovations. If that is indeed the case, why then, would any rational, profit-seeking Brazilian company be interested in participating? What would they own outright, with free and clear title, at the end of the day as the result of their efforts? What economic incentive would a Brazilian business thus have to invest?

That the Government of Brazil has endeavored at all to establish a *quasi*-market-based national innovation system is nothing less than spectacular and its significance should be heralded. It clearly reflects the prior recommendations of Brazilian and foreign experts who admonished that,

The transfer of government-financed R&D results to industry has functioned satisfactorily only when the government or the research centre has [developed or] acquired a patent which can be exploited, as in industry, by licensing agreements.⁷²² And, it seems that it is precisely this – the creation of new innovation system focusing both on the R&D innovation (science and technology) level, with participation from both scientists and industry, and on the marketplace (industrial policy) level - that is being pursued.⁷²³

At least on paper, then, the Brazilian Government has recognized the indispensability of intellectual property rights to the innovation process, and has sought to develop a national innovation system that can potentially be exploited by its industries for private as well as public economic gain. However, as one recent (2005) OECD Latin American study concludes, it requires increased R&D spending not only by the public sector, but also by the *private* sector.⁷²⁴ And this requires the *right* incentives, not just *any* incentives.

Thus, the ability of Brazil to transform itself into an innovation society, clearly depends on much more than legal frameworks and institutions.⁷²⁵ In addition, it requires an organized national industrial policy, a business-friendly environment for foreign investment, promotion of domestic entrepreneurial activity, protection of domestic private property rights, and education of the Brazilian public about the benefits of intellectual property rights.⁷²⁶ Some Brazilian trade association representatives believe that it depends also, on how the law will actually be implemented.⁷²⁷ If the enactment of the Brazilian 1996 Patent Law, alone, yielded an increase in R&D-related foreign direct investment (FDI) during 1996-2000 of approximately \$2.1 billion together with a host of local spillover benefits, one could just imagine what actual implementation of the law (i.e., enforcing IPR protections) would bring!⁷²⁸

Comparing Other State-Centric National Innovation Systems

At least one economic development expert has compared the new Brazilian innovation system with the national innovation systems of post-industrial countries, such as Germany, France, and Japan, as well as, with those of developing countries, such as Mexico, India and China. In his opinion, it seems to be shifting from a German toward an American model.⁷²⁹ The following section also compares the Brazilian innovation system with that of the regional European Union.

This expert believes that post-war Germany's development of long-term focused engineering-based education, management orientation, labor relations, small and medium-sized enterprise-based supplier networks, bank-financed investment, consensus-oriented corporate

governance, and coordinated regulatory and export policy environments, and its establishment of the global model for the publicly-funded basic research center (university), has provided it with many strengths. However, he also believes that [t]he German system [has been] ineffective with respect to getting new ideas out of the universities and research institutes and into the private sector. As a result, [p]ublic-private R&D partnerships have been uncommon, hi-tech startups have been uncommon, [and] venture capital markets have been weak.⁷³⁰

In addition, this expert has studied and acknowledged the political appeal surrounding the French national champions, namely high technology-focused entities which were planned, selected, formed, directed, and merged by the French national government. Being national champions, these entities often enjoyed state-sponsored regulatory, subsidy, and investment-related protectionist benefits. However, his research has revealed that, the technology missions... were all more-or-less [economic] failures; the national industrial champions have largely been globally uncompetitive, and the whole system tends toward fragmentation and inflexibility.⁷³¹

A recent OECD report similarly criticized France's innovation-focused poles of competitiveness' program.⁷³² That 2004 program was designed to bring[] together business and academics in 66 regional clusters with state funds and tax breaks to encourage innovation. The OECD report cast doubt on the funding of the initiative, its geographical limitations and its administration, which it said was too bureaucratic and costly. The most innovative small businesses risked being side-lined by bigger groups and universities in the new poles, the OECD said.⁷³³

Indeed, the European Community's (EC's) older and rather unsuccessful IT-focused ESPRIT and related programs⁷³⁴ raise similar issues of concern. Although initiated during the 1980's, these earlier programs were extended during the 1990's for the express purpose of closing the gap between Europe's information technologies industries and those of the U S and Japan.

[T]he world scene remains incontestably dominated by the United States as much in terms of innovation as in terms of commercial power. In 1993, the American share of patents filed in Europe in computer-related subjects reached 50.9% while that of Europe was only 26.1%. Firms such as Microsoft and Intel pursue their ascension and now rank 14th and 15th in the world-wide top 100 enterprises as established recently by the Financial Times.⁷³⁵

This technology gap was apparently attributable, in large part, to the failure of the then prevalent EU industrial policy/innovation framework, which rendered European educational and research institutions and industry unable to convert R&D (inventions) into market-relevant products (innovations).⁷³⁶

European R & D programmes often lack the underlying commercial dimension which is crucial for obtaining exploitable results. As a result, there are fewer exploitable innovations than potentially possible. Europe's scientific excellence is not translated into commercial excellence.⁷³⁷

In fact, one may conclude from the European Commission's prior assessment of the ill-fated ESPRIT program, and European industries' diminishing global competitiveness, that these problems have never truly been resolved. More recently, the EU Commission has endeavored to address European industry grievances about its lost regional and global market share and weaker innovative capabilities through pursuit of the Lisbon Agenda'.⁷³⁸ This agenda has sought to level the global economic playing field', and thus, secure scientific and technological innovation for European industry through, among other things, dominance of the international standardization process. Whether this is enough to achieve the level of innovation necessary to restore Europe's competitiveness, however, has been subject to question.⁷³⁹

The political need to satisfy the objectives underlying the Lisbon Agenda has apparently caused the Commission to undergo a painful mid-course review of its longstanding regional innovation strategy. European industry members and the media have also demanded such a reevaluation.⁷⁴⁰
⁷⁴¹ ⁷⁴² As a result, the Commission has had to recognize its prior failure to provide adequate funding for community level research and development (R&D).⁷⁴³ It has also had to acknowledge how the continuing decay of Europe's underfunded educational (universities) and basic R&D institutions (laboratories) has hampered the long-term ability of those repositories of knowledge to contribute to European commercial innovation.⁷⁴⁴ ⁷⁴⁵ ⁷⁴⁶

One recent (2004) EU Commission report confirms that the technology gap' has broadened into an innovation gap' that itself has continued to grow despite such efforts.⁷⁴⁷

Based on a set of comparable data for 12 indicators, the US and Japan are still far ahead of the EU

average and the vast majority of Member States. *The innovation gap between the US and the EU, as well as the gap between Japan and EU, still exist.* This innovation gap is measured, based on 12 common indicators. The EU innovation performance, as measured by the European Innovation Scoreboard, has been relatively constant since 1996, whereas the innovation performance in the US and Japan has further improved, thus widening the gap. The peak in the US performance innovation in 2000 & 2001 is due to the venture capital indicator. *The gap between the US and the EU can be largely explained by 3 indicators: [1] Patents (50 % of the gap); [2] Working population with tertiary education (26 %); and [3] R&D expenditures (11%) – mainly business R&D* (emphasis added).⁷⁴⁸

And, since this innovation gap⁴ has shown no sign of abating, the EU Commission has continued to recommend that key structural corrections be made to the region's industrial and innovation policies. For this reason, on June 28, 2006, the EU Commission, Parliament and Council, consistent with the Lisbon Agenda, adopted the 7th European Framework Program (2007-2013).^{749 750} The FP7 will focus on promoting education-based capacities for individuals and small and medium-sized enterprises, as well as, collaborative science and technology R&D projects for funding at the community level.⁷⁵¹

The EU Commission also likely decided to reform its regional innovation and technology policies after it had

reviewed the findings of a recent (2005) study. That study apparently shed light on the source of such innovation gap – the relatively lower *economic* value of European patents as compared to U.S. and Japanese patents.^{752 753 754 755} This, along with European industry comments submitted as part of the EU patent consultation,^{756 757} has prompted the EU Commissioner for Internal Market and Services to announce, during July 2006, that he will try once again to enact a community level patent regime by 2009.^{758 759}

If this were not enough of an obstacle for Europe to overcome in order to remain globally competitive, there is also the problem of the significant human capital gap that it has with the U.S.^{760*}

*There is a clear gap between the US and the EU as regards human capital. The US economy is ahead of the pack for both human **and** physical capital, the EU for physical capital only. This shows up in trade structures. The US mostly exports skills-intensive goods, such as high-technology products, while the EU specializes in goods of high capital intensity and medium-skill intensity, such as cars and chemicals. This puts the US and the EU in different positions vis-à-vis globalization*

... In the short run, globalization increases the world demand for those goods – and the countries that specialize in them benefit from a form of rent. Its trade specialization puts Europe on the side of globalization's winners, as its advantage is actually strengthened by the entry of new

players. This explains why European exports have thrived in recent years – and suggests that many complaints about the effects of globalization ignore its benefits to Europe. The good news, however, may stop here... *The US has about equal infrastructure, more investment in human capital, better economic institutions and a more active migration policy. Capital is thus more inclined to move there* as well as to the best-performing emerging countries. This should erode Europe's comparative advantage... *Europe's prosperity will not last if it does not address its underinvestment in human capital* (emphasis added).⁷⁶¹

As concerns Japan, this expert has determined that post-war Japan's public-private partnerships were quite successful in providing engineering-based education, efficient incremental innovation and national technological catch-up. However, he has also determined that, the government's direct support of key industries with state-backed bank financing and subsidies, technology licenses, patent pools, R&D consortia, government procurement [agreements], import and direct investment protectionism, and export promotion, [have caused] markets [to remain] highly concentrated and stagnant; government at all levels is ponderous and stifling.⁷⁶²

Moreover, this expert has acknowledged the ideological underpinnings of past developing country state-centric models of development, which were premised on abundant natural resources⁷⁶³, import substitution-based innovation (ISI), high barriers to entry, skepticism of multinational

businesses and rejection of the post-W W II liberal, G A T T - based, free trade and open investment regime[,] and, ultimately, establishment of state-owned enterprises to lead industrialization and energy creation. However, he has concluded that ISI [has] failed because it depended on markets that were too small or too poor to provide economies of scale, on demand conditions that were too isolated to produce globally competitive industries, and typically resulted in inefficient production of bad products by insulated state-owned and private enterprises.⁷⁶⁴

According to this expert, therefore, each of these failed or inferior innovation systems suffered a similar fate: the absence of individual investment incentives, namely, the protection of exclusive private property rights.⁷⁶⁵

Whatever the form of government, *economic progress tends to occur in societies in which there are clear incentives to produce, invest, and engage in mutually advantageous trade.* By contrast, societies in which predation is the norm ... are unlikely to be productive'. The conditions for economic growth in developing countries today remain essentially no different from the conditions that led to economic growth in 19th century Germany and United States and 20th century Japan: *It's all about the institutions and in particular about the establishment of such a set of property rights* [that] allow individuals in highly complex interdependent situations to be able to have confidence in their dealings with individuals of whom they

have no personal knowledge’
(emphasis added).⁷⁶⁶

Unfortunately, however, this reality⁷⁶⁷ has not prevented populist leaders in Latin America from once again, seeking to nationalize local industries and foreign industry assets for short-term political gain.^{768 769 770} Indeed, Latin America has become the prime stag[ing ground] for resource nationalism, even though its leaders recognize that they still require developed nation science and technological know-how to exploit their newly acquired ‘resources for Latin America’s benefit.’^{771 772}

It is not surprising, therefore, that the U.S. model of innovation, with its foundation in strong private property (IP) rights, higher education and publicly funded university and laboratory-led research, and its emphasis on market-based financial risk-taking and industry commercialization of know-how,⁷⁷³ remains the superior international paradigm.⁷⁷⁴

The Private Property-based U.S. Innovation System

The American Bayh-Dole Act, which provides companies with exclusive rights to their intellectual property-based inventions, has largely contributed to U.S. global leadership in innovation. Since its enactment has long been recognized as one of a number of significant changes that created global awareness of the utility of IPRs,^{775 776} it can and should be held out as a successful benchmark standard by which Brazil should gauge its own progress.

Background

It bears repeating that, perhaps, the single most important element of America’s modern innovation system and one of

the primary reasons why the U.S. has remained the global leader in science and technology,⁷⁷⁷ (besides its higher education system), is the Bayh-Dole Act (P.L. 96-517),⁷⁷⁸⁷⁷⁹ and its subsequent regulations and amendments.⁷⁸⁰ The Bayh-Dole Act was passed by Congress and signed into law by President Carter on December 12, 1980. It established

A uniform government patent policy and allowed universities and other nonprofit organizations to retain title to federally-funded inventions and to work with companies in bringing them to market. *The Act thus promoted technology transfer⁷⁸¹ by creating incentives for university researchers to consider the practical applications of their discoveries, and for universities to search out potential companies to develop them.* By enabling corporations to negotiate *exclusive* licenses of promising technologies, the Act encouraged them to invest in the additional research, development, and manufacturing capabilities needed to bring new products to market (emphasis added).⁷⁸²

The legislation effectively broke the logistical and philosophical⁷⁸³ logjam that, for many years, had prevented the American public from accessing and exploiting thousands of technology-rich government ideas and patents. Apparently, a vast portion of U.S. government (taxpayer)-funded research and patented knowledge had been developed with the assistance of private industry and academia for primarily military use during and after World

War II. But, due to national security concerns and the unworkable and inconsistent nature of restrictions imposed by the different federal agencies on the licensing of such technologies, the private sector (e.g., companies, universities and nonprofits) was essentially blocked from acquiring rights to adapt and commercialize that knowledge for civilian purposes.⁷⁸⁴

The government would not relinquish ownership of federally funded inventions to the inventing organization except in rare cases after petitions had moved through a lengthy and difficult waiver process. Instead, the government retained title and made these inventions available through *non-exclusive licenses* to anyone who wanted to practice them. *As a result, companies did not have exclusive rights under government patents to manufacture and sell resulting products. Understandably, companies were reluctant to invest in and develop new products if competitors could also acquire licenses and then manufacture and sell the same products.* Accordingly, the Government remained unsuccessful in attracting private industry to license government-owned patents (emphasis added).⁷⁸⁵

This became a serious concern during the 1960s and 1970s. At that time, intellectual property rights and innovation had become the preferred currency in foreign affairs, and many experts worried that the nation would become increasingly vulnerable to foreign competition unless it

somehow figured out how to transfer those technologies efficiently to the public.⁷⁸⁶

In the 1960s and 1970s, there was much study and debate surrounding federal patent policies. A major concern was the lack of success by the federal government in promoting the adoption of new technologies by industry. There was no government-wide policy regarding ownership of inventions made by government contractors and grantees under federal funding. Inconsistencies in policies and practices among the various funding agencies resulted in a very limited flow of government-funded inventions to the private sector. *In 1980, the federal government held title to approximately 28,000 patents. Fewer than 5% of these were licensed to industry for development of commercial products* (emphasis added).⁷⁸⁷

Clearly, the law's sponsors and their patent law advisers recognized the collective wisdom of former U.S. President Abraham Lincoln and famous American inventor Thomas Edison. President Lincoln once said that the American patent system adds the fuel of interest to the fire of genius, while Dr. Edison's invaluable insight was that, The value of an idea lies in the *using* of it .

[G]enerat[ing]... inventions is almost never the main objective of basic research... [R]ather, it is... the... researcher's... ability to see some special relationship between his [or her] scholarly work product and the public

need... which can *convert a discovery or invention into a patentable invention... [and give rise to]... innovation...* (em phasis added).⁷⁸⁸

Im agination and creativity are a national resource... [and]... [t]he patent system is the vehicle which permits the delivery of that resource to the public[.] Placing the stewardship of the results of basic research in the hands of universities and small business is in the public interest..⁷⁸⁹

[N]ew products and processes do not spring fully formed from the basic research performed at universities. *They require not only good ideas, but further development, capital, marketing, and manufacturing capability.* That is where technology transfer comes in (em phasis added).⁷⁹⁰

Yet, they also understood others' concerns about the potential for monopolistic practices and higher prices, about how the costs of the program could likely exceed its potential public benefits, about the extent to which foreign industry could unduly benefit, and about how the diffusion of knowledge to the public could be impeded by covetous ownership behavior. Congress addressed these concerns in subsequent drafts that ultimately made their way into the final legislation.⁷⁹¹

Taking all of this into account, the Congress arrived at the following policy compromise: it would provide agencies with the means to shift legal title (ownership) of federally

funded ideas and patents from the government to those private hands (approved universities, small businesses and nonprofits) most capable of securing the monies and expertise needed to commercialize them.⁷⁹²

[L]egislators and the administration concluded that the public would benefit from a policy that permitted universities and small businesses to elect ownership of inventions made under federal funding and to become directly involved in the commercialization process. *This new policy would also permit **exclusive** licensing when combined with diligent development and transfer of an invention to the marketplace for the public good. It was understood that stimulation of the U.S. economy would occur through the licensing of new inventions from universities to businesses that would, in turn, manufacture the resulting products in the U.S.* (emphasis added).⁷⁹³

Conditions and Obligations

In return for such a grant, the Bayh Dole Act would oblige title recipients (research organizations) to commit to a number of important procedural and substantive conditions. In general,

1) They could not transfer ownership of the patents to other entities (but they could license use of the patents) and 2) in the event of successful commercialization of the new technology, researchers involved in creating the invention

would have to be compensated.
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More specifically, in order for a nonprofit organization, including a university, to qualify under the provisions of the Act, it: 1) May elect to retain title of and to patent only those inventions created⁷⁹⁵ under contract⁷⁹⁶ from research funded by the government; 2) Must disclose each new invention to the federal funding agency within two months of the inventor disclosing the invention to it,⁷⁹⁶ as required by a formal written agreement executed between the contractor and the inventor⁷⁹⁷; 3) Must decide whether or not to retain title to the invention, within two years of disclosure to a federal agency⁷⁹⁸; 4) Must file a patent application within one year of deciding to retain title⁷⁹⁹; 5) Must license the rights to innovations to industry for commercial development⁸⁰⁰, giving small businesses⁸⁰¹ preference⁸⁰²; 6) Must ensure that it or any of its assignees do not grant exclusive rights to use or sell in the U.S. any invention to which title is retained, unless the product arising from the invention is substantially manufactured in the U.S., subject to reasonable exception for cause⁸⁰³; 7) Must, for any invention in which title is retained, provide the government with a non-exclusive, non-transferable, irrevocable, paid-up right license to practice or have practiced the invention on behalf of the U.S. throughout the world⁸⁰⁴; 8) Must not effectively challenge an agency's ability to offer the inventor the right to take title if the contractor does not elect to take title itself⁸⁰⁵; and 9) Must share with the inventor a portion of any revenue received from licensing the invention, and ensure that any remaining revenue, after expenses, are used to support scientific research or education⁸⁰⁶.

Notwithstanding a contractor's eligibility to receive a title grant in the first place, federal agencies possess the

discretion to decide, for compelling reasons', that title to specific work should preferably be vested in the federal government, i.e., no title transfer to that or any other contractor or assignee should occur.⁸⁰⁷ Furthermore, the government, under certain reasonable circumstances, can require a contractor already holding title to a patent for an invention to grant a license to a third party, or may itself (march in ' and) assume title to the invention and grant licenses directly to third parties.⁸⁰⁸ The government may exercise this option if the contractor or assignee fails to reduce the invention to practical use within a reasonable time⁸⁰⁹, if it is necessary to alleviate public health or safety concerns⁸¹⁰, or if public use of the invention is otherwise in jeopardy.⁸¹¹

Benefits

The success of the Bayh-Dole Act can be measured in various ways. First, one might look at the hundreds of new entrepreneurial-minded, patent-seeking university and nonprofit-based technology transfer programs that have emerged since its enactment.⁸¹² In 1972, only 30 such programs existed. By the end of 2003, there were more than 300.⁸¹³ A second measure of the Bayh-Dole Act's success is the number of patents that have been filed and the amount of licensing revenue earned since its enactment – more than 2,000 new patents, 2,200 new licensing agreements, and approximately \$ 1 billion of royalty income.^{814 815 816 817} A third measure of the success achieved by the Bayh-Dole Act is its establishment of a formal and secure mechanism to promote future university-industry joint research collaborations. In some cases, it has even yielded productive public-private partnerships'.⁸¹⁸ A fourth measure of the success of the Bayh-Dole Act is the impact that it has had on the U.S. economy, as expressed in terms of capital creation, since its enactment, i.e., the

thousands of new companies begun, the new sources of investment tapped, and the hundreds of thousands of new jobs created.⁸¹⁹ A fifth measure of the Bayh-Dole Act's success is that it did not cost nearly as much as opponents had predicted, in terms of application filing and litigation costs.⁸²⁰ A sixth way to measure the success achieved by the Bayh-Dole Act is to consider the number of other countries endeavoring to imitate it – the United Kingdom, Canada, Germany, Japan, Korea, and Taiwan.⁸²¹

Although other nations may try to develop a Bayh-Dole Act of their own, critical differences often remain. One need only review the new Brazil Technical Innovation Law to see them. One of the key features of the American model is that it rewards the *individual* innovators for their research and commercialization efforts, as well as, the *private* or public university, nonprofit organization or small business that sponsors them. Since the enactment of the Bayh-Dole Act, for example, universities became hotbeds of innovation, as *entrepreneurial professors* took their inventions (and graduate students) off campus to set up companies of their own.⁸²² This has occurred largely because of the presence of incentives; the individual(s) who actually carries out the research and adapts the know-how is entitled to receive, by law, a piece of the action – a share of the licensing royalties. This serves as a powerful motivating force to promote the creation of inventions that have patentable, useable and, thus, commercial value. The knowledge inherent in the invention is made public through its distribution throughout the public marketplace and its adaptation by other innovators to different technologies, products and/or processes. This, perhaps, is one of the primary distinctions between the Bayh-Dole Act and the state-centralized innovation model for research and development embraced by many countries, including even Brazil. The state-centric model focuses primarily on

government retention of the rights to any intellectual property created and to any licensing royalties that can be expected from product commercialization by private companies. As in the case of Brazil, it may also rely upon open source knowledge from which to develop those inventions.

Indeed, the overwhelming success of the Bayh-Dole Act was recently acknowledged by the U.S. Congress. On December 14, 2005, the U.S. House of Representatives, in concurrence with the U.S. Senate, issued a Sense of the Congress Resolution, recognizing the invaluable contribution that the Bayh-Dole Act has made to U.S. innovation and technological advancement during the twenty-five years since its enactment.⁸²³

C. BRAZIL SHOULD UNLEASH THE INNOVATIVE CAPACITY OF ITS IP-RICH INDUSTRIES

Brazil Boasts Many IP-Rich and Technology-Capable Industries

Brazil boasts a number of knowledge-based high technology companies operating within the growing life sciences,⁸²⁴ computer software, information and communication technologies,⁸²⁵ aeronautical,⁸²⁶ and energy sectors,⁸²⁷ whose balance sheets most likely reveal quite valuable intellectual property assets. It is very likely that these assets would be capable of generating significantly greater revenue and profit for each such company and their shareholders than they now do, and also trigger welfare-enhancing national economic growth and spillover benefits for many local Brazilian communities, if only the Brazilian government would choose the right path; to recognize and vigorously protect that intellectual property by rule of law.

There are also many other well regarded industrial sectors in Brazil such as, steel and iron works, automotives, and mining, etc. As they become increasingly integrated within the evolving global information and technology society, they, too, are likely to develop and utilize, and/or otherwise exploit via licensing with third parties, their own advanced know-how. And, they will do so to more efficiently and cost-effectively manufacture, process, and distribute their products. Consequently, it is extremely likely that Brazil's leading industries will soon demand the same strong intellectual property protections for their evolving know-how and technologies that OECD nation industries, including those based in the U.S., have long struggled to secure.

Lastly, there are many poorer countries within Latin America, Asia, Africa and Eastern Europe, which have traced Brazil's evolution from a developing country to an emerging economy. They, too, are keen on learning the 'magic' of Brazil's successes, including its continued use of IP opportunism to acquire foreign-held scientific and technological know-how, for purposes of establishing their own future development strategies. This, however, is one success that, arguably, should not be replicated.

As Brazilian companies seek new markets, including China, India, and Russia, and exports to China diversify beyond commodities, including technology, pharmaceuticals, and software, [one] would expect that our interests will become more closely aligned.

... The United States and Brazil today must compete in a global

economy that includes 2.3 billion people in China and India. Both offer tremendous growth opportunities, but also the challenge of intense competition. China is attracting more than one billion dollars a week in foreign direct investment. We must rise to the challenge by creating open, fair, predictable and transparent trading regimes throughout the Americas.
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Given the breadth of information concerning these industries, we have chosen to limit the scope of our discussion generally to the life sciences and computer software industries. Both of these sectors strongly rely on intellectual property as a valuable economic asset to be commercialized in the marketplace for profit, and thus, they are both critically important to the future of the Brazilian knowledge-based economy.

Life Sciences Industries

Pharmaceuticals

The Brazilian pharmaceutical industry is reportedly comprised of approximately 370 (and perhaps even more⁸²⁹) companies, representing a total market value of approximately US\$6 billion in 2004, and an estimated \$8.4 billion in 2005. It is currently the 11th largest pharmaceuticals market in the world and the second largest in Latin America after Mexico.⁸³⁰ The Brazilian pharmaceutical market grew approximately *18% in volume* from 2003 (U.S. \$5.2 billion) to 2004 (U.S. \$6.14 billion), and approximately 10% in volume from 2002 (U.S. \$5.55 billion). In 2004, Brazil imported \$1.6 -1.8 billion in

pharmaceutical products, approximately half of which came from the U.S.⁸³¹

About 80% of pharmaceutical companies operating in Brazil are national, but they are only responsible for a minority of domestic sales. Of the 12 biggest companies of the pharmaceutical industry, which combined represent around 45% of the Brazilian market, there is only one company, Aché, built with local capital.⁸³² Foreign firms are mostly from the United States and Europe and their Brazilian subsidiaries are responsible for supplying 70% of the market (around 20 companies), not including direct sales to the Government.⁸³³

According to one leading Brazilian pharmaceutical expert,

The Brazilian pharmaceutical market shows a growth potential mainly in drugs of continuous use because the population of elderly is increasing while the birthrate is going down... The government laboratories still do not have high productive capability... In the last five years national companies have intensified the partnerships with multinational companies, producing and selling their products, having as a result, the investment in the modernization and automation of the industrial plants, and in many of them, including the ones belonging to the big international corporations.⁸³⁴

The generic drug sector has grown rapidly since it was formed in 1999. It is estimated to have accounted for *12% of sales in 2005* (nearly US\$ 600 million) (as compared to \$500 million in 2004 – *a 20% increase*). The state public

health systems purchase nearly all generics production as part of the government's program to distribute medicines to the poorest.⁸³⁵ By 2008, experts expect the generic market to reach US\$ 1 billion in sales. Local generic drug manufacturers in Brazil operate at world-class levels. Approximately 85% of the raw materials used in the production of generic copies of patented drugs in Brazil are imported.⁸³⁶

The generic medicine industry has invested close to US\$1 billion in the construction and modernization of industrial plants in Brazil, providing direct employment for more than 10,000 people. During this period, 35 new laboratories for bioequivalency assays were built. Today, the top four manufacturers are established from local capital. Approximately 80% of the generic units commercialized in Brazil are produced locally. By source of capital, 74.6% of sales in the Brazilian generic market are made by local companies. Indian capital is the second most represented, with 10.3% participation, followed by companies of German (4.7%), Swiss (4.6%), US (3.8%), and Canadian (2%) origin.⁸³⁷

During the first six months of 2004, the Brazilian pharmaceutical industry exported approximately \$163.9 million in finished medicines and similar products, vaccine, serum, blood derived products and parenteral solutions... a growth of 17.85% in relation to the same period in 2003.⁸³⁸ Brazil's largest export markets for these products have been Mercosur, Argentina, Mexico, and Venezuela.

The Brazilian pharmaceutical industry urgently requires the Government of Brazil to establish *and* implement a new national mechanism for innovation based on recognition of exclusive intellectual property rights. It must quickly find a way to protect its markets and its evolving innovative capabilities from the growing competition posed by more experienced Indian⁸³⁹ and Chinese⁸⁴⁰ pharmaceutical companies specializing in the production of active pharmaceutical ingredients (APIs)⁸⁴¹ (basic building-block molecules). According to a representative of the Brazilian Association of Chemical Industries (ABAFINA), these foreign companies not only supply multinational pharmaceutical companies, but also have continued to expand their share of the Brazilian *domestic* market. ABIFINA members have thus been concerned about securing the tools necessary to increase privatization of the industry, greater integration between domestic producers of APIs and producers of finished dosage products (i.e., national laboratories)⁸⁴², and to increase investment and support for R&D in Brazil with respect to formulation of APIs, in order to improve their *domestic* competitiveness.⁸⁴³ However, ABIFINA has recently issued a position paper arguing *against* the need for strong patent protections with respect to the branded products of multinational drug companies.⁸⁴⁴ Is not their position inconsistent with their strategic goals? Does it not reflect a hidden call for protectionism?

Biotechnology

For at least thirty years, Brazilian national governments have endeavored to promote health biotechnology in the region. Until recently, they had encountered considerable obstacles, however, because the Brazil public has [had] difficulty clarifying the differences between health biotechnology [and] agricultural biotechnology . As a

result, additional efforts have been required to educate and inform Brazilian citizens about the risks and benefits of biotechnology and the science underlying it.⁸⁴⁵ For this reason, much of the work in the area of biotechnology is still being performed at the government, institute and university research levels.

Even despite these setbacks a small private sector in this field has managed to develop. And, it has rapidly expanded within a relatively short period of time – 10 years.

During the past decade, the Brazilian private biotechnology sector has quickly expanded, with most companies concentrated in the south and southeast parts of the country. In 1993, there were 76 biotechnology firms in Brazil; by 2001, their number had increased to 354. Approximately 70% are local private firms, 25% are multinational and 5% are state-owned firms. Of their combined products, 26% are for the health care market and the rest are for agricultural, environmental and industrial fields... [By 2003,] the [Brazilian] federal government [had] increased the biotechnology sector budget by 180%...to stimulate industrial development.⁸⁴⁶

According to one prominent national biotech trade association, These firms are interested in attracting foreign investment and products to provide an incentive for development.⁸⁴⁷

Medical Biotech

During the early years of this industry's expansion, the private Brazilian biopharmaceutical firm Biobras (Sao Paulo) and the Federal University of Minas Gerais (Belo Horizonte) successfully collaborated to develop and patent a process for recombinant human insulin. Biobras became one of only four companies in the world producing recombinant human insulin at the time. Biobras has since been acquired by Novo Nordisk (Bagsvaerd, Denmark).⁸⁴⁸ Brazil has also excelled in biomedical diagnostics, and has developed competencies in the manufacture of conventional vaccines (e.g., yellow fever), a recombinant vaccine for hepatitis B and other recombinant proteins.⁸⁴⁹

In addition, Brazil has begun to make favorable use of its biodiversity-rich geography – the Amazon rainforest – through the application of biotechnology. One of the projects that [] received attention from the government and from the largest pharmaceutical laboratory (Laboratorios Ache) [involved]... phytotherapeutic agents [derived from]... Brazilian flora.⁸⁵⁰

During June 2005, Ache released under the trade name Acheflan' an anti-inflammatory cream. It was developed from a unique chemical compound isolated by a University of Sao Paulo professor from the extract of a rainforest plant known as Maria-Milagrosa' (Miraculous Mary').⁸⁵¹ Although the particular compound had been identified and preliminary animal testing had been performed as early as 1980, it was not until 1998 that the company finally applied for *international* patent protection, which it ultimately was granted in both Europe and the U.S.⁸⁵²

Ache's efforts to develop and then commercialize its know-how should be applauded, especially considering the questionable local enabling environment in which the

company has had to operate. Of greater concern, however, is why the company had not applied *first* for a *Brazilian* patent. Did it *not* trust that the Government of Brazil would implement, and did the Brazilian Government actually fail to implement the 1996 national patent law reforms, which supposedly recognize patented products *as well as* processes? Were Ache's legal and economic interests therefore placed at risk?

Furthermore, the collaborative manner and timeframe in which the company was able to commercialize its invention – with *university assistance and state funding* – following an *individual scientist's discovery* of the analgesic power of a plant found within the wilderness, was also significant.⁸⁵³
⁸⁵⁴ One expert has noted how this discovery and commercialization process had unfolded similarly to the scheme articulated within the new Brazil Technical Innovation Law.⁸⁵⁵ In addition, the new law has been touted as giving rise to eleven (11) other joint R&D agreements between and among companies and universities and 11 *international* patents.⁸⁵⁶ But is this more hype than reality?

Besides Ache, two other Brazilian biotech and pharmaceutical companies – BioLab and Biosintetica - also originally applied for *international* rather than Brazilian patents. Did they, as well, lack confidence that the state-centric Brazilian Technical Innovation Law would not adequately protect their IP investments (i.e., patents, trade secrets and copyrights)? Is Brazil's Technical Innovation Law capable, in its present form, to stimulate the types of large scale and complex science and technology innovations nationwide that are necessary to ensure Brazil's future global competitiveness? If a letter recently sent by the U.S. trade association BIO to the USTR is any

indication,^{857*} the answers to these two questions would be yes and then no.

Environmental Biotech

Brazilian biotech companies have also increasingly focused on and invested in a rapidly expanding environmental services industry. For example, they have acquired environmental technologies, products and services, including biologics, to assist municipalities and farms in handling waste and pollutants, and controlling diseases. In addition, they have employed biologic techniques to prevent the environmental contamination of lakes and estuaries, and to control the consequences of eutrophication when used in farming.⁸⁵⁸

Agro Biotech

Perhaps, the fruits of biotechnology will be most extensively enjoyed by Brazil's large agricultural sector, which already serves as Brazil's greatest source of export-based revenues and economic growth. The agricultural business comprises 33% of total Brazilian exports. Sugar cane is the highest volume export, followed by soybean, corn and cassava. Complex soybean is the number one crop.⁸⁵⁹

The biggest impact of biotechnology in Brazil is expected to be on agriculture, which represents 10% of the Brazilian GDP, 40% of exports and 25% of the labor force. Due to its immense agricultural areas and favorable climate, the country became a giant market for biotechnology with a US\$30 billion market niche within

its nearly US\$200 billion agricultural market. The employment of biotechnology for the development of products and processes related to agriculture will represent a fundamental strategic factor as the quality and quantity of basic production increases in the country.⁸⁶⁰

The Brazilian government and private companies have undertaken several high profile research projects during the past few years in the area of agro-biotech, some of which may potentially contribute to the growth of the medical biotech,⁸⁶¹ agro-automotive,⁸⁶² and agro-energy (bio-fuels)⁸⁶³ sectors as well. A brief description of each follows.

1) Sugar Cane

There is a... project being developed with the sugar cane genome. Brazil is responsible for 25% of world production of sugar cane. The project is mainly focused on mapping and application of DNA markers for sugarcane genetics, and it has formed a network with 38 research groups located in public and private universities with the participation and support of Coopersucar, the major private sugar cane institute in Brazil.

In addition to improving agricultural crop yields, such research will be used to promote *Brazil's burgeoning bio-fuels industry*. *Bio-fuels* are now being used to conserve and save conventional fuels such as

petroleum and diesel, Brazil is the leader in bio-fuel usage, where it has been used in automobiles for over 25 years. Brazil currently produces 13 billion liters of bio-ethanol from sugarcane, fuelling over 3.5 million vehicles with pure ethanol. The rest of the vehicles run with approximately an 80% blend of ethanol and gasoline (emphasis added).^{864 865 866}

Indeed, Brazil may soon be able to export its ethanol and automotive technology and know-how to other countries, and thereby, further its influence in global policymaking circles.⁸⁶⁷

2) *Papaya, Corn, Soy*

There are also some *projects with transgenic plants being developed...* such as Brazilian corn used to produce growth hormone, papaya resistant to the Brazilian strain of ring spot virus⁸⁶⁸ and common beans resistant to the golden mosaic virus⁸⁶⁹ ... There are several biotechnology programs being developed by the *private sector*, such as Syngenta... in Biotech Research. It is the main project being developed in Latin America related to corn and cotton resistance to pests. Syngenta has also entered into an agreement with the Federal University of Viçosa, in the Southeastern State of Minas Gerais, for soybean improvement, aiming at the elimination of certain toxins

present in its seeds (emphasis added).^{870 871}

Chemicals

Brazil's chemical industries play a vital role in supporting its pharmaceutical, biotechnology, agricultural and industrial sectors.

Fine chemistry and enzymes are vital for the Brazilian biotech industry. *Enzymes and proteins are being used for the development of Biotechnology programs and products in the country. Companies, incubators and universities are investing in the development of enzyme production technology and there are many projects on the use of enzymes for clinical diagnostics, enzymatic processes, biological processes for waste water and technology of microbial metabolites (alcohol and organic acids). Agrochemicals have also been used for a long time in Brazil. The Brazilian agrochemical market moves approximately US\$2.5 billion per year. Herbicides represent the largest portion in Brazil (emphasis added).*⁸⁷²

The chemical industry plays an important role in the development of production activities and takes part in almost all industrial chains, in addition to supplying inputs for agricultural uses and manufacturing consumer goods (medicines, hygiene and perfumery items).⁸⁷³

In fact, chemicals comprise Brazil's second largest manufacturing industry, and a considerable percentage of national GDP.⁸⁷⁴

Computer Software & E-Commerce

Brazil is the 7th largest computer software producer in the world. Its IT sector is the largest in Latin America, accounting for every one of two dollars spent on IT products and services in the region. Computer software sales in Brazil are expected to reach \$12.1 billion during 2006. Approximately \$5.3 billion of those sales will be attributable to imports, 70% of which will come from the U.S.⁸⁷⁵

A predominant portion of the computer software developed has been devoted to e-commerce use.

Brazil is the ninth largest Internet market in the world and the first in Latin America with the most advanced Internet and e-commerce industries. According to the Brazilian Chamber of Electronic Commerce (Camara-e.net), Business-to-Business (B2B) and Business to Consumer (B2C) reached revenues of US\$ 43 billion in the first half of 2005, with business-to-business (B2B) transactions comprising 75% of that total.⁸⁷⁶

Brazil's financial sector is the largest and most extensive user of e-commerce software. The banking system software is particularly well developed, as the result of

heavy investments made by the Brazilian banking industry. As of 2003,

Through an early focus on PC banking and Internet-based offerings, Brazil has developed one of the most advanced home-banking systems in the world, of which Bradesco (the largest private Brazilian retail bank) was the pioneer. [T]he Brazilian banking sector [was] the largest single investor in IT in Brazil, accounting for 30% of total expenditures. In the banking sector, the establishment of the Brazilian Payment System (SPB) is a particular good example of how lead sectors and local idiosyncrasies can spur the development of an indigenous software industry.⁸⁷⁷

Brazil's e-government software (Government of Brazil Online) has also been at the cutting edge of global technology. It is being widely used for electronic tax filing and electronic voting.

The Federal Government is also a large and sophisticated user of software (Brazil's lead in e-government is recognized, with flag projects such as electronic voting and 98% of all personal income tax delivered electronically)⁸⁷⁸ In 1996, Brazilians began filing federal taxes online, and last year [2005] 12 million people, 95% of filers did so. All corporate returns were e-filed, and 66% of federal services

are assessed [available over the Internet through the portal] (www.Brasil.gov.br).⁸⁷⁹

Furthermore, the \$\$ amount of management software purchases has practically doubled over the past two years. Brazil has also become advanced in wireless services, particularly in wireless security. The problem, however, is that only 2% of Brazil's software industry revenues are earned through exports. Although Brazil's domestic software industry is well-developed in the financial services segment, most Brazilian software companies have not had success exporting their products. Apparently, their poor export performance is largely attributable to their inability to obtain software product certifications.⁸⁸⁰ As a result, one leading Brazilian software industry expert notes that, Brazil's domestic software industry now finds itself at a competitive disadvantage internationally vis-à-vis other more aggressive, lower-cost countries, such as India and China.⁸⁸¹

Other Brazilian software experts agree with this assessment. They have also noted how despite the industry's development of a strong domestic software market, they must now defend their home turf against very competent lower cost competition, and leverage their expertise by focusing on integrating it within other sectors throughout Brazil's industrial base.⁸⁸² IT services⁸⁸³ and telecommunications⁸⁸⁴ are just two of many industries that could benefit immensely from the cross-pollination of innovative sectors.

V. BENEFITING FROM FOREIGN DIRECT INVESTMENT AND IPR PROTECTION

**A. BRAZIL'S INCREASING TRADE SURPLUS
MAY NOT COMPENSATE FOR ITS DECLINING
FDI**

The Ebb and Flow of FDI to Brazil

It is well recognized how Brazil benefited from FDI flows during the early 1990's, and how such flows precipitously declined from 2001-2003.

FDI was a crucial source of financing for Brazil's balance of payments... during the early [19]90s... However, since 2001... [Brazil's] trade balance has improved sharply, helping produce actual current account surpluses in 2003 and 2004. This trend has enabled Brazil easily to weather the steep continuing *decline of FDI* from \$22 billion in 2001 to \$16.6 billion in 2002 and just \$10.1 billion in 2003 (emphasis added).
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Fortunately, Brazil's FDI decline abruptly reversed itself during the following year, as *[o]verall* FDI in 2004 increased 70% to reach a total of \$17 billion and Brazil became one of the top three locations for U.S. foreign direct investment.⁸⁸⁷ In fact, the 2004 amount may actually have been as high as \$18.17 billion!⁸⁸⁸ But, if recent data is any indicator, this reversal may have been only temporary and the prior trend of FDI declines may have already resumed. On January 19, 2006, Brazil's central bank once again reported a sizeable drop in FDI to \$15.19 billion.⁸⁸⁹

This data, at a minimum, confirms that, Brazil's ability to lure foreign direct investment has lagged other emerging market giants like China during the last several years.⁸⁹⁰ It may even suggest that, in the face of increasing FDI competition, Brazil will likely have future difficulties securing FDI unless it makes certain structural changes. And, this challenge may persist notwithstanding recent United Nations prognostications to the contrary.

Brazil is expected to be *the* most attractive location in Latin America for FDI in 2005-2006... [and] *the United States is expected to remain the leading source of FDI* in Latin America and the Caribbean⁸⁹¹ (emphasis added).

While Brazil's current surging trade surplus [might] allow [it] to reduce [somewhat] its dependence on foreign institutional financing,⁸⁹² and to consider International Monetary Fund (IMF) and Paris Club funding less critical to its maintenance of balance of payment and capital account surpluses,⁸⁹³ it would be unwise, and perhaps even foolish, for Brazil to extend this newfound economic and political confidence, which may only be temporary^{894 895}, into the realm of FDI.⁸⁹⁶ FDI is often facilitated by the participation of other international financial institutions such as the World Bank, the Inter-American Development Bank, the U.S. Export-Import Bank, the Overseas Private Investment Corporation, and other foreign governmental export promotion vehicles that, like the IMF, may impose their own strict conditionalities on loan facilities. Brazil must remember that FDI continues to surpass other private capital and official development assistance (ODA) to emerging and developing countries. As recently as 2004, it was reported that most resources, including funds earmarked for research and development (R&D), continued

to flow in the form of FDI.⁸⁹⁷ While Brazil may wish to self-insure‘ through large reserve holdings and a declining and less volatile stock of debt.. [by].. lessen[ing].. the need for external financial support ,⁸⁹⁸ it must still provide the necessary enabling environment (e.g., liberalized markets, private property rights and intellectual property rights protections) to attract and reassure multinational corporations. After all, MNCs (i.e., transnational corporations – TNCs), with or without government financial backing, remain the key providers of FDI.

Global R & D expenditure has grown rapidly over the past decade.. TNCs are key players in this process. A conservative estimate is that they account for close to half of global R&D expenditures, and at least two-thirds of business R&D expenditures..⁸⁹⁹

*Transnational corporations are the main providers of FDI and are thus an important source of employment. The transnational index (TNI) reveals the importance of TNCs in a domestic economy taking into account the production potential stemming from FDI inflows and the outcome of that investment.. This is especially true for Brazil... where TNCs are more important than in India, France, [and] even China (emphasis added).*⁹⁰⁰

Brazil Should Not Take MNC FDI Flows for Granted

Brazil also must not overlook how indispensable corporate-driven FDI funding of intellectual property-rich R&D remains to its ability to secure the types of sophisticated technology and know-how transfers that it seeks. It is well recognized that, The world's largest R & D spenders are concentrated in a few industries, notably *IT hardware, the automotive industry, pharmaceuticals and biotechnology* (emphasis added).⁹⁰¹ This general point was emphasized within another recently released United Nations report.

It is clear that, to date, only a small number of developing countries and economies in transition are participating in the process of R&D internationalization. However, the fact that some are now perceived as attractive locations for highly complex R&D indicates that it is possible for countries to develop the capabilities that are needed to connect with the global R&D systems of TNCs. *From a host-country perspective, R&D internationalization opens the door not only for the transfer of technology created elsewhere, but also for the technology creation process itself. This may enable some host countries to strengthen their technological and innovation capabilities...* Innovative activity is essential for economic growth and development (emphasis added).⁹⁰²

Brazil, furthermore, must not forget that it suffers from serious but largely correctable national deficits in human capital (namely, education), know-how commercialization, and implementation and enforcement of intellectual

property right (IPR) protections. These shortcomings may significantly impair the technology and knowledge diffusion/absorption that experts consider necessary for it to create a truly sustainable national innovation system.

A key determinant of the development impact on a host economy is its absorptive capacity. Indeed, technological capabilities in the domestic enterprise sector and technology institutions are necessary not only to attract R&D but also to benefit from its spillovers. Other determinants are the type of R&D conducted, and whether the R&D is linked to production. *The more a TNC interacts with a host developing country's local firms and R&D institutions, and the more advanced the country's national innovation system (NIS), the greater the likelihood of positive effects on a host economy* (emphasis added).⁹⁰³

Indeed, while the above-referenced 2005 UNCTAD reports forecast the growing desirability of Brazil as an FDI destination in the short-term, they also express certain important reservations about the nature of future FDI flows that will likely enter Brazil. In fact, with certain caveats, one of the reports warns that R&D is NOT likely to be among the primary corporate functions to be immediately relocated to Brazil.⁹⁰⁴

Respondents generally concurred that production is the corporate function most likely to be relocated. Well over 80% of those surveyed by UNCTAD expected

some production activities to be transferred overseas. At the same time, growth of offshore outsourcing in services will continue, they predict. Logistics and support services are the functions next most likely to relocate offshore, followed by distribution and sales.

*... Regional headquarters and research and development are the least likely corporate functions to be relocated abroad. TNCs expected to see less relocation of R&D activities than [Investment Promotion Agencies] IPAs and experts. Only 20% of TNC respondents expected R&D to be relocated, in contrast with more than 40% of experts and almost 60% of IPAs. This finding is particularly interesting given the recent trend towards the globalization of R&D, and reinforces the notion that since R&D involves knowledge vital to a firm's competitiveness, it is in need of maximum protection, and it is therefore less likely to be transferred overseas. A separate UNCTAD survey of the world's largest R&D spenders shows that the share of R&D funded by foreign companies will increase by 2009, with China, the United States and India as the top three recipients of FDI in R & D ... (emphasis added).*⁹⁰⁵

According to the same report, this FDI dynamic reflects the different types of R&D, namely imitative-adaptive and innovative.

... TNCs carry out different types of R&D abroad. Foreign affiliates of TNCs may undertake *adaptive R&D*, which ranges from basic production support to the modifying and upgrading of imported technologies. *Innovative R&D* involves the development of new products or processes for local, regional or (eventually) global markets. *Technology monitoring* units are established to keep abreast of technological development in foreign markets and to learn from leading innovators and clients there. (emphasis in original).

While it is difficult to quantify R&D by type, among developing host economies the evidence points to the predominance of Asia in *innovative R&D* for international markets... TNCs have so far located limited R&D in Latin America and the Caribbean. *Relatively little FDI in Latin America and the Caribbean is in R&D-intensive activities*; when it is, the R&D conducted is mostly confined to the adaptation of technology or products for local markets, called *tropicalization*⁹⁰⁶ in the Latin American context. *Some important exceptions exist in Brazil...* in particular [how ever]...⁹⁰⁷

The report's conclusion that Brazil can expect to receive mostly adaptive rather than innovative R & D is probably linked to the importance that such FDI sources ascribe to IP protections and the inability of local businesses to commercialize R&D-based know-how. It is likely also due to the uncertainties surrounding Brazil's evolving international public persona and its apparent inability and/or unwillingness to commit to these two policy objectives.

The *internationalization of R&D* is also facilitated by overall improvements in host-country investment climates have all contributed to creating a more *enabling framework*. Important policy developments relate, for example, to **intellectual property rights (IPR) protection**, reform of public research activities... (emphasis added).⁹⁰⁸

... A number of policy and institutional areas need to be addressed *to attract FDI in R&D*, to secure the benefits that it can generate and to address potential costs. *The starting point is to build an institutional framework that fosters innovation*. Particular policy attention is needed in four areas: human resources, public research capabilities, **IPR protection** and competition policy.⁹⁰⁹

In the end, the Government of Brazil must acknowledge that its success in securing FDI, and particularly, *innovative* R&D-related investments, will determine whether it can ultimately create a national innovation system that generates consistent economic growth and national

development. This, however, depends on its mastering of the push and pull dynamic that exists between multinational corporations, domestic industries and government. That relationship demands assurances that private property ownership, in general, and intellectual property rights, specifically, will be recognized and adequately protected. It also requires strengthening domestic education and local technical skills and capabilities.

The innovative capabilities of a country are directly relevant to its attractiveness as a host country for R&D by TNCs, as well as to its ability to benefit from such R&D. The quality of R&D performed abroad depends on local capabilities of the host country. The same applies to the resulting externalities in terms of how much local firms and institutions are able to absorb and learn from exposure to best practice R&D techniques and skills. Whether or not R&D

deepens over time, and how far it spreads over different activities, are the result of an interactive process between the TNCs and local actors in the host economy, and this process is in turn affected by the institutional framework and government policies of the host country.⁹¹⁰

Brazilian presidential hopeful Geraldo Alckmin clearly recognizes that Brazil should not become complacent with its current temporary trade and account surpluses,⁹¹¹ such that it abandons the pursuit of more open and market-friendly foreign investment and trade policies. In this

regard, Mr. Aلكم in aspires to improve Brazil's enabling environment for domestic entrepreneurs and foreign businesses in order to secure the FDI necessary to promote greater domestic investment, indigenous scientific and technological innovation and economic growth. This is clearly in line with the World Bank's latest research.⁹¹² In other words, unlike Mr. Lula who will try to exploit the 'feel-good factor' he has inherited largely from benign global economic conditions and the wise economic policies of Brazil's previous centrist PSDB governments,⁹¹³ Mr. Aلكم in will instead focus on what Brazil could become if the government were to adopt prudent innovation and economic policies.⁹¹⁴

Brazil... can't run the risk of losing another four years. We need to grow more quickly... My obsession will be with growth... The government can create jobs only in a complementary way. Jobs are created by entrepreneurs, the private sector. We need to attract productive investment... The government is going along one line and we are going along another... Today the line is, increase current spending, increase taxes, and cut investments.⁹¹⁵

Indeed, even the international financial community and the media are aware of how the Brazilian government recently recalculated its national finances in order to hide its worsening financial health and its growing budget deficit from foreign investors.⁹¹⁶ ⁹¹⁷ They are also aware of how President Lula dismisses these challenges,⁹¹⁸ ⁹¹⁹ even though most economists regard [Lula's pledge of 4 - 4.5%

annual growth⁹²⁰] as impossible and many have revised their predictions to around 3 percent.⁹²¹

B. BRAZIL MAY DERIVE INNOVATION BENEFITS FROM FDI-RELATED KNOWLEDGE SPILLOVERS

Indigenous Capacity-Building

A developing country's ability to take advantage of the FDI flows from knowledge-rich multinational corporations (MNCs) that are facilitated by international treaties and related domestic IPR reforms depends on two primary factors: 1) the country's level of economic development; and 2) the country's level of human capital stock. To improve their understanding of this phenomenon, economists have broken down the concept of human capital stock into two distinct elements: a) years of education/schooling; and b) innovative ability.

One recent (2004) World Bank study explored the dynamic of human capital stock in more detail. It determined that,

[K]nowledge is a significant determinant of long-term economic growth. In particular, we find that the stock of human capital, the level of domestic innovation and technological adaptation, and the level of information and communications technologies (ICT) infrastructure all exert statistically significant positive effects on long-term economic growth. More specifically with regard to the growth effects of the *human capital stock*, we find that an increase of 20 percent in the average years of schooling of a

*population tends to increase the average annual economic growth by 0.15 percentage point. In terms of innovation, we find that a 20 percent increase in the annual number of USPTO patents granted is associated with an increase of 3.8 percentage points in annual economic growth. Lastly, when the ICT infrastructure, measured by the number of phones per 1,000 persons, is increased by 20 percent, we find that annual economic growth tends to increase by 0.11 percentage point (emphasis added).*⁹²²

Another recent (2004) study came to similar conclusions in the context of evaluating the impact that a developing country's adoption of IP protections could have on its *overall* national economic growth. It found that this largely depends on the particular country's level of development, and its ability to innovate and/or imitate.

Innovative activity tends to be concentrated in a small number of advanced countries. In these countries stronger IPR protection would be expected to encourage innovation and subsequent growth. For many other countries however, and for middle-income countries in particular, imitation can be an important source of technological development and growth. [This result obtains, even though] providing stronger IPR protection to foreign firms could cripple [those] domestic industry[ies] previously relying on pirated technologies.⁹²³

Middle-income countries [such as *Brazil, Russia, India and China*]... also do not engage in innovative activities to any extent, but may well rely on imitative activities. *The lack of a relationship between IPR protection and growth in these countries is likely to reflect two opposing forces. The positive impact of IPR protection on growth that works indirectly through trade and FDI is being offset by a negative impact slowing knowledge diffusion and discouraging imitation.* Despite the lack of evidence for a significant relationship between IPR protection and growth for middle-income countries *in no case do we find evidence of a negative relationship between IPR protection and growth* (em phasis added).⁹²⁴

A more recent (2005) study addressed the concern of the previous study's authors, regarding the potential negative impact of IPR protections on imitation-oriented domestic industries (technology opportunists'). It found, to the contrary, that following IPR reforms, local affiliate output, employment levels and capital stocks had expanded significantly, and that this expansion... [led] to a higher net level of production shifting to developing countries [which] more than offset[] any possible decline in the imitative activity of indigenous firms.⁹²⁵

Furthermore, a recent (2005) United Nations study acknowledged, albeit reluctantly, that FDI flows precipitated by a developing country's adoption of IP protections can lead to the types of critical knowledge

development (learning) that will raise such country's ability to innovate and, hence, to grow economically.

Innovation is essential for economic growth and development. Research and development⁹²⁶ is only one source of innovation *but it is an important one* (emphasis added).⁹²⁷

... Developing countries could increase their attractiveness as locations for conducting R&D *by strengthening their protection of intellectual property*, but it is not necessarily considered a prerequisite in the decision-making process of TNCs. Other factors, such as the availability of human resources, infrastructure and the domestic innovative capacity in general, appear to be more important. *However, the development of domestic innovative capacity, which does affect TNCs' location decisions, is partly influenced by the IPR regime. Furthermore, to the extent that such a regime facilitates sharing of knowledge and learning, it can also help enhance the benefits of FDI in R&D* (emphasis added).⁹²⁸

Each of these studies indicates what many intellectual property right opponents, health advocates, and open source missionaries are loathe to admit: that beyond the more narrowly focused MNC benefits sought (i.e., protection of their private IP interests against unauthorized imitation and expropriation), there are even greater benefits

that await developing countries savvy enough to recognize IPRs as they keep their R&D-related FDI spigots open.

It is well known that multinational firms are concentrated in industries that exhibit a high ratio of R&D relative to sales and a large share of technical and professional workers... By encouraging FDI, developing countries hope not only to import more efficient foreign technologies but also to generate technological spillovers... [i.e.,] the facilitation of technology adoption... for local firms...⁹²⁹

The observed impacts that FDI flows can have on developing country economies generally, and on developing country companies and labor more specifically, have been described by economists as spillover effects'. The term spillover has been defined both narrowly and broadly with respect to a foreign corporation's actual investment in research and development facilities and processes in a particular developing country.

Defined narrowly, the term spillover' includes only pure externalities (such as the facilitation of technology adoption) that may [directly] accompany FDI flowing from a single company.⁹³⁰

... [I]f FDI spurs innovation in the domestic industry by increasing competition, we do not view that as a spillover' from FDI but rather a benefit enjoyed by the host country that works its way through the price mechanism and the market equilibrium. *Of course, [however,] it is very difficult to empirically isolate the pure externalities from*

FDI from its other effects that work through the market. Furthermore, policy ought to be based on the aggregate effect of FDI on welfare, not just on the extent of positive externalities from FDI (em phasis added).⁹³¹

However, it can be persuasively argued that spillovers should be defined more broadly to include also pecuniary externalities (that result [indirectly] from the effects of FDI on market structure)...⁹³² A broader definition of the term spillover would better be able to take into account any 'follow the leader' or 'copycat' behavior that might and often does occur among corporate competitors who later enter and invest in developing country markets.

An old tradition in the management literature describes the interdependence between the decision making of large multinationals as 'follow the leader' behavior...For example [in the present case], when two firms are exporting to a foreign market, a switch from exports to FDI by one creates an incentive for FDI on the other firm's part, who finds itself at a competitive disadvantage... Thus, if such trade is indeed pervasive, one should expect a strong complementary relationship between exports and FDI at the *aggregate* level (em phasis added).⁹³³

Economists generally agree that, domestic companies operating within Latin American countries, including Brazil, can significantly benefit from the spillover effects triggered by foreign direct investments made by

multinational corporations. This result obtains, in part, because such countries suffer from knowledge and human capital deficits. Latin American economies are comprised mostly of privately owned small and medium-size (SMEs), many of which possess significantly less sophisticated technical skills, know-how, and overall education than MNCs. Although many of the larger companies within Latin American countries, such as Brazil, possess high-level technical skills and knowledge, the SME deficits in those countries, when viewed on a nation-wide collective basis, can measurably reduce their country's prospects for economic advancement. This is especially true in today's fast-paced, knowledge-based, technology-centric interconnected information society.

A recent (2004) Inter-American Development Bank report sheds light on these problems and opportunities in the context of SME technology clusters⁹³⁴ (networks).⁹³⁵ It found that, among the factors that can contribute significantly to the creation of Latin American country SME innovative capabilities, are: 1) the establishment of a business-friendly, market-based enabling environment, replete with institutions that attract MNC FDI⁹³⁶ and foster MNC embeddedness and know-how exchanges;⁹³⁷ 2) a well functioning and integrated national innovation system that encourages R&D investment and a stable *property rights [i.e., intellectual property/patents]*, regulatory, and dispute settlement (judiciary) systems;⁹³⁸ and 3) effective good governance' (anti-corruption) mechanisms.⁹³⁹

Unfortunately, [d]espite overall acknowledgment of the positive effects that interaction with foreign firms can have on the competitiveness of domestic companies, including smaller firms, only Mexico, Chile, Costa Rica and Nicaragua have adopted specific instruments to promote such an interaction.⁹⁴⁰ As a result, Brazil's domestic firms

seem largely unable to provide the high qualitative standards that MNCs ask of their suppliers.⁹⁴¹

Clustered SMEs Realize Potentially Greater Benefits

The IADB report identifies a number of specific benefits that Latin American cluster-based SMEs,⁹⁴² including those from Brazil, can expect to derive from targeted FDI. They include improved host economy productivity and wages generating local investment opportunities and production variety in both upstream (supplier) (backward linkages) and downstream (customer) (forward linkages) industries.⁹⁴³

... [B]ackward and forward linkages might be a powerful channel through which FDI knowledge might spill over to [the] host economy. The main spillover channels are imitation, competition, worker turnouts and exports. FDI knowledge spillovers are said to take place when local firms increase their productivity by copying the technology of affiliates of foreign firms. Given the foreign firm's strong interest in protecting their competitive edge, and therefore, minimizing technology transfer, spillovers would most likely be vertical' (among their clients and suppliers) [rather than] horizontal' (among their competitors).⁹⁴⁴ FDI is also believed to generate positive pecuniary externalities (linkage effects) to local firms improving the local supply (quality and variety) of intermediate goods... The most relevant form of linkage for FDI is the backward one - that is, the link between

MN[C]s and local upstream suppliers (emphasis added).⁹⁴⁵

As noted above, developing country SMEs may realize their most important FDI-related benefits from the learning opportunities that arise in connection with technology (mostly process-related) transfers – i.e., from knowledge spillovers’.

Several empirical studies [have found] a positive correlation between the [local] presence of... M N [C] s and the acquisition of human capital – that is, the training or upgrading of workers and the transfer of knowledge that makes possible the generation of new [entrepreneurial] firms via spin-off mechanisms.⁹⁴⁶ Such learning may occur by way of exposure to foreign affiliates, through testing and diagnostic feedback related to the use of quality-control techniques.⁹⁴⁷ Local companies may also acquire valuable technological knowledge from the competition effect’. [This] occurs when FDI pushes indigenous firms to use existing technology more efficiently and increases the speed of adoption/imitation of new technology. Further competition between domestic firms and MNEs in both the home and foreign markets can induce domestic firms to improve their export performance.⁹⁴⁸

In addition, MNC FDI flows may facilitate many other types of knowledge spillovers to local SMEs. They include transfers of product and process technology, financial, management and marketing skills, business practices, know-how, information, and enhanced social and environmental standards.⁹⁴⁹

Benefits Depend on Local SME-MNC Dynamic

Available evidence gathered from Latin American country cluster studies suggests that an MNC's ability to facilitate successful knowledge spillovers, and an SME's ability to benefit successfully from them, depends on certain conditions. Such success depends to a large extent on the degree [to which the MNC is] embedded[] in the local relational fabric.

Embeddedness and... local acquisition of knowledge cannot take place unless several requirements are met, namely, geographical proximity, appropriate soft and hard infrastructure, and entrepreneurial activities in the private and public sector. Hence, ... [F]oreign-owned subsidiaries only contribute to cluster dynamism if they are embedded in the local economy and are autonomous enough to interact freely with entities in the cluster.⁹⁵⁰

Usually, a good amount of time must pass before a multinational company becomes embedded within a developing country. For example, it must first familiarize itself with the local conditions and develop relationships of trust with local suppliers.⁹⁵¹ In addition, such success depends upon the existence of any technology gaps between local and foreign firms. Wide technological gaps... lessen the attractiveness of outsourcing, subcontracting, and other forms of interconnections.⁹⁵² Furthermore, the success or failure of securing such a transfer depends on the absorptive capacity of the local firms, which, in turn, depends on the level of their human capital. Gaps in human capital between MNCs and local

firms can make the knowledge transfer itself difficult or impossible.⁹⁵³

These findings are consistent with a prior (2000) World Bank study that found that *any* spillover benefits resulting from R&D/IPR-focused FDI would, in large part, depend on the absorptive capacity of firms in the particular developing country in question.

*Several studies (both theoretical and empirical) indicate that absorptive capacity in the host country is crucial for obtaining significant benefits from FDI. Without adequate human capital or investments in R&D, spillovers from FDI may simply be infeasible... Thus, liberalization of trade and FDI policies may need to be complemented by appropriate policy changes with respect to education, R&D, and human capital accumulation, if developing countries are to take full advantage of increased trade and FDI (emphasis added).*⁹⁵⁴

Moreover, regional cluster studies have shown that improvements made to a developing country's underlying socio-economic environment can better enable SMEs operating within a cluster to utilize FDI-generated technology transfers to increase their absorption capacities.

FDI has a potential role in fostering development of clusters and the innovations therein... FDI can... have both positive and negative effects on host countries, the overall net benefits being a variable that depends on the

socioeconomic environment of the recipient country. In Latin American countries, the capacity of clustered firms to interlink with external sources of knowledge is therefore critical. [T]he capacity to absorb extra-cluster knowledge and diffuse it at the local level is important for fostering development and improving local performance... In general, the capacity to absorb and implement external knowledge is higher for a cluster than for a firm, and once a few firms in a cluster assimilate external knowledge its diffusion within the cluster becomes easier... MNCs usually have the potential to generate the external stimuli necessary to enhance learning and innovation locally (emphasis added).⁹⁵⁵

Benefits May Ultimately Depend on Structural Policy Changes

In the event developing country SMEs suffer from huge technological deficits and absorption limitations, then transformational structural changes capable of facilitating MNC knowledge spillovers are in order. The creation of a business cluster-, regional cluster- or even a nation-based innovation system may thus be indispensable to promoting the types of innovative activities needed for such SMEs to compete domestically and globally.⁹⁵⁶ These innovation frameworks⁹⁵⁷ must involve MNCs as well as local public institutions, including universities, research centers, and technical institutes. And they must be organized consistent with foreign market requirements (as noted previously), be receptive of new technology imports, and be supported by the public.⁹⁵⁸

The whole bundle of innovative firms, clustered geographically and surrounded by a set of supportive organizations, leads us to the RIS [regional innovation system] concept. To restate, *an RIS is built on industrial clusters, supported by an adequate infrastructure* made up of (i) universities, colleges and technical institutions that provide appropriate levels of human capabilities; (ii) research institutes and agencies, whether public or private, which provide R&D systems and S&T infrastructure; (iii) meso-institutions (chambers of commerce, associations, consultancy systems), providing appropriate communication channels between firms, and between firms and the public sector; (iv) business incubators, *which stimulate entrepreneurial activities; and most importantly, the overall regional system exhibits a dynamic path in terms of both innovation and business startups. There is a complex two-way relationship of mutual embeddedness between these institutions and organizations within an RIS, which govern the innovation processes.* International success in advanced industries is interpreted as a direct function of the conduct and the articulation of the RIS (emphasis added).⁹⁵⁹

In summary, this recent (2004) IADB report emphasizes that in order for developing country firms to remain globally competitive in today's knowledge-based

information society, their governments must not only focus their efforts on attracting external R&D-related FDI as part of their regional or national development strategies, but they must also design innovation-centric education and training policies aimed at enhancing internal market fundamentals that enable local SMEs to absorb MNC FDI spillovers.⁹⁶⁰ As noted previously, the Government of Brazil has taken several steps down the path towards creating an innovation system and industrial development policy capable of unleashing the creative potential trapped within its many IP-rich industries. Whether it is ultimately successful in this endeavor, however, will depend on its ability to increase its FDI flows, strengthen its official bilateral science and technology partnerships, secure continuing official project development funding and import financing and insurance underwriting, and maintain important export trade preferences with significant trading partners, such as the U.S.

C. BRAZIL MAY DERIVE INNOVATION BENEFITS FROM BILATERAL SCIENCE & TECHNOLOGY AGREEMENTS

The Importance of Science and Technology R&D

Brazil

Brazil obviously considers science and technology R&D to be of the utmost importance. For example, during the years 1999-2002, the Government of Brazil created 14 sectoral funds⁴ financed from a portion of national tax revenues to promote high-quality science and technology (S/T) research and development (R & D) in Brazil's industrial sectors.⁹⁶¹ The funds have been co-managed by government, academia and industry in the areas of aeronautics, agriculture, biotechnology, energy, health, hydrology, informatics,

infrastructure, minerals, petroleum, space sciences, telecommunications, transportation, and university-industry research.⁹⁶²

In addition, reforms were made to several federal government bodies. For example, a new division was created within the national agency for technology development and innovation [(FINEP)⁹⁶³, which focuses on supporting private sector R&D activities. Its purpose is to improve national venture initiatives, and change has already resulted in the growth of a number of start-up and venture capital firms, and the creation of a private venture national association. Furthermore, a new National Secretary's [federal cabinet] position was created within Brazilian government's S/T ministry to improve planning, managing, and coordinating the National Research Institutes... [and to promote] the introduction of innovation' in the core of S&T public policies, with a great emphasis in public-private cooperation.⁹⁶⁴ Also, a new national public-private organization, the Management and Strategic Studies Center, was created to support more strategic actions and coordinate technological forecast for Brazilian's [National Institute of Science] NIS.⁹⁶⁵

Lastly, the Government of Brazil has established a regional agenda for S&T in Brazil that supports [approximately] ... 100 local innovation systems and local cooperative clusters.⁹⁶⁶ This perhaps dovetails with Brazil's participation in the global Millennium Science Initiative (MSI), funded equally by the Brazilian government and the World Bank. The MSI

seeks to strengthen science and technology capacity in developing countries by supporting locally planned and executed programs that provide new opportunities for

talented scientists to excel through research, training, networking, and outreach... Local leadership helps ensure continuity, political acceptance, and familiarity with local challenges.⁹⁶⁷

Two Brazil-based M S I's are currently in operation. One is comprised of 15 S&T institutes that include specialists in mathematics, the nanosciences, tissue bioengineering and climatology. The other is comprised of two S&T institutes that include geographic specialists in semi-arid and coastal regions.⁹⁶⁸

In the field of pharmaceuticals, the Brazilian Ministries of Health and Science are planning to finance a number of university-based research projects focusing on the production of drugs obtained from Brazilian flora and fauna. The program is expected to continue through 2008. In particular, the research will seek to: 1) implement a process to develop an anti-malarial drug from the sagebrush plant *Artemesia*; 2) start pre-clinical studies of prototypes originated from Spectaline for the treatment of Alzheimer and other cerebral vascular diseases; 3) develop herbal medicine extracted from the *Vernonia Condensata* Baker bush; 4) pursue the purification of and research into the nociceptic portion of the poison from the *Durissus Collilineatus* snake; 5) develop phytomedicines for the treatment of asthma and depression; 6) conduct pre-clinical studies on phytomedicines for pharmacology and toxicological effects; 7) study biodrugs associated with nanotechnology tools for treating cancer; and 8) study the use of *Bauhinia Ungulata* plant for the treatment of diabetes and cholesterol alterations.⁹⁶⁹

Brazil is among the most S&T proficient of the developing nations. For the year ended 2002, Brazil allocated

approximately .91 percent of its GDP towards research and development,⁹⁷⁰ while for the year ended 2004, it devoted 1.6 percent of its GDP to R&D – a sizeable increase in investment.⁹⁷¹ Of the total amount of resources spent on R&D during 2004, *60.2% was derived from government sources, 38.2% from industry sources, and 1.6% from academia* and other sources (e.g., nonprofits).⁹⁷²

Notwithstanding Brazil's increasing investment in R & D, one recent (2005) report warns about its apparent shortfall in local human capital (education and technical capacity), which may limit its industries' ability to provide the technological expertise demanded by global companies.

The R & D efforts in... countries of special interest— such as... Brazil... provide a context within which to gauge *the manner in which localized and specialized resources should play an important role in two major types of activities*. First, there is the question of being able to *provide technology-based solutions to problems* that are specific to the local environment and resources. Second, there is the issue of the *establishment and maintenance of a capacity to provide technical support* to industries that are growing from within and those that are immigrating from without... [While] ... efforts are being directed toward *expansion of the inherent capabilities in both facilities and personnel*... [and R & D]... growth rates suggest that science and technology policy goals can be set and met, assuming stability... [there remain challenges].

... One of the major challenges facing the R&D establishment in Brazil is said to be the fact that too little of the local industry looks toward R&D as one of the integral inputs to their overall processes. Government initiatives are underway to encourage greater participation by industry. These initiatives include emphasis on education, incorporation of new technology- in both products and processes- with the objective of job creation and enhanced world-standard exports (em phasis added).⁹⁷³

The report also emphasizes the limited role that government support for local industry R&D activities can serve where the underlying enabling environment (infrastructure) is unfavorable to business investment. Thus, in some cases, it will be necessary to liberalize markets, establish and protect private property rights and to attract FDI in order to ensure the efficient and productive use of government R&D funding.

*In many cases, the initial government support of industry-targeted research institutes had been made with the anticipation that a funding shift- from predominant government funds to those provided by industry- would occur as the relationship between industry and the technology resources grew. To a significant degree, the transformation did not occur naturally' until changes occurred overriding government policies, such as **liberalization and***

openness to foreign investment and ownership.

This is not to say that there is an insufficient amount of government funding to support the development of modern research and high-tech manufacturing capability in emerging areas. There is a continuing effort to capture shares of the worldwide market in high-tech materials, biotechnology, aerospace, and semiconductor devices, and a commitment toward establishing the technology base that is required to support these industries (em phasis added).⁹⁷⁴

The United States

The U.S., by contrast, devoted approximately 2.59 percent of its 2003 GDP to research and development,⁹⁷⁵ and 2.7 percent of its 2004 GDP to R&D.⁹⁷⁶ Of the total amount of resources spent on R&D during 2004, *31.3% was derived from government sources, 61.2% from industry sources, and 7.3% from academia and nonprofits.*⁹⁷⁷ With respect to the distribution of the overall national R&D effort (R & D performance) during 2004, 67% of all R & D was performed by industry, 9.1% by government, and 23.9% by academia and nonprofits.⁹⁷⁸ In other words, while universities and nonprofits approximately funded only 7 percent of the R&D performed in the U.S. during 2004, they actually undertook approximately 24% of the work involved in those activities. This data implies that approximately 17% of the R&D conducted by these institutions was funded from either industry or government sources or both. According to at least one report, such data suggests the continuation of a trend reflecting significant changes in the manner in which U.S. companies acquire

[both directly and indirectly] their technological assets...⁹⁷⁹ Indeed, perhaps it is the growing R&D cooperation between U.S. industry and the U.S. academic and nonprofit communities that enables the U.S. to remain the world's undisputed leader in science and technology.⁹⁸⁰

U.S. Pharmaceutical/ Biotechnology R&D S&T Outsourcing

A recent survey that analyzed the top 100 global corporate spenders in research and development found that 41 percent of them were based in the U.S.⁹⁸¹ It also found that during 2004, the global *pharmaceutical and healthcare* sector invested more on R&D than any other of the fifteen sectors considered – a reported \$59,332,000,000 (\$59.3 billion).⁹⁸² In addition, it found that, during 2004, the pharmaceutical and healthcare sector achieved the second highest level of R&D intensity (i.e., R&D \$ spent as a percentage of \$ gross sales) of all the industries surveyed – 12.5%. The computer software industry scored highest achieving an R&D intensity of 18.2%.⁹⁸³

Another interesting pattern underlying corporate global R&D spending is that an ever-larger share of it is being outsourced' by mostly U.S.-based MNCs to companies operating outside the U.S. - within developed *as well as* developing countries. According to one recent report,

... another major development... [is]... *the extent to which U.S. companies (and others) are outsourcing R&D activities to independent, non-captive performing entities...* one of the more striking trends as of late has been the marked increase in funding from abroad that has been

supporting the performance of R&D in private industries. Italy, The Netherlands, Turkey, and Denmark have all experienced considerable increases in funding from foreign sources...The amount of R&D arising from insourcing was, within the period 1998-2002, as high as 7.6% of total funding in Switzerland and Ireland... What is more important, especially in the context of well-publicized actions taken by U.S. and other companies, is the amount of R&D that is insourced in major burgeoning R&D enterprises in, for example, China and India... Over the past few years, *there has been a remarkable growth in the amount of research and development funding that has funneled into China and India, with such funding originating primarily in the U.S.* Furthermore... it is noteworthy that the outsourcing activities go beyond software back-office operations, software development, and strictly research; it has begun to become much more involved in product development, thereby expanding the entire scope of services in support of manufacturing and operational activities (emphasis added).⁹⁸⁴

The Important Role Served By Bilateral Science and Technology Agreements

The U.S. government recognizes the importance of bilateral S&T agreements and their ability to contribute to market-building and intellectual capital accumulation in other countries. Therefore, S&T agreements, many of which

focus on the *life sciences*, usually require from national government counterparts, as a condition to procuring U.S. federal funding support, a commitment to secure and protect valuable U.S. intellectual property rights. As a result, foreign governments are often obliged to revise their national standards for protection of not only IPRs, but also investments generally. In effect, a bilateral S&T agreement may serve to promote non-S&T policy objectives, such as market liberalization, openness to foreign investment, transparency and private property ownership.

The centrality of intellectual property rights protection to U.S. bilateral science and technology policy and the agreements that implement it should not be underestimated. According to the National Institute for Standards and Technology (NIST) of the U.S. Department of Commerce (USDOC), it is not by coincidence that the U.S. government has often chosen to utilize a high-level legal instrument known as a Memorandum of Understanding (MOU) to facilitate such cooperation.

Memorandums of Understanding should only be used for binding agency-to-agency international agreements that commit both parties to specific actions, such as the protection of intellectual property. This type of agreement is typically broad in scope and would cover any cooperative activity between NIST and the foreign entities. [It] must be signed by the Deputy Director of NIST or higher (em phasis added).⁹⁸⁵

It is therefore likely that other U.S. federal agencies, including the U.S. Departments of Agriculture (USDA) and Energy (USDOE), the U.S. Food and Drug Administration

(FDA), and the U.S. Nuclear Regulatory Commission (NRC), have relied upon this same rationale when deciding to enter into MOUs with their Brazilian government counterparts.

Brazil – U.S. Science and Technology Cooperation

The United States was the first country to recognize Brazil's independence in 1822. The two countries have traditionally enjoyed friendly, active relations encompassing a broad political and economic agenda,⁹⁸⁶ including joint science and technology cooperation.

As the result of the growing consensus between Brazil and the U.S. concerning the benefits of sharing science and technology know-how and protecting the intellectual property rights that underlie it⁹⁸⁷, a number of joint projects and initiatives between the two countries have evolved. And, they have included the participation of both governmental and private (industry, university and nonprofit) institutions.

The basis for such cooperation resides in the periodic renewal of the long-term Brazil-US bilateral science and technology agreement.⁹⁸⁸ Under the auspices of this S/T umbrella agreement, other institutional agreements have been reached pursuant to which a number of joint Brazil-US R&D technical capacity and knowledge-building activities have proceeded. A variety of joint research projects and academic exchanges are being pursued, for example, in the areas of energy, earth and space science, biotechnology, engineering, and agriculture.⁹⁸⁹ They include:

- 1) The execution of a cooperation agreement between NASA and the Brazilian Space Agency;
- 2) The execution

and extension of an MOU and other cooperation agreements providing for the exchange of technical information relating to energy regulatory affairs between the Brazilian National Commission of Nuclear Energy (CNEN) and the U.S. (NRC), and resulting in other joint energy research projects focuses on renewable energy sources.⁹⁹⁰ In fact, Brazil and the U.S. are working together on two major international initiatives to develop energy technologies that will address common energy challenges, the Carbon Sequestration Leadership Forum⁹⁹¹ and the International Partnership for the Hydrogen Economy⁹⁹²⁹⁹³; 3) The progression of regulatory cooperation between Brazil and the U.S. on health care issues, including exchanges of information on how to create a drug regulatory agency modeled after the U.S. FDA; 4) The execution of research and development (R&D) cooperation agreements between national health institutes to pursue joint health care and medical research, including one that focuses exclusively on foot-and-mouth disease; 5) The continuation of cooperative dialogues between research institutes concerning the development of drugs against developing country diseases such as dengue fever and Chagas disease; 6) The execution of U.S. government-approved technology-sensitive contracts between U.S. industry and the Brazilian government to provide Brazil with the satellite surveillance capabilities to pursue climate and pollution research over the Amazon and other locations within Brazil⁹⁹⁴; 7) The commencement of joint university-level cooperation projects in the areas of space services, engineering, biotechnology, public health and agriculture;⁹⁹⁵ 8) The execution of joint cooperation initiatives, including an MOU between the USDOC – NIST) and the Brazilian Ministry of Science and Technology, to promote bilateral cooperation and learning opportunities between and among national science and technology institutions, and industries in both countries that

operate in the science, technology and innovation (ST&I), manufacturing, engineering and life sciences sectors. The MOU endeavors to ensure the development and improvement of consistent national systems of scientific, industrial, and legal metrology (measurement standards) in the chemicals, physics and engineering sciences;^{996 997 9)} The formation of a partnership between the Brazilian Agricultural Research Endeavor's Virtual Library in the United States (EMBRAPA-LABEX), staffed by Brazilian senior researchers in the United States, in partnership and the USDA/ARS (United States Department of Agriculture/Agricultural Research Service), which seeks to strengthen and broaden the scientific and technological cooperation between EMBRAPA researchers and Brazilian universities and their American partners in the area of agricultural biotechnology^{998 999}.

D. BRAZIL MAY DERIVE BENEFITS FROM CONTINUED OFFICIAL PROJECT DEVELOPMENT FUNDING

Inter-American Development Bank Brazil Programs

During his November 2005 trip to Latin America to attend the Summit of the Americas in Argentina, President Bush emphasized to a Brazilian audience how important the Inter-American Development Bank (IADB) was to encouraging private investment, supporting small businesses and promoting economic growth in the region.

The private sector is *the* engine of growth and job creation in this region, he said.¹⁰⁰⁰ Indeed, the president and his former adviser, U.S. Treasury Secretary John Snow, a member of the IADB's Board of Governors¹⁰⁰¹, could not have been more correct.

Apparently, the IADB has long been involved in numerous projects to develop the region's economies, including that of Brazil.¹⁰⁰² During the early 1990's, for example, the IADB played an active role in strengthening the protection of property rights and patents in many Latin American countries... through the use of investment sector reform loans to support broad legal and regulatory reforms.¹⁰⁰³ These loans, some of which were earmarked for Brazil, focused on promoting science and technology (R&D) infrastructure capabilities and improving *market sector* participation in such programs. While the Bank's early support for national S&T policies focused on mostly government institution-building, they have since placed a greater emphasis on supporting the [Latin American] *business sector's efforts* at technological modernization...¹⁰⁰⁴ The primary objective has been to rais[e] competitiveness by enhancing enterprise level innovation.

Access to, and competition in, external markets; productivity growth; efficiency; technological modernization and similar topics have become the overriding concerns among both entrepreneurs and policymakers in the region. This policy thrust has been felt in the area of *innovation policies*... It is increasingly understood that the central issue for innovation policy... is *how to help the productive-enterprise sector* to enhance its competitiveness while responding to the long-run challenges posed by the knowledge-based economy in terms of basic scientific research... [i.e., how]... to stimulate private sector efforts at technological innovation (emphasis added).¹⁰⁰⁵

As a result, *national innovation systems* have arisen within Latin American countries, including Brazil, that are premised on the need to increase governments' role in gathering and disseminating information, introducing new technologies, and financing research and development opportunities in order to inspire the private sector.¹⁰⁰⁶ These systems rely on

economic policy framework[s] capable of *creating a favorable business climate for private sector investment in innovative activities...* [which]... are also necessary to simulate investment in R & D ... Macroeconomic stability and the rule of law, including the existence of a reasonably efficient judicial system and ***respect for property rights***, are integral parts of the requisite environment (emphasis added).^{1007 1008}

The IADB has since released a new (2004) multiyear strategy document focusing exclusively on Brazil. Among the many projects recommended there are two that stand out: one focusing on the development of innovative technologies in the agrifood sector that can be applied to production (e.g., intellectual property-rich biotechnology-based processes for which an 80% increase in the rate of patent filings/registrations is sought by 2007), and one directed at establishing individual rights, including property rights, via establishment of a national rural property registry and the actual titling of at least 400,000 rural properties by 2007.¹⁰⁰⁹

Agriculture will be strengthened in four key areas to improve sector competitiveness: (i) a national

system for agrifood technology that will consolidate a more competitive innovation system ... (iii) implementation of a geo-referenced national rural property system and registry that will help *regularize titling and issue new property titles with legal guarantees...* (emphasis added).¹⁰¹⁰

These two IADB proposals are designated as follows: BR-L1001 – National agrifood research system ; and BR -0392 – Land register and property regulation .¹⁰¹¹ As of this writing, only the first of these loan proposals seems to have been approved for funding. Exactly what this implies about Brazil's commitment to the protection of *private real property rights* is, to say the least, unclear.¹⁰¹²

It can be said, nevertheless, that the \$60 million agrifood project, \$33 million of which the Bank plans to fund, is concerned with the creation of *intellectual property rights*, given how central agriculture is to the Brazilian way of life.¹⁰¹³

Brazil's agrifood sector is of major economic and social importance [to Brazil] as a provider of food, source of employment and foreign exchange earner... The agrifood sector has outpaced the rest of the [Brazilian] economy and is the only sector to display sustained growth... In 2000, the agrifood sector accounted for nearly 27% of GDP... provides employment to 27% of the labor force... [18 million workers]... contributes over 40% of the country's exports, concentrated in a small range of

products...Traditional export product lines are now being joined by high value products such as tropical fruits. *This diversification requires strengthening of the research and development (R&D) system...* In a globalized economy... Brazilian family farmers... face increasing demands for quality and adaptable production systems capable of satisfying demands for differentiated products in specific market niches; this requires support services and integration into agrifood chains (emphasis added).¹⁰¹⁴

A review of the loan document reveals how Brazil is endeavoring to establish a national agricultural R&D platform that can lead to the creation of new intellectual property (i.e., patents in biotechnology, biocides, etc.), the commercialization of which will lead to rural family farms employing more efficient food production and processing techniques and to the distribution of more competitively priced agricultural exports.¹⁰¹⁵

The strategy for the sector mirrors the national strategy in supporting better agribusiness competitiveness internationally, through specific interventions such as support for the research system, and modernization of the infrastructure that serves agribusiness... with a view to incorporating the family farmer and small-scale rural entrepreneur into existing production and commercial chains...¹⁰¹⁶

... The project's specific objectives are[to] strengthen[] R&D capacity for export diversification with high-quality and high-value products and greater private-sector participation; to moderniz[e] and update[e] resources to serve strategic research areas; [to expand] market access and integration of family production in agrifood and/or agribusiness chains; and [to create] a modernized management model with greater access to international knowledge.¹⁰¹⁷

To achieve these objectives, the program calls for EMBRAPA officials to be trained in, among other disciplines, intellectual property and the marketing of technology products.

[The goal is to]... [s]trengthen [the] mechanisms for managing protectable knowledge, by upgrading, updating and providing skill training *for EMBRAPA staff* in the technical, legal, and economic aspects of *intellectual property* (emphasis added).¹⁰¹⁸

In addition, it calls for the strengthening of international and bilateral relationships between Brazil's national R & D institutions and those of other countries. This presumably entails creating even closer ties with the U.S. S&T establishment in order to acquire key scientific and technical knowledge, which the LABEX program seems designed to do.¹⁰¹⁹

The project is certainly ambitious and entrusts Brazil's excellent government and university institutions with the responsibility of building what is eventually to become a

successful national agricultural R&D innovation system. However, with the program's primary focus on *government* IP capacity-building and the positioning of rural farmers along the agrifood supply and distribution chain, one is left to wonder whether there will be any place for truly *private ownership* of the intellectual property (patents) underlying the commercialized inventions thus created. Is this program really anything more than a disguised national agrarian policy?

A similar question may be raised concerning the Brazilian government's attitude towards the private property rights (i.e., patents) held by foreign pharmaceutical companies in HIV/AIDS treatment drugs. It is well known how Brazil's pharmaceutical manufacturing sector ultimately learned how to reverse-engineer and patent such drugs for itself. Yet, while international financial institutions had been indirectly involved, during the 1990's, in assisting Brazil to acquire such drugs, they had largely failed to monitor whether good manufacturing practices had been adopted, imported pharmaceutical raw materials had been used,¹⁰²⁰ and whether foreign patents had been protected.¹⁰²¹ In 1996 and 1999, the IADB funded two health-related projects said to include the acquisition of pharmaceuticals as a small component of Brazil's national program to improve medicine procurement and distribution. The loan documents had designated pharma as comprising approximately 2.6% of a \$9 million 1996 loan facility (BR-0199) and approximately 5.9% of a \$31 million 1999 loan facility (BR-0308) for such purposes. However, there is no assurance that the funds were actually used in this manner.¹⁰²² Therefore, in light of these systemic oversight failures, one is compelled to ask, to what extent were the project-related funds diverted by the Brazilian government from treatment, distribution, and drug acquisition to drug *manufacturing*?

It may be recalled that the market dynamic during this time period (1998) was such that Brazil's pharmaceutical sector had become the world's sixth largest national market in terms of value (\$10.3 billion of a total of \$302 billion), and the leading national market within Latin America, the world's then-fastest growing regional pharmaceutical marketplace.¹⁰²³ Although Brazilian pharmaceutical companies had secured only 30% of their domestic market (1997),¹⁰²⁴ they nevertheless possessed pharmaceutical reproductive capabilities i.e., they had produced both therapeutic ingredients and finished products,¹⁰²⁵ and could easily have drawn from the 60-70% of pharmaceutical raw materials they had then been largely importing.¹⁰²⁶ In other words, it is arguable that they not only possessed the intent (*mens rea*), but also the means and capability (*modus operandi*) to divert to such use institutional funds earmarked for other purposes. In the meantime, the Brazilian government, with the knowledge and acquiescence of such institutions, had been busily crafting and honing a public policy, both domestically and internationally, premised primarily on social, health, and *human rights* concerns.¹⁰²⁷ This policy, in large part, continues to this day, to the exclusion and at the expense of ALL private property and business interests, domestic as well as foreign. And it has been financed, in large part, by these very same international financial institutions.

One is also inspired to ask the same question about the intent behind Brazil's other non-health-related projects funded by the IADB and/or its Multilateral Investment Fund (MIF) arm.¹⁰²⁸ For example, during 2004 and 2005, the MIF approved funding for two Brazilian IT sector projects aimed at promoting the development of a computer software infrastructure for the benefit of SMEs. Those projects were largely, if not, completely based on the use

and dissemination of an open source, Linux-based configuration.¹⁰²⁹ Apparently, the policy objective underlying these small loan facilities is not inconsistent with Brazil's evolving national policy of requiring government agencies to procure *only* open source software programs for their internal use.¹⁰³⁰ It is also not inconsistent with the policy Brazil has advanced internationally at such forums as the World Intellectual Property Organization (WIPO) and the World Summit on Information Society (WSIS). During this past fall's (2005) WSIS, for example, the Government of Brazil publicly called for open source software to become the new international standard.¹⁰³¹ What does this say about the current Brazilian government's attitude towards the protection of *private* intellectual property rights? And, are the IADB and MIF in agreement with and supportive of this position as they had been previously concerning the Brazilian government's position on HIV/AIDS?

Obviously, Brazil has thus far been permitted to pursue what may be characterized as an open source 'science and technology paradigm because it has enjoyed long and positive relationships with the banks and their governmental donors. A review of Brazil's IADB loan portfolio, for example, reveals that In 2004, the Bank approved 12 loans, one guarantee and two MIF financings to Brazil for a total of \$2.6 billion... [And,]... [i]n 2004, total disbursements amounted to \$553 million.¹⁰³² For 2005-2006, Brazil's IADB loan portfolio reflects approximately \$750 million in productivity and infrastructure loans (\$211 million of which are designated as new), equity and human capital formation loans of approximately \$85 million, city loans approximating \$592 million, and modernization of the state loans amounting to \$144 million, for a totality of nearly \$1.6 billion.¹⁰³³

However, the continuation of such relationships and the availability of such funding should not be taken for granted, for neither is guaranteed. It should not be doubted that the U.S. government has the power to veto the disbursement of loans earmarked for Brazil by financial institutions, such as the World Bank, IMF, and the IADB, if Brazilian government policies are deemed to threaten U.S. interests.¹⁰³⁴ *¹⁰³⁵ Indeed, the rationale currently underlying continuation of World Bank or IADB funding to Brazil may yet be challenged if Brazil continues to exploit the generosity and goodwill of the institutions' board members and/or donor committees by violating privately held U.S. intellectual property interests. Given the Brazilian government's recent conscientious effort to repay its sovereign debts, it is highly likely that President Lula has already considered this possibility.

E. BRAZIL MAY DERIVE BENEFITS FROM INCREASED HI-TECH IMPORT FINANCING AND INSURANCE UNDERWRITING

U.S. Export-Import (Exim) Bank Programs

The U.S. Eximbank, which is the official export credit agency of the United States, has also assisted Brazilian companies. Its purpose has been to support U.S. exporters and to increase economic stability in emerging markets by reducing the likelihood of crises caused as the result of sharp declines in investment flows. Latin America is a priority market for U.S. exporters and has consistently also ranked as Exim bank's top market with a total of more than \$170 billion in annual sales.¹⁰³⁶ (p. 135).

... Export credit agencies (ECAs) such as Ex-Im Bank consistently play a critical role in filling the

financing gaps to emerging markets. Ex-Im Bank provided more than one-quarter of the total medium- and long-term export credits (repayment terms of more than one year) provided by the ECAs of the Organization for Economic Cooperation and Development (OECD). All told, ECAs provided about \$34 billion in medium- and long-term export credits ... *We can jump-start the economic engines of development in a number of ways— through trade, through credit, through targeted micro-loans to emerging market entrepreneurs, and through financing for power plants and infrastructure, transportation and medicines* (emphasis added).¹⁰³⁷

The Eximbank has enjoyed a productive relationship with the country of Brazil since at least the 1940s, during which time it helped to finance the construction of Brazil's first steel manufacturing plant at Volta Redonda in the state of Rio de Janeiro.¹⁰³⁸ Brazil is the Bank's second largest market in Latin America after Mexico. Between 1997 and 2004, Eximbank directly authorized for funding approximately \$3.1 billion in loans (\$1.2 billion), guarantees (\$1.1 billion) and export credit insurance (\$800 million) supporting Brazilian company purchases of U.S. goods and services.¹⁰³⁹ In 2003, Brazil imported nearly \$11.2 billion in U.S. goods and services.

The Bank has supported a few large infrastructure and commercial projects during this period that have provided social as well as economic benefits to Brazilians. On the public sector side, it has co-financed 1) a 469-megawatt combined cycle power plant in Araucaria, Brazil¹⁰⁴⁰; 2) Rio

Polimeros, a \$1.1 billion integrated ethylene and polyethylene complex in Rio de Janeiro¹⁰⁴¹; and 3) a water filtration and waste-water-treatment facility.¹⁰⁴² In addition, since at least 2000, the Eximbank has operated the Sub-sovereign Program ‘ to provide Brazilian municipalities with the financing needed to procure essential infrastructure-related goods and services.

... Because local governments and municipalities are often major buyers of everything from transportation to health-care infrastructure, as well as other goods and services, Ex-Im Bank now accepts the credit of qualified cities, states and other sub-sovereign governments in emerging markets for the purchase of U.S. exports. This alternative credit approach allows foreign borrowers with municipal, state and provincial support to gain access to Ex-Im Bank financing to buy products and services to upgrade local infrastructure. In Latin America, this initiative is available in Brazil in the states of Bahia and Ceará, and the city of Rio de Janeiro.¹⁰⁴³

In addition, Eximbank financing and/or loan guarantees have also helped to secure important goods and services purchases by Brazilian companies. They include: the acquisition of a fleet of commercial helicopters and spare parts by Lider Tax Aereo, a Brazilian offshore provider of helicopter services;¹⁰⁴⁴ the recent acquisition of oil and gas equipment by a subsidiary of Petroleo Brasileiro (Petrobras) to be used on one of the world’s largest offshore oil production platforms;¹⁰⁴⁵ previous acquisitions of power plant turbines and other oil and gas equipment by

Petrobras¹⁰⁴⁶; a hospital technology, equipment and services procured by Comunidade Evangélica Luterana São Paulo (CELSP), a private, non-profit organization in Canoas, Rio Grande do Sul, Brazil, for use in a new teaching hospital;¹⁰⁴⁷ construction equipment (cranes) acquired by Brazilian construction company Brasileira de Construções SA¹⁰⁴⁸; and manufacturing equipment (a dye extractor) purchased by Itabuna Textil, SA, a Brazilian textile manufacturer.¹⁰⁴⁹

As can be seen, the U.S. Eximbank has helped to support the purchases of heavy-duty industrial as well as specialized computer and medical technology equipment not otherwise available or susceptible to manufacture in Brazil. While such acquisitions may have included some medical products, it is highly unlikely, given the Brazilian government's poor record of protecting intellectual property rights, they included pharmaceuticals, biocides or biotechnology items on which U.S. patents are held.

Interestingly, during the 2001-2002 U.S. Congressional review of the Exim bank's reauthorization, some representatives endeavored to score political points with domestic and international health activists who called for U.S. pharmaceutical companies to internationally subsidize universal access to HIV/AIDS medicines. The representatives publicly tried to shame these owners of valuable intellectual property by proposing legislation that would deny Eximbank financing to any company that refused to give away their drug patents to developing countries essentially for free (i.e., without adequate compensation).¹⁰⁵⁰ This attempt was rebuffed by another representative who sought to impose different conditionalities on Bank lending practices. These would have denied developing country purchasers Eximbank financing if they were in any way involved in intellectual

property rights litigation with a company doing business within any of five industry sectors.¹⁰⁵¹ Fortunately, cool heads prevailed and neither proposal made its way into the final legislation. Nevertheless, an uncomfortable political precedent was established, and the same debate could easily resurface during the upcoming Eximbank reauthorization hearings that will be convened by the U.S. Congress later this year (2006).

Brazilian companies that have thus far benefited from Eximbank purchase-financing, therefore, should carefully monitor the mood of the U.S. Congress as well as any proposed legislation bearing an intellectual property component. They must remember that it is ultimately the U.S. Congress which bears the legal and political responsibility for deciding whether to reauthorize through appropriations the Bank's international lending activities. Based on representatives' prior concerns, it is not likely to take its responsibility lightly, especially when foreign interests are exploiting the Bank's benefits at the expense of American taxpayers.¹⁰⁵²

Overseas Private Investment Corporation Programs

The OPIC, a U.S. government development agency, has helped Brazilian companies to procure the financing and associated insurance coverage needed to acquire capital assets and investments from U.S. sources without risk of impairment or loss. OPIC effectively compliments the private sector in managing the political risks¹⁰⁵³ associated with foreign direct investment. OPIC's core mission is to support economic development by promoting U.S. private investment in developing countries and transition economies.¹⁰⁵⁴

As recent as January 2006, OPIC approved a \$5.4 million loan to a small Houston-based company that will use gas compression technology to secure and transport natural gas from Brazilian state-owned pipelines to Brazilian consumers and industries. The loan was issued under the U.S. Clean Energy Technology Exporters Initiative, a federal multi-agency program aimed at encouraging the export of U.S. clean energy technologies to developing and emerging economies.¹⁰⁵⁵ It likely followed from an earlier scheduled Renewable Energy Trade Mission to Brazil organized during October 2005 by the U.S. Department of Commerce and attended by OPIC representatives.¹⁰⁵⁶

From 2000-2004, OPIC helped finance the purchase by Brazilian companies of approximately \$626 million of capital goods and related technical services provided by U.S. companies. During the same period, OPIC sold approximately \$899 million of political risk insurance coverage to compensate for possible asset losses before completion of the underlying goods and services contracts.¹⁰⁵⁷ These contracts entailed the provision, installation and/or expansion of telecommunications, cellular and internet services and networks, the construction of gas and hydroelectric power plants and hotels, the leasing of power plant turbines and railroad equipment, and the development of oil and gas fields.¹⁰⁵⁸

Even before the change of millennia, Brazil had been a major beneficiary of OPIC assistance. During 1999, for example, OPIC issued \$200 million worth of loan guarantees in support of a \$570 million project to construct a natural gas pipeline spanning 390 miles from Bolivia to western Brazil. The guarantee was issued to a consortium of companies that included Enron Corporation, Shell International Gas, the employees of the Bolivian state-owned oil company and a Bolivian pension fund.¹⁰⁵⁹ As far

back as 1996, it had been determined that, of the nations receiving U.S. private investment backed by OPIC, *Brazil* had been *the* largest recipient benefiting from over \$1 billion of new U.S. investment (emphasis added).¹⁰⁶⁰ And prior to that, in 1995, OPIC had approved a total of \$250 of financing and political risk insurance for two projects in Brazil -- a banking project and a beverage container manufacturing project.¹⁰⁶¹

F. BRAZIL MAY DERIVE BENEFITS FROM CONTINUED EXPORT TRADE PREFERENCES

Brazil's Growing GSP-Eligible Exports to the U.S.

Since at least 1997, Brazil has enjoyed a growing trade relationship with the United States, which still remains Brazil's single largest trading partner. During 2004, Brazil exported approximately \$20.3 billion worth of goods to the U.S.¹⁰⁶² During 2003, Brazil's exports to the U.S. were valued at US\$ 21.3 billion, 14 percent of which (approx. \$3 billion) enjoyed duty-free status pursuant to the U.S. Generalized System of Preferences (GSP).¹⁰⁶³

During 2004, in particular, Brazil's GSP-eligible exports to the U.S. amounted to approximately \$3.2 billion overall. Such trade spanned numerous industry sectors and included mostly automobile parts (\$545 million), finished and unfinished wood products (\$465 million), forged iron and steel products (\$121.8 million) and copper wire and cathodes (\$112.2 million). These categories of imported items totaled approximately \$1.125 billion and comprised 39% of all GSP-eligible Brazilian exports (approx. \$3.2 billion) to the U.S. in that year.

At the recent Doha Round trade negotiations that took place in Hong Kong during late November and early

December 2005, the U.S. and the EU became of one mind concerning the serious threat posed to their joint prosperity by widespread IP opportunism in developing countries. However, recognizing that not all developing countries possess the means and capabilities to address that growing threat through regulation and law enforcement, especially those least developed, US Commerce Secretary Carlos Gutierrez and EU Trade Commissioner Peter Mandelson arrived at a temporary solution.

[T]he EU and US had agreed on a joint initiative to fight intellectual property violations... follow [ing] a World Trade Organisation (WTO) announcement... that it had given developing states an extra seven-and-a-half years to supply trademark and copyright protections, extending a January 1 deadline many could not meet. The extension agreed on in Geneva on Tuesday gives the WTO's 32 poorest members, including Uganda, Cambodia and Tanzania, until July 1 2013 to establish intellectual property protections.¹⁰⁶⁴

However, this extension does NOT apply to other more advanced emerging economies, such as Brazil, China or India; nor does it apply to *any* country with respect to *patents or trade secrets*.

Brazil's GSP Status Could Be Lost if IP Opportunism Continues

The U.S. GSP program, initiated during the 1970s, extends duty-free treatment to certain products that are imported from designated developing countries. The U.S. GSP

program presently covers over 4,600 product categories imported from over 140 Beneficiary Developing Countries (B D C s). In addition, it also covers 1,783 product categories from least-developed countries. In 2003 total imports under the GSP program amounted to \$21.9 billion. The program s' prim ary objective is to prom ote econom ic growth and development in qualifying developing and least developed countries by stimulating their exports. The program was last reauthorized until December 31, 2006.¹⁰⁶⁵ Although the U.S. GSP program has been renewed by Congress many times since its enactment, its renewal should *not* be taken for granted.¹⁰⁶⁶ In fact, the USTR recently requested public com m ents to determ ine w hether the program [,among other things,] should be changed so that benefits are not focused on trade from a few countries... In 2004, Brazil was among the top ten recipients of U.S. GSP benefits.¹⁰⁶⁷

According to James E. Mendenhall, (then) Acting General Counsel to the U.S. Trade Representative, GSP status is offered to developing countries as an incentive to promote conduct consistent with U.S. trade policy,¹⁰⁶⁸ including recognition and protection of strong intellectual property rights.

The U.S. provides reduced tariff rates to developing *countries provided they show a commitment to protect IP rights* and promote other priorities of U.S. trade policy. An American company that is struggling to protect its IP in a developing country should check whether that country receives these kinds of benefits. USTR also administers the Generalized System of Preferences (GSP) program and other tariff preference programs.

*The carrot of preserving GSP benefits is an effective incentive for countries to protect IPR. In fact, the filing of a GSP review petition or the initiation of a GSP review has in some cases produced positive results. For example, in response to an extended GSP review of Brazil this past year, the Government of Brazil adopted a new National Action Plan to enforce copyrights and reduce piracy. According to our industry, the Brazilian Government appears to be moving in the right direction and is now committing significant fiscal and personnel resources to anti-piracy efforts (emphasis added).*¹⁰⁶⁹

His testimony preceded by a day letters of outrage received by the USTR from several U.S. congressional representatives. On May 24, 2005, letters were sent to U.S. Trade Representative Robert Portman by Representatives Ginny Brown-Waite, Mario Diaz-Balart, and Ileana Ros-Lehtinen, who were concerned about Brazil's apparent disregard for U.S. companies' intellectual property rights. The letters petitioned the USTR to conduct a formal, full-scale review of its trade policy with Brazil.

As you well know, Brazil has remained on the special 301 Watch List since 2001 due to its lack of enforcement of intellectual property rights. USTR has, in our view, gone too far in extending the review of Brazil's Generalized System of Preferences. The result is that it enjoys tremendous access into our market. Meanwhile, our leading exporters continue to report

rampant instance of counterfeiting and piracy in Brazil. Endowing Brazil with rich trade benefits defies logic.

... We do not have to emphasize to you, Ambassador Portman, how reliant the American economy is upon the protection of innovation and technology. By turning the other cheek repeatedly with large countries like Brazil, we risk jeopardizing the long-term vitality of the economy. We cannot afford to forfeit our inventions to our competitors.

... The Senate has already intervened recently in the debate about the revaluation of China's currency, voting to place large tariffs on their imports. *We should make it known that the U.S. would consider similar sanctions against Brazil if it steals these drug patents without impunity from our government or if the administration does not quickly act to halt Brazil's move on this front* (emphasis added).¹⁰⁷⁰

A similar letter had been sent that day to Mr. Portman by Congressman Joe Wilson, who essentially characterized Brazil's threat to declare a compulsory license as IP opportunism.

By declaring a national emergency, Brazil is trying to purchase the drugs at deeply discounted prices or trying to produce generic versions of them. This would be an unprecedented

action, since the claim of a national emergency ' in this case is questionable. *Using this provision would normally envision a developing country battling an outbreak of infectious disease...* While the TRIPS [A]greement provides for circumstances where compulsory licenses can be issued under certain narrow exceptions, the legitimate interests of the patent holder must also be protected. The circumstances do not appear appropriate to invoke the TRIPS [A]greement. *I believe bilateral relations will be compromised if Brazil proceeds with these actions* (emphasis added).¹⁰⁷¹

During the prior week (on May 17, 2005), it was reported that Deputy United States Trade Representative Peter Allgeier had emphasized similar points as he testified before the U.S. House Ways & Means Committee's Subcommittee on Trade.

Allgeier, the chief negotiator responsible for U.S. trade negotiations with Europe and the Middle East, Latin America, the Caribbean, Mexico, and Canada, and the negotiation of the Free Trade Area of the Americas (FTAA) *has sent a strong warning to Brazil's government in his comments that theft of American patents will not be tolerated.* Negotiations with Brazil are best done in a cooperative mode with the pharmaceutical companies, and not doing it in a way that is very confrontational and that is

threatening to break patents as a negotiating ploy to reduce prices,' said Allgeier in response to questioning on Brazil by Illinois's Republican Congressman Jerry Weller. Priority should be given to the *long term interests of Brazil in meeting its public health needs... not upon some longer term commercial calculation on the part of industrial authorities in Brazil as to where they would like to be ten years from now in terms of production,*' Allgeier continued (emphasis added).¹⁰⁷²

It should be recalled that these comments did not merely represent U.S. government and industry frustration with the most recent of Brazil's many threats to invoke compulsory licenses on American pharmaceutical company HIV/AIDS drug patents. Rather, the Government of Brazil's latest threat was, in fact, different - it assumed the form of a proposed law declaring all such patents *invalid* as a matter of public interest'. In this regard, the U.S. response likely revealed a long-held and justified suspicion concerning what has since been proven to be, at best, the Brazilian government's playful obsession with IP opportunism 'and, at worst, its growing populist rejection of private property rights and market-based economics.

After all, during January 2001, the United States Trade Representative (USTR) had placed Brazil on the Special 301 Watch List in response to a petition filed by the International Intellectual Property Alliance (IIPA). The petition had cited the Brazilian government's chronic failure to enforce its own *copyright* laws.¹⁰⁷³ The petition was then followed by increased calls from intellectual property rights advocacy groups for the USTR to deny

renewal of Brazil's overall GSP status or its eligibility to receive preferential tariff rates on certain high volume exports. According to unverified Brazilian media sources, these pleas ultimately prompted the USTR, on April 4, 2005, to warn the Brazilian government that, unless it reversed its intellectual property abuses within six months, it would lose its favored trade status with the United States.¹⁰⁷⁴

On January 13, 2006, the USTR decided to close its review of Brazil's copyright enforcement practices under the U.S. GSP trade program (case 013-CP-05).¹⁰⁷⁵ The U.S. computer software industry's apparent failure to protest the USTR's decision is somewhat surprising given the substantial amount of piracy losses the industry alleged it had suffered in Brazil. During 2003 and 2004 alone, the industry claimed that it had lost an estimated \$519 million and \$659 million, respectively, to software *copyright* piracy. These figures clearly reflect a trend not only of *increasing software piracy losses*, but also of *increasing rates of software piracy* (from 61% to 64%) in Brazil during those years.¹⁰⁷⁶ Perhaps industry's silence may be explained by its members' decision to seek alternative remedies, or by the greater reliance they intend to place upon the patents that underlie the functions and operations of company software products, as compared to the copyrights covering their look and feel, i.e., expressions.¹⁰⁷⁷ Or, the software industry may be planning to eventually file, either alone or in conjunction with the pharmaceutical industry, a new petition calling on withdrawal of Brazil's GSP status for failure to address rampant *patent or trade secret* opportunism.¹⁰⁷⁸ The industry may be even be temporarily distracted by the new focus placed on Russian and Chinese copyright piracy¹⁰⁷⁹, and Russia's WTO accession demands.¹⁰⁸⁰

The USTR's closure of this GSP case may also have been motivated by larger economic and/or political concerns. The U.S. government may have decided that it needs to persuade Brazil to resume negotiations with the U.S. on the hemisphere-wide Free Trade Area of the Americas (FTAA), or to agree to mutual concessions at the Doha Round.^{1081 1082 1083} Or, it is also possible that the USTR has, for the time being, refocused its sights mainly on Chinese and Russian IP piracy issues.^{1084 1085 1086 1087 1088} The U.S. government's motivations may even go beyond the realm of the USTR to include hemispheric strategic and national security issues.¹⁰⁸⁹ However, despite the presence of even national security concerns, the U.S. Supreme Court's decision in *Mitchell v. Harmony* would arguably preclude the U.S. government from sacrificing the private intellectual property (IP) rights of U.S. citizens and businesses to fulfill Brazil's, China's or Russia's ostensible public needs.

Notwithstanding the immediate reason behind the closure of this case, Brazil should keep in mind that there is nothing to prevent the USTR from investigating new U.S. industry and/or third party claims alleging the Brazilian government's continued IP opportunism – i.e., its continued failure to aggressively enforce privately held U.S. *patent/trade secret* rights, and its continued *threats* to issue compulsory licenses to secure substantially reduced drug and medicinal agent prices.¹⁰⁹⁰ There is also nothing to prevent the USTR and the International Trade Commission from investigating Brazil's practices *ab initio*. Under either scenario, it remains possible that the short-term, politically motivated decisions of certain Brazilian government officials can result in Brazil being once again placed on a 301 Watch List.¹⁰⁹¹

VI. CONCLUSION - BRAZIL'S CONDUCT COMPROMISES ITS ABILITY TO ACQUIRE THE TOOLS OF INNOVATION

A. WHAT OTHER COUNTRIES ARE DOING TO STRENGTHEN IPRs AND THEIR ABILITY TO INNOVATE

In the words of one Ugandan-born American bioscientist,

The key to economic development is the presence of the institutions of a free society: *property rights*, the rule of law, free markets and limited government. *Strong intellectual property rights*, administered and enforced in an impartial manner, have been an important part of this framework. As a result, countries, which have [put this] institutional framework [] in place have experienced the growth of knowledge-based industries – to the benefit of all (emphasis added).¹⁰⁹²

An increasing number of developing countries have discovered the important role that IPRs can play in establishing the proper enabling environment for innovation and economic development, and have stepped forward to increase protection of IPRs.

Patents

China

Just recently, the World Intellectual Property Organization announced that China had filed 44 percent more patent applications (2,452) under the WIPO Patent Cooperation Treaty¹⁰⁹³ during 2005 than it had during the previous year.

The Patent Cooperation Treaty... allows inventors to use a single registration to seek patents in many countries simultaneously. This... 44 per cent increase... means China has overtaken Australia, Canada and Italy to become the tenth biggest user of the treaty, adopted in 2000... The number of patents filed by developing countries grew by 20 per cent between 2004 and 2005, and now represent 6.7 per cent of the total [number of patents filed globally]. Leading this growth are China (with 2,452 patents in 2005), India (648), South Africa (336), *Brazil* (283) and Mexico (136) (emphasis added).¹⁰⁹⁴

This seems to reflect the growing awareness within Chinese government and industry circles that legal protection of their indigenous intellectual property assets, including patent (and even copyrights) will actually help rather than hinder the technological advancement and global competitiveness of Chinese companies.¹⁰⁹⁵ Yet, one must remain circumspect about whether this rash of patent applications actually reflects innovations that are made *by* rather than simply *in* China – i.e., whether they were merely the result of reverse-engineered products coupled with newly synthesized processes of manufacture. The importance of intellectual property was discussed during a recent interview conducted by the Xinhua news agency

w ith the C om m issioner of C h in a 's S ta te In te llectu al
P ro p erty O ffice (S IPO).

Im p ro v em en t of C h in a 's ex is tin g
in te llectu al p ro p erty sy ste m w ill
s tim u la te in no v a tio n - b a s e d
c o m p e ti t iv e n e s s ' , s a id T i a n L i p u ,
c o m m i s s i o n e r o f t h e S ta t e
I n t e l l e c t u a l P r o p e r t y O f f i c e (S I P O) ,
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w i t h X i n h u a , T i a n s a i d *h i s o f f i c e
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a t h e l p i n g b u i l d a n i n n o v a t i v e
n a t i o n i n 2 0 0 5 .* T h e g o v e r n m e n t
s h o u l d c r e a t e a f a v o r a b l e
e n v i r o n m e n t f o r b r e e d i n g
t e c h n o l o g i c a l i n n o v a t i o n s b y
w o r k i n g o u t n e w p o l i c i e s a n d
a d o p t i n g i n c e n t i v e m e a s u r e s . T h e
s y s t e m o f i n t e l l e c t u a l p r o p e r t y r i g h t
p r o t e c t i o n i s a l s o t a r g e t e d a t
s p u r r i n g i n n o v a t i v e a c t i v i t i e s o f
i n d i v i d u a l s ' , T i a n s a i d . *A s t h e
b a c k b o n e o f i n t e r n a t i o n a l m a r k e t
c o m p e t i t i o n ' , T i a n s a i d ,
e n t e r p r i s e s s h o u l d b e e n c o u r a g e d
t o i n v e s t m o r e i n r e s e a r c h a n d
d e v e l o p m e n t a n d s h o u l d h a v e m o r e
t e c h n o l o g i e s w i t h i n t e l l e c t u a l
p r o p e r t y ' (e m p h a s i s a d d e d) .*¹⁰⁹⁶

Nevertheless, only the passage of time will determine whether the entire Chinese government will see the virtue of stepping up their national protection of *foreign* intellectual property rights. In this regard, China's cooperation with the U.S. on intellectual property enforcement matters, particularly, its willingness to promptly provide the U.S. with details about Chinese IPR enforcement activities is essential to diffusing the current tensions. In fact, earlier this year, certain information

delays prompted some American politicians and advocacy groups to call for WTO retaliation.¹⁰⁹⁷ Indeed, on February 15, 2006, the U.S. Trade Representative announced that it was setting up an enforcement office to ensure China complies with international trade rules, the first time such a targeted mechanism has been aimed at a specific country.¹⁰⁹⁸

Notwithstanding this announcement, however, it should be recalled that, although China possessed the opportunity, at one point, to declare a national health emergency for the purpose of issuing compulsory licenses on foreign patented HIV/AIDS drugs, it did *not*, like Brazil, threaten to do so. Rather, unlike Brazil, which had originally been outraged by suggestions that it promote HIV/AIDS prevention through use and distribution of condoms¹⁰⁹⁹ and later relented,¹¹⁰⁰ China suffered no such umbrage at all, and sought pragmatic ways to encourage these practices.¹¹⁰¹

And, China ultimately decided not to issue a compulsory license for valid and principled reasons.

Theoretically, China can declare that the country is in an emergency situation and impose compulsory licensing to allow it to make generic drugs,' says Wen Xikai, an official with the patent bureau of the State Intellectual Property Office. But we have to take some economic factors into consideration,' she adds. Imposing compulsory licensing reduces but does not eliminate costs. *We should offer satisfactory compensation to the drug makers who own the patents,*' Wen says. Moreover, *simply reducing prices is not the root solution. Even if drug prices*

are cheaper, most farmer[s] will still not be able to afford them.' Some experts say that compulsory licensing also has its negative side. If the quality of the drugs so produced is poor, they will bring no benefit to the patients. *Moreover, the practice will encourage mainland pharmaceutical manufacturers to produce the generic drugs rather than develop new ones and thus become less competitive in the world market* (emphasis added).^{1102 1103}

Hopefully, such reasoning will continue to prevail following China's recent enactment of a national compulsory licensing law. The law requires payment, in most instances, of just (reasonable) compensation' to foreign owners of patented medicines.¹¹⁰⁴

It must be remembered that, despite their different stages of development and cultural idiosyncrasies, Brazil and China arguably face a similar domestic innovation conundrum that, if not managed properly, can impair their respective long-term economic growth prospects. Like Brazil, China has had significant difficulties in translating its know-how into market-relevant innovations.

Although Chinese science is developing rapidly, as reflected in growing numbers of patent filings, the country's efforts, to translate ideas into commercially successful innovations have so far been disappointing. Many structural barriers stand in the way. They include[:] [1] an ivory tower approach to engineering education; [2] weak links between universities

and business; [3] academic corruption; [4] *ineffective intellectual property protection*; [5] state-owned industries' domination of large markets[;] and [6] scarcity of venture capital funding. Many of those handicaps are deep-seated and will require bold action to dislodge (emphasis added).¹¹⁰⁵

Therefore, the Chinese government should act prudently when adopting and implementing its new compulsory licensing and information technology laws. If it does not, it could inadvertently extinguish the primary incentive for foreign life sciences and IT companies to enter into joint venture agreements with local Chinese companies in the first place. This could, in turn, prevent the types of knowledge spillovers that can lead to indigenous innovations from which Chinese companies and citizens might otherwise benefit. Hopefully, Chinese President Hu Jintao's recent pledge to uphold foreign private intellectual property rights indicates that, China remains determined to continue down its present economic development path towards innovation rather than opportunism.^{1106 1107 1108}

India

Despite considerable domestic debate,¹¹⁰⁹ during January 2005, the Indian government enacted national legislation providing TRIPS-level protections to pharmaceutical patents. According to Dr. Ragnath A. Mashelkar, a prominent Indian scientist and one of India's representatives at the WHO,¹¹¹⁰ R&D spending, by both domestic and foreign companies, has increased markedly since such changes were made.

*Indian drug and pharmaceutical companies have increased their R&D spending by 400% in the past 4 years... in anticipation of the new challenges that will follow ... and... are now looking to hire hundreds of P.h.D 's. They also are shifting toward more in-house innovative research. Rather than just copying drug molecules made by others, the R&D programs of these industries now are trying to create new therapeutic molecules. In a similar fashion, the Indian automobile industry now is exporting indigenously designed and manufactured cars such as the Indica to European markets. Multinational companies are locating their R&D resources in India to create proprietary knowledge for private good--that is, for the stockholders--through private funding... Why are the foreign companies, some of whom have budgets larger than India's entire \$6 billion R&D budget, moving a sizable portion of their R&D infrastructures to India? ...[A s]... Jack Welch... G E 's... [form er]... chief operating officer [once said]... *India is a developing country, but it is a developed country as far as its intellectual infrastructure is concerned. We get the highest intellectual capital per dollar here* ' (emphasis added).¹¹¹¹*

In addition, M r Kam al Nath, India's M inister for Commerce and Industry noted in December 2004, that since 97 percent of all drugs m anufactured in India are

off-patent, [they would] remain [largely] unaffected [by the new patent law – i.e., no] spiraling prices of medicines... A feature of patent protection is that it spurs research so that constantly alternatives keep appearing in the market. Thus price control is inherently built in,' he elaborated. ¹¹¹²

Several business management and international studies scholars have also commented about how foreign industry perceptions have changed since India decided to enact TRIPS-consistent patent legislation. They have noted how these changes, when considered together with India's highly educated workforce, have led many of the largest U.S. technology companies to invest in India.

Harbir Singh, a management professor at Wharton pointed out that all the leading pharmaceutical companies have set up research operations in India. These companies have realised that India is not just a location where clinical trials can be conducted, basic research can also be done there,' he added... Still, India faces major challenges as it attempts to grow into an R&D powerhouse. Saikat Chaudhuri, a management professor at Wharton, believes India faces three crucial challenges as it strives to become a global R&D player. *The first impediment, which is steadily improving, is the intellectual property regime, or perhaps its perception,*' he says. The second challenge, according to Chaudhuri, is the brain drain... The third obstacle, said Chaudhuri is the *lower levels of basic research. This can be achieved by investing in R&D facilities and improving*

the research atmosphere in Indian universities, he added.¹¹¹³

In the estimation of one international legal expert, Indian industry and society will benefit from the country's enactment of strong TRIPS-compliant patent legislation because much has changed within India since the enactment of the prior Patent Act of 1970. First, India's rapid economic growth rate and expanding middle class militate in favor of a stronger domestic *branded* drug market. And, this, in turn, will likely facilitate greater R&D related FDI that, in part, will address previously neglected local diseases.¹¹¹⁴ Second, India has a growing capacity for performing lower cost R&D and conducting sophisticated clinical trials. When combined with stronger domestic patent protection, this will contribute significantly to India's rate of indigenous innovation and global competitiveness.¹¹¹⁵ Third, the TRIPS Agreement will not adversely affect Indian consumers (e.g., with higher drug prices) as had been previously feared. Any risks that may later arise may be mitigated by use of the flexibilities inherent in the agreement.¹¹¹⁶

Jordan

Arguably, the Kingdom of Jordan has realized many benefits since it implemented the strong intellectual property provisions contained within the free trade agreement executed with the U.S. in 2000. They include level drug prices, increased access to medicines, rising foreign direct investment, improved scientific and innovative capacity, and a growing volume of pharmaceutical exports.

Jordan... saw a dramatic increase in foreign investment from major pharmaceutical companies. Many

firms opened offices in Jordan or expanded their commercial and research activities in Jordan. Jordanian exports of pharmaceuticals increased by 33% between 1999 and 2001. At the same time, prices for new, patent-protected medicines did not exceed pre-patent prices, and the generic industry benefited from an increase in foreign investment that generated work for these companies. Since 2000, there have been 32 new innovative drug launches in Jordan, greatly increasing Jordanians' access to medicines. Beyond these innovations, the foreign direct investment seen in Jordan from the pharmaceutical sector – a high-tech, knowledge-based industry – has had the important secondary impact of improving the science base and clinical science, building capacity, and helping with scientist and physician retention.¹¹¹⁷

A separate study performed by the International Intellectual Property Institute came to similar conclusions. It found that the Kingdom of Jordan's adoption of stronger IPRs resulted in knowledge spillovers (acquisition of scientific and technical knowledge) that, in turn, contributed to substantial growth in Jordan's domestic health care and education sectors, rate of employment, and national economy, the development of new domestic clinical research, drug trial and medical tourism¹¹¹⁸ sub-sectors, and new export markets, the expansion of scientific and technology cooperation with the international community, and to greater access to medicines generally for Jordanian citizens.¹¹¹⁹

Singapore

Singapore has dramatically improved its record of intellectual property protection since the late 1990's. This led to its removal from the U.S. Special 301 Watch List during April 2001. Singapore's legal system, which is based on UK common law, has provided the government with an effective means of recognizing and enforcing private property rights.

The Singapore government has taken the recently executed U.S.-FTA intellectual property commitments to heart, having enacted amendments to the national Trademarks Act, the Patents Act, a new Plant Varieties Protection Act, and a new Manufacture of Optical Discs Act, all of which went into effect during July 2004. During January 2005, Singapore's amended Copyright and Broadcasting Acts also went into effect. Furthermore, the Singapore government has actively pursued civil and criminal enforcement of counterfeit and pirated goods. According to the U.S. State Department,

Singapore's new and amended IP laws...[when]... fully implemented... should help alleviate ongoing problems related to the availability of pirated optical discs, use of unlicensed software by businesses, the transshipment of pirated material through Singapore, and a cumbersome process for removing infringing material from Internet sites...

As recently reported by the editors of Foreign Direct Investment Magazine, besides remaining one of the world's leading manufacturing sectors, Singapore also

lays claim to the best intellectual property (IP) regime in Asia as a strong protector of IP rights and signatory to all international IP agreements. A 2003 report by Political and Economic Risk Consultancy ranked Singapore as the Asian country with the lowest risk for intellectual property violations, ahead of Japan (emphasis added).¹¹²¹

Similarly, one Motorola representative has emphasized that, while China's huge cost advantages will ensure that Motorola's plant in Tianjin continues to churn out mobile handsets and phone components... Singapore will remain a firm plank in the company's pan-Asian operations... for high-end technologies that depend on constant refinement by on-site engineers and full protection of intellectual property.¹¹²²

Two management scholars have also noted the significance of the Singapore government's decision to create an institutional environment that facilitates trust among foreign and domestic parties through promotion of greater protection of patents, contract law and private property rights. They have found that this trust factor has resulted in greater technological development and expanded science and technology collaborations and alliances among different companies operating within the information and communications technology sector, and hence, contributed to increased foreign direct investment.¹¹²³

Mexico, Chile and Morocco

The Governments of Mexico, Chile and Morocco have also realized many benefits following their ratification of the

free trade agreements each previously entered into with the United States. For example, since their enactment of strong intellectual property protections consistent with those treaties, there has been a marked increase in domestic and foreign pharmaceutical company investment in plant and equipment and research and development in each such country.¹¹²⁴

Indonesia

At least, one prominent official from the government of Indonesia believes that developing countries will be better off scientifically, technologically and economically once they recognize that aid alone will not suffice. He recognizes how it is both a matter of common sense and a necessity for developing countries to create the indigenous capacity needed to innovate and convert ideas triggered by research and development efforts into commercially viable market-based products that can generate domestic and export wealth. In his view, this requires vigorous protection of exclusive intellectual property assets.

Once a country is aware that it has a set of talents' that can be cultivated and developed, it is already looking at potential advantage... *[T]he sort of talents we are talking about here have to do with invention, research, creation, art and design, culture -- covetable intellectual assets that have a high worth...* But the very attractiveness of these assets, their visibility as they are exposed by today's high-powered technology, make them extremely vulnerable. It is this vulnerability, and the consequent need for protection, that make the urgent establishment of

an efficient IP regime, and of IP rights as a matter of course in all countries, such an all-important necessity.

Without proper protection, a country's exclusive assets are as good as worthless, because they can be appropriated or pirated by others...Thus, the developing countries must imperatively develop and master a strong system of safeguards if they want to protect their own intellectual resources from unlawful appropriation by others in order to turn them into marketable products, capable of generating wealth for their own economies. IP rights revolve entirely around this notion of ownership. In other words, a country, business or person must be able to claim exclusive ownership of their assets in order to protect the latter from exploitation by others. This notion is central to the ability of individual countries to make use of their intellectual resources as instruments of development. ¹¹²⁵

Korea

Korea, as well, has apparently made some measurable efforts to strengthen its national intellectual property regime since being placed, during 2004, on the USTR's Priority 301 Watchlist.¹¹²⁶ The USTR has recognized Korea's progress by lowering it from the Priority Watch List in 2004 to the regular 301 Watch List in 2005.¹¹²⁷ It has also recently (during June 2006) entered into bilateral trade negotiations with the South Korean government in the

hope of promoting even greater cooperation on IPR issues. Although these negotiations have recently encountered some unforeseen obstacles,^{1128 1129 1130} it is believed that progress will be forthcoming.

Judging from the remarks made by at least one key official from Korea's Ministry of Finance, it is clear that Korea understands how important this FTA is to promote reform of Korea's enabling environment, which is believed to be necessary to ensure its industries' future economic competitiveness.

Korea sees the deal... as a catalyst for the kind of broader reform that will help propel South Korea to the next stage in its remarkable economic transformation. This will help us upgrade our whole economy – weak sectors such as agriculture will be strengthened and over-protected sectors such as the film industry will become more competitive', [said] Kwon Tae-shin, South Korea's vice-finance minister... And there will be knock-on improvements for corporate governance, the accounting system and government bureaucracy. All of these areas can meet global standards.'¹¹³¹

Indeed, Korea's trade officials and academics also recognize how the FTA would expand bilateral industrial cooperation, thus improving Korea's overall ability to attract FDI and foster indigenous innovation.

A free trade agreement with the U.S. would help facilitate further industrial cooperation between the two countries and would help us

turn the current situation around by taking advantage of the [innovation] potential that exists in Asian markets... China has been receiving the main bulk of foreign direct investment and if this continues, we will be sidelined by China', says Young Soo-gil, an influential economist who heads the National Strategy Institute, an independent think-tank.¹¹³²

Commerce Minister Chung Sye-kyun, during a meeting organized by the Korea Chamber of Commerce and Industry... highlighted the long-term benefits of a bilateral trade pact with Washington. *An FTA would allow the country to entice high-tech business, as well as research and development centers, which are crucial for sustainable growth,* the minister said (emphasis added).^{1133 1134 1135}

Test Data and Trade Secrets

Besides the U.S., other WTO members have adopted TRIPS-consistent data exclusivity legislation. They include Australia¹¹³⁶, Chile¹¹³⁷, Colombia¹¹³⁸, the European Union¹¹³⁹, Japan¹¹⁴⁰, Jordan¹¹⁴¹, Korea,¹¹⁴² Mexico¹¹⁴³, Morocco¹¹⁴⁴, New Zealand¹¹⁴⁵, Singapore¹¹⁴⁶, Taiwan,¹¹⁴⁷ and even China¹¹⁴⁸. In addition, they include the parties to the recently executed Central American Free Trade Agreement (CAFTA), namely, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua.¹¹⁴⁹ Furthermore, the U.S. free trade agreements recently negotiated with Peru¹¹⁵⁰ and Colombia¹¹⁵¹ contain identical provisions protecting clinical testing data and

trade secrets from unauthorized third party exploitation. These provisions expressly do not affect [either country's] ability to take necessary measures to protect public health by promoting access to medicines for all, particularly in circumstances of extreme urgency or national emergency.¹¹⁵²

B. BRAZIL MUST EVOLVE

Brazil Suffers From an IP Identity Crisis

Economists generally recognize that the practice of industrial and technology IP opportunism should, to some extent, be expected. Developing countries and emerging economies face enormous pressures to maintain an evolutionary track in a world that continually progresses. These pressures are exacerbated in the current information society, which is taking shape much more rapidly than previous globalization eras due to significant and continuous scientific, technology and communication advances. Consequently, in the absence of indigenous capacity, the acquisition of advanced technologies through opportunistic abuse of international intellectual property laws serves as the most effective means by which such countries may, at least initially, maintain a modicum of forward momentum.

Developing countries face different concerns with regard to intellectual property and globalization. These countries have less economically valuable intellectual property and hence are often significant importers of innovative technologies and expertise. This prospect may trigger protectionist responses in certain developing countries and

tempt them to simply ignore foreign intellectual property rights. This is especially true because during the period in which a patent applies, intellectual property rights guarantee that its owner can charge prices substantially greater than its marginal costs to produce the good. Hence, recourse to piracy or counterfeiting can significantly reduce the costs of a given patented product in a developing country (emphasis added).¹¹⁵³

However, such practices cannot continue and be justified forever. Once developing countries are able to attract foreign direct investment (FDI), to create innovation capacity, and to become emerging trade-based economies, such as Brazil, they must move beyond minimal TRIPS standards and vigorously protect IPRs – i.e., they must grow up and evolve!^{1154 1155}

While it may be understandable that a lack of natural and/or human capital resources may give rise to a national sense of inadequacy, insecurity, and urgency, such feelings, if unchecked, could nevertheless devolve into something much more harmful. Arguably, Brazil is now demonstrating a type of intransigence at international institutions, through its efforts to help reform and replace the current paradigm of international intellectual property law. It also refuses to enter into regional trade agreements that require it to recognize and enforce foreign intellectual property rights. While Brazil's bravado has garnered the applause and admiration of less fortunate impoverished nations and socialist-minded activists and advocacy groups, it likely threatens the interests of most other countries, the established global system of innovation and economic growth, and the economic prospects for Brazil itself.

At least one expert in clinical psychology and international affairs¹¹⁵⁶ has evaluated Brazil's conduct in psychological terms. In his estimation, Brazil is an adult that often acts like an adolescent.¹¹⁵⁷ It is suffering from an acute sense of inadequacy, which prompts it to continually 'act-out' on the world stage in search of its true identity. On the one hand, Brazil is frustrated because it is caught, developmentally speaking, between childhood and early adulthood. Although it has become, because of its economic size and newfound technological potential, a major actor (an 'adult') both in the hemisphere and in the world, it believes that it has not yet been taken seriously enough by older and more established actors. As a result, Brazil (the 'adult') feels that it must aggressively assert itself (as would an adolescent) in international affairs to command the respect and acknowledgement it believes it (as an 'adult') deserves. Simultaneously, however, Brazil often finds it convenient to regress back and assume the posture of a weak enfeebled adolescent so that the OECD nations (the 'older adults') will excuse its prior intransigent behavior.¹¹⁵⁸

According to this expert, it is to be expected that some OECD nations, including the United States, which have invested much to maintain the established global order, will insist that Brazil be punished. They are justified in believing that this is necessary in order to teach other adventurous emerging and developing economies (true adolescents) a lesson. The problem, however, is that once the Government of Brazil has 'acted out' publicly on the world stage, its behavior has been indelibly etched in the minds of those other governments, and cannot be erased without considerable effort. Undoubtedly, Brazil's peers and the less fortunate developing countries have taken notice of Brazil's opportunistic conduct and are likely to try

repeating its successful tactics in the future to the detriment of the world community.¹¹⁵⁹

Lastly, this expert believes that the Brazilian government's continued ability to exact sympathies from OECD nations as it opportunistically acquires their technologies in the name of public health and information sharing, has only further reinforced its sense of invincibility and derring-do. This, in turn, has encouraged the Government of Brazil to persist in its opportunistic conduct to the point of obsession. As a result, the government has become unable to distinguish between 'right' and 'wrong', and no longer finds it necessary to disguise its true contempt for the current world intellectual property system. Therefore, it has embarked on an all-out campaign of opportunism to disrespect all intellectual property, including that created by its own industries, even if it harms itself in the process.¹¹⁶⁰

Other Countries Will Not Pay for Brazil's Continued Opportunism

The past failure and/or inability of Brazil and other emerging economies, such as Russia, India and China (the 'BRIC' nations), and of developing countries, to vigorously uphold the exclusive private property rights of individual and corporate owners in intellectual property has contributed further to OECD nations' subsidization of the cost of global innovations. This has occurred through payment of the higher prices charged for technology-rich products invented, commercialized, and sold within such countries, coupled with stiffer local enforcement of intellectual property laws.¹¹⁶¹ Higher prices have resulted chiefly from OECD country industries' inability to recover their costs of investment, let alone, to earn a reasonable profit. Emerging and developing country governments' non-protection of IPRs, strict price controls on health care

and other products, and allowance of parallel trade in below-cost and illicit generic drugs and computer software have also contributed to this problem. Arguably, price controls, parallel trade and limited IPR protections should be the exception rather than the rule – and that exception should apply only to *least* developed countries suffering from actual verifiable health emergencies and lacking actual manufacturing capacity.

Since the U.S. has had the strongest enforcement of IPRs among the OECD nations, an increasing number of know-how-rich industries including those based within the Member States of the European Union have continued to relocate their R&D enterprises within U.S. borders. The cost of innovation has thus been reflected mostly in the higher prices of technology-rich products sold to and/or within the U.S. These prices are higher than those paid by consumers in other regions that offer relatively weaker IPR protections - from Europe and Canada to emerging and developing economies. Two cases in point are pharmaceuticals and computer software. As the result of BRIC and developing nation non-enforcement of IPR laws already on the books, U.S. and other OECD member nation industries have had no other choice but to raise the prices of their products and services in order to recoup their costs of investment in both R&D and commercialization, and to earn a reasonable profit.

The insistence by socialist-minded governments, and anti-private property and anti-market activists and academics, that the world should essentially become flat, with free and open source and universally accessible knowledge, further encourages IP opportunism and threatens the industries and innovation systems of OECD nations. It also ensures that OECD nation prices for knowledge-based products and services will continue to increase rather than

decrease, since current company pricing strategies are largely based on a national pricing model that must compensate for pricing inadequacies elsewhere. In other words, to the extent that companies based or doing business within OECD nations have been unable to earn a reasonable profit, or have incurred an economic loss in developing country markets, they have had to substantially raise their prices and to impose significantly tighter restrictions on the use of and access given to their products and services within their home country markets.¹¹⁶²

Anecdotal evidence suggests, for example, that prior to 2006, U.S. purchasers of patented/ copyrighted software programs could often load their software onto as many as three different computers, which enabled many families to afford the purchase of such products. Since January 1, 2006, however, many such products are now limited to use on only a single computer. In addition, the cost of pharmaceuticals continues to rise and negatively impact the cost of U.S. health care, putting it beyond the reach of many Americans. And, while U.S. generic and universal access drug laws can alleviate some of these pressures, and open source software and other universally accessible information technology platforms that lead to cheaper products can temporarily provide U.S. consumers with more bang for the buck, they still do not address industry's long-term difficulty of securing an adequate enough return on investment to facilitate future investments in invention and innovation.

Therefore, if the Government of Brazil and sympathetic activists and academics are able to prevail, innovative OECD nation industries would need to employ a global *at-or-below-cost*, fixed-price, volume-based business model that would likely be publicly supported, in some way, by governmental subsidies or through imposition of

international, national and/or local taxes. Pursuant to such a model, innovative product/service providers would essentially be guaranteed 'a minimal national and/or international market share in return for everyday low-priced products and services. Indeed, while the concept of an advanced market commitment',¹¹⁶³ which had been previously floated by G-8 member nations this past February (2006) may have been embraced by pharmaceutical companies as the least worst alternative,¹¹⁶⁴ it was, nevertheless, recently rejected for economic and political reasons during early July 2006.^{1165* 1166}

If OECD nation companies cannot protect their exclusive private intellectual property from exploitation by others, and are unable to earn an adequate market-rate return on investment, *plus* a reasonable profit to boot, they will have *less* of an incentive to invent and innovate. Tax and financial incentives such as R&D credits and subsidies and other academic-style contests and awards are, indeed, helpful mechanisms - but they do *not* compensate for the opportunity (time) and economic costs incurred to convert basic R&D into commercially relevant innovations. Markets are *profit-*, not cost-driven. Volume-based business models with tight profit margins are an extremely risky investment in the long term, even if supported by government efforts to artificially 'make markets' by providing advanced market commitments'. Since the natural tendency of markets is to fluctuate in response to the sometimes volatile supply and demand of raw materials, goods-in-process, finished products, etc., as well as, to consumer perceptions and idiosyncrasies, it would be extremely difficult to gauge in advance the true economic value of such a guarantee in terms of profitability. After all, nothing can be guaranteed forever, let alone for the extended period of time that may be required to develop,

manufacture and distribute a successful life-saving drug to needy patients free of complications.

Consequently, with governments regulating company profit margins internationally and domestically without truly guaranteeing markets for more than the short-term, a company's (and investors') incentive to enter into any such arrangement is likely to disappear very quickly.¹¹⁶⁷ In fact, top-down government market-making mandates, no matter what form they assume, including newly proposed patent buy-outs,^{1168 1169} provide even greater *disincentives* to invest and innovate in the longer term, unless, of course, they can be manipulated by a desperate industry as disguised protectionist devices. Rather, what is most needed is a national *bottom-up*, market-first approach towards innovation. This is not rocket science, but simply, human nature.¹¹⁷⁰

Unless all countries, including Brazil, work together to protect IPRs globally, invention, innovation, consumer prices, and public access to critical new life science and information technologies will likely suffer. This could conceivably result in a significant cost-of-living increase for, and a measurable diminution in the quality of life of, OECD *as well as* developing nation citizens that will be difficult for them to bear. Presently, the Brazilian ruling party's opportunistic behavior is perceived by Brazilian and foreign industry and by OECD nation citizens to threaten their future interests and livelihoods. If common Brazilian citizens also start believing that this is true, it is likely to trigger a very painful domestic political backlash against the current Brazilian government.

Brazil, an emerging economy and an aspiring global power, has arrived at the stage in its development where it is expected to exercise prudence and responsibility in its

domestic and international affairs. Therefore, the Government of Brazil must choose the right path by pursuing innovation rather than opportunism.¹¹⁷¹

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ENDNOTES

¹ See, e.g., William New, UN Researcher Envisions Framework for IP, Innovation and Development, Intellectual Property Watch (9/6/06), at: (<http://www.ip-watch.org/weblog/index.php?p=392&res=1280&print=0>). This article proudly reports about a new survey conducted by Padmeshree Gehl Sampath, a researcher at the United Nations University – MERIT in the Netherlands. Basing her findings largely on the controversial April 2006 report issued by the World Health Organization Commission on Intellectual Property Rights, Innovation and Health (CIPIH), discussed later in this article, this researcher concludes that intellectual property is *not* essential for innovation. *While intellectual property policy is a key element of innovation policy, the focus has been selective, and has placed too much emphasis on one or the other... The link between intellectual property and innovation is very nuanced', she said... and depends on a variety of factors.* Gehl Sampath has been collecting

surveys in the developing world, including an extensive one of the pharmaceutical industry in India. There, most of the firms are small to medium-sized, but a few have gained international stature. The big firms have begun to pursue intellectual property rights as they move from unregulated to regulated markets through exports, she said. But at [a September 4] event sponsored by the South Centre, Gehl Sampath said intellectual property rights contributed little to the rise of the Indian pharmaceutical industry, though that might be changing with India's accession to the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). I think the Indian pharmaceutical industry would have proceeded more or less in the same direction without intellectual property protection', she said. But an emphasis on innovation is necessary for firms to move from the status quo, she added. Innovation, the process of acquiring technological knowledge and building on it, requires a variety of market and non-market institutions. It is not science or technology or invention, but rather the application of knowledge, she said. *Gehl Sampath said that in general, I do not think IP is very important for development. Intellectual property is only of use to nations once they reach a particular state of development, she said, as history has shown...* Gehl Sampath also said that while patents can create markets for technology, there is little evidence that developing country researchers are on equal footing to those in developed countries. *IP regimes and liberal trade will help to tackle underdevelopment only when the market for information (as facilitated by IPRs) are balanced with other non-market incentives for innovation.* For instance, R&D subsidies, tax exemptions, promotions for scientists', she said... *Gehl Sampath said a difference between intellectual property and innovation is that IP is dominated by the market failure argument, and that the key source of technological advance, research and development, suffers from the twin failures of uncertainty and low appropriability.* This means that policy intervention is necessary to correct low investments in socially useful information, she said (emphasis added). *Ibid. See also Padmashree Gehl Sampath, India's Product Patent Protection Regime: Less or More of Pills For the Poor?* UNU-MERIT Working Paper Series #2006-019, United Nations University (2006) at: (<http://www.merit.unu.edu/publications/wppdf/2006/wp2006-019.pdf>); Padmashree Gehl Sampath, *Indian Pharma Within Global Reach?* UNU-MERIT Working Paper Series #2006-031, United Nations University (2006) at: (<http://www.merit.unu.edu/publications/wppdf/2006/wp2006-031.pdf>).

² The U.S. is the world's largest humanitarian aid donor, providing \$3.3 billion in 2003. It also is the world's largest source of bilateral and multilateral support to combat HIV/AIDS, malaria, and other infectious diseases, including \$2.4 billion in international HIV/AIDS programs. Yet the U.S. is often criticized for not providing enough resources for development. The basis for this criticism is the theory that if only aid flows increased, developing countries would achieve economic growth and development. Economic analysis and the historical record do not support this reasoning. The United States and other donor nations have spent over \$2.3 trillion on bilateral and multilateral development assistance (in 2003 dollars) since 1960 to help poor countries attain economic growth and prosperity—about a fourth of it in sub-Saharan Africa. Few recipients have achieved substantial improvements in per capita income, and in no case has a development success story been clearly attributable to economic assistance. **The evidence provided by numerous studies indicates that this failure is due not to insufficient funds, but to the poor policies of recipient countries.** [A]bout half the countries in sub-Saharan Africa experienced negative growth in real per capita incomes despite hundreds of billions of dollars in aid invested over the past two decades. Instead of desperately needed economic growth, sub-Saharan Africa as a region saw a decline in per capita GDP from \$575 in 1980 to \$536 in 2004 (in 2000 dollars). [W]ithout high, sustained levels of economic growth, sub-Saharan Africa will not close the gap with the developed countries. The poor growth record undermines improvements in human development as well. World Bank estimates indicate that sub-Saharan Africa will require annual growth of 7 percent to halve severe poverty— one of the United Nations' indicators for the Millennium Development Goals (MDGs)— by 2015. With the support of donors and private-sector innovations in medicine, science, and agriculture, sub-Saharan Africa has experienced improvements in literacy, school enrollment, infant mortality, and life expectancy (although it has decreased since its 1990 high of 50 years to 46 years due to AIDS and the higher incidence of other diseases such as malaria). However, in most cases, these improvements have fallen short of advances elsewhere in the developing world because poor economic growth erodes the resources governments and individuals have to invest in improving these indicators. **While foreign assistance may be able to finance short-term improvements, these achievements are transitory without economic growth to sustain and improve upon them ... the record discussed above clearly shows that large disbursements of development assistance did not lead to the economic growth in sub-**

Saharan Africa that many aid advocates envisioned. However, *achieving high per capita economic growth is possible even in low-income countries. This fact is illustrated by successful development by countries in East Asia.* Per capita GDP in East Asia and the Pacific was lower than in sub-Saharan Africa in 1960 but has since far eclipsed sub-Saharan Africa. How did this happen? *Economic studies indicate that sound economic policies, the rule of law, and good governance are the key. Over the past decade, economic studies have concluded that economic freedom, good governance, and the rule of law are key drivers in promoting economic growth and reducing poverty.* A 1997 World Bank analysis of foreign aid found that, *while assistance positively affects growth in countries with good economic policies (free markets, fiscal discipline, and the rule of law), countries with poor economic policies did not experience sustained economic growth regardless of the amount of foreign assistance received...* Why would **economic freedom**, globalization, and the rule of law contribute to economic growth? Rigid labor policies, high regulation and bureaucratic red tape, high official taxation, corruption, and trade barriers are obstacles that create a drag on economic growth. **The greater the level of government intervention in the economy, the lower the probability that individuals, investors, and businesses will be able to prosper because costs on private economic activity become higher.** This leads talented people to leave the country for more advantageous opportunities or to engage in activities that do not contribute to GDP (such as government service) and enrich themselves through rent seeking and corruption. *The practical result is that countries with anti-market economic policies and bad governance are more likely to be poor*, to be isolated from the international economy, and to find it more difficult to escape that poverty. [The Heritage Foundation has been analyzing the effect of economic freedom on development for many years... The central product of this research is the *Index of Economic Freedom*, co-published annually by The Heritage Foundation and *The Wall Street Journal*. The *Index* analyzes 50 economic indicators in 10 independent factors: trade policy, fiscal burden of government, government intervention in the economy, monetary policy, capital flows and foreign investment, banking and finance, wages and prices, property rights, regulation, and informal market activity. Those 10 factors are graded from 1 to 5, with 1 being the best score and 5 being the worst score. Those scores are then averaged to give an overall score for economic freedom. Countries are designated free, mostly free, mostly unfree, and repressed based on these overall scores (emphasis

added). See Brett D. Schaefer, How Economic Freedom Is Central to Development in Sub-Saharan Africa, Heritage Lecture #922 Heritage Foundation, (2/3/06), at: (<http://www.heritage.org/Research/TradeandForeignAid/hl922.cfm>).

³ Even though President George W. Bush has pledged to double aid to Africa by 2010 and the Group of Eight industrialized nations agreed to cancel the debt of 18 of the poorest countries in the world, these noble financial commitments are woefully insufficient... A recent World Bank study has found that micro-enterprise investment for entrepreneurial activities is much more successful in helping poor families achieve economic prosperity than traditional foreign aid. What we need is a new type of Peace Corps, an Entrepreneurial Corps of faculty, students, and business leaders... in partnership with African entrepreneurs... This would satisfy America's Millennium Goal obligations... See Kyle Urey, An Opportunity to Unleash African Entrepreneurship, Financial Times Comment (8/24/06), at p. 9.

⁴ *The American understanding of freedom— based on the right of the individual to life, liberty, and the pursuit of happiness as expressed in the Declaration of Independence— is often quite different from definitions embraced by other countries, particularly those from a Communist, Socialist, or even Continental European tradition. In economic rights, the Anglo-Saxon and Continental European traditions tend to come into direct conflict. The Anglo-Saxon tradition of Adam Smith and John Stuart Mill asserts that economic and political freedoms are indivisible, that they adhere to the individual and his enlightened self-interest, and that one cannot exist without the other. Political freedom in the absence of economic freedom becomes a mere token and does not involve the exercise of real individual choice or power. **Economic freedom in the absence of political freedom can exist only up to a point, beyond which it becomes a threat to the political leadership of the moment.** Emphasis on one or the other tends to endanger both (emphasis added). See Helle C. Dale, Economic and Political Rights at the UN.: A Guide for U.S. Policymakers, Heritage Backgrounder #1964, Heritage Foundation (8/30/06), at: (<http://www.heritage.org/Research/WorldwideFreedom/bg1964.cfm>).*

⁵ In addition to its efforts to help reform the World Trade Organization's (WTO's) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, Brazil has also endeavored to expand its 'open source' paradigm to biotechnology, chemistry, music, art, and science and know-how in general, through various United Nations agencies: the UN Education, Science and Cultural Organization – UNESCO; the UN World Intellectual Property Organization (WIPO);

the UN International Telecommunications Union (ITU) – World Summit on the Information Society (WSIS); the UN World Health Organization (WHO); the UN Convention on Biological Diversity (CBD)/ United Nations Environment Program (UNEP); the United Nations Development Program (UNDP); and the UN Human Rights Commission (UNHRC) . In each case, the purpose and effect is to promote national development and prepare Brazilian industry for international trade by opportunistically exploiting, even violating, international trade rule flexibilities for however long it takes to secure Brazil's economic and technological independence.

⁶ Brazil has related acquisition of technological and scientific R&D know-how with the UN notion of sustainable development, as concerns both the healthcare and ICT sectors. For example, the Brazilian government's Green Book on the Information Society explains how critical ICT sector know-how is to Brazil's future global competitiveness and national welfare. The goal of the Information Society Program is to integrate, coordinate and foster actions for the utilization of ICT, in order to contribute to the social inclusion of all Brazilians in the new society and, at the same time, help the country's economy secure the necessary conditions to compete on the global market... Research and development: *knowledge is the wealth of nations*... The new economy requires continual development and command of new learning and skills. Within this context, it's particularly strategic to possess advanced knowledge of ICT that today are in the center of the dynamics of innovations and are a primordial factor to bolster economic competitiveness. Considering the accelerated evolution of the global technological scenario, Brazil must have flexible and dynamic programs to foster research, focused on the mastery of key technologies, for the development of Brazilian industry... In order to be able to keep up with the rapid speed of development of the global technical-productive base, the country must still maintain a consistent policy of investment in human resources, of modernization of the scientific-technological infrastructure, of support for greater integration between universities and private initiative, and of active international cooperation... For Brazil, a country with rich and strategic natural reserves, the prospect of *sustainable development* is a basic aspect that must to be incorporated into its project for an information society... With the support of ICT, it's possible to create advanced systems and services of information and of prevention against environmental threats that can assist, as well as serve as a warning, for the formulation of government policies, business strategies and social assistance actions. With the new medias and electronic networks, more

favorable conditions are also created to provide greater information to the public and raise public awareness in respect to the need to preserve the environment, environmental education, and national and international cooperation in this area, facilitating the implementation of a more *sustainable model of development* (emphasis added). See Chapter 1: The Information Society, Information Society in Brazil: Green Book, Implementation Group of the Information Society Program (Programa Sociedade da Informacao (SocInfo), Ministry of Science and Technology (2000), at pp. 31-32.

⁷ The assumptions, tools and frameworks that leaders have used to make decisions over the past decade appear inadequate. It is imperative for leaders of all walks of life to develop new capabilities. See e.g., Creativity, Radar Magazine, Sustainability (April 2006), at p. 2, quoting Professor Klaus Schwab, at: (<http://www.sustainability.com/insight/radar-article.asp?id=264>). See also pp. 3-4, 12, 15, and 25 *Ibid*.

⁸ The notion of sustainable development was effectively mainstreamed at the United Nations Conference on Environment and Development (UNCED) convened in Rio de Janeiro in June 1992 (the Earth Summit). UNCED produced the Rio Declaration on Environment and Development, a non-binding set of broad principles and a non-binding agreement called Agenda 21, which is essentially a global action plan to achieve sustainable development.

⁹ The US Trade Act 1974 established a link between IPR protection and trade. However, for a long time, at the international level, there was no consensus about such a link. Developing countries were concerned about their own development. They claimed that *transfer of technology* was needed for development. They also pointed out the risk of being obliged to patent inventions related to public health and nutrition (UNCTAD 70). See Dr Barbara Rosenberg, Director, Secretariat of Economic Defence, Brazilian Ministry of Justice, Presentation Made at Workshop: Global Intellectual Property From a Brazilian Perspective, University of Oxford Centre for Brazilian Studies (11/4/05), at: (<http://www.brazil.ox.ac.uk/confreports/IP%20report%20final3.pdf>).

¹⁰ See Martin Khor, Globalization and the Crisis of Sustainable Development United Nations University (2002), at: (<http://www.unu.edu/interlink/papers/WG1/Khor.doc>).

¹¹ The United Nations Conference on Environment and Development (UNCED) was a historic watershed that raised hopes of people around the world of the emergence of a new global partnership. This new partnership, arising from the Spirit of Rio, would change the present

course of international relations, tackle the growing global environment crisis and simultaneously strive for more equitable international economic relations that would be the basis for promoting sustainable development globally and in each country... It generated an international community, of governmental, non-governmental, and inter-governmental officials, agencies and individuals, that shared an understanding (however tentative) of the integrated nature of environment and development, and *a recognition that in the next few years there was the crucial need and the unique window of opportunity to change the course of history, in order to save Humanity and Earth from environmental catastrophe and social disorder* (emphasis added). See Martin Khor, Effects of Globalisation On Sustainable Development After UNCED Third World Network (May/June 1997), at: (<http://www.twinside.org.sg/title/rio-cn.htm>).

¹² Sustainable development, as so defined, reflects the fears of Thomas Malthus and remains a vague and tired concept that essentially means development that is consistent with future as well as present needs. A more recent dire Malthusian prognostication was reported by the UK Guardian on March 30, 2005. The human race is living beyond its means. A report backed by 1,360 scientists from 95 countries – some of them world leaders in their fields – today warns that almost two-thirds of the natural machinery that supports life on Earth is being degraded by human pressure. The study contains what its authors call a stark warning for the entire world. The wetlands, forests, savannahs, estuaries, coastal fisheries, and other habitats that recycle air, water and nutrients for all living creatures are being irretrievably damaged. *In effect, one species is now a hazard to the other 10 million or so on the planet, and to itself.* Human activity is putting such a strain on the natural functions of Earth that the ability of the planet's ecosystems to sustain future generations can no longer be taken for granted, it says... In many cases, it is literally a matter of living on borrowed time' (emphasis added). See Tim Radford, Two-Thirds of World's Resources Used Up, UK Guardian (Mar. 30, 2005). Indeed, the United Nations recently issued a report on collective global threats that cited the need to achieve sustainable development to ensure global collective security. This was emphasized within the FIRST of the report's many sections identifying and discussing collective global threats. As the report reveals, however, the attainment of sustainable development and economic growth are two distinct goals. See A More Secure World - Our Shared Responsibility - Report of the High-level Panel on Threats, Challenges and Change (2004), at paragraphs 52-59, at: (<http://www.un.org/secureworld/report2.pdf>).

¹³ American internationalists (apologists) believe that it is absolutely necessary to begin rehabilitating America's image internationally, which, they allege, has been sullied by the foreign policy initiatives of the current presidential administration. To do so, they call upon Americans to collectively concede their exceptionalism 'as a nation without peers, as well as, to sacrifice their inalienable individual constitutionally guaranteed private property rights, including intellectual property rights, for the benefit of developing countries and in furtherance of global harmonization. This doctrine of American internationalism is likely to have negative repercussions for the United States, which holds most of the know-how and technologies that the world wishes to obtain. *See, e.g.,* Congressman to Secretary Leavitt on W H A R & D Resolution IP-Health (5/19/06), at: (<http://lists.essential.org/pipermail/ip-health/2006-May/009569.html>); (<http://www.cptech.org/ip/health/who/59wha/congress05192006.pdf>). This letter was signed by three well-known congressional Democrats: Tom Allen-D. ME; Lloyd Doggett-D. TX; and Dennis Kucinich-D. OH; one Independent: Bernard Sanders-I. VT; and one Republican: Dan Burton-R. IN. It restates the arguments made by Brazil's socialist ruling party and international health activists, such as James Love and Ralph Nader. Coincidentally, the U.N. World Health Organization also happens to embrace these arguments. The position these politicians, bureaucrats and activists have articulated threatens to weaken the U.S. system of exclusive private property rights, especially intellectual property rights, and America's competitive advantage in international trade. By advocating in favor of internationalizing health-related technology R&D through means of a UN-style public-private partnership 'R&D treaty, these congressmen and activists would obligate the U.S. government to follow UN dictates to instruct U.S. companies how they may conduct basic research and development and how much profit they can make commercializing inventions based on federally-funded R&D. Consistent with the WHO CIPIH's position, the letter's supporters reason that intellectual property rights, by themselves, are insufficient to promote an adequate economic incentive for U.S. industry to commit significant funds to research and development of drugs, medical treatments and technologies that benefit third world country citizens, but don't explain why that is necessary if the companies can't make a profit doing so. They also allege that the WHO proposal for an international R&D treaty, first proposed by Love and Nader, will actually reduce the cost of drugs to U.S. citizens because other countries' governments would be obligated under such a treaty to pay their fair (equitable) share of R&D costs, which they

would derive by taxing industry and citizens. However, they do not provide evidence that this would actually occur, because no such evidence exists. These proposals are idealistic and unworkable at best, and misrepresentative at worst. The recommendations set forth in this letter would essentially amount to another hidden tax on American consumers. They also would violate the U.S. Constitution – i.e., it would result in a government taking ‘of private property for public use’ without just compensation’, in much the same way that U.S. Supreme Court Justice Stevens’ majority ruling in last year’s highly controversial *Kelo* decision would deny individual citizens their private real property rights by providing government with broad discretion to exercise its eminent domain power via regulation. Furthermore, once this international/national template (framework) is established, it will then likely be applied to the U.S. information and communication technology (ICT) sectors. Apparently, at least one US-based internationalist-minded foundation is not very worried about weakening U.S. constitutional property right protections, nationally and abroad, and has recently awarded the NGO operated by health and environmental activists James Love and Ralph Nader a \$500,000 start-up grant. Their NGO, Knowledge Ecology International was formerly known as CPTech.. See Judy Sarasohn, An Honor and a Boon for Nine Nonprofits, Washington Post, The Federal Page (8/24/06), at p. A19.

¹⁴ American internationalists‘ include business leaders, as well. In a recent Financial Times op-ed article, IBM chief executive Sam Palmisano argues in favor of more globally, and thus, culturally integrated multinational companies that open up access to and freely share technologies and business standards with other countries and their industries, which are now made more easily available by the evolving global information technology and communications infrastructure. He reasons that such information and technology sharing (give-aways) would enable such companies to connect more intimately with partners, suppliers and customers, and most importantly... to engage in multifaceted collaborative innovation. This kind of innovation is much more than the creation of new products, he states. It is also how services are delivered... This kind of innovation changes how business processes are integrated, how companies and institutions are managed, how knowledge is transferred, how public policies are formulated – and how enterprises, communities and societies participate in and benefit from it all.. Today, innovation is inherently global.. But shifting to the model of globally integrated enterprises also presents big challenges for leaders in every sector of society... This will mean significant changes

in organizational culture, new forms of partnership among multiple enterprises and segments of society and new standards for managing a complex marketplace. ***In other words, companies will have many masters, including and beyond governments*** (see below)*. Interestingly, if U.S. companies don't subscribe to his thinking, the alternative is unthinkable. These changes will take time. But *the alternative to global integration is not appealing: left unaddressed, the issues surrounding globalization will only grow. People may ultimately elect governments that impose strict regulations on trade or labour, perhaps of a highly protectionist sort. Worse, they might gravitate toward more extreme forms of nationalism, xenophobia, and anti-modernism [a oblique reference to terrorism]* (emphasis added). See Samuel Palmisano, *Multinationals Have Been Superseded*, Financial Times (6/12/06), at p. 15. The editors of the Financial Times, of course, picked up on this rhetoric. Sam Palmisano, head of International Business Machines, today calls on multinationals to evolve into a new type of corporation *if they are to avoid an anti-globalization backlash* that leads to the election of governments hostile to the interests of big business (emphasis added). See Francesco Guerrera and Richard Waters, *IBM Chief Wants End to Colonial Companies*, Financial Times (6/12/06), at p. 1. It is arguable whether Mr. Palmisano is actually apologizing for the success of American capitalism/globalization, and that he actually recommending that Americans sacrifice their technologies and innovations (i.e., their constitutionally protected private property rights) for the greater good of global society to avoid mass anti-globalization activism. *See also, *How to Regulate the Global Corporation*, Editorial, Financial Times (6/13/06), at p. 14. Mr. Palmisano's principal suggestion is to develop a global regulatory system through better cooperation between regulatory agencies (as apposed to creating a single behemoth). Companies might operate globally diverse supply chains. But they are still technically domiciled in one place and beholden to one set of shareholders. It should be the task of politicians everywhere to encourage greater cooperation between jurisdictions and to improve corporate governance. But this can only be part of the answer. As the world continues to integrate, reconciling tensions between efficient global economics and local democratic politics will test everyone's imagination. *Ibid.*

¹⁵ Some American economists, as well, fall into **the internationalist-apologist camp**, such as Joseph Stiglitz, a well-known spokesperson for political liberalism (social justice, environmentalism). According to a recent New York Times book review, Stiglitz's new book entitled,

Making Globalization Work, focuses on how neoliberal economics – derided as *market fundamentalism* ‘or the Washington consensus’ – **vandalized the developing world** (emphasis added). It also describes how smart people in Washington and New York with the correct ideas can help set the world right. Dr. Stiglitz’s vision for **more equitable globalization** – with caveats about the toughness of the task – entails freer trade (no more loopholes for rich countries or corporate lobbies), **curtailed intellectual property rights** (*monopolies*) and **green accounting** (*factoring resource depletion and ecological damage into G.D.P.*). It also means more transparency in international finance (to curb corruption), debt forgiveness (foolhardy creditors must take responsibility, too) and democracy (less secretive procedures opened to nongovernmental organizations and others). It seemed terribly unfair, he writes, that in a world of richness and plenty, so many should live in such poverty. ‘Unfair it is. Designing a new global trade regime is a snap for Dr. Stiglitz. But how might it be put into place?... Often, he exhorts. **Rich countries, he writes, should simply open up their markets to poorer ones, without reciprocity.**’ As for global enforcement of rules, what is needed is an international tribunal. ‘Would its judges be appointed or elected? Would there be some disincentives, too, for global class-action suits? Details omitted. There is another catch. Developing countries, after getting their fair share, ‘must use the money well,’ he writes. So they’ll need nonkleptocratic governments, uncensored media, enforced property rights, the rule of law. How to acquire them? He wants ‘developed country governments to provide role models,’ and to inhibit the collusion in malfeasance abroad. **Intent on championing regulation over an unfettered market, he turns to postwar Japan and South Korea as examples of how governments can pilot an economic boom, though this view has been undermined on empirical grounds.** He commends China for go-slow liberalization, without noting that the late-70’s dismantling of peasant communes was a liberalizing big bang or that critics inside China today accuse the central government of abandoning economic liberalization, under the guise of gradualism, to gorge on the spoils of office (emphasis added). See Stephen Kotkin, *Aiming to Level a Global Playing Field*, New York Times, *Off the Shelf* (9/3/06), at: (http://www.nytimes.com/2006/09/03/business/yourmoney/03shelf.html?_r=2&oref=slogin&oref=slogin). See also Joseph Stiglitz, *We Have Become Rich Countries of Poor People*, *Financial Times Comment* (9/8/06), at p. 11. We see **an unfair global trade regime that impedes development** and an unstable global financial system in which poor

countries repeatedly find themselves with unmanageable debt burdens... Globalization seems to have unified so much of the world against it, perhaps because there appear to be so many losers and so few winners... Growing inequality in the advanced industrial countries was a long predicted but seldom advertised consequence: full economic integration implies the equalization of unskilled wages throughout the world... ***Unfettered globalization actually has the potential to make many people in advanced industrial countries worse off, even if economic growth increases***... The Scandinavian countries have shown there is another way. Investment in education and research and ***a strong safety net*** can lead to a more productive and competitive economy. At the core of many of globalization's failures is a simple fact: economic globalization has outpaced the globalization of politics and mindsets (emphasis added). *Ibid.*

¹⁶ In November 2004, Brazil and Argentina alleged that WIPO [the World Intellectual Property Organization] even though being a UN Agency - was not acting in accordance with the Millennium Development Agenda goal. A development agenda was co-sponsored by a group of other twelve countries, referred to as the Group of Friends of Development. The GFD proposed reforms at WIPO to guarantee a transparent, pro-development and balanced agenda for WIPO's mandate, governance, and norm-setting, as well as equal representation in the Organization's activities, and increase access to knowledge and technology, together with technical assistance programs to harmonize developing countries' legislation to the standard of developed countries. See Introduction - Workshop: Global Intellectual Property From a Brazilian Perspective, University of Oxford Centre for Brazilian Studies (11/4/05), at: (<http://www.brazil.ox.ac.uk/confreports/IP%20report%20final3.pdf>).

¹⁷ The doctrine of sustainable development is arguably a social welfare doctrine. While it has been advertised as a triad entailing three primary concerns - environment, social *and* economic - it nevertheless continues to be described in a negative fashion that ignores the economic component, and as a necessary remedy to the failures of free market capitalism, unbridled economic growth, rapid technological innovation and strong legal protection of proprietary contract and intellectual property rights. The implication is that these pursuits are inherently inconsistent with sustainable development, which must instead focus primarily on ensuring health and environmental protection on a global level through wealth, health and other know-how redistribution. Indeed, the negative paradigm of sustainable development emphasizes how the new millennium presents many

dangerous challenges (global hazards) that must be met by slower economic and technological growth and development, and expansive pro-environment and health policies that have primacy over economics. Hence, there is always an urgent need for more and more ant-market regulations and related technical standards that effectively weaken individual private property rights, and for more social standards and third-party audit and verification schemes (accountability mechanisms) to implement them. The EU, Brazil and other developing nations (former European colonies) have increasingly called upon World Trade Organization and United Nations member governments to infuse this negative notion of sustainable development into the established international legal order for purposes of changing it. See Lawrence A. Kogan, *Precautionary Preference: How Europe's New Regulatory Protectionism Imperils American Free Enterprise*, Institute for Trade, Standards and Sustainable Development, Inc. (July 2005), at p. 93, at: <http://www.itssd.org/White%20Papers/PrecautionaryPreference-EURegProtectionism-FULLVERSION.pdf>).

¹⁸ In a very revealing 2001 interview, Reason Magazine questions Stanford economist Paul Romer about how to deal with anti-globalization protestors who don't understand the New Growth Theory of developmental economics he has articulated. How would you convince protestors of the benefits of globalization? [As stated by Romer,]... First, just look at the facts. The protestors are amazingly ignorant about what has happened in terms of, say, life expectancy. *Life expectancy for people in the poorest countries of the world is now better than life expectancy in England when Malthus was so worried about it.* Then you look at the variation of experience between the poor countries that have done best and the ones that have done worst, and try to see what the correlations are. Which countries did best? ***Was it the countries that adopted the market most strongly, embraced foreign investment, and tried to adopt property rights? Or was it the other countries? The evidence again is clear.*** One of the untold stories about the '80s and '90s was the really dramatic turnaround in the developing world that took place on this issue. If you track the legislative history on foreign investment, you see a colonial legacy, even as late as the '70s, where developing countries have laws designed to keep corporations out. Then there's this dramatic turnaround as they saw the benefits that a few key economies received by inviting in foreign investment. *It's not the people from the developing world who are making the argument that Nike is a threat to their sovereignty or well-being. It's people in the United States. The people in the developing world understand pretty clearly where their self-interest lies...* For

Europe and the United States, I think we need to be thinking very hard about how we can restructure our institutions of science. How can we restructure our system of higher education? How can we make sure that it has the benefits of vigorous competition and free entry, especially of those bright young people who might do really different kinds of things? We should not assume that we've already got the ideal institutions and the only thing we need to do is just throw more money at them. Unfortunately, I think a lot of countries have a long way to go to catch up to the state where we are in the United States -- and I'm not that happy about where we are in the United States. *Many European countries simply have not recognized the power of competition between institutions. So they have monolithic, state-run university systems. That stifles competition between individual researchers and slows down the whole innovative process. They also need to let people move more flexibly from the university into the private sector and back.* This is something that many countries watching venture capital start-ups have become aware of, although they've been slower to get their institutions to adjust' (emphasis added). See Post-Scarcity Prophet - Economist Paul Romer on Growth, Technological Change, and an Unlimited Human Future, Interview with Ronald Bailey, Reason Magazine (Dec. 2001), at: <http://www.reason.com/0112/fe.rb.post.shtml>).

¹⁹ See Lawrence A. Kogan, 'Enlightened' Environmentalism or Disguised Protectionism: Assessing the Impact of EU Precaution-Based Standards on Developing Countries, National Foreign Trade Council (April 2004), at: http://www.wto.org/english/forums_e/ngo_e/posp47_nftc_enlightened_e.pdf); Brett D. Schaefer, How Economic Freedom Is Central to Development in Sub-Saharan Africa, Heritage Lecture #922, *supra*.

²⁰ I do not assert that men living in democratic communities are naturally stationary; I think, on the contrary, that a perpetual stir prevails in the bosom of those societies, and that rest is unknown there; but I think that men bestir themselves within certain limits, beyond which they hardly ever go. *They are forever varying, altering, and restoring secondary matters; but they carefully abstain from touching what is fundamental.* They love change, but they dread revolutions. Although the Americans are constantly modifying or abrogating some of their laws, they by no means display revolutionary passions. It may be easily seen from the promptitude with which they check and calm themselves when public excitement begins to grow alarming, and at the very moment when passions seem most roused, that they dread a revolution as the worst of misfortunes and that every one of them is

inwardly resolved to make great sacrifices to avoid such a catastrophe. *In no country in the world is the love of property more active and more anxious than in the United States; nowhere does the majority display less inclination for those principles which threaten to alter, in whatever manner, the laws of property.* I have often remarked, that theories which are of a revolutionary nature, since they cannot be put in practice without a complete and sometimes a sudden change in *the state of property* and persons, are much less favorably viewed in the United States than in the great monarchical countries of Europe; if some men profess them, the bulk of the people reject them with instinctive abhorrence. I do not hesitate to say that most of the maxims commonly called democratic in France would be proscribed by the democracy of the United States. This may easily be understood: in America men have the opinions and passions of democracy; in Europe we have still the passions and opinions of revolution (emphasis added). See Alexis de Tocqueville, *Democracy in America*, Book II, Chap. XXI *Why Great Revolutions Will Become More Rare*, at: (http://xroads.virginia.edu/~Hyper/DETOC/ch3_21.htm). Perhaps these observations hold equal relevance today, among those concerned about promoting economic and political freedom abroad in order to quell the modern day threat of international terrorism.

²¹ Remnants of old socialist/communist thinking, such as statism, privileged elitism, paternalism, and an 'above the law' ethic for the privileged elite continue to pervade Latin American countries, including Brazil. Such thinking is practiced by ideological political groups that take advantage of Brazil's high illiteracy rates and poor access to information. Civil society also has a growing influence within Brazil and it often manipulates public opinion by distorting factual truths. In some cases, civil society works cooperatively with entrenched socialist governments to resurrect the failed 'property-less' society of prior Marxist periods. This can prevent countries like Brazil from promoting recognition and enforcement of private IPRs in order to meet the challenges of the current science and technology era. See Antony P. Mueller, *The Ghost That Haunts Brazil*, Ludwig von Mises Institute (8/5/02), at: (<http://www.mises.org/story/1020>); Augusto Zimmermann, *In Brazil The Law Is Never For You When You Have Friends*, *Brazzil Magazine* (1/23/06), at: (<http://www.brazzil.com/content/view/9509/78>) and (<http://www.hacer.org/current/Brazil096.php>); Augusto Zimmermann, *The Brazilian Landless Movement Won't Rest Until They Get Their Revolution*, *Brazzil Magazine* (10/25/05), at: (<http://www.brazzil.com/content/view/9449/79>) and

(<http://www.hacer.org/current/Brazil087.php>); Augusto Zimmermann, Who Will Save Democracy in Brazil? The Left Has Shown That It Won't, Brazzil Magazine (1/11/06), at: (<http://www.brazzil.com/content/view/9503/78>); Augusto Zimmermann, In Brazil Work Is A Dirty Word Unless You Hold Public Office, Brazzil Magazine (2/3/06), at: (<http://www.brazzil.com/content/view/9517/78>) and (<http://www.hacer.org/current/Brazil097.php>); Aleksander Boyd, São Paulo Forum: The Backbone of Communism & Terrorism Spread in Latin America – Interview With Olavo de Carvalho, VCrisis (11/21/05), at: (<http://www.vcrisis.com/index.php?content=letters/200511210932>) and (http://www.olavodecarvalho.org/textos/vcrisis_interview_1.htm).

²² One would not be mistaken to assert that, although Brazil constitutes the largest Catholic country in the world, the Brazilian clergy comprises one of the main ruling groups that have done its uttermost to undermine the rule of law in this country. While some clergymen, to be fair, do favour the rule of law, *other prefer to instead promote in its place an understanding of class struggle' based on radical Marxist principles of revolutionary socialism. Those of such an ideological orientation believe that private property and free initiative are routes to hell*, the only corrective of which is a violent socialistic revolution to lead the nation toward a sort of 'tropical paradise' or 'God's Kingdom on Earth' (emphasis added). See Augusto Zimmermann, The Church Is Keeping Marx Alive in Brazil and Undermining the Rule of Law Brazzil Magazine (5/10/06), at: (<http://www.brazzil.com/content/view/9599/78/>)

²³ As counter-intuitive as it may seem, there are even some libertarian ideologue extremists who, lacking any business understanding or background, believe that IP rights are too unnatural (counter to pure laissez faire, state of nature' competition - anarchy) for their liking. And, they have difficulty comprehending that there exist different types and classes of private property that may have slightly different treatment under the U.S. Constitution, or federal statutory and common law. They have even employed economic theory to arrive at contorted results that conflict with basic human nature and suit their ideological purposes. See [Michele Boldrin](#) and [David K. Levine](#), The Case Against Intellectual Monopoly, Federal Reserve Bank of Minneapolis Research Department Staff Report 339 (June 2004), at: (<http://minneapolisfed.org/research/sr/sr339.pdf>); [Michele Boldrin](#) and [David K. Levine](#) *Against Intellectual Monopoly*, (Nov. 2005), at: (<http://levine.sscnet.ucla.edu/general/intellectual/against.htm>). It is

common to argue that intellectual property in the form of copyright and patent is necessary for the innovation and creation of ideas and inventions such as machines, drugs, computer software, books, music, literature and movies. In fact intellectual property is not like ordinary property at all, but constitutes a government grant of a costly and dangerous private monopoly over ideas. We show through theory and example that intellectual monopoly is not necessary for innovation and as a practical matter is damaging to growth, prosperity and liberty. *Ibid.* Jim Harper, Director of Information Policy Studies at the Cato Institute, a known extremist libertarian font, is another such advocate. He recently hosted a CATO conference to debate the thesis of this book. See Intellectual Monopoly, The Technology Liberation Front (4/26/06), at: (<http://www.techliberation.com/archives/038409.php>): The Big CATO Conference Wrap-Up: The Debate That Wasn't, Techdirt, at: (<http://www.techdirt.com/articles/20060428/1516211.shtml>). See also, Privacilla Editor Joins Cato Institute – Harper Will Continue to Edit Privacilla, Expand Repertoire to Full Array of Information Policy Issues (9/17/04), at: (<http://www.privacilla.org/releases/press031.html>).

²⁴ [I]n the United States... significant pressure is building for patent reform ... [There are]... two major problems with the current patent regime in the United States... the cost problem and the quality problem. The cost problem arises from two sources. First, the process of securing global patent protection is unnecessarily costly and inefficient, and, second, the cost of litigation required to enforce one's exclusive rights is excessive... Even though it is now possible to use a common application to secure patent protection in most countries, the patent offices in the US, the European Union, and Japan each independently determine whether an applicant's claims are novel, useful, and non-obvious to those skilled in the relevant arts... Our investigation found that the cost of enforcing a patent is much greater in the United States than in Europe or Japan. Part of the difference is due to features in US law that introduce highly subjective elements into litigation, and thus require an extraordinarily costly and time-consuming process of discovery to establish facts and motivations. We found four specific legal doctrines – all unique to the United States – that in combination significantly raise the cost of litigation... With the surge in global patenting that occurred during the boom of the 1990s came a growing perception that many patents were being granted that failed the common-sense test for novelty or that appeared to lack a perceptible inventive step [-]... the quality problem ... Such inventions

may be novel (in the sense of having no exact precedent), but common sense tells us that they would be obvious to a person possessing ordinary skill in the relevant arts. Some have argued that the granting of low-quality patent is simply a consequence of the overwhelming increase in applications, which have grown much faster than the pool of trained examiners. But we found that the problem has another important dimension. *Most of* the patents failing a common sense test for novelty or non-obviousness were issued in new areas of technology, such as genomics and internet-enabled business methods... Our diagnosis was that the US patent system is not well designed to cope quickly and effectively with emerging areas of technology... The failure to cope effectively with emerging technologies is also attributable to the time and cost required to clarify standards of patentability through litigation. *See* Presentation by Richard C. Levin, Patents in Global Perspective, Sir Purshotamdas Thakurdas Memorial Lecture at the Indian Institute of Banking and Finance (Jan. 2005), at: (http://www.domain-b.com/economy/general/2005/20050112_perspective.html).

²⁵ For example, recent hearings held by the U.S. Senate Judiciary Committee, Subcommittee on Intellectual Property, highlight the current debate within the U.S. about the scope and nature of legal and administrative mechanisms currently available within the U.S. patent system to address the competing private interests at stake. *See* Perspectives on Patents: Post-Grant Review Procedures and Other Litigation Reforms, United States Senate, Committee on the Judiciary (5/23/06), at: (<http://judiciary.senate.gov/hearing.cfm?id=1911>). *See also*, Anne Broache Senators Offer Sweeping Patent System Changes, CNET News.com (8/4/06) at: (http://news.com.com/2100-1028_3-6102493.html); Senator Hatch Introduces Patent Reform Legislation, The Senator's Press Releases (8/7/06) at: (http://hatch.senate.gov/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=1642); Leahy, Hatch Introduce Sweeping Patent Reform Bill - Bipartisan Legislation Overhauls U.S. Patent Code, Administrative Review Process, U.S. Senator Patrick Leahy Press Release (8/4/06), at: (<http://leahy.senate.gov/press/200608/080406.html>); Declan McCullagh, A Fix For a Broken Patent System?, CNET News.com (6/8/05), at: (http://news.com.com/A+fix+for+a+broken+patent+system/2100-1028_3-5737961.html?tag=nl); Donna Meuth, Proposed Patent Reforms Will Change Business Pace, Boston Business Journal, Vol. 25, No. 34 (Sept. 23-29, 2005), at: (http://www.wilmerhale.com/files/upload/BBJ_Meuth.pdf); The

Patents Depend on Quality Act of 2006 , HR 5096, at: (http://www.house.gov/berman/pdf/pkb_009_xml.pdf), and the accompanying overviews at: (http://www.boucher.house.gov/index2.php?option=com_content&do_pdf=1&id=678) and (http://www.house.gov/list/speech/ca28_berman/Patent_Quality.html).

²⁶ The political debate about the scope of patent rights has recently spilled into the courts. *See Ebay Inc., et al., v. MercExchange, LLC*, 547 U. S. ____ (2006), 126 S. Ct. 1837, 1839 (2006), at: (<http://www.supremecourtus.gov/opinions/05pdf/05-130.pdf>). The U.S. Supreme Court reversed the decision of the Court of Appeals for the Federal Circuit, which had itself reversed the decision of a lower federal district court. The appellate court had ruled that a general rule ‘, [existed] unique to patent disputes, that a permanent injunction will issue once infringement and validity have been adjudged ‘except in the unusual‘ case, under exceptional circumstances‘ and in rare instances... to protect the public interest.‘ In reversing the appellate court and remanding the case back to the district court, the Supreme Court unanimously ruled that such an automatic rule did not exist. Rather, it applied the traditional rule of equity which places the burden on the petitioner to first prove irreparable harm before permanent injunctive relief can be granted. The traditional four-factor test applied by courts of equity when considering whether to award permanent injunctive relief to a prevailing plaintiff applies to disputes arising under the Patent Act. That test requires a plaintiff to demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. The decision to grant or deny such relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion. These principles apply with equal force to Patent Act disputes. [A] major departure from the long tradition of equity practice should not be lightly implied. *Weinberger v. Romero-Barcelo*, 456 U. S. 305, 320. Nothing in the Act indicates such a departure. *Ibid.*, at p. 1. In his concurring opinion, Justice Kennedy reasoned that, Both the terms of the Patent Act and the traditional view of injunctive relief accept that the existence of a right to exclude does not dictate the remedy for a violation of that right.. In cases now arising trial courts should bear in mind that in many instances the nature of the patent being enforced and the economic function of the patent holder present considerations quite

unlike earlier cases. An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees... For these firms, an injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent. See *ibid.* When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest. In addition injunctive relief may have different consequences for the burgeoning number of patents over business methods, which were not of much economic and legal significance in earlier times. (Kennedy, J., concurring).

²⁷ The U.S. Supreme Court is scheduled to hear two other decisions concerning the scope of patents this coming fall term. See High Court Hears PFF, Takes Cert in *KSR v. Teleflex*, The Progress and Freedom Foundation Media Advisory (6/26/06), at: (http://gal.org/pff/notice-description.tcl?newsletter_id=2191067). In *KSR International Co. v. Teleflex Inc. and Technology Holding Co.*, the Court will consider the definition of the 'obviousness' requirement under U.S. patent law. The case involves patents covering 'gas pedal' technology for cars and light trucks, which the petitioner was accused of infringing. The U.S. Court of Appeals for the Federal Circuit reversed an earlier court decision that had found that the patents held by respondent Teleflex were 'obvious' and therefore invalid. See Petition for a Writ of Certiorari (April 6, 2005), at: (http://patentlaw.typepad.com/patent/4_2D06_2D05Certpetition_formatted.pdf). In *Laboratory Corp. of America Holdings v. Metabolite Laboratories*, the US Supreme will chart the frontiers of patentability and consider whether the correlation of a result of a blood test with a vitamin deficiency diagnosis can be patented... Although *Lab Corp.* is a case about a patent on a medical diagnostic method, it has been seen by some as an opportunity to roll back patent protection of business methods' and to do so through the courts, rather than through legislation. *Lab Corp.* has become a test case because the patent it involves is directed not at a device, but essentially to the act of observing a correlation - between a protein found in the human blood stream and a certain vitamin deficiency. So, the patent strikes some critics as involving a claim to an abstract idea or scientific principle that should be off-limits under the U.S. patent laws... [T]he [C]ourt's decision could fundamentally change the patent protection available not

only in regard to medical diagnostics, but also for business and financial methods that currently are patentable. See Supreme Court to Rule on Benchmark Patent Cases in 2006 – A Q & A With White & Case’s Scott Weingaertner, (1/19/06), at: (<https://www.whitecase.com/news/detail.aspx?news=956>). These cases will be decided in light of a recent business method patent ruling issued by the U.S. Patent and Trade Office Board of Appeals that defined the boundary of patentability with respect to business methods. In *In Re Lundgren*, [t]he Board of Appeals reversed a rejection of a patent application on a method of determining executive compensation, holding that it is not necessary that an invention involve technology in order to receive patent protection... The Patent Office [had previously] rejected the application as failing to meet a technology threshold for patentability. On appeal, the Board of Appeals reversed. The Board rejected the notion of a technology litmus test for patentability... Far more protection is available for inventions in the US than in other jurisdictions. Most, if not all, foreign countries have a technology requirement rejected in the *Lundgren* case and few business methods can pass that test, as applied by foreign patent offices. *Ibid.*

²⁸ See e.g., Dianne N. Irving, Revisiting the Bayh-Dole Act (1980): Spawned Big Biotech, Now Has Opposite Debilitating Effects, Lifeissues.net (9/22/05), at: (http://www.lifeissues.net/writers/irv/irv_104bayh_dole.html), citing Clifton Leaf, The Law of Unintended Consequences, Fortune Magazine (9/19/05), at: (<http://www.fortune.com/fortune/fortune75/articles/0,15114,1101810,0.html>); Bayhing for Blood or Doling Out Cash?: A landmark law has allowed American universities to profit by patenting their innovations. But the costs are adding up. The Economist (12/20/05), at: (http://www.economist.com/science/displayStory.cfm?story_id=5327661)

²⁹ See David Mowery, Milton W. Terrill, Venice II, Updating and Fleshing out the Development Agenda United Nations Industrial Development Organization (10/3/02), at: (<http://www.unido.org/en/doc/7983>). The Bayh-Dole Act has been widely cited without much evidence as a key factor in the so-called new economy and competitive revival of the United States in the 1990s, back when the US was, people thought, being competitively revived. And a number of other economies, particularly in the OECD, but also increasingly developing economies are debating, or actually have undertaken initiatives, modeled very consciously on the Bayh-Dole Act, precisely to encourage university industry technology

transferring and commercialization. Is Bayh-Dole a model for other economies? I think the answer there is a qualified no *Ibid.* See also, David C. Mowery and Bhaven N. Sampat, The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?, *The Journal of Technology Transfer*, Vol. 30 No.s 1-2 (Dec. 2004), at pp. 115-127, abstract at: (<http://springerlink.metapress.com/inxpqj4510lgpv2qxvsy1nf/app/home/contribution.asp?referrer=parent&backto=issue,9,19;journal,7,67;linkingpublicationresults,1:104998,1>); Sara Boettiger & Alan B Bennett, Bayh-Dole: If We Knew Then What We Know Now, *Nature Biotechnology* 24, 320 - 323 (2006), at: (<http://www.nature.com/nbt/journal/v24/n3/pdf/nbt0306-320.pdf>); David C. Mowery, Richard R. Nelson, Bhaven N. Sampat and Arvids A. Ziedonis, The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980 Research Policy, Vol. 30 Issue 1 (2001), at pp. 99-119.

³⁰ Essential Inventions is asking the Bush Administration to adopt a simple rule -- U.S. consumers should not pay more for drugs invented on government grants," said *Essential Inventions President James Love*. But NIH rejected this proposal, arguing that companies that obtained licenses to government-funded inventions have a duty only to commercialize the inventions. NIH does not have authority to consider the price at which a product is sold, and the impact of the price on access, the agency ruled (emphasis added). See Robert Weismann, Drug Price Gouging OK'd, *Multinational Monitor* Vol. 25 No. 9 (Sept. 2004) at: (<http://multinationalmonitor.org/mm2004/09012004/september04front.html>).

³¹ These debates have recently been elevated in the U.S. Senate to proposed federal legislation – an amendment to U.S. patent law – which **arguably violates the U.S. Bill of Rights Fifth Amendment Takings clause**. On May 25, 2006, Senator Patrick Leahy (D-VT), the ranking Democrat on the Senate IP subcommittee, introduced legislation – S.3175, entitled, The Life-Saving Medicines Export Act of 2006 – A bill to amend title 35, United States Code, with respect to establishing procedures for granting authority to the Under Secretary for Commerce for Intellectual Property and Director of the Patent and Trademark Office to grant compulsory patent licenses for exporting patented pharmaceutical products to certain countries consistent with international commitments made by the United States, and for other purposes... See Congressional Record – Senate (May 25, 2006), S5245-5252, at p. S5245, at: (<http://frwebgate.access.gpo.gov/cgi->

[bin/getpage.cgi?dbname=2006_record&page=S5245&position=all](#)).

Under my bill, U.S. generic manufacturers would be allowed to make generic versions of patented drugs *without the consent of the patent holders*. Those patent holders would receive compensation in the form of a royalty payment under a so-called compulsory license³² and the generic companies would then be required to sell those less-expensive generic drugs only to least-developed or developing nations. Use of a compulsory license occurs when Congress determines that there is an important need which should be addressed (emphasis added). STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS -- (Senate - May 25, 2006), *Ibid.*, at p. S5246, at: http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=S5246&dbname=2006_record). A pharmaceutical product for purposes of the bill is defined as, any patented pharmaceutical product, or pharmaceutical product manufactured through a patented process, including any drug, active ingredient of a drug, diagnostic, or vaccine needed to prevent or treat public health problems. S. 3175 Sec. 5(a)(7) at Cong. Rec. pp. 5250-51.

³² The Leahy bill, if adopted, would implement a proposed amendment to the WTO TRIPS Agreement provisions entitling pharmaceutical exporting country governments to issue compulsory licenses on privately owned patented drugs for the benefit of developing countries that lack their own drug manufacturing capacity. The amendment will go in effect, for those nations which adopt it, once 2/3 of the member nations adopt it. The current waiver approach, allowing nations to implement it now, will remain in place until the permanent amendment is adopted. Section 3 of the Leahy bill specifically requires the Director of the United States Patent and Trademark Office to issue a compulsory license (permission to make and sell a patented product under this new Act) to permit generic companies to make and export medicines under the terms of WTO international agreements under several conditions. Section 3 of the Leahy bill also grants the U.S. government (i.e., the PTO Commissioner) the authority to determine the price of the drugs and what the royalty rate shall be. The holder of the compulsory license shall pay a royalty to the patent holder, as determined by the Director of the PTO within a limited range of possible rates set forth in the bill, taking into account such factors as humanitarian needs, the economic value to the importing nation, and the need for low-cost pharmaceutical products by persons in the importing nation... The maximum royalty for any shipment shall not exceed 4 percent times the commercial value of the pharmaceutical

products to be exported under this Act under that supply agreement. Thus, Section 3 of the bill only requires that Efforts must have been made by the generic company to buy the right to make and sell the medicine under normal business arrangements with the patent holders. It does, not, however, require that *reasonable* efforts be made to negotiate a *fair arms-length* price. Moreover, Section 3 of the Leahy bill would grant broad discretion to the PTO Commissioner to issue compulsory licenses for the benefit of *multiple* developing countries at the same time, and, without any benchmarks, to arbitrarily waive the provisions of the bill when deemed necessary to achieve the bill's underlying objective. In addition, the Director may accept combined applications from multiple eligible countries. Note that *in emergency situations the Director may waive provisions of the bill in a manner consistent with the WTO agreements* (emphasis added). Section 4 of the bill expressly declares that (***Not a patent infringement***): This section makes clear that compulsory licenses issued under this Act shall not be considered an infringement of a patent (emphasis added). Consequently, the Leahy bill would allow U.S. generic drug firms to manufacture low-cost generic versions of patented medicines for export to nations in need when a voluntary agreement between the generic and the brand-name U.S. compan[ies] cannot be negotiated. Those patent holders would get royalty payments, and the generic firms would then be required to sell those less-expensive drugs only to the poorest countries... Leahy's bill would amend U.S. patent law to allow implementation of the low-cost drug provisions of a 148-nation agreement completed last year. The Bush Administration itself has not proposed any implementing legislation... See Leahy Unveils Bill to Foster Low-Cost Drugs for World's Poorest, Press Release (5/21/06), at: (<http://leahy.senate.gov/press/200605/051906.html>). The European Union previously promulgated its own regulation to implement the proposed WTO waiver. See discussion *infra*.

³³ It is not surprising that Senator Leahy justifies the need to enact his bill *on moral grounds*, much like Brazil's President Lula Inacio da Silva justifies his repeated threats against U.S. pharmaceutical companies to issue compulsory licenses and to abrogate drug patents in order to secure at-or-below cost HIV/AIDS drugs. Senator Leahy's bill seeks to accomplish the same policy objective thus far achieved by Brazilian President Lula: to nationalize (take) ALL privately developed pharmaceutical products needed to treat serious diseases (foreign private property) under the suspicious guise of Brazilian public interest, without ensuring the payment of fair market value (just compensation), as required by the U.S. Constitution and the

TRIPS Agreement. *This is a moral issue. I am working with a number of religious groups, humanitarian organizations, international assistance groups, and generic drug companies on this effort* (emphasis added). *Ibid.* In addition, Senator Leahy justifies this taking of private property for public use without just compensation as necessary to enhance America's image in the world and to contain diseases in other nations before they strike Americans and others traveling abroad, who can then bring the diseases with them back to America. Thus, the bill addresses both the urgent needs of millions of low-income families in impoverished nations while protecting the interests of the patent owners of these life-saving medicines and will hopefully help enhance America's image in the world. *For those only interested in self-interest rather than humanitarian aid, note that because of the globalization of travel our Nation is at risk from failure to contain diseases in other nations.* America has a strong self-interest in combating diseases in foreign nations. A surprising number of new diseases have emerged in recent years. Some of these new diseases are variations of existing diseases. The volume of people and cargo going to and from distant nations is astounding. According to *Rx for Survival*³⁴ by Philip Hilts, if you count only travel between nations with a heavy burden of disease and those with less disease, more than a million people a week are making the trip. The more viruses and bacteria mutant inside animals and people, and the more people and goods travel throughout the world, the more residents living in the United States are at risk of being harmed by dangerous diseases. STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS -- (Senate - May 25, 2006), *Ibid.*, Cong. Rec.-Senate at p. S5246, *supra*.

³⁴ It is arguable that the patent and R&D debates spawned within the U.S. by the American apologists seriously threaten constitutionally protected U.S. exclusive private property rights abroad. For one thing, it is almost certain that these debates are being closely observed, monitored, and perhaps, assisted by foreign government lobbying efforts. If foreign governments either believe, or make it appear, that we, in America, are uncertain of what the scope of private property rights, including IPRs, should be, they will *opportunistically* seek to take advantage of our uncertainty to the detriment of U.S. private property owners abroad. We must ensure that the type of IP message we convey abroad is a positive one, and that it will be perceived as such to the emerging BRIC economies - Brazil, Russia, India and China - whose IP regimes desperately need to be strengthened. We must also consider whether our actions and deeds at home could reasonably be

interpreted as hypocritical. How can we demand that such nations protect our IP *and* invest in their own IP, if we take measures domestically that weaken long established U.S. Constitutional IP protections? We must remember that what we say and do here, in the U.S., concerning IP rights (i.e., patents, data exclusivity, trade secrets, etc.) will reverberate throughout the world and have an impact on both the international IP framework and other countries' IP laws and policies. If we demand that the international community respect and enforce private property rights, shouldn't we, as the international vanguard of IP rights, also embrace them at home? How can we call on other countries to respect and protect U.S. private intellectual property rights when we steadily chip away at those same rights here in America?

³⁵ Much has been written about the polarization of leftwing politics in Latin America, between the radical populism of Venezuela and Bolivia at one end and the pragmatic orthodoxy of center-left governments in Chile and Uruguay at the other. Mr. Lula da Silva has sought to steer a middle course, matching commitment to economic stability with concern over social issues. Yet in its policy for South America, Brazil has made leadership its priority. In the past... [Brazil's] policy was designed to promote development at home, through trade and investment, and to maintain good relations with Brazil's neighbors...

[But under Lula, leadership has been pursued for its own sake rather than to serve other interests' [says Peter Hakim of the Inter-American Dialogue]... While sticking to economic orthodoxy at home, Mr. Lula has been much friendlier with populists such as Hugo Chavez of Venezuela, Mr. Morales and Nestor Kirchner of Argentina... [but] doesn't treat Chile and Uruguay the same way'... *Mr. Lula da Silva... began his political life as a fierce proponent of policies espoused by Mr. Chavez and Mr. Morales, including a deep distaste for the International Monetary Fund, the Washington consensus and neo-liberalism* '. It was just before taking office, when investors' fears over his politics sent prices of Brazilian assets plummeting, that... da Silva converted to economic orthodoxy. This is the big contradiction', says Rubens Barbosa, former [Brazilian] ambassador to London and Washington. *At home, he is following economic policies that he and his party are against, and internationally he is following policies that he and his party support but can't maintain.*' Between a swing to populism at home and a move to more pragmatic foreign policy, the latter appears more likely – though some analysts fear the former should Mr. Lula da Silva win a second term at elections in October. *What causes concerns among many investors in Brazil is that... Brazil's*

embrace of pragmatism and orthodoxy may owe more to expediency than conviction (emphasis added). See Jonathan Wheatley and Daniel Dombey, 'Bolivian Nationalisation Leaves Lula's Foreign Policy in Disarray', *Financial Times* (5/15/06), at p. 6.

³⁶ ... Brazil has developed rapidly, but it still lacks the institutional capacity to manage problems of scale and complexity that only can be handled efficiently by an educated population. The failure to develop human capital is one of the legacies of slavery... one sad aspect of this failure to develop human capital is seen in the response of the political class to the corruption crisis of Lula's government, generating many accusations but few proposals on how to overcome these difficulties. Brazilians are a hardworking people that... still lack the skills to manage the complex systems spontaneously created by a population that has multiplied tenfold over the past century, urbanizing fast and continuously incorporating a vast array of new technologies. Education tends not only to reduce corruption, but also strengthens cooperation and endows people with capacities to develop other opportunities for themselves. Brazil would have a brilliant future if its institutional blockages can be overcome. See Normal G. All, 'Democracy 4: Brazil Needs a New Strategy - Lula and Mephistopheles', Braudel Papers, Fernand Braudel Institute of World Economics (© 2005), at p.11.

³⁷ The quality of the human capital stock in Brazil is relatively low. Large income differentials generally coincide with a low overall level of human capital endowment. Brazil is one of the countries with the highest degree of inequality in the world and there is substantial evidence that inequality in low-income countries is detrimental to economic growth. Not surprisingly, Brazil scores relatively low on human capital and education indicators given its GDP per capita income levels. Education levels are perhaps the best proxy of human capital. On this measure, Brazil compares poorly... Whether one looks at enrolment ratios or average years of schooling, the conclusion is the same. The overall level of education in Brazil is relatively low, but the upside potential is substantial. See Markus Jaeger, 'Brazil: O país do futuro? Economic scenarios for the next 15 years', Deutsche Bank Research (5/30/06), at p. 3, at:

(http://www.dbresearch.com/PROD/DBR_INTERNET_DE-PROD/PROD000000000199361.pdf).

³⁸ New Growth Theory divides the world into 'ideas' and 'things.' What do you mean by that?... [According to Stanford University economist Paul Romer,] *The paper* that makes up the cup in the coffee shop *is a thing*. The insight that you could *design* small, medium, and large cups so that they all use the same size lid -- *that's an idea*. The

critical difference is that only one person can use a given amount of paper. Ideas can be used by many people at the same time. What about human capital, the acquired skills and learned abilities that can increase productivity? *Human capital is comparable to a thing. You have skills as a writer, for example, and somebody – [R]eason [Magazine] -- can use those skills. That's not something that we can clone and replicate. The formula for an AIDS drug, that's something you could send over the Internet or put on paper, and then everybody in the world could have access to it*[that's an *idea* says Romer]. Human capital is how we make ideas. It takes people, people's brains, inquisitive people, to go out and find ideas like new drugs for AIDS. Similarly, when we make human capital with kids in school, we use ideas like the Pythagorean theorem or the quadratic formula. *So human capital makes ideas, and ideas help make human capital. But still, they're conceptually distinct.* (emphasis added). See Post-Scarcity Prophet - Economist Paul Romer on Growth, Technological Change, and an Unlimited Human Future, Interview with Ronald Bailey, Reason Magazine, *supra*.

³⁹ According to New Growth Theory economist Paul Romer, ... there are [different] stages in the development of ideas. Think about the basic science that led to the discovery of the structure of DNA. *There are some kinds of ideas where, once those ideas are uncovered, you'd like to make them as broadly available as possible, so everybody in the world can put them to good use. There we find it efficient to give those ideas away for free and encourage everybody to use them. If you're going to be giving things away for free, you're going to have to find some system to finance them, and that's where government support typically comes in...* Basic research got government support; for applied product development, we'd [the United States] rely on the market. Over time, people have recognized that that's a pretty artificial distinction. What's becoming more clear is that it's actually the combined energies of those two sets of institutions, often working on the same problem, that lead to the best outcomes. I think it's important to have a distinct realm of science and a distinct realm of the market, but it's also very good to have interaction between those two. One of the best forms of interaction is for people who work in one to move into the other. *The people in university biology or biochemistry departments complain when they see somebody go on leave from the university and start a company that's going to develop a new drug. That's not the way it was done 30 years ago. But this is the best way to take those freely floating, contentiously discussed ideas from the realm of science and then get them out into the market process, because the*

reality is that there are virtually no ideas which generate benefits for consumers if there's not an intervening for-profit firm which commercializes them, tailors them to the market, and then delivers them. You can point to examples where things jump right from science to benefits for the consumer, but that's the exception, not the rule... Well, some people would say that everything should be patented. The danger is that if you went that far, you could actually slow the discovery process down. There are very good theoretical reasons for thinking that market and property rights are the ideal solution for dealing with things, but there are also strong theoretical reasons for thinking that in the realm of ideas, intellectual property rights are a double-edged sword. You want to rely on them to some extent to get their benefits, but you want to have a parallel, independent system and then exploit the tension that's created between the two (emphasis added). *Ibid.*

⁴⁰ According to one recent report, Despite distortions and injustices institutionalized in chronic inflation, Brazil led all major economies in growth from 1870 to around 1980. Yet high rates of economic expansion have foundered since 1980 on institutional weaknesses leading to surging urban violence, recurrent debt crises and hyperinflation. The list of Brazil's other institutional weaknesses is awesome. In education, barely half of pupils entering the first grade finish primary school and only 37% complete a secondary education, with functional illiteracy common in the higher grades. In Sao Paulo, the world's third largest metropolis with 17 million people, 40% of all heads of households did not study beyond the fourth grade. One-fifth of all births in Brazil are to adolescent mothers ages 15 to 19. According to the World Bank, the richest 20% of Brazilians, including the middle class, gets 65% of all income, against 2% for the poorest 20%. *Ibid.*, at p. 9. ... Today Brazil is a rich, productive country, but it still has too many poor citizens... Not only is Brazil the world's 12th largest economy, but it is a crucible of long-term processes of modernization. Its dismal social statistics hide centers of excellence in both public and private life. See Normal Gall, Democracy 4: Brazil Needs a New Strategy - Lula and Mephistopheles, *Braudel Papers supra*, at p. 10.

⁴¹ ... Brazil appears to have reached unanimity on three points: the existence of the "*mensalão*," or the monthly kickback scheme; the lack of investments in education as the principal cause of our inequality and backwardness; the refusal to take resources from another area to cover the deficit in education... In the Brazilian imagination, education is, at best, a means towards financial success. Even those who invest in their children's education have in mind the future salary that they will earn,

and not the fact that their children will be educated. Besides this, the Brazilian society does not have a common vision... And without a common vision, it has no long-term one. See Cristovam Buarque, Brazil Agrees It Needs More Education But Nobody Wants to Foot the Bill, *Brazzil Magazine* (4/20/06), at: <http://www.brazzil.com/content/view/9581/78>.

⁴² During a series of conferences in the mid-1970's, the Group of 77 [developing countries] formulated its ultimate agenda for restructuring the global economy. The main thrust of the call for the New International Economic Order came during the Sixth Special Session of the UN General Assembly in late spring 1974, where members adopted the Declaration and Program of Action on the Establishment of a New International Economic Order... The NIEO demands were wide-ranging but can be classified into four broad themes: economic sovereignty; trade; aid; and participation. A substantial amount of concern was expressed over the lack of real sovereignty, that is, over the lack of freedom from outside control and influence in national economic and political affairs and decision-making process... This concern led to calls for greater national control over natural resources, freedom from outside intervention, regulation over the activities of transnational corporations, and a reaffirmation of the right to nationalize foreign holdings. A primary target was transnational corporations and their relationships to host governments. In the area of trade, the major concern was market structures. On the one hand, developing countries sought a means by which to stabilize commodity markets and their export earnings. They wanted to create international regulatory machinery and other institutional arrangements. On the other hand, these states desired preferential access on nonreciprocal basis to the economies of the industrialized market countries... The Group of 77 called for significant increases in financial assistance in line with specific targets. See Thomas G. Weiss, David P. Forsythe, and Roger A. Coate, *The Call for the New International Economic Order*, The United Nations and Changing World Politics, 3rd Ed., Westview Press (© 2001), at (pp. 239-240). The NIEO movement ran out of steam [during the 1980's,]. Developing countries had the votes inside the United Nations, but they lacked economic and military power outside the world organization that could be converted to bargaining success. *Ibid.*, at pp. 242-243). Arguably, Brazil's role in supporting developing countries' current efforts to restructure the international legal order in the realm of intangible property rights may reflect a desire to revisit the principles of the NIEO.

⁴³ The definition, allocation, and protection of property rights is one of the most complex and difficult set of issues that any society has to resolve, but it is one that must be resolved in some fashion. For the most part social critics of property rights do not want to abolish those rights. Rather, they want to transfer them from private ownership to government ownership. Some transfers to public ownership (or control, which is similar) make an economy more effective. Others make it less effective. The worst outcome by far occurs when property rights really are abolished. See Armen A. Alchian, Property Rights - A Concise Encyclopedia of Economics, The Library of Economics and Liberty, at: (<http://www.econlib.org/LIBRARY/Enc/PropertyRights.html>).

⁴⁴ For the first time in perhaps a decade, the National People's Congress, the Communist Party-run legislature... is consumed with an ideological debate over socialism and capitalism that many assumed had been buried by China's long streak of fast economic growth. *The controversy has forced the government to shelve a draft law to protect property rights* that had been expected to win pro forma passage and highlighted the resurgent influence of a small but vocal group of socialist-leaning scholars and policy advisers. These old-style leftist thinkers have used China's rising income gap and increasing social unrest to raise doubts about what they see as the country's headlong pursuit of private wealth and market-driven economic development... The divide does not appear likely to derail China's market-led growth... *Legislative officials insist that the proposed law, which has taken eight years to prepare and is intended to codify a more expansive notion of property rights added to the Constitution in 2003, will sooner or later be enacted*, though possibly with some significant modifications (emphasis added). See Joseph Kahn, A Sharp Debate Erupts in China Over Ideologies, New York Times (Mar. 12, 2006), at p. 1, at: (<http://www.nytimes.com/2006/03/12/international/asia/12china.html?ex=1142830800&en=daacfd934cf71907&ei=5070&emc=eta1>).

⁴⁵ China's efforts to damp speculation in its property market were directed at a new target yesterday when the State Council approved measures to restrict foreign investment in the sector. The new rules – the latest move undertaken by Beijing in recent months to curb a surge in investment – is designed to make it harder for foreign companies and individuals to acquire property. See Geoff Dyer, Foreign Property Investors Targeted, Financial Times (7/25/06), at p. 2.

⁴⁶ In China... ideological debates in various guises are alive and kicking and play a pivotal role in policymaking. Chinese and foreigners ignore them at their peril. The clearest sign that ideology is back came

with *the demise of the property law earlier this year*, shelved after a campaign against it by a law professor at Peking University. *The law aimed to entrench legal protection of private property rights*, but Gong Xiantian whipped up a storm by arguing it would only protect the rights of the rich and succeeded in pushing it off the legislative agenda. That Professor Gong's argument won the day is astounding. After all, the Chinese who have made the most money from property in the past decade did so by throwing ordinary citizens out of their homes in collusion with local governments. For individuals in China, by contrast, the ability to buy a home has been tremendously empowering. With the protection of the law and independent courts, the property market would enrich both them and the country. The key to Prof Gong's victory was that he was able to frame the debate in a code that still packs a punch in Chinese politics. *The bill, he said, would undermine China as a socialist state. Or to use the code, the measure was surnamed capitalist, not surnamed socialist, a turn of phrase not heard since the early 1990's, when the late Deng Xiaoping was fighting a rearguard action in defense of market reforms* (emphasis added). See Richard McGregor, *Power Not Socialism is Today's Chinese Ideology*, Editorial Comment, *Financial Times* (7/26/06), at p. 9.

⁴⁷ [The 136,000 members of France's Taxpayers' Association (CA) are becoming more vocal in demanding that the state slashes its spending and leaves more money in their pockets... The CA argues that France's high tax burden and mounting public debt are stifling enterprise and crowding out private-sector investment. See John Thornhill, *Lone Voice Calls On France To Tame The State*, *Financial Times* (4/26/06), at p. 3.

⁴⁸ France is one of several countries in the EU that is certain to miss the deadline to transpose the EU directive on the enforcement of intellectual property rights into their national law s... *In light of rising piracy and counterfeiting rates, and different procedures for dealing with patent infringement* as well as Community trademarks and Community designs across EU countries, *the directive aims to rewrite national civil laws on all IP-related rights and bring them under one EU hat...* The main reason for France's delay – a delay that could extend far into next year or even 2008 with French presidential elections taking the limelight in 2007 – is that *the French government is still busy trying to implement the EU's 2001 copyright directive, more than three years after the December 2002 implementation deadline for that directive...* The issue concerning the copyright directive is that *the debate about the scope of the new law on digital rights management (DRM) does not seem to have come to a*

conclusion. Last December a controversial amendment to the new law was passed which would have allowed online users to download unlimited songs and films from file-sharing services for a small fee. In the latest draft, however, this provision has been scrapped, though punishments for illegal downloaders have also been reduced... *But another proposed amendment, which is the main hold-up of progress at the moment, could have detrimental effects for companies such as Apple and its iTunes online music service in France.* The proposed provision foresees that all digital files will have to be playable on any devices. Songs downloaded from Apple's iTunes music store can only be played on iPods, which under the draft law would have to be changed, meaning that if Apple does not make digital content available in all formats, consumers may have to use software to convert digital files (emphasis added). See Stephanie Bodoni, Half of EU Countries Set to Miss Enforcement Directive Deadline, Managing Intellectual Property (3/15/06) at: <http://www.managingip.com/default.asp?page=9&PubID=198&SID=619370&ISS=21503&LS=EMS67693>.

⁴⁹ On May 3, 2006, the media reported that French lawmakers might not require online music stores to use interoperable DRM systems to protect their wares. A committee of French senators had recommended that... the bill [be amended]... to remove a requirement that makers and users of DRM systems provide technical details to their competitors to enable the development of interoperable systems. The measure... is widely seen as an attack on Apple Computer, Inc., which, with its iPod music player and iTunes Music Store service, has taken a dominant share of the music download market. See Peter Sayer, French Copyright Bill Changes May Favor Apple, IDG News Service (5/3/06) at: <http://www.macworld.com/news/2006/05/03/french/index.php>.

⁵⁰ Legislation dubbed 'state-sponsored piracy' by Apple Computer was approved by the upper house of the French parliament [on May 11, 2005], triggering a fierce protest from industry. *The law would force interoperability' on media groups, challenging Apple to make songs downloaded from its iTunes online music store playable on devices that rival its own iPod music player.* The IT industry has lobbied hard for the draft law to be overturned since it was approved by the lower house in March... French lawmakers responded... by scrapping a provision that would have forced Apple and its peers to remove copy protection from their products. Instead, a new agency will be created to examine individual cases of interoperability... [T]he Business Software Alliance, a trade body whose members include Apple, Microsoft and Dell, said

the concession did not go far enough... The draft law will not be examined by a parliamentary committee, where further changes are possible, before it is approved by President Jacques Chirac (emphasis added). See Tom Braithwaite, French Senate Backs Forcing Apple to Share iTunes, *Financial Times* (5/12/06), at p. 4. See also Peter Sayer, Amended French Copyright Bill Gives Apple a Break, *IDG News Service* (5/11/06), at: (<http://www.computerworld.com/action/article.do?command=viewArticleBasic&articleId=9000376>); Delphine Strauss and Kevin Allison, France Tones Down iPod Threat to Apple, *Financial Times* (7/17/2/06) at p. 2

⁵¹ Perhaps, France's cultural preference for open source methods rather than closed software systems explains why France was so determined to impose interoperability rules on online music stores that would make it possible for their music to be transferred on to other players, potentially breaking Apple's closed system... Competitors such as Sony and Microsoft would also have to comply with the legislation, but some rivals see it as a chance to break Apple's grip on the online music market... But others in the IT industry said forcing Apple to admit competitors to a new market it was instrumental in creating sent the wrong signal to technology companies... The copyright law, which implements an EU directive on intellectual property, has already been the source of controversy. See Tom Braithwaite, France to Take Bite Out of Apple Monopoly on iTunes, *Financial Times* (3/21/06), at p. 2.

French lawmakers yesterday approved a controversial law that threatens to throw Apple Computer's digital music business model wide open... The copyright legislation, which will now go to the upper house... force[s Apple]... to remove software barriers that stop consumers playing downloaded tracks on any digital device other than Apple's iPod. [It]... also imposes the concept of interoperability on Apple's rivals. Francisco Mingorance, European director of policy at the Business Software Alliance, whose members include Apple, Microsoft and Dell said: It deprives authors and software publishers of the rights they have enjoyed until now. See Tom Braithwaite, French Download Law Will Hit Apple, *Financial Times* (3/22/06), at p. 1. See also Rob Pegoraro, France Takes a Shot at iTunes, *Washingtonpost.com* (3/26/06), at: (<http://www.washingtonpost.com/wp-dyn/content/article/2006/03/25/AR2006032500102.html>).

⁵² The French Conseil Constitutionnel [Constitutional Court] has since found portions of France's controversial copyright law, which had threatened to mandate interoperability between Apple Computer and

rival online music players' digital rights management, to be unconstitutional. It also proposed changes to the law that would subject persons found reverse-engineering DRM [in order] to aid interoperability between two DRM-incompatible systems— Apple's and Microsoft's, for example... The law had previously allowed individuals to circumvent DRM if doing so to enable interoperability. The Conseil removed the provision, saying the definition of interoperability was too vague. The law will also now introduce a DRM licensing authority for companies using rights protection, which will have the power to order companies such as Apple to provide information to competitors to enable interoperability. ***The Conseil has now amended the law to order that, in such cases, those being forced to open their DRM should receive compensation*** (emphasis added). See Estelle Dumont and Jo Best, *Apple Gets Reprieve From French DRM-Busting Law*, CNET News (7/31/06), at: http://news.com.com/Apple+gets+reprieve+from+French+DRM-busting+law/2100-1027_3-6100629.html.

⁵³ Indeed, France's inability to compete against the likes of Microsoft and Apple has likely triggered trade protectionism. A recent report on the French software industry, entitled the Truffle 100, prepared by Truffle Venture, CXP, Mar-Tech Finance and Synatec, shows that France has no software maker with revenues of more than 1 billion euros and only two above 200 million euros: Dassault Systemes and Business Objects, which is U.S. listed... [T]he combined revenue of France's top 100 software companies is still smaller than the three biggest companies in the sector, Microsoft, Oracle and SAP. See Martin Arnold, *France Still Trailing in High-Tech Research*, Financial Times (4/26/06), at p. 2.

⁵⁴ Apple Computer's iTunes online music store could be shut down across Scandinavia following joint action by three Nordic nations to force it to make downloaded songs usable on all digital music players... Ultimately, Apple can be put of business', said Thorgeir Waterhouse, a senior adviser to the Norwegian Consumer Council. Pressure on Apple to open its walled garden' and remove software that blocks music being played on rival devices started earlier this year in France. Legislation is in its final stages that would force all media companies to heed the spirit of interoperability' where all purchased content can be played on any device. *With a dominant position in most countries, Apple is seen as the most threatened by such pressure, which now spreading across Europe... Lawyers and IT industry groups have argued that Apple should be able to enjoy the fruits of its success... The ruling has implications for Apple worldwide should other jurisdictions*

outside Scandinavia also decide that iTunes breaches consumer protection legislation... Analysts have compared the company's growing troubles with the attempt by European antitrust regulators to force greater interoperability on Microsoft and its software (emphasis added). See David Ivison and Tom Braithwaite, *Apple Faces New Threat to iTunes*, *Financial Times* (6/10/06), at p. 2.

⁵⁵ A Swedish political movement seeking drastic changes to intellectual property law is resonating internationally, according to a spokesman for the group called the Pirate Party. The party, whose platform calls for fair and balanced copyright, *the abolition of patents* and increased individual privacy protection, last month put its principles into action with the launch of a commercial darknet⁵⁵ that lets Internet users swap content anonymously... The Pirates want national law reformed to regulate only commercial use and copying of protected works. To share copies, or otherwise spread or use works for non-profit uses, must never be illegal since such fair use benefits all of society', its Declaration of Principles states. It urges reduction of the term of protection for commercial copyrights to five years from date of publication, with an immediate right to make derivative works... *Patents are obsolete and unnecessary and should be abolished, the Pirate Party said. By keeping information on things like file formats and interfaces secret, [large corporations] try to create vendor lock-in, thereby limiting competition with a blatant disregard for the value of free market forces'* (emphasis added). See Dugie Standeford, *Swedish Pirates' Call For IP Reform Spurs Global Interest*, *Intellectual Property Watch* (9/4/06), at: (<http://www.ip-watch.org/weblog/index.php?p=390&res=1280&print=0>).

⁵⁶ Apparently, there is a parallel effort to force the notion of 'interoperability' at the EU level as well. A great concern is that by creating a dominant proprietary standard, one software house may lock in 'the whole market, making it impossible for other programs to interoperate, and so impossible for them to compete. As the Microsoft case made clear, anti-trust laws can take a very long time to operate, by which time the marketplace may have utterly changed. EU copyright laws recognise this danger, and Directive 91/250/EEC, Articles 5(2) and (3) and 6, allow decompilation of a program to investigate its interfaces, although the decompiled source code may not be made public, and decompilation is permitted only if the information is not otherwise readily available. The CEC article 6 (and various amendments that rewrite it) uphold this right of decompilation. But this is of little help in achieving *interoperability* when interfaces are patented: interoperation would be possible only by securing a valid

licence for the patent. Decompilation is a problem only in the context of copyright. Allowing it in the contexts of patents means allowing nothing. So an amendment of fundamental importance is ITRE-15 (Article 6(a)), which would create a similar protection for interoperability in the face of patent rights... Art 30 TRIPs does not allow unreasonable limitations on the enforceability of patents...The TRIPs treaty needs to be taken seriously. In fact the directive is a good opportunity to concretise the meaning of the treaty. *The TRIPs treaty imposes an obligation to limit patentability and patent enforceability in systematic ways which are not motivated by trade protectionism or adhoc policy considerations in favor of one or the other local interest group. Art 6a is about systematic limitations to patent enforcement, similar in nature to the exemptions for university research. It is not about exceptions to the exclusive rights conferred by a patent, and it does not prejudice legitimate interests of patent owners, since there is (arguably) no legitimate interest to control the use of communication standards.* Thus Art 6a provides a way of solving potential competition problems caused by software-related patents, and a concretisation of Art 30 TRIPs (em phasis added). See, Interoperability and the Software Patents Directive: What Degree of Exemption is Needed Foundation for a Free Information Infrastructure (FFII), at: (<http://swpat.ffii.org/papers/eubsa-swpat0202/itop/index.en.html>). The U.S. government previously filed objections to this directive during 2003. See US Gov't Promoting Patent Extremism in the European Parliament, Free Information Infrastructure (FFII), at: (<http://swpat.ffii.org/papers/eubsa-swpat0202/usrep0309/index.en.html>).

⁵⁷ Even in the United States, there is a current, ongoing debate about what rights the Government possesses, under so-called eminent domain, to take private property for larger, public purposes. See U.S. constitutional law discussion, *infra*.

⁵⁸ See, e.g., Amy Kazmin, Socialist Legacy Stops Vietnam Realizing Its Full IT Potential, Financial Times (4/24/06), at p. 6. Although Hanoi is eager to develop high-technology industries as a cornerstone of the economy, analysts say progress is being hindered by vested interests from the state-controlled past. These legacies include a vast, inefficient – and deeply corrupt – state sector that still gets preferential access to scarce capital, and tight government controls over the university system which stifle innovation and creativity... [D]espite the country's increased integration into the global economy, Vietnam's leaders still want the state sector to dominate and are pouring resources into state companies... 'The party and the government have been

consistent in their objective of keeping the commanding heights of the economy state-controlled or state-owned', said Jonathan Pincus, a Hanoi-based economist for the United Nations Development Programme. The fledgling private sector, though dynamic, remains small and constrained. There are almost no large private companies, and the sector lacks substantial heft, a potential obstacle to technological progress. Meanwhile, universities and higher education institutes are controlled by education ministry bureaucrats, who dictate the entire curriculum, including mandatory extensive study of Marxist-Lenin theory and Ho-Chi Minh thought'. Universities produce almost no original research and are detached from business or industry. *Ibid.*

⁵⁹ The two extremes in weakened private property rights are socialism and commonly owned' resources. Under socialism, government agents— those whom the government assigns— exercise control over resources. The rights of these agents to make decisions about the property they control are highly restricted. People who think they can put the resources to more valuable uses cannot do so by purchasing the rights because the rights are not for sale at any price. Similarly, common ownership of resources— whether in what was formerly the Soviet Union or in the United States— gives no one a strong incentive to preserve the resource. See Armen A. Alchian, Property Rights - A Concise Encyclopedia of Economics, The Library of Economics and Liberty, *supra*.

⁶⁰ See Arvind Panagariya, The Pursuit of Equity Threatens Poverty Alleviation, Financial Times (6/1/06), at p. 11. Recent election victories by the Marxist Communist party in the Indian states of West Bengal and Kerala, the strong showing by Ollanta Humala in the first round of Peru's presidential election, the election of Evo Morales as Bolivian president and land grabs by local officials have re-energized leftwing critics of pro-market policies in the developing world. They had previously argued that such outward-orientated policies led to increased poverty, but the evidence from China and India has decisively laid that charge to rest. Therefore, they have now shifted their critique to equity, arguing that market reforms widen the gap between rural and urban populations. They further claim that this lamentable phenomenon is turning the citizens of India, China and Latin America away from reforms. But the argument is wrong and pernicious. In China, the land grabs are to be attributed to the absence of democratic institutions rather than to rising rural-urban inequality. In India, aspirations aroused by rapidly rising incomes, rather than by inequality, have been translated into politically effective demands for yet more improvement, as reflecting in the frequent

uprooting of incumbent governments... But, if inequality is a red herring, the faulty diagnosis also endangers the process of growth and poverty alleviation. No country illustrates this better than India, which placed equity at the centre of policymaking in the early decades of development with devastating results. Virtually all anti-growth and anti-poor policies India has been struggling to shed for two decades had their origins in the pursuit of equity. *Ibid.*

⁶¹ See George Parker and Tobias Buck, 'Washington Briddles at EU's Urge to Regulate', *Financial Times* (5/12/06), at p. 2. Senior officials see the latest step in the creation of a behemoth [the European Union] that will use its economic weight to impose European values on the rest of the world, often through excessive regulation. According to Rockwell Schnabel, the former US ambassador to Brussels, Europe is increasingly seeking to act as the world's economic regulator... As Mr. Schnabel notes: 'Washington regulates far less than Brussels or the EU member states, and when it does regulate, it is less likely to act on the principle of precaution'. *Ibid.*

⁶² Over the broad sweep of human history, technological progress and economic growth were painfully slow. Why has it sped up now?... According to economist Paul Romer, '... One answer is that the more people you're around, the better off you're going to be... Another answer is that we developed better institutions. Neither the institutions of the market nor the institutions of science existed even as late as the Middle Ages. Instead we had the feudal system, where peasants couldn't decide where to work and the lord couldn't sell his land. On the science side, we had alchemy. What did you do if you discovered anything? You kept it secret. The last thing you'd do was tell anybody.' How did the better institutions come about?... So where do these institutions come from? It was a process of discovery, just as people discovered how to make bronze. They also discovered ways to organize political life. We can use democratic choice as an alternative to, say, a hereditary system of selecting who's the king. What's subtle here is, how do those discoveries get into action?... There was a process of persuasion when somebody discovered that, hey, this would be a better way for us to organize ourselves. So we had political and economic thinkers -- Locke, Hobbes, Smith -- who managed to persuade some of their peers to adopt those institutions. So institutions came from a combination of discovery, persuasion, adoption -- and then copying. When good institutions work somewhere in the world, other places can copy them... New Growth Theory describes what's possible for us but says very explicitly that if you don't have the right institutions in place, it won't happen. If anything, it was the old style of theory which made

it sound like technological change falls from the sky like manna from heaven, regardless of how we structure our institutions. This new theory says technological change comes about if you have the right institutions, which we have had...[For example,]... Ming China was very advanced. It had steel. It had clocks. It had movable type. Yet it was far from generating either the modern institutions of science or the institutions of the market. *The market and science differ in their treatment of property rights, but they're similar in that they rely on individuals who are free to operate under essentially no constraints by authority or tradition. It took a special set of historical circumstances to persuade people that things could work if you freed people, within certain institutional constraints, to pursue their own interests.* This is where Ming China was very far away from modern notions. ***Part of the answer to this big question about human history has been the acceptance of relatively unfettered freedom for large numbers of individuals.*** *It's something we just take for granted, but if you described it in the abstract to the people of 50,000 years ago, they would never believe it could possibly work. They were conditioned to systems where there was the head man or the chief, and as numbers got at all large, there was a sense that you had to have somebody with kind of dictatorial control. It was a deep philosophical insight and deep change in the whole way we viewed the world to tolerate and accept and then truly celebrate freedom. Freedom may be the fundamental hinge on which everything turns'* (emphasis added). See Post-Scarcity Prophet - Economist Paul Romer on Growth, Technological Change, and an Unlimited Human Future, Interview with Ronald Bailey, Reason Magazine, *supra*.

⁶³ For example, it has doubled the life expectancies throughout the world in the last century, and could make greater strides in the next 50.

A girl born in Chile in 1910 could expect to live only to age 33. Since then, her life expectancy has more than doubled to its current level of 78 years. See Dean T. Jamison, Investing in Health Chap. 1, *Disease Control Priorities in Developing Countries* 2d Ed. (DCP-2), The International Bank for Reconstruction and Development / The World Bank, (2006), at p. 4, at: (<http://files.dcp2.org/pdf/DCP/DCPFM.pdf>); (<http://files.dcp2.org/pdf/DCP/DCP01.pdf>). Between 1950 and 1990 alone, technologic improvements increased life expectancy in developing countries from forty to sixty-three years, while, at the same time, greatly reduced pain and suffering, and improving both objective, and subjective, standards of living. *Ibid.*, at Preface, p. xvii, citing Jamison et. al., Preface, *Disease Control Priorities in Developing Countries*, (DCP1) (1993). See also Stephen Moore and Julian L.

Simon, *The Greatest Century That Ever Was* (1999), which reported among other things that, during the course of the 20th century, human life expectancy had increased by 30 years, the annual deaths from major killer diseases such as tuberculosis, polio, typhoid, whooping cough and pneumonia fell from 700 to fewer than 50 per 100,000 of the population; agricultural workers fell from 41 to 2? percent of the work force; household auto ownership rose from 1 to 91 percent. *Ibid.*

Over the past 17 years, successive generations of AIDS drugs have restored a total of three million years of life to HIV-positive Americans and prevented an estimated 2,900 infants from becoming infected, a new study finds... three million extra years of life is impressive [] [c]onsidering the billions of dollars that have been spent on research[...] the research proves that it's really worth it'... said study co-author A. David Paltiel, an associate professor of public health at Yale School of Medicine in New Haven, Conn. See Randy Dotinga, *HIV Drugs Have Given Americans 3 Million Years of Life - They've also prevented 2,900 infant infections since 1989, new study finds*, *Health Day Reporter* (6/22/06), at: (<http://www.medicinenet.com/script/main/art.asp?articlekey=62628>); (http://news.yahoo.com/s/hsn/20060623/hl_hsn/hivdrugshavegivenamericans3millionyearsoflife); (<http://www.healthcentral.com/newsdetail/408/533402.html>).

⁶⁴ It is apparent that American apologists and Eurocentrists are clamoring to portray the international system America helped to create following World War II, and America's current international influence and standing as on the wane. In fact, some have cited America's poor international standing as the result of misplaced policies that arguably defend longstanding American values, such as life, liberty and the pursuit of happiness, political and economic freedom, a market-orientated rules-based trading system and strong private property right protections guaranteed by the U.S. Constitution. Perhaps these grumblings reflect the introduction of a new international policy platform developed by primarily one political party, that is willing to sacrifice individual Americans' constitutional rights in order to enhance America's international image. See e.g., Jacob Weisberg, *The Inconvenient Truth About Gore*, *Financial Times* (6/1/06), at p. 11.

Whether or not one concurs with the judgment of the historian Sean Wilentz that he is the worst president in history', George W. Bush has already done enough damage to America's position in the world to earn a spot in the bottom tier. *Ibid.* See also, Barry Lynn, *Globalization Must Be Saved From the Radical Global Utopians*, *Financial Times* (5/30/06), at p. 15. Most of us are hard pressed just to maintain the

illusion that the present system is not breaking down, to deny with conviction what everyone knows – that the grand trade liberalization project is, at best, on life support.. Few outside the U S doubt that America 's free-trade system, constructed with such care in the decades after the war, is crumbling fast.. [T]here is no better time than now to grasp that the real question is not, as Americans like to frame it, free trade versus protectionism. It is whether the world trading system will be regulated by private companies that are answerable only to the rich and powerful, and are profoundly unequipped for the task of processing complex information for the sake of society, or by states built to assess risk and to be answerable to all citizens... By far the greatest obstacle to understanding the failings of post-cold-war globalization is the U S 's own utopian ideology. For most of the nation 's history, America was guided by deeply realistic thinking, and idealistic rhetoric was trotted out mainly to clothe cold strategic aims. But after the fall of the Berlin Wall, in that moment of self-congratulatory euphoria, much of the U S 's ruling elite came to believe the rhetoric itself. The result was a uniquely American, *fin-d-siecle* paganism – absolute faith in the ability of an all-determining market mechanism to deliver universal prosperity and peace in perpetuity – which was then hawked abroad with evangelical zeal...The biggest reason for hope is the prospect of a reformed, sober U S . Once the American mind is exorcised of today 's mechanistic utopianism, the most probable result will be a return to a far more realistic, practical, ethical internationalism . *Ibid.*

⁶⁵ What do you see as the necessary preconditions for technological progress and economic growth? [According to Paul Romer,]... *One extremely important insight is that the process of technological discovery is supported by a unique set of institutions.* Those are most productive when they're tightly coupled with the institutions of the market. The Soviet Union had very strong science in some fields, but it wasn't coupled with strong institutions in the market. The upshot was that the benefits of discovery were very limited for people living there. ***The wonder of the United States is that we've created institutions of science and institutions of the market.*** They're very different, but together they've generated fantastic benefits. *When we speak of institutions, economists mean more than just organizations. We mean conventions, even rules, about how things are done. The understanding which most sharply distinguishes science from the market has to do with property rights. In the market, the fundamental institution is the notion of private ownership, that an individual owns a piece of land or a body of water or a barrel of oil and that individual has almost unlimited scope to decide how that resource should be used.* In science

we have a very different ethic. When somebody discovers something like the quadratic formula or the Pythagorean theorem, the convention in science is that he can't control that idea. He has to give it away. He publishes it. What's rewarded in science is dissemination of ideas. And the way we reward it is we give the most prestige and respect to those people who first publish an idea.' Yet there is a mechanism in the market called patents and copyright, for quasi-property rights in ideas... [Romer agrees] *That's central to the theory. To the extent that you're using the market system to refine and bring ideas into practical application, we have to create some kind of control over the idea. That could be through patents. It could be through copyright. It might even be through secrecy. A firm can keep secret a lot of what it knows how to do. So for relying on the market -- and we do have to rely on the market to develop a lot of ideas -- you have to have some mechanisms of control and some opportunities for people to make a profit developing those ideas...* I think it's important to have a distinct realm of science and a distinct realm of the market, but it's also very good to have interaction between those two' (emphasis added). See Post-Scarcity Prophet - Economist Paul Romer on Growth, Technological Change, and an Unlimited Human Future, Interview with Ronald Bailey, Reason Magazine, *supra*.

⁶⁶ See Armen A. Alchian Property Rights - A Concise Encyclopedia of Economics, The Library of Economics and Liberty, *supra*.

⁶⁷ See Daniel W. Drezner, U.S. Trade Strategy Free Versus Fair: Critical Policy Choices, Council on Foreign Relations (2006), at p. 22, at: (<http://www.cfr.org/content/publications/attachments/CPCTrade.pdf>).

⁶⁸ See Andrew Beckerman-Rodau, Are Ideas Within The Traditional Definition of Property? A Jurisprudential Analysis, Suffolk University Law School Intellectual Property Paper No. 5 (Berkeley Electronic Press 1994), at p. 25, at: (<http://lsr.nellco.org/cgi/viewcontent.cgi?article=1005&context=suffolk/ip>); (<http://www.law.suffolk.edu/arodau/site.asp?page=publications&id=articles/ideasjuris>).

⁶⁹ See, e.g., Guy De Jonquieres, Asia Needs a More Active Market in Ideas, Financial Times Comment (8/31/06), at p. 13. Typically, Asia's way is to cope with the world as it is, not to try radically to change it: roadblocks are there to be circumvented, not bulldozed. The approach has often paid off handsomely. Business' flair for turning obstacles into opportunities is the key to much of the region's dynamism. Similarly, pragmatism by governments in the region has

enabled economic integration to advance, in spite of the deep mistrust that often divides them. Rather than trying to promote integration through laws and treaties, they have left market forces to take the lead. However, a bias towards acquiescence in the status quo also has costs. It does not foster the vigorous spirit of inquiry needed to spark the innovation that many emerging Asian economies are eager to encourage... Asia will need a more active market in ideas if it is to respond to the huge challenges thrown up by its future development. Increasingly, these extend across borders, in fields as diverse as health, migration, transport and the environment. The region's lack of common institutions and forums in which to develop joint solutions makes the need for smart thinking all the greater. *Ibid.*

⁷⁰ *Ibid.*, at pp. 25-26.

⁷¹ Tracing the philosophical and intellectual origins of freedom reveals that a disparity has existed for centuries between the notions of individual freedom brought forth by the American Revolution and the collectivist overtones of the European philosophical tradition. Understanding these historical origins is key to understanding the use of freedom in contemporary usage. The English liberal tradition and the American Revolution provided a crucible in which the ideas of John Locke, Edmund Burke, David Hume, and Thomas Jefferson were molded into the American concept of individual freedom. At its core, this tradition of freedom is rooted in the natural rights of man. Natural rights are derived from the idea of common human nature and, as such, are inalienable. They cannot be bought, sold, or taken away. The highest priority in this tradition is the right of life, liberty, and security of person...***From this definition emerges a picture of freedom that seeks to liberate the individual's creative and intellectual capabilities.*** Additionally, the legacies of Voltaire, Jefferson, and the Magna Carta promote freedom of thought, consciousness, and religion... In addition to providing intellectual and creative freedoms, the individualist tradition sought to define freedom externally, in relation to society. Individual freedom is predicated on the right to life; therefore, that right should be equally protected before the law. Government is necessary to secure these rights, with the consent of the governed, and should do so with blind justice. These are ideas that can be traced to John Locke and the Magna Carta. The right to be free from slavery is a further extension of the natural rights of man and one of the core tenets of liberalism. As Locke, Montesquieu, Hume, and Jefferson pointed out, however, the individual must be free not only from enslavement to others, but also from enslavement to the government. They sought to preserve freedom by protecting individuals from arbitrary arrest, deten-

tion, or exile, *as well as from arbitrary deprivation of property* (emphasis added). See Helle Dale, Economic and Political Rights at the U.N.: A Guide for U.S. Policymakers, Background #1964, *supra*.

⁷² In 1776, Thomas Jefferson, in the American Declaration of Independence, wrote, "We hold these truths to be self-evident, that all men are created equal, that they are endowed by their creator with certain unalienable rights, that among these are Life, Liberty, and the pursuit of Happiness. Jefferson's phrasing, while one of the most memorable aphorisms, tapped into an already established vein of discourse about human rights. Jefferson stood most directly on the shoulders of John Locke, whose design of government for the protection and promotion of life, liberty, and property was a foundation stone of the American constitutional system. Locke, in turn, built on far older religious and philosophical antecedents. The older writings on human rights, from ancient times through the founding of the United States, consistently included among the listed rights the rights to marry, to raise a family, to safeguard one's property, and to pursue a calling. Property often was closely linked to marriage, family, and related institutions. Rights to property were conceived in many societies as part of the constellation of rights properly guaranteed to assure familial success. Over time, property rights were assimilated into individual rights, as the individual came to have identity, and to enjoy rights, independent of family. Over time, as well, property rights developed several distinct but related strands. One strand encompasses the right to own property and to control its use and disposition. Another strand focuses on the right to work, to retain the fruits of one's labor—in essence, to translate labor into property. A third strand addresses the rights associated with enjoyment of the benefits from contributions to scientific and intellectual advancement. All of these strands are intertwined and share common roots. All of these strands also play important roles in modern economies... At the most fundamental level, basic property rights are an extension of the self and of the prohibition on slavery. Ownership of one's own body implies ownership of one's own labor. (That point has been made repeatedly, starting with Thomas Aquinas, and then elaborated by Locke.) All of the other property rights protected as core human rights flow from that ground. Together, these rights allow individuals to exercise a measure of control over their surroundings. They allow us to plan our lives with some security, not that we have full control, but that we can decide for ourselves how best to invest our energies, based on our own values and expectations. The importance of property rights to individual self-development is related

to, though different from, their contribution to societal wealth and, derivative of that, to society's capacity to promote a wide variety of other rights and interests. This relationship was first noted by Aristotle, who observed that property tended to be most productive when it was owned individually rather than collectively. The twentieth century offers something as close as one gets in real life to a controlled experiment on the virtues of collective versus individual ownership. The unambiguous lesson of the century is that greater individual ownership has a marked advantage over greater collective ownership in producing wealth for society. See Ronald A. Cass, Intellectual Property and Human Rights, Engage Vol. 7, Issue 1 (March 2006), at pp. 87-88, at: (<http://www.fed-soc.org/Publications/Engage/March%202006.pdf>).

⁷³ The notions underlying U.S. patent law were substantially derived from English traditions. One of those fundamental notions was that patent and copyright protections encouraged innovation and national development.

... By the late 1700's, Britain had the longest continuous patent tradition in the world, one whose origins traced back to 1449... As former subjects of the English King, the newly minted Americans were familiar with the doctrine of the public interest, as incorporated into Britain's Statute of Monopolies (1624). *Ibid.*, at p. 26. It gave a fourteen-year monopoly to the true and first inventor of new manufactures – a law in effect for more than 150 years before the American Revolution. *Ibid.*, at pp. 26-27. Likewise, the colonists were familiar with Britain's copyright law, the Statute of Anne, which was enacted in 1710. Under that act, the monopoly power of publishers was weakened and the rights of authors of new works were strengthened with copyright protection for fourteen year, with the possibility of a fourteen year renewal. And while the Statute of Monopolies did not apply in the colonies, the various colonial governments enacted patent laws that imitated it. After independence and before the ratification of the U.S. Constitution, twelve of the thirteen colonies enacted copyright laws based on the Statute of Anne. See Pat Choate, *HOT PROPERTY: The Stealing of Ideas in an Age of Globalization*, Alfred A. Knopf (©2005), at p. 27.

⁷⁴ One of the primary purposes of the U.S. constitution, according to one of its primary authors, as set forth in *The Federalist Papers*, was the preservation of inalienable individual rights, including ownership and enjoyment of private property. *The Federalist Papers* were a series of 85 articles written under the pen name of Publius, by Alexander Hamilton, James Madison, and John Jay. Their purpose was to garner

public support for the then-proposed U.S. Constitution. *The Federalist Papers* outlined how the new American government would operate and why this type of government was the best choice. James Madison, wrote in Federalist Paper #10, previously reported in the New York Packet of November 23, 1787, that, The protection of... the faculties of men, from which the rights of property originate... is the first object of government. Madison, again, in Federalist Paper #54, previously reported in the New York Packet of February 12, 1788, wrote that, Government is instituted no less for protection of the property, than of the persons, of individuals. The one as well as the other, therefore, may be considered as represented by those who are charged with the government. Madison, yet again, in an article published in the National Gazette of March 29, 1792, entitled, Property, wrote that the U.S. Government is instituted to protect property of every sort; as well that which lies in the various rights of individuals... his being the end of government, that alone is a *just* government, which *impartially* secures to every man, whatever is his *own*... That is not a just government, nor is property secure under it, where the property which a man has in his personal safety and personal liberty, is violated by arbitrary seizures of one class of citizens for the service of the rest. [Property] means that dominion which one man claims and exercises over the external things of the world, in exclusion of every other individual'... [I]t embraces everything to which a man may attach a value and have a right; and *which leaves to every one else the like advantage*. In the former sense, a man's land, or merchandize, or money is called his property. In the latter sense, a man has a property in his opinions and the free communication of them ... He has a property very dear to him in the safety and liberty of his person. He has an equal property in the free use of his faculties and free choice of the objects on which to employ them. In a word, as a man is said to have a right to his property, he may be equally said to have a property in his rights (emphasis in original).

⁷⁵ The U.S. Constitution and accompanying Bill of Rights provide that governments shall not take 'private property, no matter where it is located, for public use' without just compensation'. See discussion, *infra*.

⁷⁶ French author and historian Alexis de Toqueville, in the Introduction to his famous book, *Democracy in America*, makes reference to the liberating power of private property to promote democracy, as well as, scientific and creative discovery and innovation: ***As soon as land began to be held on any other than a feudal tenure, and personal property could in its turn confer influence and power, every discovery***

in the arts, every improvement in commerce of manufactures, created so many new elements of equality among men. Henceforward every new invention, every new want which it occasioned, and every new desire which craved satisfaction were steps towards a general leveling [of the classes]. The taste for luxury, the love of war, the rule of fashion, and the most superficial as well as the deepest passions of the human heart seemed to co-operate to enrich the poor and to impoverish the rich. *From the time when the exercise of the intellect became a source of strength and of wealth, we see that every addition to science, every fresh truth, and every new idea became a germ of power placed within the reach of the people.* Poetry, eloquence, and memory, the graces of the mind, the fire of imagination, depth of thought, and all the gifts which Heaven scatters at a venture turned to the advantage of democracy; and even when they were in the possession of its adversaries, they still served its cause by throwing into bold relief the natural greatness of man. Its conquests spread, therefore, with those of civilization and knowledge; and literature became an arsenal open to all, where the poor and the weak daily resorted for arms (emphasis added). See Alexis de Tocqueville *Democracy in America*, Preface/Introduction at: (<http://xroads.virginia.edu/~Hyper/DETOC/preface.htm>).

⁷⁷ See Article 17 of the Universal Declaration of Human Rights. 1. Everyone has the right to own property alone as well as in association with others. 2. No one shall be arbitrarily deprived of his property. See discussion, *infra*.

⁷⁸ The citizens of Mongolia are enjoying the following rights and freedoms... 3) The right to fair acquisition, possession, and inheritance of movable and immovable property. Illegal confiscation and requisitioning of the private property of citizens are prohibited. If the State and its bodies appropriate private property on the basis of exclusive public need, they may only do so with due compensation and payment... 8) The right to engage in creative work in cultural, artistic, and scientific fields and to benefit thereof. Copyrights and patents are protected by law. See Mongolia-Constitution, at: (<http://www.concourt.am/wwwconst/constit/mongolia/mongol-e.htm>).

⁷⁹ The Members of the World Trade Organization have agreed that there is a need to promote effective and adequate protection of intellectual property rights[,] to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade... [to] recognize[e] that intellectual property rights are private rights... [to] recognize[e] the underlying public policy objectives of national systems for the protection of intellectual

property, including developmental and technological objectives [and to]... establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (emphasis added), and to give effect to the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

⁸⁰ According to some commentators, however, the property right conferred upon patent holders pursuant to Article 28 of the TRIPS Agreement is a negative⁴ right of exclusion that is subject to public policy principles, rather than a positive property right. Members to ensure that patent owners enjoy exclusive rights, and details the minimum content of such rights, which may be exercised with regard to acts performed *during* manufacturing as well as to acts performed *after* manufacturing. The exclusive nature of the rights conferred is inherent to patent grants, though not to all forms of intellectual property. It permits the title-holder, if successful in the exploitation of the invention, to obtain significant rents during the lifetime of the patent, thus fulfilling one of the basic purposes of patent grants. While defining the patentee's rights as exclusive, the Agreement makes it clear that patents confer a negative right, that is, the legal faculty to prevent others from doing certain acts relating to the invention (*ius excluendi*), rather than a positive right with regard to his products or processes... Thus, the acquisition of a patent right on a product does not empower the patent owner to produce it if this were contrary, for instance, to environmental regulations, or to commercialize it, if prior marketing approval were required. See Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement, United Nations Conference on Trade and Development and the International Centre for Trade and Sustainable Development, Chapter 22 Patent Rights Conferred⁴ at p. 44 (Cambridge University Press May 2005), at: (http://www.iprsonline.org/unctadictsd/docs/RB2.5_Patents_2.5.6_updated.pdf).

⁸¹ It is the core purpose and objective of the World Intellectual Property Organization, as noted in Article 3 of the WIPO Convention, signed on July 14, 1967, and subsequently amended on September 28, 1979, to: (i) to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization; and (ii) to ensure administrative cooperation among the Unions.

⁸² The American Declaration on the Rights and Duties of Man, approved by the Ninth International Conference of American States in 1948, also provides clearly for the minimal protection of private

property rights in intellectual property. It states in article 13, that: Every person has the right to take part in the cultural life of the community, to enjoy the arts, cultural life of the community, to enjoy the arts, and to participate in the benefits that result from intellectual progress, especially scientific discoveries. He likewise has the right to the protection of his moral and material interests as regards his inventions or any literary, scientific or artistic works of which he is the author .

⁸³ The International Covenant on Economic, Social and Cultural Rights was opened for signature, ratification and accession by United Nations General Assembly Resolution 2200A (XXI) on December 16, 1966. Although it has not yet been ratified by the U.S., it has been ratified or acceded to by 153 countries around the world. It provides for the minimal protection of private property rights, including intellectual property rights, and states, in Article 15, that: The States Parties to the present Covenant recognize the right of everyone: 1. a) To take part in cultural life; b) To enjoy the benefits of scientific progress and its applications; c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author ... 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity .

⁸⁴ The Universal Declaration on the Human Genome, adopted at UNESCO's 29th General Conference on November 11, 1997, and endorsed by United Nations General Assembly Resolution A/RES/53/152 on December 9, 1998, provides for the minimal protection of private property rights, including intellectual property rights, and states, in the preamble that: States should take appropriate measures to foster the intellectual and material conditions favorable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research...

⁸⁵ The Vienna Declaration and Programmed of Action, adopted by the World Conference on Human Rights on June 25, 1993, and endorsed by United Nations General Assembly Resolution 48/121 on December 20, 1993, provides clearly that private property rights, including intellectual property rights, may not be abridged for lack of development. It states, in Part I, Paragraph 10, that: the right to development, as established in the Declaration on the Right to Development, as a universal and inalienable right and an integral part of fundamental human rights. As stated in the Declaration on the Right to Development, the human person is the central subject of

development. While development facilitates the enjoyment of all human rights, the lack of development may not be invoked to justify the abridgement of internationally recognized human rights .

⁸⁶ See Armen A. Lechian Property Rights - A Concise Encyclopedia of Economics , The Library of Economics and Liberty , *supra*.

⁸⁷ See Andrew Beckerman-Rodau, Are Ideas Within The Traditional Definition of Property? A Jurisprudential Analysis , at p. 26.

⁸⁸ Dr. De Soto conducts his work on behalf of the millions of informal landowners in Latin America. His work focuses on helping them to register informal title to real property, and to help the government recognize those titles by drafting laws that allow exploitation and require protection thereof. De Soto speaks fundamentally about the importance of acquiring formal title to real property which can then be alienated and exploited by its owners as collateral for credit, as property for sale, etc. Formal recognition of private ownership of real property also enables the growth of a formal entrepreneurial class in developing countries that can fight off government socialism and state capture by large, entrenched private interests that demerit from government, small businesses and the working class.

⁸⁹ See Mystery of Capitalism: Why Capitalism Triumphs in the West and Fails Everywhere Else, Introduction. See also Transcript of The Hudson Institute International Development Seminar - Guest Speaker, Hernando de Soto, (Jan. 12, 2004), at: (http://www.hudson.org/index.cfm?fuseaction=publication_details&id=3219). ... Mystery of Capitalism, was really a more in-depth exploration of the ideas in the Other Path. It was really looking at what he terms the hidden architecture of capitalism , primarily, property rights and the importance of property rights to wealth creation, again, to the bubble up, trickle up theory of development. *Ibid*.

⁹⁰ [C]ountries that are currently excluded from the globalised economy will have to make huge adjustments to their legal systems and governance in order to fully benefit... [F]our billion people, or 80% of the world's population, are not included in the system ... For instance, you cannot trade unless you can sign a bill of lading or make a bank transfer. You have to have a proper address to make a deal. Four billion have no property rights. Without a fixed identity, they cannot get credit. **These people might easily come to see the system of international trade as an abuse against them. They can be whipped up into a frenzy against the West or globalization, and that underlies every global problem that exists...** From our experience, I'd have to say yes... [A]ll countries can become capitalist economies... Take Tanzania, for instance: this is one of the poorest

countries in the developing world. Yet when we worked there, we discovered that people were already implementing their own legal system at a local level. Special committees run by local officials known as mwenyeketi issued documents to establish legal property and business rights of individuals in the rural areas. They even had documents that enabled people to use their land as collateral for borrowing money. We found it hard to find a cow or bull that did not have private property markings. *So, in my view, no culture is incapable of going the same way as the rest of the world* (emphasis added). See Morice Mendoza, Global Liberalisation: Anti-poverty campaigner Hernando de Soto believes that globalization, with all its faults, can only help the poor. But property laws will need to change first, World Business (May 2006), at pp. 25-26

⁹¹ See Mark F. Schultz and David B. Walker, How Intellectual Property Become Controversial: NGOs and the New International IP Agenda, *Engage*, Vol. 6, Issue 2 (Oct. 2005), pp. 82-98, at 85, at: (<http://www.fed-soc.org/Publications/Engage/Oct%2005.pdf>).

⁹² According to economist Paul Romer of Stanford University, ideas are a type of goods (non-rival) that everyone can use at the same time, and which, while expensive to produce [initially,] are cheap, almost costless to reproduce. Thus the total cost of a design does not change much, whether it is used by one person or by a million. At first glance the manufacture of ideas might seem like a profitable business to invest in. However, upon further inspection, one sees clearly that if there are no barriers to entry into such a business, i.e., it is free to enter, it is not worth doing so, because competition pares the price of a design down to the negligible cost of reproducing it. Unless idea factories can enjoy some measure of monopoly over their designs – by patenting them, copyrighting them, or just keeping them secret – they will not be able to cover the fixed cost of inventing them. See The Growth of Growth Theory - The riddle of technology and prosperity is explored in a fine new book, The Economist (5/18/06), at: (http://www.economist.com/displaystory.cfm?story_id=6943519).

[T]he unique thing about knowledge was not so much its indivisibility but rather its nonrivalry... There was indeed something indivisible about a lighthouse or a recording or a software program. It didn't exist until it was built or made or turned on, and doing that inevitably entailed a fixed cost. Once created, however, a nonrival good could be copied endlessly at almost no cost and used over and over again, without being used up'. Many people could possess it precisely because it was nonrival. It was indivisible, too. But its indivisibility was not the important thing. A nonrivalrous good could be almost

anything whose content lent itself to copying. A symphony, or the performance of it by a particular orchestra; a painting, or a reproduction of it on a coffee mug; a chemical formula, or its instantiation in a pharmaceutical pill. Indeed, it was when excludability entered the picture that things really got interesting. *Nonrival goods were excludable in varying degrees, depending on the circumstances... Secrecy was one device to preserve commercially valuable nonrival goods. Patents, trademarks, secret ingredients, access codes, proprietary standards, continual innovation were some others* (emphasis added). See David Warsh, *Knowledge and the Wealth of Nations – A Story of Economic Discovery*, (W.W. Norton & Co. ©2006), at pp. 285-86.

⁹³ See, e.g., *Doing Business 2007 – How to Reform*, Overview, The International Bank for Reconstruction and Development / The World Bank (2006), at: (http://www.doingbusiness.org/documents/DoingBusiness2007_Overview_Eng.pdf). *Doing Business 2007: How to Reform* is the fourth in a series of annual reports investigating the regulations that enhance business activity and those that constrain it. *Doing Business* presents quantitative indicators on business regulations and the protection of property rights that can be compared across 175 economies– from Afghanistan to Zimbabwe– and over time. Regulations affecting 10 areas of everyday business are measured: starting a business, dealing with licenses, employing workers, registering property, getting credit, protecting investors, paying taxes, trading across borders, enforcing contracts and closing a business. The indicators are used to analyze economic outcomes and identify what reforms have worked, where and why. *Ibid.*, at p. 3. See also Krishna Guha, *World Bank Praises Pro-Business Reforms in Many African Countries*, *Financial Times* (9/6/06), at p. 4.

⁹⁴ Defining and publicizing property rights through registries has proven good for entrepreneurs as well. Land and buildings account for half to three quarters of wealth in any economy. Securing rights to property strengthens incentives to invest and facilitates trade. And with formal property titles, entrepreneurs can obtain mortgages on their homes or land and start businesses... Even though the 14 procedures for registering property are the same in all analyzed states, in practice different states make it easier or more difficult to register. The cost and time vary considerably... With identical requirements to register, the wide variation in the time to transfer property is puzzling ... Costs come largely from transfer taxes, registry charges and registration fees– all determined at the state or municipal level... Brazil has an unusually

high number of requirements for registering property: 11 different clearance certificates (*Certidão Negativa*) are required (including certificates confirming that the company has no pending labor settlements, and that the company has funded its pension plan). See *Doing Business in Brazil* The International Bank for Reconstruction and Development / The World Bank (2006), at pp. 6-7, at: (http://www.doingbusiness.org/documents/doing_business_in_brazil_07.pdf).

⁹⁵ See, e.g., *Doing Business 2007 – How to Reform*, Overview, *supra*, at Table 1.2, at p. 6.

⁹⁶ See Robert M. Sherwood, *Intellectual Property and Economic Development*, Chap. 9: Protection: A Powerful Development Tool (Westview Press 1990), at: (http://www.kreative.net/ipbenefits/iped/body_9_chapter.htm).

⁹⁷ Does New Growth Theory give us some new insights on how to think about monopolies? [According to Stanford economist Paul Romer,] *There was an old, simplistic notion that monopoly was always bad*. It was based on the realm of objects -- if you only have objects and you see somebody whose cost is significantly lower than their price, it would be a good idea to break up the monopoly and get competition to reign freely. So in the realm of things, of physical objects, there is a theoretical justification for why you should never tolerate monopoly. *But in the realm of ideas, you have to have some degree of monopoly power. There are some very important benefits from monopoly*, and there are some potential costs as well. What you have to do is weigh the costs against the benefits. Unfortunately, that kind of balancing test is sensitive to the specifics, so we don't have general rules. Compare the costs and benefits of copyrighting books versus the costs and benefits of patenting the human genome. They're just very different, so we have to create institutions that can respond differentially in those cases' (emphasis added). See *Post-Scarcity Prophet - Economist Paul Romer on Growth, Technological Change, and an Unlimited Human Future*, Interview with Ronald Bailey, Reason Magazine, *supra*.

⁹⁸ [When industries have huge research costs and low production costs, they tend to evolve toward what economists call a **monopoly** a situation where companies charge more for their goods than what it cost to produce the last unit. *If you forced anyone in the world of ideas to sell their product at the cost of producing the last unit, they'd go bankrupt,*' says Romer. His appreciation of the role monopolies plays in the economy lands Romer in the neo-Schumpeterian camp named after Joseph Schumpeter, who almost 50 years ago recognized *the*

importance of monopolies in capitalist societies... Problem is, a monopoly isn't supposed to happen according to classical economics. In Ricardo's insular world, competition is perfect: many small firms compete against each other, but none is able to set prices; the cost of entry into the market is nil; and prices reflect the cost of production. But the economics of high technology shatter this convenient scheme. *Because the cost of research is so steep, the price of market entry is often enormously high. As a result, big firms often slug it out, and by simultaneously trying to fund new discoveries while paying for old ones, they charge far more than the cost of production. The economics of monopolistic competition, as it has been branded, is the economics of the technology age.* But there's a big conundrum for monopolies and monopolistic societies. What price is the right price to charge for a new idea, for a new software tool? The classical notion of price-setting worked well. More often than not, demand equaled supply; and competition kept suppliers from charging more than consumers would pay. This classical understanding of pricing provided the ideological cover for market economies to flourish... But everyone assumed that monopolies would rarely arise. And if they did, most agreed, the government should step in. So now what? If our goal is simply to encourage the production of new bitstreams, *Romer says*, prices must be set very high. But, he asks, what's the right price to make sure a new bitstream is used efficiently? *You can't overuse an idea. Anybody in the world who can benefit should be free to use it,' he says. So the right price is zero.'* To promote economic growth, policymakers want to encourage the development and diffusion of new ideas... *So there's a deep economic problem to solve - setting a high price to encourage research but a low price to encourage use.* The economic problem '*Romer says*, *is really about configuring all our institutions so that we search efficiently through this space of possible ideas, finding better and better ones.'* Here Romer's technological economics turns into a set of policies for the technological age. He *believes that companies must derive some monopoly profits for taking the risk to develop new ideas. In fact, without the incentive of capturing such profits, he concludes, companies would not engage in research. But Romer also supports government funding for basic research and advocates revamping patent and copyright laws to limit the control companies can exert over new technologies.* The balance, he hopes, will provide enough incentive for companies to pursue new technologies and, at the same time, allow other individuals and companies access to the ideas that flow from research... Romer warns that governments must pursue intelligent technology policies... He opposes the kinds of handouts to

industry the federal government's Advanced Technology Program has spearheaded. You don't want pork barrel programs to get in the way of effective economic outcomes,' he warns. At the same time, he believes it's vital that government supports basic research, the birthplace of ideas. *Romer suggests concentrating funds on universities, both to stimulate basic research and to create cadres of highly educated people who will fan out into the economy and generate new technologies... Some economists, for instance, dispute the importance of Romer's thesis when it comes to developing countries.* They hold that if poorer nations such as India manage to educate their populations and accumulate more capital, then growth will automatically follow. *Not so, Romer argues. To develop successfully, countries must be open to new ideas and capture the benefits of the latest technologies. The only logical path, he suggests, is to embrace free trade and encourage investment by large corporations. These companies will then bring the necessary knowledge of industrial organization, international markets, and product differentiation to allow developing nations to become truly global players. Romer's theory hints at an unexpected benefit of free trade: access to new ideas* (emphasis added). See Kevin Kelly, Paul Romer: The Economics of Ideas, Wired Magazine Issue 4.06 (1996), at: (<http://www.wired.com/wired/archive/4.06/romer.html>).

⁹⁹ For much of the 20th century they were industrial powerhouses that pioneered global breakthrough medicines, from aspirin to the birth control pill. Today, Germany's pharmaceuticals companies are weaklings. Germany has destroyed its industry', says Sir Tom McKillop, the former head of AstraZeneca. The market has become progressively more awful. It's a very sorry tale'. See Andrew Jack and Patrick Jenkins, The Birthplace of Aspirin Finds Its Drug Innovation Numbered, Financial Times (3/31/06), at p.9.

¹⁰⁰ On Tuesday the European Parliament (EP) proposed a number of changes to the directive on the patentability of computer-implemented inventions, including a change to the name of the directive *to make it clear that software cannot be patented*. Confusion over just what would be patentable under the directive has been such that it has become widely known as the software patents directive... Michel Rocard, the rapporteur for the EP's Legal Affairs Committee (JURI), has drafted amendments to the directive which, if agreed by the committee next week, will be voted on by MEPs in a plenary session of the European Parliament in July. Rocard has proposed that the expression 'computer-aided invention' should be used rather than 'computer-implemented invention' throughout the directive text, including the title of the

directive. This change is needed to make it clear that innovations can only be patented if they use software to aid the performance of the invention and not if they comprise software only, according to Rocard.

The expression 'computer-implemented' is not suitable, because it may let one think that an invention can be wholly realised by means of a computer, which would mean that software can be patentable. Since both the [European] Commission and the [EU] Council agreed that software should not be patentable, the scope of the directive has to be defined so as to exclude this case, said Rocard in the draft amendment document.

Some of the proposed amendments revert to the changes introduced by the European Parliament in the first reading, which were later removed by the EU Council. This includes a change to make it clear that innovations in the field of data processing cannot be patented (emphasis added). See Ingrid Marson, 'EU Prefers Computer-Aided Patents', ZDNet UK (6/14/05), at: (<http://news.zdnet.co.uk/business/legal/0,39020651,39203722,00.htm>). For a discussion of the earlier removed changes, See Munir Kotadia 'EU Votes Through Software Patent Changes' ZDNet UK (5/18/04), at:

(<http://news.zdnet.co.uk/business/legal/0,39020651,39155028,00.htm>).

The European Council on Tuesday voted through controversial changes to the European Union's Software Patents Directive that will pave the way for widespread patenting of software in Europe. *Ibid.*

¹⁰¹ The Foundation for a Free Information Infrastructure (FFII) is a non-profit association registered in several European countries, which is dedicated to the spread of data processing literacy. FFII supports the development of public information goods based on copyright, free competition, open standards. *More than 650 members, 3,000 companies and 90,000 supporters have entrusted the FFII to act as their voice in public policy questions concerning exclusion rights (intellectual property) in data processing* (emphasis added). See Foundation for a Free Information Infrastructure, at: (<http://www.ffii.org>). *Our constituents' basic interest is to keep the software free from patents, regulated by copyright only* (emphasis added). See FFII interests and the EU Software Patent Directive, at: (<http://swpat.ffii.org/analysis/needs/index.en.html>).

¹⁰² Charlie McCreevy, the European Union internal market commissioner, will on Monday launch an initiative to help European companies secure better protection for their intellectual property. Mr McCreevy wants to make one final effort to resolve years of deadlock over the creation of a low-cost EU-wide patent, in an effort to

bridge the innovation gap between Europe and the US. The absence of a functioning EU-wide patent regime is one of the biggest complaints of business leaders in Europe. According to a recent study commissioned by Brussels, the cost of registering patents across the EU typically varies between €37,500-€57,000 (\$45,500-\$69,200). By contrast, the cost of registering a US patent is about €10,000 – a factor often cited by Brussels officials as part of the explanation for the EU’s failure to improve its levels of innovation. Efforts to create an EU-wide community patent have been stalled for several years because member states cannot agree which languages patents should be published in. Another proposal – to clarify the rules on patents in the software industry – had to be withdrawn last year after fierce protests in the European Parliament and opposition from smaller companies and individual software developers. See Tobias Buck, ‘One Final Effort’ to Create a Low-Cost EU Patent, FT.com (1/15/06), at: <http://news.ft.com/cms/s/6bfc7f6a-85e7-11d1-8ee0-0000779e2340.html>).

¹⁰³ In general, the European patent system appears to work pretty well, at least in comparison with the US system, and members of the European Software Association have not encountered the difficulties created by trivial or dubious patents. In the US, too many low quality patents have been granted and this is one of the reasons, which explains the on-going attempt to reform the patent system in the US. The European Software Association thus insists that Europe should avoid the excesses and mistakes of the US patent system, and maintain a restrictive approach for granting patents, as it is the case up to now. *This is not to say that the patent system in Europe cannot be improved. Patents are too expensive, and the litigation system too complex.* The Commission’s actions should focus on those two practical issues rather than try to build a new system. The improvements can be done within the existing legal framework through the creation of a common court system and the adoption of administrative measures (reduced fees for SMEs, reduced delays in decisions on oppositions, etc.) (emphasis added). See European Software Association: Response to the European Commission’s Consultation on the Patent System in Europe at p. 1, at: http://www.europeansoftware.org/pdf/EuSftwAssn_Response_to_patent_questionnaire.pdf).

¹⁰⁴ One legal commentator has tried to develop a TRIPS-based *legal* argument against the patentability of drugs, premised on the French civil law notion of ‘*Ordre Public*’ and morality, and to extend it to the realm of copyrights. This argument is likely relied upon by Brazil and

other countries to justify abrogation of HIV/AIDS and other drug patents. See Austen Zuege, *Applicability of TRIPS' Allowance For Exemptions From Patentability For Ordre Public and Morality to the Realm of Copyright* (April 2002). As this author describes it, ordre public comes from French law... [and it] encompasses several and distinct concepts. The first concept... incorporates two distinct powers. Judges are allowed limited discretion by virtue of certain articles of French Civil Code to prevent enforcement of transactions which are held to offend public order'. There are also some statutory requirements around which parties may not contract, as their application is mandatory. The second concept, termed ordre public externe, is related to the first and, in the area of private international law, is interchangeable with public policy. It may be invoked to prevent the application of foreign law, otherwise applicable under principles of international law, on the basis that foreign law would sanction conduct that offends against the forum's concept of fundamental norms'... Therefore, ordre public would appear to provide an escape device where, in limited circumstances, domestic interest may trump foreign interests and public policy may trump ordinary domestic standards for patentability. States may only exclude an invention on the basis of ordre public where the results of providing such protection include commercial exploitation or an offense against the forum's concept of fundamental norms' . *Ibid.*, citing Timothy J. Ackerman, Comment, *Disordre'ly Loopholes: TRIPS Patent Protection, GATT, and the ECJ*, 32 *Tex. Int'l L.J.* 489, 495 (1997).

The second category of exemptions under TRIPS is for morality. Morality overlaps some aspects of ordre public. However, it may also have results more related to ethical considerations than to the negative social effect of policies'. The protection of human, animal or plant life or health and avoidance of serious prejudice to the environment are listed in art. 27.2 as nonexhaustive justifications for the two exemptions and should be viewed as broadening the already potentially broad scope of the grounds for derogation'...At least once commentator believes that the TRIPS exclusionary provisions do not provide enough guidance to determine permissible bounds of exclusions in practice... Bounds of permissible ordre public exemptions may be seen if simultaneous bans on distribution or sale are required. *Ibid.*, citing Timothy J. Ackerman, Comment, *Disordre'ly Loopholes: TRIPS Patent Protection, GATT, and the ECJ*, supra, at pp. 495,-496, and 510; *Ibid.*, citing Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 *Tul. J. Tech. & Intell. Prop.* 1, 9 (2001).

¹⁰⁵ See F.M. Scherer, *The Pharmaceutical Industry and World Intellectual Property Standards*, *Vanderbilt L. Rev.* 53:6 (2000) at pp. 2245-2254, 2247-48. Many nations excluded drug products from patentability because they considered drugs (and for analogous reasons, food products) to be of such great importance to the national welfare. Even Switzerland, home to three of the world's leading pharmaceutical companies, abstained until 1977, from granting drug patents. *Ibid.*

¹⁰⁶ See e.g., Marco Pistis, *The European Convention on Human Rights: Copyright Implications*, Antonelli Cocuzza & Associati (6/4/06), at: (http://www.mondaq.com/article.asp?articleid=40204&email_access=on).

¹⁰⁷ See Lawrence A. Kogan, *Exporting Europe's Precaution: How Europe's Risk-Free Agenda Threatens American Free Enterprise*, Washington Legal Foundation, (Nov. 2005), at: pp. 37-42, at: (<http://www.wlf.org/upload/110405MONOKogan.pdf>).

¹⁰⁸ And, profit-minded European-based pharmaceutical companies holding valuable private property (e.g., drug patents and trade secrets), who are accountable for their financial performance primarily to corporate shareholders and debt-holders, are likely to accelerate their shifting of R&D assets to the U.S., in light of recent actions unilaterally taken by the EU Commission and the European Council. These actions, if unopposed, will severely curtail the future profitability and economic sustainability of such companies' European operations, given the broad scope of the privately owned pharmaceutical and medicinal products that will likely be subject to a 'taking' for third country public use' without just compensation'. See *Adoption Of A Regulation On Compulsory Licensing Of Patents Relating To The Manufacture Of Pharmaceutical Products For Export To Countries With Public Health Problems*, Council of the European Union, PRES/06/120 (4/28/06), at: (<http://europa.eu.int/rapid/pressReleasesAction.do?reference=PRES/06/120&format=HTML&aged=0&language=EN&guiLanguage=en>).

This Regulation aims at facilitating and regulating at Community level the granting of compulsory licenses for the supply of patented pharmaceutical products to countries in need. After its entry into force, it will allow to handle cases of public health emergencies, *such as the avian flu*, in poor developing countries lacking the capacity to manufacture such medicines locally (emphasis added). This regulation was first proposed during 2004. See *Proposal For A Regulation Of The European Parliament And Of The Council On Compulsory Licensing Of Patents Relating To The Manufacture Of*

Pharmaceutical Products For Export To Countries With Public Health Problems and the accompanying Explanatory Memorandum , COM/2004/0737 final - COD 2004/0258, Europa at: (http://europa.eu.int/prelex/detail_dossier_real.cfm?CL=en&DosId=191926#367639). See also Compulsory Licensing System For The Production And Export Of Generic Medicinal Products To Developing Countries Europa at: (<http://europa.eu/scadplus/leg/en/lvb/121172.htm>). This regional European regulation was obviously crafted in response to the (political) 2001 Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/Dec/2) (11/20/01), which acknowledges circumstances under which a waiver(s) may be granted from the obligations set forth in TRIPS Article 31(f) (concerning the issuance of compulsory licenses by developing countries lacking their own drug manufacturing capacity, primarily for the supply of their domestic markets) and Article 31(h) concerning the payment of adequate remuneration for pharmaceuticals subject to a compulsory license). Paragraph 6 of that Declaration was subsequently elaborated upon by a formal and legally binding WTO TRIPS Council Decision Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement on Public Health (WT/L/540) (9/1/03). And, this Decision was subsequently crafted into a Proposal For A Decision On An Amendment To The TRIPS Agreement (i.e., proposed WTO Waiver(s)) by the TRIPS Council for ultimate adoption by WTO members. See Implementation of Paragraph 11 Of The General Council Decision Of 30 August 2003 On The Implementation Of The Doha Declaration On The TRIPS Agreement And Public Health (IP/C/41) (12/6/05).

¹⁰⁹ President Luiz Inacio Lula da Silva appears to understand the important role that business investment and innovation must play in Brazil if he is to deliver on his promises to improve the life of the poor. *But like many a socialist, Lula appears to also believe that government can take what it likes in the interest of the public good.* The contradiction between property grabs and the desire to attract investment came into focus in March when the government announced a new industrial development plan. Four anointed strategic sectors, two new bureaucracies designed to implement initiatives and an allocation of \$5.2 billion are all part of this effort to revive the slumping economy... [O]ne of the chosen strategic sectors is the pharmaceutical industry, a market where property rights have been battered beyond recognition under the Lula government. By designating the pharmaceutical industry a key strategic sector, it hopes to not only develop businesses that will fabricate generic medicines but

also attract a fertile, cutting-edge biomedical industry. ... Ireland and Singapore offer appealing tax structures but they have not sprouted robust, innovative pharmaceutical sectors *without a reliable property-rights regime as well* (emphasis added). See Mary Anastasia O'Grady, 'There's No Such Thing As a Free HIV Cocktail', *Wall Street Journal* (4/30/04), at: (<http://www.aegis.com/news/wsj/2004/WJ040405.html>).

¹¹⁰ See Robert M. Sherwood, *Intellectual Property and Economic Development*, Chap. 9, *supra*.

¹¹¹ 'Surprise, surprise, the WTO talks in Geneva are suspended.' But in truth, hardly a surprise, since in May France's agricultural minister said, 'I would prefer that the negotiations fail rather than... raise questions about... agriculture' ... What was surprising was the far more relaxed tone of Brazil's Foreign Minister Celso Amorin, who until now has acted with India as a co-spokesman for the developing nations. Yet not once in his press conference did he mention the U.S. by name, though several times he singled out the EU – from whom I didn't hear all I wanted to hear'. And, he added, the breakdown of talks was especially sad for Brazil because the Doha talks can't be compensated by bilateral or regional deals. That's quite a shift for a Brazilian minister, since Rio has put so much effort into Mercosur, its home-grown idea for an integrated South American economy. Yet now, with Venezuela's Hugo Chavez's sudden emergence as a Mercosur partner – and one who proposes to take Mercosur in a very different direction – the failed WTO talks must look even more important than before. Their breakdown, Mr. Amorin concluded, now meant trade would revert to the law of the jungle'. See Bernard K. Gordon, 'Doha A Ground', *Wall Street Journal* Opinion (7/26/06), at p. A 14.

¹¹² One may argue that America's ability to continue innovating is being threatened not only by the efforts of foreign governments, such as Brazil, to deny U.S. knowledge-based commercial products strong national IP protections and to weaken the global intellectual property system at large, but also by government efforts to deny U.S. companies market access - the capacity to market new products effectively during the period of time when the exclusive intellectual property rights exist.

Although intellectual property protection is a necessary condition for encouraging innovation in all sectors, it is the ability to market products effectively that provides the incentive for continued innovation and generates the returns on investment necessary to fund new research and development and production of new products. This cycle of innovation produces significant economic and social benefits by accelerating economic growth and raising standards of living. See 2005 Special 301 Report, United States Trade Representative, at pp. 9-10, at:

(http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_Special_301/asset_upload_file195_7636.pdf).

¹¹³ The International Intellectual Property Alliance (IIPA) has alleged that Brazil's continued theft of intellectual property rights cost American businesses an estimated US\$ 900 million in losses in 2003 alone. Intellectual property related industry in the United States accounts for 15% of GDP and 10% of the American workforce. *See* Breaking Patents Is Not the Way to Go, Says US to Brazil, *Brazzil Magazine* (5/18/05), at: (<http://www.brazzilmag.com/content/view/2470/49>).

¹¹⁴ *See* Robert J. Shapiro and Kevin A. Hassett, *The Economic Value of Intellectual Property, USA for Innovation* (Oct. 2005), at p. 3. Furthermore, two international public accounting firms released reports during the past three years that confirm the increasing share of U.S. public company balance sheet asset values attributable to intangible assets such as intellectual property. According to one report prepared by Ernst & Young, [i]ntangibles such as *R&D, proprietary intellectual property* and workforce skills, world-class supply networks and brands are now the key drivers of wealth production while physical and financial assets are increasingly regarded as commodities (emphasis added). *See* Clear Advantage: Building Shareholder Value, *GEMI* (Feb. 2004), at pp. I and II, at: (<http://www.gemi.org/GEMI%20Clear%20Advantage.pdf>), *citing* Clark Eustace, *The Intangible Economy: Impact and Policy Issues*, Report of the High Level Expert Group on the Intangible Economy, Enterprise Directorate-General (Brussels Oct. 2000), at pp. 6-7. With the arrival of the new information technologies, the structure of enterprises have changed dramatically, shifting the focus of value creation from tangible-based activities to intangible-based value creation. The value of intangible assets has therefore constantly increased in the last two decades from an average of 40% of total market value of business corporations at the beginning of the 1980's to over 80% at the end of the 20th century. In knowledge intensive industries, like in the software business, a corporation's book value is often lower than 10% of its market value, of which the largest part are constituted by intangible assets... *See* Juergen Daum, *The New FASB Rules for Reporting on Intangible Assets – The U.S. versus the European Way*, *The New Economy Analyst Report* (Nov. 10, 2001), at: (http://www.juergendaum.com/news/11_10_2001.htm). Another recent report analyzing the U.S. market prepared by PricewaterhouseCoopers (PWC), found that intangible assets and goodwill [together] constituted 74 percent of the average *purchase*

price of acquired companies in 2003 (with, respectively, intangible assets representing 22 percent and *residual goodwill 52 percent*) (emphasis added). See Tony Hadjiloucas and Richard Winter, Reporting the Value of Acquired Intangible Assets, at: (http://www.buildingipvalue.com/05_SF/364_368.htm).

¹¹⁵ This essentially reflects how Americans today... in terms of real per capita income... are seven times richer than they were in 1900. How did that happen?... [According to Stanford economist Paul Romer]... many things contributed, but the essential one is technological change... [T]he discovery of better ways to do things. In most coffee shops these days, you'll find that the small, medium, and large coffee cups all use the same size lid now, whereas even five years ago they used to have different size lids for the different cups. That small change in the geometry of the cups means that somebody can save a little time in setting up the coffee shop, preparing the cups, getting your coffee, and getting out. Millions of little discoveries like that, combined with some very big discoveries, like the electric motor and antibiotics, have made the quality of life for people today dramatically higher than it was 100 years ago... [But, that] seven-fold increase in income – that's [only an] official statistic[]... [In] truth... if you look at the actual change in the quality of life, it's larger than the number suggests.' See Post-Scarcity Prophet - Economist Paul Romer on Growth, Technological Change, and an Unlimited Human Future, Interview with Ronald Bailey, Reason Magazine, *supra*.

¹¹⁶ For this reason Brazil must be careful to cultivate the proper international image. However, as at least one recent media report noted Brazil's image concerns surrounding Venezuela's joining the Mercosur regional economic bloc. In Brazil, spokespersons for several sectors were concerned that a president like Chávez could bring a controversial political emphasis to the group, because of his hostility to the United States. See Humberto Marquez, New Member Venezuela Politicizes Mercosur, Inter Press Service New agency (7/5/06), at: (<http://www.ipsnews.net/news.asp?idnews=33873>).

¹¹⁷ Latin America has been the central axis of Brazilian foreign policy under Mr Lula da Silva and he distances himself with alacrity from his critics. The Brazilian conservative right wanted us to start a war with Bolivia,' he says. I preferred to negotiate and start looking for a solution... Bolivia needs to sell gas to Brazil and Brazil needs to buy gas from Bolivia'... The same perception of mutual self-interest underpins Mr Lula da Silva's sanguine attitude to Mr Chávez. Venezuela's entry this month to Mercosur, the South American trade pact formed 15 years ago by Argentina, Brazil, Paraguay and Uruguay,

represents an important stage in regional integration. Venezuela, he says, has a lot of oil, a lot of gas and we want to build together strategic development projects for the continent'. On the subject of Mr Chávez's anti-Americanism, the president says Venezuela and the US need each other. One day I spoke to Bush and Chávez,' he says. I said this fight between you is very interesting. Venezuela could stop selling oil and create a delicate situation for the US. Bush could stop buying and do the same. But you both keep buying and selling.' Nevertheless, he and Néstor Kirchner of Argentina have talked to Mr Chávez to try to take the tension out of hemispheric relations. *See* Richard Lapper and Jonathan Wheatley, *Why Lula Will Shun the Populist Path*, *Financial Times*, 7/11/06, at: (<http://www.ft.com/cms/s/1b048dd4-1109-11db-9a72-0000779e2340.html>). *See also* Richard Lapper and Jonathan Wheatley, *Interview Transcript: Luiz Inácio Lula da Silva*, *Financial Times* (7/11/06), at: (<http://www.ft.com/cms/s/6d42ae3a-110b-11db-9a72-0000779e2340.html>).

¹¹⁸ President Luiz Inacio Lula da Silva of Brazil will try to give new impetus to the struggling Doha round of world trade talks during the St. Petersburg summit. Although trade is not on the formal agenda of the Group of Eight summit, Mr. Lula da Silva told the *Financial Times* in an interview: It is not possible that the presidents of the most important countries in the world can meet and the most important subject in the world not be discussed'. Brazil has played an important role in giving voice to poorer agricultural economies through the G20 group of developing nations. Mr. Lula reiterated the need for the US to reduce agricultural subsidies and the European Union to lower barriers to farm imports. He said such moves would form two legs of a triangle for progress, the third being access for manufactured goods to developing markets. *See* Richard Lapper and Jonathan Wheatley, *Brazil's Lula to Promote Doha Trade Talks During G8 Summit*, *Financial Times* (7/12/06) at p. 6.

¹¹⁹ *See* Lawrence A. Kogan, *Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science*, *National Foreign Trade Council* (May 2003), at: (http://www.wto.org/English/forums_e/ngo_e/posp47_nftc_looking_behind_e.pdf); Lawrence A. Kogan, *EU Regulation, Standardization and the Precautionary Principle: The Art of Crafting a Three-Dimensional Trade Strategy that Ignores Sound Science*, *National Foreign Trade Council* (Aug. 2003), at: (http://www.wto.org/English/forums_e/ngo_e/posp47_nftc_eu_reg_fin_al_e.pdf). *See also* Lawrence A. Kogan, *Enlightened*

Environmentalism or Disguised Protectionism: Assessing the Impact of EU Precaution-Based Standards on Developing Countries , *supra*.

¹²⁰ See Mark F. Schultz and David B. Walker, How Intellectual Property Become Controversial: NGOs and the New International IP Agenda *supra*, at p. 82.

¹²¹ See e.g., Lawrence A. Kogan, EU Regulation, Standardization and the Precautionary Principle: The Art of Crafting a Three-Dimensional Trade Strategy that Ignores Sound Science , National Foreign Trade Council (Aug. 2003), *supra*, at: pp. 57-61.

¹²² Unfortunately, this type of thinking and the initiatives it breeds are encouraged by none other than Pascal Lamy, WTO Director General. In a speech made at a recent European Society of International Law forum about the relationship between WTO and non-WTO law, Mr. Lamy proposed the following eloquent and facially persuasive argument. The effectiveness and legitimacy of the WTO depends on how it relates to norms of other legal systems and on the nature and quality of its relationships with other international organisations... [T]he WTO, far from being hegemonic as it is sometimes portrayed to be, recognizes its limited competence and the specialization of other international organizations. In this sense the WTO participates in the construction of international coherence and reinforces the international legal order. *The WTO, its treaty provisions and their interpretation, confirms the absence of any hierarchy between the WTO norms and those norms developed in other fora: WTO norms do not supersede or trump other international norms... [T]he WTO, recognizes explicitly that trade is not the only policy consideration that Members can favour. The WTO contains various exception provisions referring to policy objectives other than trade, often under the responsibility of other international organisations...* The revolution brought about by WTO jurisprudence was to offer a new teleological interpretation of the WTO that recognizes the place of trade in the overall scheme of States' actions and the necessary balance that ought to be maintained between all such policies... The linkage between the WTO and other sets of international norms was also reinforced when the Appellate Body stated that in WTO, exception provisions - referring to such non-trade concerns (environment, morality, religion etc...) - are not to be interpreted narrowly: exceptions should be interpreted according to the ordinary meaning of the terms of such exceptions. In this context, our Appellate Body has insisted that exceptions cannot be interpreted and applied so narrowly that they have no relevant or effective application... Our jurisprudence has determined that the control exercised by the chapeau of Article XX of GATT, against

disguised protectionist measures, is in fact an expression of the good faith general principle or an expression of the principle against the abus de droit ... I hope it is now clear that ***WTO Members' trade restrictions imposed to implement non-trade considerations, will be able to prevail over WTO market access obligations so long as they are not protectionist... Absent protectionism, a WTO restriction based on non-WTO norms, will trump WTO norms on market access.*** In so doing, it expands coherence between systems of norms or legal order (emphasis added). See Pascal Lamy, La place et le rôle (du droit) de l'OMC dans l'ordre juridique international, Speech before the European Society of International Law (5/19/06), at: (http://www.wto.org/english/news_e/sppl_e/sppl26_e.htm). See also, Lamy Urges Members to Support Environmental Accords, WTO News: Speeches – DG Pascal Lamy (5/30/06), at: (http://www.wto.org/english/news_e/sppl_e/sppl28_e.htm).

¹²³ It must be remembered, however, that Mr. Lamy, a Frenchman enamored of the French and European state-centric and welfare-based governance model, was previously the EU's Trade Commissioner. In that capacity, he argued in favor of WTO Members permitting cultural preferences' as a new broad category of derogations from WTO norms that would have the effect of reconciling WTO and non-WTO concerns and simultaneously camouflaging European Union protectionist designs. See Lawrence A. Kogan, Exporting Europe's Protectionism, The National Interest No. 77 (Fall 2004), 91-99, at pp. 96-97; Lawrence A. Kogan, Precautionary Preference: How Europe's New Regulatory Protectionism Imperils American Free Enterprise, *supra.*, at pp. 11 and 95. Mr. Lamy's preference for state-centric socialist solutions to regulatory governance and to conflicts between trade and non-trade issues was confirmed recently by his spokesperson, WTO Deputy Director General, Rufus Yerxa. Mr. Yerxa said that Lamy is a committed internationalist and, informed by his past associations with the European Commission and French Socialist party, believes in the importance of creating better multilateral mechanisms. Lamy wants to put a human face on the WTO and open it to greater scrutiny and transparency in order to help the world better understand the WTO's mission. He remains convinced that multilateralism is a central component of the global economic governance regime... See Conversation with Rufus Yerxa, WTO Deputy Director-General, on the Doha Round, Presentation made at the Carnegie Endowment For International Peace (5/24/06) at: (<http://www.carnegieendowment.org/events/index.cfm?fa=eventDetail&id=888&&prog=zgp&proj=zted>).

¹²⁴ This author had a direct exchange with Mr. Yerxa at that event.

Lawrence Kogan of the Institute for Trade, Standards, and Sustainable Development asked about the purpose of the WTO: is it fundamentally a rules-making or a rules-harmonizing organization? He also inquired about the changing scope of the WTO's mandate, specifically so-called regime shifting tactics. Mr. Yerxa responded that the WTO respects the role of governments but seeks to underpin their policies with the mutually agreed principles of nondiscrimination and transparency. An acceptable balance must be maintained between national and multilateral interests, but the WTO can provide the incentives needed for international cooperation. Some forms of international cooperation are less controversial (border measures) and some more so (environmental agreements), and the WTO is the forum where such debates can take place. *Ibid.* Indeed, Mr. Yerxa, himself, has been directly involved with Brazilian and other developing country government efforts to import non-WTO concepts (environmental concepts from the Convention on Biological Diversity) into WTO (TRIPS) law. See Communication from Brazil, India, Pakistan, Peru, Thailand and Tanzania, Doha Work Programme – The Outstanding Implementation Issue on the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity, recently submitted to the General Council Trade Negotiations Committee, WT/GC/W/564 TN/C/W/41 (31 May 2006), at p. 1, at: (<http://www.ip-watch.org/files/PROPUESTA%20ENMIENDA%20ART%2029BIS.doc>). In the Doha Ministerial Declaration, Ministers agreed that negotiations on outstanding implementation issues shall be an integral part of the Work Programme they established. The relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) is an outstanding implementation issue. *In addition to the intensive technical work in the TRIPS Council since then, the Director General has undertaken dedicated consultations through his Friends, including more recently through Mr. Rufus Yerxa, Deputy Director General* (emphasis added). *Ibid.*

¹²⁵ *Ibid.*, citing Proposal to Establish a Development Agenda for WIPO: An Elaboration Of Issues Raised in Document WO/GA/31/11,7 (April 6, 2005) (submission by the Group of Friends of Development to WIPO Intersessional Intergovernmental Meeting IIM/1/4-2005), at: (www.wipo.int/edocs/mdocs/en/iim_1/iim_1_4.pdf).

¹²⁶ Perhaps, Brazil, like the European Union, should take a closer look at the negative impact that its opportunistic assault on WTO principles, namely, the enactment and maintenance of strong intellectual property right protections, is having on the international community. [The call

this week of... Bill Thomas, chairman of the powerful ways and means committee of the US House of Representatives... to give up on the Doha global trade talks and focus on bilateral deals should make the world take notice... Not only is frustration widespread at the grindingly slow progress of the four-year-old round. Growing U.S. trade tensions... and jingoistic furor... clearly signal rising protectionism ... [P]romising to preserve our way of life' by opposing liberal trade, investment... policies is an increasingly popular campaign theme. What makes these trends even more troubling is that European politicians are banging the same drum ... The Doha round would not survive US withdrawal, which would threaten to marginalize the WTO indefinitely as guardian of open world markets... *Erosion of WTO principles and disciplines would replace the rule of law with the law of the jungle. Nations' use of trade policies as offensive political and economic weapons would no longer be restrained by multilateral rules, increasing the risk of economic conflict. And as rival trade deals proliferated, global markets would fragment.* The world has already been down that path: it led ultimately to economic depression, tyranny and war (emphasis added). See Doha in the Doldrums – Rising Protectionism is Putting the World Economy at Risk , Editorial, Financial Times (Apr. 6, 2006), at p. 12. This possibility has become potentially greater in light of the Bush Administration's recent decision to reassign United States Representative Robert Portman, a former legislator, to the White House budget office, a move that signals growing concern over runaway federal spending and a downgrading of trade policy in the administration's second term ... the decision to move Mr Portman after only 11 months as the United States Trade Representative suggests the White House regards trade as less of a political priority. Mr Portman was brought in as USTR to conclude the Doha Round world trade agreement and shore up waning congressional support for Mr Bush's trade agenda. There is an awful lot of negativism now about the prospect of trade liberalisation and a backsliding on trade, a leading Republican strategist confirmed. There is a sense of giving up on bilateral trade deals and on Doha. See Caroline Daniel, US Reshuffle Signals Downgrading of Trade Policy , FT.com (4/18/06), at: (<http://news.ft.com/cms/s/067476e4-cede-11da-925d-0000779e2340.html>).

¹²⁷ Apparently, the US' confidence in the WTO system is beginning to wane as the result of the failure of foreign governments to recognize, protect and accord nondiscriminatory treatment to American assets. For example, in the context of the Doha round negotiations and U.S. farm-based exports, Susan Schwab, America's new top trade official,

said she was prepared to let the Doha round of global trade talks fail rather than water down US demands for substantial new access to foreign markets... Ms. Schwab said that a Doha lite with little market opening for farm exporters could not pass the US Congress. A big reduction in US demands could end up killing the round rather than saving it. Influential lawmakers in the US Congress have echoed the administration's position. Charles Grassley, Republican chairman of the Senate Finance Committee [said] 'We only get one bite at the apple every 10 years and I don't want to waste it on a minimalist approach.' Ms Schwab added that the US would continue to pursue bilateral trade deals with or without a deal in Doha. Everyone knows if there is no Doha agreement, we're perfectly capable of moving ahead on the bilateral track,' she said. See Alan Beattie and Edward Aiden, 'US Not Prepared to accept Doha Lite', *Financial Times* (6/10/06), at p. 5.

¹²⁸ See Laurence R. Helfer, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking', *Yale Journal of International Law*, Vol. 29 (2004), at p. 6, at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=459740.

¹²⁹ *Ibid.*, at p. 7.

¹³⁰ *Ibid.*, at p. 8.

¹³¹ *Ibid.*

¹³² *Ibid.*, at p. 10.

¹³³ *Ibid.*, at p. 11.

¹³⁴ *Ibid.*

¹³⁵ *Ibid.*

¹³⁶ *Ibid.*, at pp. 11-12.

¹³⁷ *Ibid.*, at p. 12.

¹³⁸ *Ibid.*, at p. 13. Regime shifting serves a cross-pollinating function... Where actors move lawmaking initiatives from one discrete regime to another they often introduce new issues into venues that previously operated within tight subject-specific parameters. This 'issue-area incorporation' spawns new relationships among different actors and institutions, redefines issue area boundaries, and wears away at the distinctions among regimes. It may also increase competition among intergovernmental organizations and conflicts between competing principles, norms and rules – both of which are useful for actors seeking to contest or supplant existing legal prescriptions... So defined, regime shifting is a game that both strong and weak actors can play. *Ibid.*, at p. 14.

¹³⁹ *Ibid.*, at p. 37.

¹⁴⁰ *Ibid.*, at p. 38, citing Jose Marco Nogueira Viana, 'Intellectual Property Rights, the World Trade Organization and Public Health: The

Brazilian Perspective, 17 Conn. J. Intl Law, 311, 311 (2002) (explaining efforts by Brazil to promote access to medicines in international fora including the WHO).

¹⁴¹ *Ibid.*, at p. 38.

¹⁴² *Ibid.*, at pp. 38-39, citing World Health Organization, Revised Drug Strategy Resolution W H A 52.19 par.2(7) (May 24, 1999).

¹⁴³ See Sub-commission on the Promotion and Protection of Human Rights, Intellectual Property Rights, and Human Rights, Res. 2000/7, E/CN.4/Sub/2/2000/L.20 [2000 Sub-commission Intellectual Property Resolution].

¹⁴⁴ See, e.g., Laurence R. Helfer, Human Rights and Intellectual Property: Conflict or Coexistence?, 5 Minn. Intell. Prop. Rev. 47, 56 (2003).

¹⁴⁵ One NGO in particular, Consumer Project on Technology (CPTech), has argued that access to health [care] or medicine and access to knowledge [A2K] are human rights. See Mark F. Schultz and David B. Walker, How Intellectual Property Become Controversial: NGOs and the New International IP Agenda, citing CPTech, Health Care and Intellectual Property, at: <http://www.google.com/custom?q=human+rights+&sa=Google+Search&cof=AH%3Acenter%3BAWFID%3A3b5c352b544b655c%3B&domains=www.cptech.org&sitesearch=www.cptech.org>; CPTech, Access to Knowledge (A2K), at: <http://www.google.com/custom?q=A2K&cof=AH%3Acenter%3BAWFID%3A3b5c352b544b655c%3B&domains=www.cptech.org&sitesearch=www.cptech.org>. Dr. Khor is director of the Third World Network, a Penang-based NGO, and works with developing country governments in opposing the WTO agenda. Dr. Khor notes how participants who attended an A2K experts meeting co-organized by CPTech, the International Federation of Library Associations and the Third World Network, during the February 2005 Geneva W IPO Secretariat's Development Agenda Meeting. proposed... that a treaty on access to knowledge should be based on the human rights model, in which access of knowledge is acknowledged as a human right, that this right is primary, and the rights to holders of copyrights or patents are seen as secondary or exceptions, and should thus be limited and in ways that would not threaten the primary human rights. See, Martin Khor, Offsetting IPRs' Adverse Effects on Access to Knowledge, South-North Development Monitor (Feb. 4, 2005), at: <http://lists.essential.org/pipermail/a2k/2005-February/000083.html>; <https://arl.org/Lists/SPARC-OAForum/Message/1594.html>.

¹⁴⁶ For example, [The United Nations] Sub-commission [on the Promotion and Protection of Human Rights] set out an ambitious new agenda for intellectual property lawmaking within the UN human rights regime. The principle animating this new agenda was the primacy of human rights obligations over economic policies and agreements'... *The first resolution sponsored by Brazil in 2001*, mandates that states, in implementing the right to the highest attainable standard of health, adopt legislation or other measures, in accordance with applicable international law', to safeguard access' to such medications from any limitations by third parties'... [essentially] ... call[ing] into question the impact of TRIPS (emphasis added). *Ibid.*, at p. 45, citing Sub-commission on the Promotion and Protection of Human Rights, Intellectual Property Rights, and Human Rights, Res. 2000/7; Commission on Human Rights Resolution 2001/33 (April 23, 2001); Commission on Human Rights Resolution 2002/32 (April 22, 2002); Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria, Commission on Human Rights Resolution 2003/29 (April 22, 2003).

¹⁴⁷ *Ibid.*, at p. 39 and fn # 187.

¹⁴⁸ *Ibid.*, at pp. 39-40, citing World Health Organization, Globalization, TRIPS and Access to Pharmaceuticals, WHO Policy Perspectives on Medicines, No. 3, WHO/EDM 2001.2 (Mar. 2001); World Health Assembly, Revised Drug Strategy Resolution, Scaling Up the Response to HIV/AIDS, WHA 54.10 par. 1(10) (May 21, 2001); World Health Assembly, Revised Drug Strategy Resolution, WHO Medicines Strategy, WHA 54.11 par. 1(5) (May 21, 2001).

¹⁴⁹ *Ibid.*, at p. 40, citing World Health Assembly, Intellectual Property Rights, Innovation and Public Health, WHA 56.27 pars. 1(1), 1(2), 2(2) (May 28, 2003).

¹⁵⁰ *Ibid.*

¹⁵¹ *Ibid.*, citing the Doha Declaration on the TRIPS Agreement and Public Health.

¹⁵² See, e.g., Mark F. Schultz and David B. Walker, How Intellectual Property Become Controversial: NGOs and the New International IP Agenda, *supra*.

¹⁵³ See World Health Assembly Scaling Up Treatment and Care Within a Coordinated and Comprehensive Response to HIV/AIDS, WHA 57.14 pars. 2(4) and 2(6) (May 22, 2004), at: (http://www.who.int/gb/ebwha/pdf_files/WHA57/A57_R14-en.pdf).

¹⁵⁴ The draft Resolution, co-sponsored by Brazil, was originally submitted to the WHO EB during November 2005.

¹⁵⁵ The resolution, for example began with the statement, [M]indful that more than 70% of new drug approvals are for medicines that do not provide incremental benefits over existing ones... Apparently, pharmaceutical industry critics have faulted it for developing and marketing many 'me-too' drugs... Although the term 'me-too' has come to be used in different ways, historically, it has most often referred to a new drug entity with a similar chemical structure or the same mechanism of action as that of a drug already on the market. That is, a 'me-too' is a new entrant to a therapeutic class that had already been defined by a separate drug entity that was the first in the class (sometimes referred to as the breakthrough drug) to obtain regulatory approval for marketing. See Joseph A. DiMasi and Cherie Paquette, *The Economics of Follow-on Drug Research and Development Trends in Entry Rates and the Timing of Development*, *Pharmacoeconomics* 22 Suppl. 2: (2004), at pp. 8-10, at: (<http://biag.org/BIAG/images/articles/art06.pdf>). According to the study's authors, The original approval in a drug class is often referred to as a breakthrough drug. It is thought by some that drugs in the class that follow the breakthrough drug typically do not contribute anything that is clinically noteworthy. *Ibid.*, at p. 8. However, their findings show the opposite to be true. They suggest a development race for drugs in a new therapeutic class, rather than a scenario where firms engage in a low risk imitation of a proven breakthrough. This conclusion is further buttressed when we look at the development history of the breakthrough drug and compare it with the development histories of the follow-on drugs in its class... [I]n a substantial number of cases in recent periods, the first drug in a class to reach the US marketplace was not the first to enter clinical testing either in the US or anywhere in the world (emphasis added). *Ibid.*, at p.10.

¹⁵⁶ See EB117.R13 (Jan. 27, 2006), *supra*.

¹⁵⁷ Recalling Resolutions W H A 52.19... W H A 54.10, W H A 56.27 and W H A 57.14... See World Health Assembly, Executive Board Proposal, [G]lobal framework on [e]ssential health research and development, EB117.R13 (Jan. 27, 2006), at: (http://www.who.int/gb/ebwha/pdf_files/EB117/B117_R13-en.pdf).

¹⁵⁸ It is entitled *Global Framework on Essential Health Research and Development*, at: (http://www.who.int/gb/ebwha/pdf_files/EB117/B117_R13-en.pdf).

The resolution was introduced and tabled for consideration at the very recent 59th World Health Assembly meeting in Geneva, Switzerland (5/21-5/28/06).

¹⁵⁹ Fortunately, the U.S. government opposed this resolution. A health attaché at the US mission in Geneva told *Intellectual Property Watch* that some of the brackets in the resolution, including those in the headline, have been suggested by the United States. He said the United States opposes the suggestion that R&D in this area should be subject to intergovernmental procedures and a binding treaty, adding that the US wants a different approach to the same problem. He said the US acknowledges that there is a problem but said how the framework suggested in the resolution would work is 'utterly beyond us.' He was not able to clarify exactly what approach the United States would suggest, however... In his remarks to the briefing, [US Health and Human Services Secretary Mike] Leavitt did not mention the R&D resolution specifically, but said that the US would continue to advocate the position that intellectual property creates incentives. But William Steiger, special assistant to the secretary for international affairs, when asked about the resolution, said that the United States is still studying a number of aspects in the resolution and is engaged in discussions. He said that a treaty is not the best answer, and the United States would prefer not to see such a rigid structure. See US Declares Opposition To WHO R&D Resolution As Proponents Raise Questions *Intellectual Property Watch* (5/22/06), at:

(<http://www.ip-watch.org/weblog/index.php?p=311&res=1280&print=0>).

¹⁶⁰ The EU Commission, as well, has objected to the resolution. The EC seems to: [(1)] Reject any proposal towards establishing a global framework for R&D, and claim that new structures are not needed they are prescribing more of the same; [(2)] [S]eek instead to promote a system based on incentives without specifying who would benefit from these incentives; [(3)] [S]eek greater involvement of regional economic groupings, which would increase the involvement of DG trade in this debate; [(4)] [P]ropose, instead of an intergovernmental working group, a working group including WIPO and the Commission; [(5)] [C]onsider it outside the WHO mandate to explore alternative systems for the protection of IP with a view to enhancing access to health innovations and building capacity for product development, uptake and delivery in developed and developing countries; and [(6)] [T]out the role of intellectual property in bringing knowledge into the public domain and in promoting follow-on research, thus contradicting the core findings of the Commission on Intellectual Property, Innovation and Public Health report (CIPH)... See Ellen Hoen, WHA latest: European Commission against Global Framework for essential health R&D, *Ip-health NEWS* on European Commission position at the

WHA (5/24/06), at: (<http://lists.essential.org/pipermail/ip-health/2006-May/009596.html>).

¹⁶¹ As expected, the resolution has become, to some degree, a partisan political issue in each region. *See, e.g.,* Congressman to Secretary Leavitt on W H A R & D Resolution IP-Health (5/19/06), *supra*; 64 MEPs Call to the World Health Assembly, to the European Commission, the Council and to the national governments for a Global Framework on essential health research and development IP-Health (5/19/06), at: (<http://lists.essential.org/pipermail/ip-health/2006-May/009561.html>); Rowan Gillies and Ellen Thoen, Patients' Needs Are What Must Drive Drug Research Financial Times, Comment (5/25/06), at p. 11, at: (<http://news.ft.com/cms/s/0ba21e04-eb8b-11da-823e-0000779e2340.html>).

¹⁶² *See Susan K. Sell and Aseem Prakash, Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights (2002), at: (<http://www.sog-rc27.org/Paper/DC/Sell.doc>).* [A] transnational NGO network has proposed an alternative frame to interpret the implications of TRIPS patent laws on the HIV/AIDS crisis. Unlike the business network that attributes the HIV/AIDS crisis to poverty and poor governance, ***the NGO network constructs the policy problem as one of excessively stringent IPR norms that make HIV/AIDS medicines unaffordable, thereby working against public health objectives.*** As a solution, the NGO network supports developing countries' desire to provide low cost access to HIV/AIDS drugs by compulsory licensing the local production of patented HIV/AIDS drugs – a solution that business networks claim violates their patents. ***ACT UP Paris, a health policy advocacy group, frames the NGO position as copy = life.*** This underscores the point that ***through copying (that is, not honoring IPRs of pharmaceutical firms), many lives can be saved (emphasis added).*** *Ibid., at pp. 4-5. The NGO network's normative position is that public health concerns should take precedence over IPR protection, or at least be on par with it.* As a result, the Access Campaign supports developing countries' rights to avail themselves of compulsory licensing provisions (Articles 30 and 31) under TRIPS to produce and to import generic equivalents of life-saving HIV/AIDS drugs in case of national emergencies. When a state grants a compulsory license, rights to produce a product are licensed to another party without the patent holder's permission, thereby bringing down the drug price (emphasis added). *Ibid., at pp. 27-28.* [T]he NGO strategy includes discouraging the USTR from penalizing governments that have invoked compulsory licensing and parallel importation. ***The NGOs have reiterated in***

policy-relevant international forums (such as the World Health Organization, WHO) that governments have the right to issue compulsory licenses, build alliances with the generic pharmaceutical industry to produce HIV/AIDS drugs and to make them available at low cost. Further, they have sought to mobilize international donors to purchase such drugs and to make them available to countries facing the HIV/AIDS crises. In the 1980s, the NGO network did not present an effective normative and policy position on IPR issues. In the early 1990s, some NGOs began to mobilize against the high prices of prescription drugs... *The HIV/AIDS crisis presented NGOs with a new opportunity to mobilize*. Undoubtedly, the impetus for the successful transnational NGO mobilization can be traced to the severity of the HIV/AIDS epidemic that received substantial coverage in the media (*emphasis added*). Ibid., at p. 28. *Over time, an increasingly broad array of NGOs, specifically Ralph Nader's Consumer Project on Technology (CPT) headed by James Love, Amsterdam-based Health Action International (HAI), ACT UP, the Nobel-prize winning group Medecins sans Frontieres (MSF), and Oxfam* joined forces. *Though Nader and Love had been working on these issues since the early 1990s*, in 1996 HAI got involved in these issues; this was the first time that a public health group actively got involved. HAI's initial focus was exposing drug scams (e.g., placebos, bad drugs) but it became increasingly interested in the intellectual property aspects of pharmaceuticals. In 1998 MSF contacted CPT and decided to join the campaign. In 1999, ACT UP Philadelphia invited *James Love* – a key policy entrepreneur for the NGO network -- to speak about compulsory licensing. This led to an important partnership that had a decisive impact on getting the Clinton administration to switch its position on South Africa. In October 2000, Oxfam, known for its developmental work and non-partisan policy positions, also joined this network.

Importantly, the NGO network mobilized support from key international organizations: the World Bank, the United Nations Development Program (UNDP), and the WHO. The World Bank's support was crucial because the Bank has impeccable credentials in supporting and promoting the neoliberal economic agenda of which IPR protection is a crucial item. However, the World Bank had an instrumental reason in supporting compulsory licensing and parallel importation – it purchased \$800 million dollars of pharmaceuticals annually and compulsory licensing and parallel importation would significantly reduce the overall bill (Vick, 1999: A18). The NGO network sought to discredit the business agenda by highlighting the astronomical profits that pharmaceutical companies were earning by

selling HIV/AIDS drugs... This strategy put pharmaceutical companies on the defensive regarding allegations of profiteering from the HIV/AIDS crisis (emphasis added). *Ibid.*, at pp. 28-29.

¹⁶³ In sum, ***this paper demonstrates that a critical issue in policy contests is whose frame dominates the debates.*** The business network argued that stringent IPR laws sustain R&D and generate funds for finding new and better cures, whereas the NGOs maintained that such IPR laws deny low cost access to critical drugs and ultimately harm public health. Clearly, both frames have their own champions (emphasis added). *Ibid.*, at p. 41.

¹⁶⁴ See Andrés Mejía-Vergnaud, Drug delusions at the WHO Manila Times (5/2/0/06), at: (<http://www.manilatimes.net/national/2006/may/20/yehey/opinion/20060520opi6.html>). “At first glance, the resolution being proposed to the World Health Organization’s annual World Health Assembly jamboree in Geneva seems unobjectionable. It starts with concerns such as the need for appropriate, effective and safe tools for patients living in resource-poor settings and the urgency of developing new medicines to address emerging health threats.’ It is difficult to disagree with these things, which should be the main goals of medical R&D: creating new products that address unmet needs. But much of the proposal seems to be driven more by ideology than reason. It complains that some 70 percent of all-new drugs offer little benefit over older ones— a claim that ignores the actual nature of product development, which proceeds not in a series of bangs but in a continuous process of improvement and refinement. With this false premise, it is hardly surprising that the proposal envisages a very different future for medical R&D. Under the new Global Framework,’ priorities and parameters of medical research and development would be defined by a new bureaucratic agency, not by the real needs of patients... The resolution says member-states should make health and medicines a strategic sector. Such words are all the justification populist governments need to confiscate and overregulate. Bolivia recently claimed that oil and gas were strategic sectors. Then the troops came in. Brazil has already threatened to ignore the patent on any drug it deems essential. *Ibid.*”

¹⁶⁵ See also Mark F. Schultz and David B. Walker, How Intellectual Property Become Controversial: NGOs and the New International IP Agenda, at p. 90,

¹⁶⁶ See Dr Tim Hubbard, Reply to the comments requested by CIPH and WHO to the CPTech proposal for a Medical Research and Development Treaty (MRDT) (8/15/05), at:

(<http://www.who.int/intellectualproperty/submissions/SubmissionsHubbard.pdf>). The treaty creates a legal obligation on each country to support [fund] medical R&D while allowing them flexibility in a way that they support it. Countries that support medical R&D to the required level (fraction of GDP) are granted flexibility to incentivise R&D innovation through mechanisms other than just marketing monopolies. Countries whose support for R&D is deemed not to meet the required level immediately lose these flexibilities. *Ibid.*, at pp. 1-2. The MRD Treaty proposes a new international framework for financing pharmaceutical research through public funding as an alternative to the patent system. The premise underlying the MRD Treaty proposal is that the current system is designed to increase drug prices, as the sole mechanism to increase investments in R&D. See Mark F. Schultz and David B. Walker, *How Intellectual Property Become Controversial: NGOs and the New International IP Agenda*, at p. 87, citing Letter from James Love, Director, CPTECH, to World Health Commission on Intellectual Property, Innovation and Health (Feb. 24, 2005), at: (<http://www.cptech.org/workingdrafts/rndsignonletter.html>).

¹⁶⁷ [The TRIPS] agreement on intellectual property rights... is an unbalanced treaty, based solely on enforcing patent rights worldwide as a mechanism to reward innovation. We believe the way forward is to modify Trips in healthcare to require countries to maintain a GDP-related contribution to research and development, while being free to choose how they finance it. *New methods of research - such as non-profit collaboration or prizes for exceptional ideas - would allow innovation to be rewarded directly, removing the need for marketing monopolies, and allow competition. Drugs could then be sold close to the cost of manufacture... Evidence that alternative business models can support innovation comes from a variety of areas including open-source software development, the human genome project and open-access publishing.* Last year, 69 respected scientists and economists wrote to the World Intellectual Property Organisation, a UN agency, asking that alternatives such as collaborative open models be considered. Yet the developed world continues to resist change. *It is hard to avoid the suspicion that the dogged advocacy of intellectual property law as the only way to stimulate innovation is more about maintaining world economic power than anything else* (emphasis added). See: Tim Hubbard and James Love, *We're Patently Going Mad: Lifesaving Drugs Must be Developed Differently - For All Our Sakes*, *The Guardian* (3/4/04), at:

(<http://www.guardian.co.uk/life/opinion/story/0,12981,1161123,00.html>).

¹⁶⁸ Intellectual property advocates, dispute the viability of these recommendations, which they equivocate with socialism. According to one such advocate, the ... article in The Guardian... entitled 'We're Patently Going Mad - Lifesaving Drugs Must Be Developed Differently - For All Our Sakes.' Written by James Love and Tim Hubbard from, respectively, the Consumer Project on Technology and the Wellcome Trust Sanger Institute... advocates that the existing system of patents and private production be scrapped in favor of a model that relies on GDP-related contributions to R&D by individual nations, non-profit collaboration, and prizes for exceptional ideas. The current system, the authors claim, increases global prices by an unnecessary \$300 billion per year, whereas theirs would allow drugs to be sold close to the cost of manufacture. Part of their argument is that experience with the open source software movement demonstrates that alternative business models are possible, and they cite a 2003 letter in which 69 respected scientists and economists⁴ asked that the World Intellectual Property Organization examine collaborative open models as an alternative to property-based regimes. The letter cited not only software, but the Internet, the human genome project, and other ventures. ***Socializing an important area of invention and commerce - - for that is what this recommendation entails -- is a dangerous prescription. One would have thought the world would have learned from the utter economic failure and vast human tragedy of the nations that embraced socialism as a basic organizing principle, and would be wary when the same mechanism is advocated for any single sector... This proposal is closely connected to a phenomenon called the Free Culture Movement... which seems to be opposed to intellectual property and markets as a means of organizing any economic activity involving creativity.*** Most of its attention has been focused on music and movies and the issue of P2P file-sharing (they are for it), and on software. The pharmaceutical issue is a new departure, but it is not a surprise to find that among the 69 respected scientists and economists⁴ who signed the WIPO letter are many familiar names from the controversies over entertainment and software, including a passel of law professors, public interest⁴ advocates, and free software gurus... On one point the authors are dead right. They say: It is hard to avoid the suspicion that the dogged advocacy of intellectual property law as the only way to stimulate innovation is more about maintaining world economic power than anything else⁴... *The great thing about capitalism, based on property rights and the free market, in all its*

messy, wasteful, and often irritating splendor, is that it puts world economic power in the hands of the people (emphasis added). See James V. DeLong, *Peddling Dope: Open Source Drug Development*, *supra*.

¹⁶⁹ See Joseph A. DiMasi and Henry G. Grabowski, *Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D* (6/25/04), at p. 4, at: (<http://www.who.int/intellectualproperty/news/en/Submission3.pdf>).

A recent paper by Hubbard and Love (2004) questions the value of the patent system as a mechanism for funding pharmaceutical R&D relative to a number of other frameworks. The authors suggest that current levels of pharmaceutical R&D can be maintained along with lower costs for medicines if one or all of the alternative mechanisms that they promulgate replaced the patent system wholesale. *Ibid.*, at p. 2. Our main concern with HL's proposals centers around the compulsory termination of the patent system, given the strong role that patents have played in encouraging drug R&D and innovation. Our analysis should not be construed as a critique of supplements to the patent systems, including prizes and R&D partnerships, which are designed to increase R&D activities for particular socially meritorious ends. *Ibid.*, at p. 16.

¹⁷⁰ See Kevin Outterson, *Nonrival Access to Pharmaceutical Knowledge*, Submitted to the WHO Commission on Intellectual Property Rights, Innovation & Public (1/3/05), at: (<http://www.who.int/intellectualproperty/submissions/KevinOutterson3january.pdf>). Pharmaceutical knowledge is nonrival, and can be shared without diminishing anyone else's knowledge. The only reason not to share pharmaceutical knowledge is to promote future innovation. Nonrival access proposals must account for retaining optimal innovation incentives. One model of nonrival access would permit marginal cost production (MCP) for low income populations, without patent rent extraction (ie, no royalty). Appropriation would be supported by rent extraction (patent laws) in high income markets. This is the compulsory license model. Alternatively, nonrival access could be achieved if all pharmaceutical patent rights for low income populations were purchased and donated to the public domain. Appropriation would be supported by the combination of the buyout prices and continuing rent extraction (patent laws) in high income markets. This is the patent buy out model. In separately published reports, several economists have embraced proposals which are consistent with nonrival access. The DEFEND Proposal is a patent buy-out of exclusive licenses for poor countries. Scherer suggests that

pharmaceutical patent rent extraction is unnecessary and inappropriate for the poorest countries, and that free riding should actually be encouraged... Lanjouw and Jack suggest that poor countries really shouldn't be expected to contribute much to global pharmaceutical R & D, with the possible exception of locally endemic diseases. *Ibid.*, at pp. 2-3.

¹⁷¹ See Dean Baker, Financing Drug Research: What Are the Issues? , Center for Economic and Policy Research (9/22/04), at p. 3, at: (<http://www.who.int/intellectualproperty/news/en/Submission-Baker.pdf>).

¹⁷² Medicines are knowledge goods, sharing an important characteristic with many other knowledge goods. It may be expensive to develop a medicine, but it is often not expensive to copy one... In 2005, Representative Sanders [I-VT] introduced HR 417 in the U.S. Congress. This legislation is a working model for a new paradigm of drug development – The Medical Innovation Prize Fund... It... provides incentives to develop products that would address global public health problems, including new treatments for neglected diseases such as malaria or emerging health problems such as severe acute respiratory syndrome (SARS) or avian flu. The Medical Innovation Prize Fund would eliminate monopolies for medicines in the United States, driving prices close to marginal costs. It is not an attack on intellectual property but a new system of intellectual property: one that separates the market for innovation from the market for the physical copies of the knowledge good. The Prize Fund approach would require a new global trade framework to deal with the issue of sharing the global burden of the costs of research and development.. See James Packard Love, Drug Development Incentives to Improve Access to Essential Medicines , W H O Roundtable – Special Theme – Intellectual Property Rights and Public Health, Bulletin of the World Health Organization 84(5): 405-411 (May 2006), at p. 408, at: (<http://www.who.int/bulletin/volumes/84/5/405.pdf>).

¹⁷³ Patent dependent financing for prescription drug research is leading to ever greater problems. The economic distortions associated with monopoly pricing are growing at a rapid rate, with the deadweight loss alone likely exceeding \$100 billion annually within a decade. The waste associated with excessive marketing and sales efforts are growing at a corresponding rate. In addition, the corruption of the research process that is the predictable outcome of this form of government intervention in the market is becoming ever more pronounced. As a result, there is increasing interest in alternatives to

the patent system for supporting prescription drug research. *Ibid.*, at p. 25.

¹⁷⁴ See discussion, *infra*.

¹⁷⁵ See Jonathan Kahn, Rights and Practical Access to Medicine, WHO Roundtable – Special Theme – Intellectual Property Rights and Public Health, Bulletin of the World Health Organization, *supra*, at p. 409.

¹⁷⁶ See The End of AIDS: A Global Summit with Bill Clinton, CNN Presents, CNN.com (4/29/06), at: (<http://www.cnn.com/CNN/Programs/presents>).

¹⁷⁷ See, e.g., Richard Holbrooke and Mark Moody-Stuart, Business Has Vital Role to Play in Fighting Aids, FT.com (5/22/06), at: (<http://news.ft.com/cms/s/e9c83790-e8f2-11da-b110-0000779e2340.html>).

It should be noted that the Global Business Coalition on HIV/AIDS (GBC), now the world's largest organisation of businesses committed to fighting Aids was initially funded by the Bill and Melinda Gates Foundation, the United Nations Foundation and the Open Society Institute. The first and third of these organizations are well-known advocates of the open source/universal access to knowledge (A2K) and healthcare anti-IP right paradigm embraced by Brazil and other developing nations. Cf. Carlo Stagnaro and Lawrence A. Kogan, Corporate Social Restriction, TCSDaily.com (4/4/06), at: (<http://www.tcsdaily.com/article.aspx?id=040406F>).

¹⁷⁸ On November 20, 2001, WTO Members adopted the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) which recognized, in paragraph 4, that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In paragraph 1, the WTO Members recognized the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. This broad language has the potential to cover almost any disease, now and in the future, that can be characterized as having reached epidemic proportions. Anti-private property and free market bureaucrats, activists, and academics are interpreting this provision to mean that, when it comes to health care and essential medicines, public rights to health care will *always* trump private property rights, including patents, trade secrets, copyrights, trademarks, etc.

¹⁷⁹ The United States Department of Commerce recently published a study of pharmaceutical pricing in high income countries which calls for higher patented drug prices in Canada, Europe, Japan, Australia and

other OECD countries. (DOC 2004, fig. 5) The report concludes that these countries have been free riding off American patent rent extraction by setting government reimbursement prices too low ... A recent speculative estimate, based on industry data and calculations... suggests that eliminating OECD price controls on patented drugs would increase revenues by \$17.6 to \$26.7 billion per year, with additional R&D of \$5.3 to \$8 billion per year. (US DoC, at 29). Implicit in this estimate is the assumption that about a third of incremental revenues would be spent on R & D ... *Ibid.*, at pp. 3 and 1.

¹⁸⁰ Indeed, privately financed health aid programs such as the Gates Foundation, begun and maintained by philanthropists Bill and Melinda Gates, go beyond the politically appealing HIV/AIDS campaigns to address additional diseases inflicting developing country populations. The Gates Foundation supports efforts to prevent and treat diseases and conditions that meet three criteria: (1) they cause widespread illness and death in developing countries; (2) they represent the greatest inequities in health between developed and developing countries; and (3) they receive inadequate attention and funding. See *Priority Diseases and Conditions, Global Health, Bill and Melinda Gates Foundation*, at: (<http://www.gatesfoundation.org/GlobalHealth>). And there are many other such programs financed by other private philanthropic causes.

¹⁸¹ The [President's Emergency Plan for AIDS Relief \(PEPFAR\)](#) is a five-year, \$15 billion [federal government] program that directs funding for HIV/AIDS, tuberculosis and malaria primarily to 15 focus countries and provides funding to the [Global Fund To Fight AIDS, Tuberculosis and Malaria](#). See *Bush Touts Foreign HIV/AIDS Funding As 'Great Compassion' And 'In Our National Interest'*, *Medical News Today* (2/7/06), at: (<http://www.medicalnewstoday.com/medicalnews.php?newsid=37072>). On the domestic front, Bush urged Congress to reauthorize the Ryan White CARE Act, which expired on Sept. 30. The CARE Act provides funding for care and services to HIV-positive people in the U.S. See also *Politics and Policy: Bush Touts PEPFAR, Urges Congress To Reauthorize Ryan White CARE Act*, *Daily HIV/AIDS Report Kaiser Network.org* (12/20/05), at: (http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=34092).

¹⁸² See Maggy Farley, *14 Nations Will Adopt Airline Tax to Pay for AIDS Drugs - France leads the effort meant to provide greater access to medicines. The U.S. opposes the levy*, *Los Angeles Times* (6/3/06), at: (<http://www.latimes.com/news/nationworld/world/la-fg->

[unaids3jun03.0.6919605.story?coll=la-home-headlines](http://www.unaids.org/jun03/0,6919605,story?coll=la-home-headlines)). A three-day [United Nations] AIDS conference set a goal Friday of doubling spending to slow the spread of the disease, and 14 countries announced an airline ticket tax to fund greater access to AIDS drugs... [The] group of 14 nations, led by France, announced a new mechanism to provide greater access to drugs, funded by a tax on airline tickets that is expected to raise more than \$258.3 million a year. France has voluntarily imposed an economy class levy ranging from 1 euro – about \$1.30 – in Europe to 4 euros for longer flights. For first and business class, the fee is 10 euros in Europe and 40 euros elsewhere. The U.S. opposes the tax, but Brazil, Chile, Cyprus, Congo, France, Gabon, Ivory Coast, Jordan, Luxembourg, Madagascar, Mauritius, Nicaragua, Norway and Britain have pledged to implement it. Starting July 1, France will collect the fee from all flights entering or leaving France. Every person in the world who can afford to buy an air ticket can afford this very mild, minimum-level tax upon it,' said Erik Solheim, Norway's minister for International Development. The funds will go to buying AIDS drugs in bulk *to help reduce the prices, and to give incentives to drug companies to produce more antiretroviral drugs for children, which are now more expensive and less in demand than adult formulations* (emphasis added). *Ibid.*

¹⁸³ See Public Health, Innovation and Intellectual Property Rights , Report on the Commission on Intellectual Property Rights, Innovation and Public Health World Health Organization (April 2006), at: (<http://www.who.int/intellectualproperty/documents/thereport/CIPIH23032006.pdf>).

¹⁸⁴ *Ibid.*, at p. 10.

¹⁸⁵ The development of innovative capacity requires an array of interlocking policies, including in the spheres of education, intellectual property and technology transfer. *Ibid.*, at p. 163. ... Weak intellectual property regimes in the past facilitated learning for all the countries studied. The policy environment which facilitated this (e.g., the absence of product patents in India, or weak intellectual property protection in the first decades of technology development in Egypt and the Republic of Korea) has now changed for most developing countries as a result of the TRIPS Agreement. That is one reason why, in countries such as China and India, intellectual property protection and enforcement have become controversial issues. *Ibid.*, at p. 168. ... Intellectual property rights, in particular patents, may impinge upon the transfer in a number of ways... *Ibid.*, at p. 171.

¹⁸⁶ A key message of the report is that because the market demand for *diagnostics, vaccines and medicines* needed to address health problems

mainly affecting developing countries is small and uncertain, the incentive effect of intellectual property rights may be limited or nonexistent. Because intellectual property rights may not be an effective incentive in this area, there is need for other incentives and financial mechanisms to be put in place and for collaborative efforts between different stakeholders. Without access to the products of innovation, there can be no public health benefits (emphasis added). See Tomris Turmen and Charles Clift, Public Health, Innovation and Intellectual Property Rights: Unfinished Business, Editorial, Bulletin of the World Health Organization, Vol. 84, No. 5 (May 2006), at pp. 337-424, at: (<http://www.who.int/bulletin/volumes/84/5/338.pdf>).

¹⁸⁷ See Comments of Dr. Carlos Correa and Dr. Pakdee Pothisiri, *Ibid.*, Annex at p. 224.

¹⁸⁸ Such agenda favors a government-centric, process-based approach over a market-centric, final product/service-based approach to national health care. Pursuant to the first approach, government identifies the public's healthcare needs (the public good), as far as health products and services are concerned. Government then enlists industry to serve as its agent in fulfilling those needs. To ensure that government's public obligations and society's needs are satisfied, in terms of quality, safety, efficacy, and affordability, government shapes and then regulates precisely how industry undertakes the innovation process - from discovery to development to delivery. Pursuant to the second approach, the consumer market, consisting of individual patients, industry health plan procurers, and individual and institutional health care providers, and the health care suppliers, namely industry (drug companies, hospitals, laboratories, etc.), and private and public universities, and research institutes, laboratories, etc., usually identify the consumers' (the public's) healthcare needs and how to meet them. Government's role is primarily to encourage and facilitate innovation and to see that the market efficiently supplies those healthcare demands, beginning with R&D through product/service delivery. Where necessary, government regulates how the market fulfills its obligation to provide consumers with high quality healthcare products and services that are both safe and efficacious. Pricing is generally determined by the markets, with government oversight.

¹⁸⁹ One anti-private property and anti-market activist who is also an advisor to the Government of Argentina and the WHO is legal academic named Carlos Correa. Through his writings and participation at the WHO, he has actively tried to reframe the international debate on intellectual property rights and health care. In an interview appearing within the recent WHO Bulletin, Correa reiterates his position against

patents. Why do we need alternatives to the patent system? One basic problem with *the patent system is that it works only where markets are lucrative and profits are high*. In a situation where the public health need is great, but the market is small, patents do not work at all. *New drugs are discovered – in the vast majority of cases – not by private companies but by universities and public research institutions. The monetary reward provided by the patent system does not play a major role in this phase...* At Duke University, they are looking at ways to develop clinical studies for the public good. '... Are there other solutions? Governments need to take a different approach... *New mechanisms should be established to set R&D priorities and coordinate activities with increasing participation from developing countries*. For example, WHO could consider a global plan of action to foster drug investment and discovery for diseases in developing countries. '... The patent system was originally established to encourage researchers to share their findings for the public good. Today, research results can be accessed worldwide using the internet; why do we need the patent system? *The justification for the patent system has changed. In the 19th century it was to give inventors an incentive to disclose what they had developed. The idea was that without the patent, they would keep this information secret. Today, the patent system is regarded more as a way of permitting the recovery of investment based on the argument that, in the absence of exclusive rights, companies will not invest in developing products because once these are available, others can imitate them.* Why are there such entrenched positions on intellectual property and health between campaigners and the pharmaceutical industry? Is there no middle ground? ... *The key point is that people in developing countries should not be deprived of medicines just because these are patented. This is unethical and against human rights.* '... *The United States allows patenting of discoveries as well as of inventions, is this right? What is the public health impact? From a public health perspective, this is not the right policy, nor is it right under the fundamental principles of patent law.* '... Are universities benefiting from the patent system? The pressure on universities to patent distorts the role of universities as the source of science for the public good. The problem is that what universities patent is often closed to science, so patenting can hinder research. '... But if we look at the other side of the coin, patents are also bringing benefits. They may encourage the development of technologies that could otherwise remain unexploited. *But in the case of the United States, for instance, the revenues that patents generate just cover the universities' cost of transfer of technology offices', and acquiring patents, etc., so it doesn't*

seem to generate a very significant net benefit. Are there alternative ways, such as *open access publication*, to motivate and reward pharmaceutical development? *An open source approach* can be used to undertake some phases of the R&D process. Prizes, ex-ante subsidies and advance purchase contracts are other possible ways of motivating and funding drug development' (emphasis added). See Bulletin interview: Do Patents Work For Public Health? - Interview with Carlos Correa, WHO News, Bulletin of the World Health Organization, Vol. 84, No. 5 (May 2006), at pp. 349-350, at: (http://www.who.int/bulletin/volumes/84/5/who_news.pdf).

¹⁹⁰ *Ibid.*, at p. 31. ... In regard to our inquiry, a key issue is whether or how the patent system is relevant to encouraging innovation in the biotechnology and pharmaceutical sectors... In the context of our work, one of the important points is that, where the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market... Intellectual property rights have an important role to play in stimulating innovation in health care products in countries where financial and technological capacities exist, and in relation to products for which profitable markets exist. In developing countries, the fact that a patent can be obtained may contribute nothing or little to innovation if the market is too small or scientific and technological capability inadequate. *Ibid.*, at pp. 34- 35.

¹⁹¹ Developing health technologies for the world's poor people increasingly requires the wise management of intellectual property (IP)... Seeking to promote the development of new health technologies for developing countries... nonprofit organizations have led to a reassessment of the IP role in making health products available to the poor... [W]e now know that creatively managing IP can both facilitate access to health solutions and speed the development of products. New research shows that misuse or waste of IP slows the development of new health technologies for developing countries... Van Zimmeren et al. examine an issue of much current interest: the extent to which patent pools, single licensing authorities, royalty collection authorities, and other such cooperative ventures can facilitate product development. According to the authors, it is unclear whether these mechanisms can be set up easily and administered efficiently: it may be better for each party to seek to protect the interests of the public sector rather than establishing new, potentially cumbersome and expensive schemes... The papers by Winters and Musungu call for various international mechanisms to assess and monitor the impact of IP on

research and development (R&D) and health in developing countries. These would be extremely valuable advances, although the assessment protocols need a more solid intellectual foundation. See Anatole K rattiger and R ichard T. M ahoney, Intellectual Property and Public Health , Editorial, Bulletin of the World Health Organization, Vol. 84, No. 5 (May 2006), at pp. 340-341, *supra*, citing E. van Zimmerman, B. Verbeure, G. M athijs, and G. V an O verw alle, A Clearinghouse For Diagnostic Testing: The Solution To Ensure Access To And Use Of Patented Genetic Inventions? *Bull World Health Organ* 2006; 84:352-9; D. W inters, Expanding Global Research And Development For Neglected Diseases , *Bull World Health Organ* 2006; 84: 414-6; S.F. M usungu, Benchmarking Progress In Tackling The Challenges Of Intellectual Property And Access To Medicines In Developing Countries , *Bull World Health Organ* 2006;84: 366-70.

¹⁹² As for intellectual property rights, an [the] undifferentiated recommendation, as the one that the reader might infer from the report, that all developing countries should lower IP standards, *is not supported by analysis*... Patent protection per se does not create monopoly positions in the final market... Countries that do not protect pharmaceutical patents do not necessarily experience higher rates of access, even if generic products are manufactured locally (em phasis added). See Comments of Dr. Fabio Pam m olli , *Ibid.*, Annex at p. 226. The actual level of patenting, the scope of protection, and the effects of such factors on price and competition were not adequately examined. *Instead of collecting empirical data, the report relies on the untested assumption that relaxing IPR rules will generally benefit developing countries.* The assignment of intellectual property rights, however, may lead to more efficient use of resources (information, etc.) and licensing can promote the transfer of technology into the local economy. Furthermore, small patents around basic technology can work as a barrier against monopolization and help local businesses or applied research enter the markets [Dr. Yamane refers to the practice of 'patent flooding', discussed, *infra*]... Patents do not necessarily confer significant market power... *The report did not analyze the effects of patents on competition in developing countries.* (em phasis added). See Comments of Dr. H iroko Y am ane , *Ibid.*, Annex at p. 227.

¹⁹³ The report implies a direct link between patent ownership, product price, and access in the developing world. Patents rarely confer a monopoly in a therapeutic field and are not the basis for price-setting... Concerning access, patents are not the issue, but the overwhelming poverty of individuals, absence of state healthcare financing, lack of medical personnel, transport and distribution infrastructure plus supply

chain charges which can make affordable originator or generic products unaffordable... The report calls for further reform of the patent system'. There is a need to improve the competence of the patent agencies and enforcement procedures in developing world countries but the basis for granting a patent and the TRIPS Agreement do not need reform, especially following the WTO General Council Resolution of December 6th 2005. See Comments of Dr. Trevor Jones, *Ibid.*, Annex at p. 225.

¹⁹⁴ See discussion, *infra*.

¹⁹⁵ [T]he industry model [of innovation]... does not focus on the connection between basic research and the development of vaccines and medicines valuable for human health. The scientific and technical components of the discovery and development process represent only one aspect... We prefer to consider innovation as a cycle... [a] discovery-development-delivery continuum ... [I]t applies principally to developed countries and the diseases which predominantly affect them, where effective demand and the population's health needs most closely coincide... [I]t broadly works for the developed world and sustains biomedical innovation directed at the improvement of public health. *Ibid.*, at p. 35. ... Broadly speaking, the innovation cycle does not work well, or even at all, for most developing countries... Our concept of innovation sees the process as a cycle consisting of three major phases that feed into each other: discovery, development and delivery. This is in contrast to conceiving of innovation as an entirely linear process that culminates in the launch of a new product. *Within the innovation cycle, public health need creates a demand for products of a particular kind*, suited for the particular medical, practical or social context of the group in question, and feeds into efforts to develop new or improved products (emphasis added). *Ibid.*, at p. 36. ... *The linear model*...whereby universities or public research institutions did basic or fundamental research and the private sector picked up and developed what was capable of commercial application *has become regarded as outmoded* (emphasis added). *Ibid.*, at p. 39.

¹⁹⁶ Although much of this report is couched in the language of science, medicine, economics, or law, *it should not be forgotten that there is an underlying moral issue*. While we have the technical capacity to provide access to lifesaving medicines, vaccines, or other interventions, which are indeed widely available in the developed world, millions of people, including children, suffer and die in developing countries because such means are not available and accessible there (emphasis added). *Ibid.*, at p. 21.

¹⁹⁷ Frustration and lack of opportunity, rather than just material gain, have been important reasons why talented scientists have emigrated to developed countries. For instance, *countries such as China and India have provided large resources of human capital to developed countries*, in particular the United States, through students undergoing advanced education and then contributing to R&D and to the application of new technologies in the developed world. *To a considerable degree, developed countries have benefited from this migration through the influx of fresh talent from around the globe* (emphasis added). *Ibid.*, at p. 166.

¹⁹⁸ Currently WHO mentions the recognition of access to essential medicines as a human right at the state level among the priorities in the framework of implementation of pharmaceutical policies in the period 2004-2007, and WHO's joint effort with the United Nations Committee on Economic Social and Cultural Rights, the body in charge of the surveillance of the International Covenant on Economic, Social and Cultural Rights (ICESCR), has resulted in the inclusion of access to essential medicines in the *core content* to the right to health (emphasis in original). See Xavier Seuba, *A Human Rights Approach to the WHO Model List of Essential Medicines*, WHO Roundtable – Special Theme – Intellectual Property Rights and Public Health, Bulletin of the World Health Organization, *supra*, at p. 405,

¹⁹⁹ See International Covenant on Economic, Social and Cultural Rights, Adopted and opened for signature, ratification and accession by General Assembly, resolution 2200A (XXI) of 16 December 1966, *entry into force* (1/3/76), at: http://www.unhchr.ch/html/menu3/b/a_ceschr.htm).

²⁰⁰ With regards to whether property rights should prevail over the right to health, the United Nations sub-Commission on the Promotion and Protection of Human Rights has pointed out that the right to the protection of moral and economic interests resulting from scientific research is a human right *subject to public interest limitations*' [(emphasis added)]. In this sense, within the framework of the World Trade Organization (WTO) Dispute Settlement Understanding, the *right* to access to essential medicines provides powerful arguments to states reported to be infringing intellectual property rights... Approaching access to essential medicines as a right not only opens a subjective dimension that refers to individual enforceability of the right to health, but modifies issues such as the relationship between access to medicines and intellectual property rights, strengthening the patient's position. Likewise, it allows a merely ethical valorization to be overcome in favour of the analysis of actions adopted in the

framework of public health in a context of legal enforceability. See Xavier Seuba, A Human Rights Approach to the WHO Model List of Essential Medicines, WHO Roundtable – Special Theme – Intellectual Property Rights and Public Health, Bulletin of the World Health Organization, *supra*, at p. 406.

²⁰¹ Most governments have committed to take steps ensuring that various fundamental human rights are fulfilled. Human rights have an authority that is not trivial; most countries have already acknowledged the primacy of human rights by signing and ratifying the international agreements in which they are enshrined, and many have further made provision in national constitutions and legislation. In this context, the relevant human right agreed [to] in the International Covenant on Economic, Social and Cultural Rights (art. 12.1) is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. This language reflects the overarching objective in the WHO's Constitution, which is the attainment by all peoples of the highest possible level of health'. A minimum, human rights, and the right to health, in particular, prescribe that States have an obligation to give consideration to the health implications of their policies... General Comment No. 14 to Article 12, the Committee on Economic, Social and Cultural Rights enumerates *core obligations, which include the provision of essential biomedical innovations...* [T]he Committee emphasizes that *it is incumbent on States and other actors in a position to assist* [private companies] *to provide international assistance and cooperation, especially economic and technical, to enable developing countries to fulfill their obligations under the Covenant* (emphasis added). See Public Health, Innovation and Intellectual Property Rights, Report on the Commission on Intellectual Property Rights, Innovation and Public Health World Health Organization, *supra*, at p. 22. *Governments which have ratified the covenant have a duty to take concrete steps towards the realization of the right to health, a core element of which is access to biomedical innovations* (emphasis added). *Ibid.*, at p. 23.

²⁰² At least one French NGO has recently argued that 3. Morocco's policies on access to medicines and the realization of human rights are threatened by strict trade-related intellectual property (IP) rules in trade agreements. Of particular concern is the United States – Morocco Free Trade Agreement (FTA) that was signed in March 2004 and came into force on 1 January 2006... 5. Therefore, it is important that the government of Morocco commission an independent human rights impact assessment of the effect of trade-related IP rules on the cost of medicines and the enjoyment of human rights in Morocco. 6.

Moreover, it is crucial that the government revise its IP legislation in the light of the results of this impact assessment, in order to ensure that IP rules are consistent with development and human rights commitments... We believe that human rights mechanisms such as the Committee on Economic, Social and Cultural Rights can help attain this objective by reminding States that compliance with international trade rules cannot justify non-compliance with human rights obligations. 7. This submission to the Committee on Economic, Social and Cultural Rights outlines 3D's main concerns relating to the impact of trade-related IP rules on access to affordable medicines and the enjoyment of human rights in Morocco. These concerns support the Committee on Economic, Social and Cultural Rights' questions on the right to health submitted to the government of Morocco in June 2005. See Trade-Related Intellectual Property Rights, Access to Medicines and Human Rights – Morocco, 3D (April 2006), at: (http://www.3dthree.org/pdf_3D/3DCESCRMorocco_April06Eng.pdf).

²⁰³ The UN Committee on Economic, Social and Cultural Rights recently issued a General Comment distinguishing intellectual property rights from human rights. While intellectual property rights can be allocated, trade, amended, forfeited, and are basically limited in time and scope, human rights are timeless expressions of fundamental entitlements of the human person. See Helena Nygren-Krug & Hans V. Hogerzeil, Human Rights: A Potentially Powerful Force For Essential Medicines, WHO Roundtable – Special Theme – Intellectual Property Rights and Public Health, Bulletin of the World Health Organization, *supra*, at p. 410, *citing* General Comment No. 17, (2005).

²⁰⁴ See Elisabeth Rosenthal, A WHO Report Finds System Fails The Poor International Herald Tribune (5/21/06). The current system of "research and development has not yet produced the results hoped for, or even expected, for the people of developing countries," the report of the Commission on Intellectual Property Rights, Innovation and Public Health says. While in richer nations the system broadly works to provide the health care required by their inhabitants, this is far from being the case in developing countries. 'The pharmaceutical industry and many developed countries insist that the current system of granting lucrative patents for new drugs is crucial for encouraging and financing the invention of much-needed medicines, which are almost always produced in the private sector. But the commission, led by former President Ruth Dreifuss of Switzerland, said that this path to innovation was inadequate, because people in the developing world often cannot afford to pay for high-priced new drugs, and because they sometimes

need treatments that offer little profit for drug companies. Governments should therefore develop and finance an alternate system for drug development and distribution in the developing world, the report concluded. More controversially, it suggested that drug companies should not seek patents in poor countries. *Ibid.*

²⁰⁵ The proposed title of the resolution is Public health, innovation and intellectual property rights [a global plan of action], which was contained within a recently prepared WHO CIPIH Executive Board report. See Action by the Health Assembly - Intellectual Property Rights - Commission on Intellectual Property Rights, Innovation and Public Health: Report of the Meeting of the Committee of the Executive Board, Fifty-Ninth World Health Assembly A59/16 Add.1 Provisional agenda item 11.11 (5/18/06), at par. 8, at: (http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_16Add1-en.pdf).

Noting that the Report of the Commission requests that *WHO should prepare a global plan of action* to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries,].

2. URGES Member States [and, where applicable, regional economic integration organizations] [1- to consider the recommendations of the report and *to contribute actively to the development of a global strategy and plan of action*]; Or [1- to consider the recommendations of the report taking into account their national context and priorities] *for the implementation of the recommendations* directed towards Member States [implementation respecting existing health, economic and finance systems and structures in the WHO Member States] (emphasis added). *Ibid.*, at p. 3. In particular, the resolution attacks the notion of exclusive private property rights, particularly patents.

Conscious of the opportunities opened up by advances in biomedical science, and the need to harness them more effectively to develop new products, particularly in order to meet public health needs in developing countries; Noting that *intellectual property rights are an important incentive for the development of new health-care products; Noting, however, that this incentive lacks efficacy for the development of new products to fight diseases where the potential paying market is small or uncertain; Noting that the exclusive rights conferred by patents* can affect the price and availability of medicines and other health-care products... (emphasis added). *Ibid.*, at p. 3.

²⁰⁶ The resolution takes direct aim at U.S. bilateral free trade agreements' TRIPS-plus' provisions. 2. URGES Member States [and, where applicable, regional economic integration organizations]... [3- *to ensure that bilateral trade agreements do not seek to incorporate*

TRIPS-plus protection in ways that may reduce access to medicines in developing countries]... (em phasis added). *Ibid.*, at p. 4.

²⁰⁷ See Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action, W H A Resolution 59.24 (5/27/06), at: (http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf).

²⁰⁸ See The Doha Declaration on Intellectual Property Rights and Public Health W T M IN (01)D EC /2 (11/20/01).

²⁰⁹ See ANNEX 1 - Draft resolution, paragraph 2: additional text submitted by Brazil, *Ibid.*, at p. 5.

²¹⁰ The Swiss chair of the drafting group proposed a text merging a resolution proposed by Brazil and Kenya on a global framework for essential medicine research and development (EB117 E13) and a resolution contained in a report on the WHO Commission on Intellectual Property, Innovations and Public Health's (C I P I H) report published in April (*IPW*, Public Health, 24 May 2006). The resolutions are under discussion in a technical committee at the assembly, which is the annual meeting of the 192 member states of the World Health Organization... The original resolution based on the Brazil and Kenya proposal for a framework on essential health research and development called for a working group of interested member states to be set up to consider alternative incentive mechanisms for needs-driven research, consistent with appropriate public interest issues. The chair's new proposed text titled, Public health, innovation and intellectual property rights: a plan of action with special focus on essential health research, proposed the setting up of an intergovernmental working group open to all interested member states, which was suggested by both of the original resolutions. The working group is to develop a global strategy and plan of action which would provide a medium term framework for action to implement the recommendations of the commission. See Tove Iren S. Gerhardsen and William New, World Health Assembly Debates New Draft Text Merging IP Resolutions, Intellectual Property Watch (5/25/06), at: (<http://www.ip-watch.org/weblog/index.php?p=316&res=1280&print=0>).

²¹¹ The World Health Organisation is to start talks on a global plan of action for research on priority health needs in developing countries. The WHO will hope to encourage development of medicines neglected by private industry. The WHO's 192 member states approved a consensus resolution on Saturday establishing an intergovernmental working party to come up with a strategy and action plan within two years... The WHO accord followed what health officials called a miraculous change of tack by *the US*, which had previously indicated

strong opposition to any steps that might imply a weakening or sidestepping of the drug patenting system. In return, developing countries led by Brazil and Kenya dropped demands for a binding research and development framework and explicit support for open access' and other models of promoting health research outside the patent system (emphasis added). See Francis Williams, WHO To Prompt R&D For Poorer Countries, Financial Times (5/28/06). See also WHO Agree Breakthrough Deal to Research and Develop Drugs, Deutsche Presse-Agentur (5/27/06) (The World Health Organization's governing body approved a resolution Saturday that aims to overhaul drugs research and provide affordable drugs on a needs-driven basis. The agreement will create a new framework to stimulate research and development in areas of public health priority, and could change the way some new drugs are funded and brought onto the market.).

²¹² A recent May 29, 2006 e-mail exchange between two health activists (James Love and Thiru Balasubramaniam) at CP-Tech, a Ralph Nader organization, discusses the Financial Times article citing the compromise WHO resolution noted above. According to James Love: I agree with the miraculous' part of this article. However, the Kenya/Brazil resolution (EB117.r13) had never included a demand for binding' anything, only the start of a conversation about a new global framework. *([A] proposal for discussions about a treaty was proposed by Brazil in the CIPIH resolution, but not discussed).* The Kenya/Brazil resolution referred to considerations of soft or hard obligations, and all sorts of mechanisms to advance the idea of a multilateral R&D initiative. *It is most likely that short term work will involve softer norms, but everything is still on the table, including the possibility for hard norms as a longer term project. I think the public sector, open access and open source type things are still in the mix,* mentioned specifically in the CIPIH report itself, and implicit in other parts of the new resolution, such as the graphs: Recognizing the importance of public and private investment in the development of new medical technologies'; Concerned about the impact of high-prices of medicines on access to treatment'; Aware of the need to promote new thinking on the mechanisms that support innovation'. James Love was responding to a prior message sent by Thiru Balasubramaniam, who quoted the FT article: The WHO accord followed what health officials called a miraculous' change of tack by the US, which had previously indicated strong opposition to any steps that might imply a weakening or sidestepping of the drug patenting system. In return, developing countries led by Brazil and Kenya dropped demands for a

binding research and development framework and explicit support for 'open access' and other models of promoting health research outside the patent system. See [Ip-health] Financial Times: WHO to prompt R & D for poorer countries, at: (<http://lists.essential.org/pipermail/ip-health/2006-May/009641.html>).

²¹³ See Armen A. Alchian Property Rights - A Concise Encyclopedia of Economics, The Library of Economics and Liberty, *supra*.

²¹⁴ See The Universal Declaration of Human Rights, adopted and proclaimed by United Nations [General Assembly Resolution 217 A \(III\)](#) (Dec. 10, 1948), at: (<http://www.unhchr.ch/udhr/>).

²¹⁵ The Preamble states, *Whereas* it is essential... that **human rights** should be protected by rule of law,... *Whereas* the peoples of the United Nations have in the Charter... determined to promote social progress and better standards of life in larger freedom, *Whereas* Member States have pledged themselves to achieve, in co-operation with the United Nations, the promotion of **universal** respect for and observance of **human rights** and fundamental freedoms, *Whereas* a common understanding of these **rights** and freedoms is of the greatest importance for the full realization of this pledge, *Now, therefore, The General Assembly Proclaims...* **Article 2** Everyone is entitled to **all the rights and freedoms** set forth in this **D eclaration**... **Article 3** Everyone has the right to life, liberty and security of person... **Article 8** Everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law... **Article 12**... No one shall be subjected to arbitrary interference with his privacy... **Article 17 I**. Everyone has the right to own property alone as well as in association with others. 2. No one shall be arbitrarily deprived of his property... **Article 25**. Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family... **Article 27** 1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. (2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author. **Article 28** Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized... **Article 29**... 2. In the exercise of his **rights** and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the **rights** and freedoms of others... **Article 30** Nothing in this Declaration may be interpreted as

implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any rights and freedoms set forth herein (underlined emphasis added).

²¹⁶ Recognizing that, in accordance with the Universal Declaration of Human Rights, the ideal of free human beings enjoying freedom from fear and want can only be achieved if conditions are created whereby everyone may enjoy his economic, social and cultural rights, as well as his civil and political rights... PART I, *Article 1*... 2. All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation... PART II *Article 2*... 2. The States Parties to the present Covenant undertake to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status... *Article 4* The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society... *Article 5* 1. Nothing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights or freedoms recognized herein... PART III... *Article 15*... The States Parties to the present Covenant recognize the right of everyone: 1. a) To take part in cultural life; b) To enjoy the benefits of scientific progress and its applications; c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author ... 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity... *Article 25* Nothing in the present Covenant shall be interpreted as impairing the inherent right of all peoples to enjoy and utilize fully and freely their natural wealth and resources (underlined emphasis added). Notwithstanding these provisions, anti-IP opponents, through the WHO's recent report, have nonetheless sought to justify the imposition of increased obligations upon private corporations (i.e., pharmaceutical companies) to support (subsidize) the public health needs of national governments. They rely for their support on Comment 14 of CESCR Article 12. It declares that it is incumbent on States and other actors in a position to assist' - this means you, American

business firms! to provide international assistance and cooperation. The General Comment, while not legally binding, is considered authoritative guidance' and therefore constitute[s] an important foundation for arguments that treat access to essential treatments, preventives and diagnostics as a right.' See John Gardner, 'Healthcare in the Developing World: Obstacles and Opportunities', *TCS Daily.com* (5/19/06), at: (<http://www.tcsdaily.com/article.aspx?id=051906B>).

²¹⁷ HIV/AIDS activists, nevertheless, are now more likely to argue that such a hierarchy does indeed exist in the U.S., relying upon a recently decided US Federal Circuit Court case, *Abigail Alliance v. Eschenbach*, 04-5350 (D.C. Cir., May 2, 2006), at: (<http://caselaw.lp.findlaw.com/data2/circs/dc/045350a.pdf>). The federal court, in a split-decision, interpreted federal statutory and US constitutional due process law to hold that where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient's informed access to potentially life-saving investigational new drugs, determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials, warrants protection under the [Fifth Amendment to the US Constitution's] Due Process Clause. *Id.*, at p. 29. It is conceivable that activists would seek to equate such a fundamental US constitutional due process right with what they allege is a fundamental human right to access to essential medicines under international human rights law. Activists may argue that, once a federal drug agency is required to provide access to the drug based on the existence of such a right, pharmaceutical and biotech companies would also be obliged to supply the drugs at affordable least cost prices to terminally ill patients, irrespective of the companies' right to fair compensation for the drug. Given the large numbers of terminally ill HIV/AIDS victims in developing and middle income countries, it is likely that activists and foreign governments will reference human rights law and US constitutional law to justify their imposition of compulsory licenses, further exploiting the Doha Declaration flexibilities. The case is likely to be appealed to the US Supreme Court given the uncertainty that is likely to flow from this split decision. The majority, consisting of Chief Judge Ginsburg and Judge Rogers, finds that terminally ill patients have a fundamental right at stake, and it remands for a determination of whether the FDA's limits on the availability of Phase II and III drugs is narrowly tailored to serve a compelling government interest. Judge Griffith dissents, arguing that the majority has woven a new constitutional right out of whole cloth. In his view, the FDA has total discretion in determining the conditions under which an experimental drug may be made

commercially available. Subjecting that discretion to judicial review only gives rise to a host of new questions about government regulation in the fields of medicine and science. See *Divided D.C. Circuit Finds New Due Process Right for the Terminally Ill*, Decision of the Day Blogspot at: (<http://appellatedecisions.blogspot.com/2006/05/divided-dc-circuit-finds-new-due.html>); *Abigail Alliance v. FDA* *Pharm a's Cutting Edge* (5/3/06), at: (<http://blog.crownstoneinsights.com>). The Appeals Court ruled 2 to 1 to remand the case to the District Court for trial (the Court had earlier dismissed the case), citing the terminally ill patient's right to due process under the Constitution as a basis for contesting FDA's restricted access to such medicines. The minority opinion, by Judge Griffith, disagrees with the due process argument:

Our Nation's concept of ordered liberty, along with our traditions and history, do not call for courts to usurp the judgment of the scientific and medical communities, expressed through Congress and the Executive Branch, that science does not warrant allowing the early access to experimental drugs the Alliance demands.' *Ibid.* See also, Roger Pilon, *Whose Life Is It Anyway?*, Rule of Law, Wall Street Journal (6/3/06), at p. A9. The problem with Mr. Pilon's argument, however, is that it does not address *who will pay* the pharmaceutical companies for the drugs to which he and the court claim individuals are constitutionally entitled. If the patient cannot afford to procure the drug in question, which can be quite costly at the early stage of clinical trial testing, what would Mr. Pilon, a pure libertarian, recommend as a solution? Is it the government's responsibility to finance the purchase? Does the drug company have a moral obligation to donate the drug to the patient for free? Does the public at large have a moral responsibility to organize a philanthropy-based fund for the patient?

²¹⁸ In view of human-rights arguments and an ethical imperative to protect the health of people, irrespective of their nationality, the international community can become an agent for the dispossessed '... the international community can act to protect certain populations in a variety of circumstances, the most critical of which occur when a government systematically violates human rights; another is represented by those failed states that are chronically incapable of meeting the basic security needs of their own populations. Natural or artificial disasters, which may temporarily paralyse otherwise effective governments, are another area for international action. See Dean T Jamison, Julio Frenk, and Felicia Knaul, *International Collective Action in Health: Objectives, Functions, and Rationale*, *The Lancet*, Vol. 351 (2/14/98), at p. 516, at:

(<http://download.thelancet.com/pdfs/journals/0140-6736/PIIS0140673697114519.pdf>).

²¹⁹ According to Ugandan journalist Andrew Mwenda, The primary problem for Africa is one of governance. The poor in Africa do not have basic social services because they are ruled by repressive, corrupt and incompetent governments. These *governments spend millions of dollars annually on their corrupt and ineffective militaries, on ostentatious consumption by the political class, and on obese, profligate and highly incompetent bureaucracies*. The institutions are very corrupt and incompetent that they stifle both domestic entrepreneurial initiative and frustrate foreign direct investment. **These actions are not sustainable** in the long term, of course, as these governments eat away the very economic foundation of their political survival. *Foreign aid is the subsidy governments in Africa employ to avoid facing the consequences of their own folly*. Without aid, many governments in Africa would stare regime collapse in the eye. Some would be stupid, retain the old ways and collapse. But many would be forced to reform their monetary and fiscal policies, to be frugal and prudent, to put in place public policies and political institutions that favor rapid economic growth and capital accumulation. *They would have to listen more to their own people and foreign investors in policy making and policy orientation*. In short, they would be forced to establish good, effective, accountable and democratic governments. **Good and accountable government is not a product of altruism, but enlightened self-interest**. Sachs, Bono, Geldof, Tony Blair -- and all the many good but naive people of the West -- need to learn that simple, commonsense logic (emphasis added). See Richard Tren, Freedom and Sedition, an Interview With Andrew Mwenda, Political Editor of The Monitor, Uganda, TCSDaily.com (5/23/06), at: (<http://www.tcsdaily.com/article.aspx?id=052306C>).

²²⁰ *Improved health has contributed significantly to economic welfare*. Per capita GNP rose rapidly in developing countries in the decades following 1960, and economic research suggests that health improvements led to perhaps 10 percent to 15 percent of that GNP growth (emphasis in original). See Dean T. Jamison, Investing in Health Chap. 1, *Disease Control Priorities in Developing Countries* 2d Ed., The International Bank for Reconstruction and Development / The World Bank, (2006), at p. 4, at: (<http://files.dcp2.org/pdf/DCP/DCPFM.pdf>); (<http://files.dcp2.org/pdf/DCP/DCP01.pdf>).

²²¹ A key conclusion... of the United Nations Millennium Project... is that innovation for medicines and other products 'must be situated

within a wider picture of efforts across sectors to improve health and development. Another is that *other products' should include those for improved diagnosis and prevention – including existing well proven but low technology interventions* that can be brought to bear on complex public health challenges (em phasis added). *Ibid.*, at p. 21.

²²² Some of the most important impediments to the effective management of the growing body of developing country knowledge... are the limited institutional resources in the form of skilled staff that can deal with intellectual property issues... But the main point that needs to be emphasized here is the need to build the required institutional framework (e.g., patent office, administrative and court procedures) and the requisite skill set. *Ibid.*, at p. 171. ... A factor in technology transfer in the area of production is the relative lack of experience and skill of developing country enterprises to conclude adequate legal arrangements to acquire the necessary technology. Other issues include the limited capacity of domestic firms to operate further up the value chain, and a lack of capacity to adapt acquired technology to local needs. *Ibid.*, at p. 172. One approach to facilitating technology transfer – *provided that technology owners are willing to part with it* – is to enhance the capacity of developing countries to receive and use these complex technologies... The TRIPS Agreement provides that *developed countries shall provide incentives to their enterprises and institutions* to promote and encourage the transfer of technology to least developed countries (Article 66.2). This provision was reemphasized in the Doha Declaration (em phasis added). *Ibid.*, at p. 173. ... Developed countries and *pharmaceutical companies (including generic producers) should take measures to promote the transfer of technology and local production of pharmaceuticals in developing countries, wherever this makes economic sense and* promotes the availability, accessibility, affordability, and security of supply of needed products (em phasis added). *Ibid.*, at p. 174.

²²³ At least one recent (2006) study has concluded that, developing country citizens have been denied access to essential medicines because of the abject poverty and poor environmental conditions existing within their borders, misdirection of government health budgets, inefficient bureaucratic administration of public services, weak physical and institutional health infrastructures, lack of good governance, high tax and tariff rates imposed on imported biotechnology and pharmaceutical products, strict regulatory restrictions on medicines approved in other countries, lack of available and affordable private health insurance, etc. See Civil Society Report on Intellectual Property, Innovation and

Health, International Policy Network (March 2006), at: (http://www.policynetwork.net/uploaded/pdf/Civil_Society_text_web.pdf). This report is a response from a global coalition of concerned civil society groups to the World Health Organization's Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH). *Ibid.*, at p. 5. *See also*, Andy Webb-Vidal, Chavez Opts For Oil-Fueled World Tour While Progress Slows on Social Issues in Venezuela, *Financial Times* (5/1/06), at p. 3. Challengers point to the socialist president's failures in housing and poverty ahead of December's elections... Some of the president's supporters are protesting that, after seven years in power, the government has little to show in terms of its pledges to create jobs, provide homes for the poor and tackle crime... The Chavez administration's record on social and economic progress is brittle. Housing provision has been a disaster... Mr. Chavez, a self-described 21st-century socialist, is not admitting any failures, however. *Ibid.*

²²⁴ Brazil imposes an import tariff of 11.7%, a VAT of 18%, and a state government tax of 6% on imported pharmaceuticals... And because the impact of hidden costs is compounded, each hidden cost has a carry-on effect. *See* Libby Levison and Richard Long, The Hidden Costs of Essential Medicines, *Essential Drugs Monitor, Medicine Prices Special Supplement, Issue No. 33*, (2003), at pp. 20-21, at: (http://mednet2.who.int/edmonitor/33/EDM33_20-21_Hidden_e.pdf). In other words, taxes and fees are imposed repeatedly at each wholesale and retail level of the distribution chain – taxes and fees at one level are determined based on the prior level's price, which already includes previously imposed taxes and fees. This had been corroborated by the U.S. Department of Commerce Foreign Commercial Service. Taxes applied on medicines in Brazil are among of the highest in the world. The Government collects over US\$1 billion in taxes from the pharmaceutical sector. The cascading tax method applied on manufactured goods in Brazil affects several industries, and is one of the most important topics that private industry has raised with the Government. The process aimed at reducing these taxes on pharmaceutical production is slow and bureaucratic. *See* Jefferson Oliveira, Overview of Brazilian Pharmaceutical Sector, *International Market Research Report, U.S. & Foreign Commercial Service and Department of State* (2003), at: (<http://strategis.ic.gc.ca/epic/internet/inimr-ri.nsf/en/gr106591e.html>).

²²⁵ *See* Normal Gall, Democracy 4: Brazil Needs a New Strategy - Lula and Mephistopheles, *Braudel Papers*, Fernand Braudel Institute of World Economics, *supra*, at pp. 12-14; Jonathan Wheatley, *New*

Corruption Charges Target Brazil Deputies , Financial Times (5/11/06) at p. 3. The year-old corruption scandal surrounding the government of Luiz Inacio Lula da Silva, Brazil's president, has taken a fresh turn with accusations that a third of the lower house of Congress received bribes to made amendments to the country's national budget. *See also* Jonathan Wheatley, Lula Accused of Knowing About Bribery , Financial Times (5/8/06), at p. 4; Cristovam Buarque, Brazil Agrees It Needs More Education But Nobody Wants to Foot the Bill , *supra*; *See also* Jonathan Wheatley, Senators Push For Corruption Inquiry Into Lula's Associates , Financial Times (4/21/06), at p. 8; Jonathan Wheatley, Common Killing or Political Crime? Brazil's Corruption Probe is Reignited , The Financial Express (4/20/06), at: (<http://www.financialexpress-bd.com/index3.asp?cnd=4/20/2006&id=16&newsid=21158&spcl=yes>); Raymond Collitt, Voters Should Decide Lula's Fate: Brazil Candidate , Reuters (4/19/06), at: (http://today.reuters.com/news/articlenews.aspx?type=winterOlympics&storyid=2006-04-19T223017Z_01_N06399833_RTRUKOC_0_US-BRAZIL-POLITICS.xml); Raymond Collitt, Brazil Corruption Scandal Dogs Lula, Not Congress Reuters (4/5/06), at: (http://www.boston.com/news/world/latinamerica/articles/2006/04/06/brazil_corruption_scandal_dogs_lula_not_congress); Jonathan Wheatley, Brazil Markets Steady But Scandal Will Not Go Away , Financial Times (3/31/06), at p. 4; Steve Kingstone, Call For Brazil Corruption Action , BBC News (3/29/06), at: (<http://www.turkishweekly.net/news.php?id=28959>); Jonathan Wheatley, How a Murder Case is Reviving Brazil's Furore Over Corruption , Comment and Analysis, Financial Times (3/28/06), at p. 15; Jonathan Wheatley, Brazil Poll Contenders Yet to Show Their Hands , Financial Times (3/24/06), at p. 4 (Indeed, corruption has reared its head again in the past week, with evidence mounting that Antonio Palocci, finance minister, misled a congressional inquiry over his relationship with a group of lobbyists); Monte Reel, Brazil's Corruption Scandals Loom on President's Political Horizon , Washingtonpost.com (9/28/05), at: (<http://www.washingtonpost.com/wp-dyn/content/article/2005/09/27/AR2005092701676.html>); Steve Kingstone, Q & A : Brazil Corruption Claims BBC News (8/13/05), at: (<http://news.bbc.co.uk/2/hi/americas/4676435.stm>) (Mounting claims of corruption within Brazil's ruling Workers Party (PT) are threatening to snowball into an extremely damaging scandal.); Brazil's Corruption Scandal Topples Mighty Chief of Staff , Brazill

Magazine (6/17/05), at:
<http://www.brazzilmag.com/content/view/2853/49>). Jonathan
 W heatley, B razil C orruption P roves H ard to F ight , F inancial T im es
 (4/24/05), at:
[http://www.globalpolicy.org/nations/laundry/regions/2005/0424brazil.
 htm](http://www.globalpolicy.org/nations/laundry/regions/2005/0424brazil.htm));

²²⁶ In addition to increasing costs, some governments display questionable priorities... B razil [is] aggressively funding space program s... [even though it]... faces no external threats... A lthough sovereign nations can and should determine their own spending priorities, they open themselves to criticism when they claim inability to meet the basic health needs of citizens but spend money on projects largely calculated to enhance their prestige. See Mark F. Schultz and D avid B . W alker, H ow I ntellectual P roperty B ecome C ontroversial: N GOs and the N ew I nternational I P A genda , at p. 89, *supra*, citing D aniel D utra, B razil S pace P rogram to G et G reater F unding , B razzil Magazine (1/28/05), at:
<http://www.brazzilmag.com/content/view/1283/53>).

²²⁷ H ow does health influence G D P per person? H ealthy w orkers are more productive than workers who are similar but not healthy. Supporting evidence for this plausible observation comes from studies that link investments in health and nutrition of the young to adult wages (Strauss and Thomas 1998). Better health also raises per capita income through a number of other channels. One involves altering decisions about expenditures and savings over the life cycle. The idea of planning for retirement occurs only when mortality rates become low enough for retirement to be a realistic prospect. Rising longevity in developing countries has opened a new incentive for the current generation to save— an incentive that can dramatically affect national saving rates. Although this saving boom lasts for only one generation and is offset by the needs of the elderly after population aging occurs, it can substantially boost investment and economic growth rates while it lasts. Encouraging foreign direct investment is another channel: investors shun environments in which the labor force suffers a heavy disease burden. Endemic diseases can also deny humans access to land or other natural resources, as occurred in much of West Africa before the successful control of river blindness. Boosting education is yet another channel. Healthier children attend school and learn more while they are there. A longer life span increases the returns on investment in education. See D ean T. J amison, *Investing in Health* Chap. 1, *Disease Control Priorities in Developing Countries* 2d Ed., The

International Bank for Reconstruction and Development / The World Bank, *supra.*, at pp. 7-8.

²²⁸ See M eraiah Foley, W H O U rges N ations to B ypass Patent Law , Associated Press (9/22/05), at: (<http://mmrs.fema.gov/news/publichealth/2005/sep/nph2005-09-26b.aspx>).

²²⁹ *Examination of the implications of intellectual property rights on access to medicines is a recent development in the field of public health Not long ago, this topic was confined to economists and lawyers specializing in intellectual property...* The 49th World Health Assembly, which was held in May 1996, changed this by bringing the consequences of globalization and trade agreements on access to medicines to the forefront. In that year the World Health Assembly adopted the Revised Medicine Strategy resolution to be incorporated into WHO medicines policy, which included gathering information on the impact of the World Trade Organization on national policies for essential medicines'... *In Brazil, discussion of the implications that trade agreements have on public health is firmly established in the government's agenda and has resulted in specific actions. I am sure that the countries in this region also welcome industrial policies that promote social justice and equity for their populations...* Publications such as this one bring to light background conflicts between social and economic policies and contribute to inform different groups of persons in a globalized world who need information to act with caution, maturity and directed towards the public good. This is not the first, nor the last publication in this genre. *Whether you agree or not with the authors' positions, these debates have definitely been inserted into the health agenda* (emphasis added). See Humberto Costa, Foreword,

Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health, WHO/PAHO Collaborating Center for Pharmaceutical Policies, National School of Public Health Sergio Arouca, Oswaldo Cruz Foundation, Jorge Bermudez and Maria Auxiliadora Oliveira, Eds., (Sept. 2004), at pp. 10-11, at: (http://www.who.int/intellectualproperty/submissions/Trips_ingles%20nova%20versao%202005.pdf).

²³⁰ During January 2006, Brazil's news agency reported that Representatives from 19 Latin American and Caribbean nations... [agreed to]... act as a bloc to try to reduce the price of AIDS medication... The countries also said they would invest together and exchange information to begin producing the drugs themselves. The announcement was made after a three-day meeting in Brasilia aimed at discussing regional AIDS prevention. The conference's final report will

be presented at the U.N.'s General Assembly in May. *It's fundamental the countries unite ... to build effective mechanisms to produce medication locally,*' said Pedro Chequer, the head of Brazil's AIDS program. *The sole negotiation of price reduction won't guarantee sustainability in the long term.*' The final report is expected to recommend the creation of methods to measure access to AIDS prevention and treatment, the Agencia Brasil said. *The countries also will call for the help of the international community to overcome political and economical barriers in price negotiations...* Chequer had said at the beginning of the conference that Latin American countries that cannot afford increasingly expensive AIDS medication should consider sidestepping foreign patent holders and manufacture the drugs themselves (emphasis added). See 19-Nation Bloc to Negotiate Price of AIDS Drugs CNN World, (1/14/06), at: (<http://www.cnn.com/2006/WORLD/americas/01/14/aids.drugs.ap/index.html>).

²³¹ See the discussion about the 'just compensation' requirement with respect to the indirect taking of patents, *infra*.

²³² Another charge that PhRMA makes is that Brazil is not compliant with the 'data exclusivity' provisions of TRIPS. 'Data Exclusivity' refers to the legal restrictions on access to clinical test data presented to regulatory authorities by a patent-holding company seeking approval for a new drug. This form of intellectual property keeps competitors out of the market and helps maintain high prices for a longer period. Competitors have to replicate trials, at great expense, or wait until the 'exclusivity' expires. In some countries even government authorities cannot use an originator's data to assess an equivalent product made by another company, thus further postponing competition. The 'exclusivity' term lasts up to 10 years in Europe, and can extend several years beyond the product patent. TRIPS requires that national law protect data against unfair *commercial* use by third parties... See Brazil Fights For Affordable Drugs Against HIV/AIDS, *Revista Panamericana de Salud Pública*, (The Global Health Council, *Pan Am J Public Health* 9(5)), (Vol.9 No.5) (May 2001) 331-337 at p. 336, at: (http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S1020-49892001000500018).

This report was based on a May 2001 Oxfam Great Britain report entitled *Drug Companies vs. Brazil: Threat to Public Health*, at: (<http://www.scielosp.org/pdf/rpsp/v9n5/5137.pdf>).

²³³ The Indian Pharmaceutical Alliance (IPA) is, therefore, adamant that India should not permit data exclusivity. Says Dilip Shah, secretary-general, IPA which groups some of the largest pharma firms.

"As of now, we do not accept the principle of exclusivity. All that global majors want is to extend the market exclusivity of patented products beyond the regulation 20 years." The 10-member organisation accounts for almost 90% of the private sector R&D spend in the country and is affiliated to the Brussels-based International Generic Pharmaceutical Alliance. Its contention is that if countries like India, Brazil, China and Korea are bound by data exclusivity, their generics would not be able to enter the big markets of Western Europe and the US for another 10 years after a patent expires. There is, admittedly, some dissension in the industry. Nicholas Piramal India has walked out of the IPA because it says data exclusivity will bring in more pharma BPO, such as clinical trials. And the Organisation of Pharmaceutical Producers of India backs this view. Introducing product patents without data exclusivity, it thinks, is pointless. See Data Exclusivity: The Cost of Protecting Data, Business World (1/26/04), at: (<http://www.businessworldindia.com/Jan2604/indepth01.asp>).

²³⁴ This may have as much to do with the Egyptian government's lack of understanding concerning the common law notion of trade secrets and unfair competition, as it does with its desire to protect Egyptian generic manufacturers against foreign competition. It seeks to do this by reinterpreting the competition-focused nondisclosure requirements of the TRIPS agreement in an excessively narrow manner so as to limit or even prevent the grant of an intellectual property known as market exclusivity. In addition, there are those within the Egyptian government who wish to creatively interpret the definition of the term 'undisclosed' as it relates to test data information on original drugs previously submitted, reviewed, and approved by other national governments. According to cabinet spokesman Magdy Rady, a former adviser to the minister of health, [T]here are two ways by which medicine can be registered in Egypt. The first, the most common route, is to use benchmark approvals. This means that if a drug is registered and approved in countries such as the US, certain members of the EU or Japan – and we can verify that this drug is registered and has been tested by their regulatory agencies – we accept the registration of the drug.' Benchmark approval operates on the principle that if a drug was able to pass the stringent requirements of regulatory agencies in developed countries, it should be able to pass the less restrictive requirements of the Egyptian government. This not only spares the government the enormous time and cost of drug testing, it avoids the need for demanding drug makers to submit their trade secrets. I don't request a formula or any other piece of information from the company,'

says Rady. The onus is on the company to prove to me that this exact same product is registered and approved in these countries. Only in cases where a drug is not already approved in a benchmark country does the Ministry of Health apply the second method of registration, drug testing and data gathering. In this case, the ministry requests that the drug company submit its previously undisclosed data on a drug's formula, efficacy and trials for it to review. *It's only in this case that data is considered exclusive,*' says Rady. But this scenario has never actually taken place in Egypt.' See Réhab El-Bakry, Cover Story, Business Monthly, American Chamber of Commerce in Egypt (April 2005), at: <http://www.amcham.org.eg/publications/BusinessMonthly/April%2005/coverstory.asp>).

²³⁵ In some countries, however, such as the United States, a *sui generis* regime was adopted prior to the TRIPS Agreement under which, for a period of five years from marketing approval, no other company may seek regulatory approval of an equivalent product based on that data without approval of the originator company... If the patent period has expired or there is no patent on the product, this *sui generis* data exclusivity may act independently of patent status to delay the entry of any generic companies wishing to enter the market. This is because the regulators cannot use the data in the period of protection to approve a product, even if the product is demonstrated to be bio-equivalent where required. The only alternative for a generic company would be to repeat clinical trials, which would be costly and wasteful, and would raise ethical issues, since it would involve replicating tests in humans to demonstrate what is already known to be effective... These *sui generis* regimes, which provide for data *exclusivity* need to clearly differentiate from the TRIPS Agreement's requirement for data *protection* (emphasis in original). See Public Health, Innovation and Intellectual Property Rights, Report on the Commission on Intellectual Property Rights, Innovation and Public Health World Health Organization, *supra*, at p. 143.

²³⁶ See Carlos María Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement, The South Centre (2002), at: <http://www.southcentre.org/publications/protection/protection.pdf>).

²³⁷ The functions of an international organisation are the actions that allow the organisation to cope with the problems it intends to solve. Therefore, the tasks of an organisation are strictly linked with its mandate. For this reason, this chapter is meant to be an introduction to World Health Organization's main tasks in order to better understand

the next part, which will deal with WHO's mandate... The second part of this work will deeply analyse the central issue of the WHO's mandate. Early in its history, the WHO specified a series of actions, among which, for example, a programme to address yaw s... Despite this historical introduction about WHO's tasks, the legal source of WHO's functions is article 2 of the Constitution.. It contains 22 paragraphs which describe a wide range of activities and functions. What impresses the reader is the unsystematic way in which they are listed, as they do not seem ordered according to any particular priority. Paragraphs (h) and (i) actually represent activities, as the prevention of injuries or the improvement of nutrition, housing and sanitation, rather than proper functions. Even though the way article 2 is drafted does not facilitate the categorisation of the functions, many authors have tried to classify them in different groups. The research for the present contribution found out different attempts of classifications, which show the controversies and the difficulties to reach a final categorisation. The main problem concerning the categorisations is that they are not characterised by a clear rationale for what should be included, and, as a consequence, they often reflect the biases of the authors. The result is, therefore, often a confused view on what the WHO should do. In the following paragraphs, first, I will present some of the attempts of categorisation; secondly, I will try to define which WHO's functions constitute its comparative advantage; thirdly, *I will describe one of the most important WHO's functions, that is the quasi-legislative' one...*

(emphasis added). See Elisabetta Minelli, World Health Organization: The Mandate of a Specialized Agency of the United Nations, Part I – The Institution, Chap. 4, WHO Functions and Their Categorization, Geneva Foundation for Medical Education and Research, Aldo Campana Ed. (8/13/03), at: (http://www.gfmer.ch/TMCAM/WHO_Minelli/Index.htm); (http://www.gfmer.ch/TMCAM/WHO_Minelli/P1-4.htm).

²³⁸ The Open Society Institute, a George Soros Foundation civil society' NGO, also advances a new paradigm of supranational global governance of health, much as it also supports the establishment of a new global paradigm of open source methods' in the ICT sectors, each of which endeavor to reduce the importance of private property rights, including IPRs. The Law and Health program seeks to advance public health priorities and open societies by supporting civil society's capacity in law and health and promoting the practice and discipline of law and health... The Law and Health program is also addressing key issues at the intersection of law and health, such as the global governance of public health. This includes the overarching regulatory

framework for public health like the Global Fund to Fight AIDS, Tuberculosis and Malaria and their Country Coordinating Mechanisms (CCMs). A key aim for OSI within these new global structures is to ensure the participation of civil society and to develop new legal models for governance, participation, and transparency. See Public Health Program – Law and Health, Open Society Institute & Soros Foundation Network, at: (<http://www.soros.org/initiatives/health/focus/law>). See also David Horowitz, The Cult of Soros: A New Foreign Policy, Wall Street Journal, Letters to the Editor (8/24/06), at p. A11.

²³⁹ Although responsibility for health remains primarily national, the determinants of health and the means to fulfill that responsibility are increasingly global. The situation is best addressed through international collective action. The paradox is that, because sovereignty resides in individual nation states, the world community lacks the authority to enforce the kind of international financial and organisational policies that national governments can implement to assure collective action within their own borders (eg, taxation, regulations, and the financing or direct production of public goods)... *In theory, this paradox could be resolved if individual nation states gave up sovereignty in favour of supranational governance, as exemplified by the European Union in certain policy areas.* Worldwide, however, current political arrangements make this approach unfeasible for the foreseeable future. *The alternative is shared sovereignty*, whereby individual nation states pool their resources into a multilateral organisation or their commitments into an international treaty– which then become vehicles for international collective action (emphasis added). See Dean T Jamison, Julio Frenk, and Felicia Knaul, International Collective Action in Health: Objectives, Functions, and Rationale, The Lancet, Vol. 351 (2/14/98), at pp. 514-15, at: (<http://download.thelancet.com/pdfs/journals/0140-6736/PIIS0140673697114519.pdf>).

²⁴⁰ The WHO normative function, after all, keeps the same characteristics of the law-making of many other specialised agencies of the United Nations and of international organisations as a whole. The reason of the developing of a *quasi-legislative function* originates from the fear of national governments to lose their authority. Even if governments are totally in favour of international organisations, because they facilitate collaboration among member states, they are often not willing of shifting their normative prerogatives towards a superior entity. Thus, although governments understand the importance and necessity of a universal legislation, they do not want international

organisations to undertake their exclusive powers. See Elisabetta Minelli, World Health Organization: The Mandate of a Specialized Agency of the United Nations, Part I – The Institution, Chap. 4, WHO Functions and Their Categorization, *supra*, citing Scruton, R., *WHO, WHAT and WHY?, Trans-national government, legitimacy and the World Health Organization*, The Institute of Economic Affairs, London, 2000.

²⁴¹ See Dean T Jamison, Julio Frenk, and Felicia Knaul, International Collective Action in Health: Objectives, Functions, and Rationale, *supra*, at p. 515.

²⁴² Indeed, Brazil has been involved in this quasi-legislative norm-building process for many years since, at least, its active participation in the preparatory process of the Framework Convention on Tobacco Control (FCTC). The participation to the preparatory process of this document is so wide that the FCTC was defined by *Ambassador Amorim of Brazil, the chairman of the Intergovernmental Negotiating Body*, as the first multilateral instrument to cover a public health concern ‘... The fact is that tobacco is an issue which touches various kind of people and sectors, because it does not respect national boundaries, cultures, societies and socio-economic strata. As Dr Brundtland said, the FCTC will activate all those areas of governance that have a direct impact on public health. Science and economics will mesh with legislation and litigations. Health ministers will work with their counterparts in finance, trade, labour, agriculture and social affairs ministries to give public health the place it deserves’ (emphasis added). See Elisabetta Minelli, World Health Organization: The Mandate of a Specialized Agency of the United Nations, Part I – The Institution, Chap. 4, WHO Functions and Their Categorization, *supra*, citing Ambassador Amorim’s Brazil speech at the Meeting of the Interested Parties 2002 (MIP). *Ibid.*, at fn 24.

²⁴³ See Unofficial English translation of Declaration of Ministers of South America Over Intellectual Property, Access to Medicines and Public Health’, IP-Health (5/24/06), at: (<http://lists.essential.org/pipermail/ip-health/2006-May/009594.html>).

The original Spanish version was signed by the Ministers of Health from Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay and Venezuela gathered in the city of Geneva, on 23rd May 2006. *Ibid.*

²⁴⁴ WE DECLARE OUR COMMITMENT TO ... 4. Maintaining the flexibilities provided in the TRIPs Agreement in bilateral and regional agreements, while seeking to a. facilitate the use of compulsory licences, parallel importing and Bolar exceptions; b. avoid the

broadening of the scope of patentability and the extension of patentable areas (for example: therapeutic methods, plants and animals), and second uses; c. avoid the linkage between the granting of the patent and the granting of the marketing approval, in addition to avoiding any other clause that may include TRIPs-plus arrangements... *Ibid.*

²⁴⁵ Arguably, the Latin American Declaration is intended to undermine the bilateral free trade agreements the U.S. already has and will have with Chile, Peru and Colombia. Chile has been a bilateral trading partner since 2004, the U.S. Peru Trade Promotion Agreement was signed by both parties on April 12, 2006, and the negotiations for the US-Colombia Trade Promotion Agreement concluded during late February 2006.

²⁴⁶ Apparently, pharmaceutical companies, sensing the political heat emanating from the WHO CIPIH and the NGO community, have tried to put a positive spin on the World Health Assembly resolution. For example, the International Federation of Pharmaceutical Manufacturers & Associations, a non-profit, non-governmental organisation representing national industry associations and companies from both developed and developing countries, issued the following statement:

The IFPMA notes positively the 59th World Health Assembly Resolution (A59/A/Conf. Paper No. 8, 27 May 2006) on Innovation, essential health research and intellectual property rights: towards a global strategy and plan of action and the establishment of an intergovernmental working group to draw up a global strategy and plan of action to address essential health research and development relevant to diseases that disproportionately affect developing countries. The IFPMA looks forward to representing the pharmaceutical industry in the joint development of this strategy, along with WHO Member States and other stakeholders. *See* World Health Assembly Resolution Recognizes IP is Important Incentive for Development of New Health-Care Products, IFPMA News Release (5/31/06), at: <http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=5022>.

However, readers should not mistake this statement for an endorsement of the resolution or its underlying premise.

²⁴⁷ This past June, the International Law Association adopted a proposed resolution, based on a report recently released by its Committee on International Trade Law, which focused, in part, on so-called 'abuses' associated with the proliferation of bilateral and regional TRIP-plus' agreements. *See* Draft Seventh Report of the Committee [on International Trade Law], International Law Association at:

(<http://www.ila-hq.org/pdf/Trade%20Law/Draft%20Report%202006.pdf>). The resolution calls upon Governments... to refrain from using bilateral and regional trade negotiations and agreements to limit or eliminate flexibilities in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights which are recognized in the Doha Declaration on the TRIPS Agreement and Public Health to support the protection of public health and to promote access to medicines for all. See RESOLUTION No. 3/2006, of the International Trade Law Committee, adopted on June 8, 2006 at the 72nd Conference of the International Law Association, held in Toronto, Canada, (6/4-6/8), at: (<http://kathryn.garforthmitchell.net/?cat=3>); I L A Resolution on TRIPS and Public Health , (6/12/06), at: (<http://lists.essential.org/pipermail/ip-health/2006-June/009727.html>).

²⁴⁸ See World Health Assembly Adopts New International Health Regulations – New Rules Govern National and International Response to Disease Outbreaks , World Health Organization (5/23/05), at: (http://www.who.int/mediacentre/news/releases/2005/pr_wha03/en/index.html). See World Health Organization, 58th World Health Assembly, Revision of the International Health Regulations, A58/55 (5/23/05) at: (http://www.who.int/gb/ebwha/pdf_files/WHA58/A58_55-en.pdf); (http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_3-en.pdf).

²⁴⁹ Judging from the transcript of a recently held conference convened by a group of non-profit institutes whose Cold War-inspired academic programs focus on war strategy, national security, presidential policy and general public administration policy issues, some U.S. civilian and military policymakers may yet consider the WHO and its Revised International Health Regulations useful and essential to maintaining international and U.S. national health security. In particular, the transcript reveals that, on January 14, 2005, 11 former ministers and heads of government from Europe and North America participated in a simulated bioterrorism attack. [Operation] Atlantic Storm [<http://www.atlantic-storm.org>] illustrated that much might be done in advance to minimize illness and death as well as the social, economic, and political disruption that could be caused by a bioterror attack or international epidemic... Atlantic Storm illustrated– as do many real-world biosecurity crises such as severe acute respiratory syndrome (SARS) or an influenza pandemic... that... Health issues have become integral elements of national security. Developed countries are only as secure as the world's weakest public health system ... *The United States should work with the international*

community to augment greatly the capacity of the World Health Organization (WHO) to respond to the health and medical consequences of biological attacks or pandemics... The new International Health Regulations, approved in early 2005, may help bolster WHO's clout internationally, but resources still will be severely limited... Policymakers discovered that some issues cannot be addressed even by a stronger WHO... [such as]... who would decide which countries should receive scarce vaccines or medicines... during a global outbreak... During Atlantic Storm, principals hoped that WHO could serve as an independent honest broker for such politically sensitive decisions. In reality, such decisions are likely to be made only by the national leaders who control these scarce medical resources... These concepts require not only the trust of other partners, but also their active cooperation, which means they must be embedded in new diplomatic approaches. For instance, how should arms control treaties geared to states be adapted to nonstate actors? *The global legal regime focuses on the activities of states, not subnational groups or individuals... [T]here is currently a critical lack of new medicines and vaccines for all infectious diseases, not just those that could be used as weapons.* National and international investments should be directed toward four areas... *The lack of sufficient vaccine stocks and the severely limited capacity to produce new vaccine eliminated many of the strategic options that the leaders could have used to respond to the epidemic, thus forcing them to consider measures such as closing borders and large-scale quarantine that could have had severe economic, social, and political repercussions. This lack of vaccine stocks and production capacity is not specific to smallpox; investment in the development of medicine and vaccines for virtually all infectious diseases has been declining for decades, resulting in pipelines that are producing only a trickle of new lifesaving products to counter infectious disease threats... But the real answer is re-creating drug design and manufacture so we can develop whatever is needed on short notice...* [T]he United States and the international community should build medical and public health information systems that would provide leaders with enough situational awareness to make decisions and direct resources in response to a bioattack... **Information technology tools and platforms could be designed to share such information.** *If these systems are built correctly, they also will improve the routine functioning of hospitals...* (emphasis added). See Daniel S. Hamilton and Bradley T. Smith, Atlantic Storm: Facing the Bioterror Challenge, at pp. 65, 69-73, in The Future of Transatlantic Security Relations Colloquium Report, Richard A. Chilcoat, Joseph R.

Cerami and Patrick B. Baetjer, Editors (Sept. 2006), at: (http://www.eisenhowerseries.com/pdfs/final_06/TransConfRpt.pdf). See also UN High-Level Report Seeks Expanded UN Mandate: Promoting Sustainable Development to Prevent Collective Threats, Institute for Trade, Standards and Sustainable Development, Inc. (May 2005), at: (<http://www.itssd.org/Issues/ITSSDissues-UNCollectiveThreatsReport-UNreform.pdf>). After reviewing these and other related documents, one is inspired to pose the following questions: Is there a silent but growing consensus among US policymakers that the US government should steadily cede US sovereignty to international organizations such as the WHO, in order to address the uncertain global threat of bioterrorism? Does the US government intend to, and can it actually, take the lead in writing new global health regulations that would either dovetail with or supercede the recently revised IHR(2005)? To what extent would these new regulations dictate how pharmaceutical R&D and manufacturing will be conducted and financed? Would such regulations dictate the degree of interoperability required for software platforms and interfaces developed for private and government healthcare facilities? Would such regulations preserve the value of U.S. private intellectual property rights and assets (patents, trade secrets and copyrights), both here and abroad, by ensuring that foreign governments render payment of just compensation should those assets be expropriated? What type of events could trigger the suspension of U.S. constitutional protections herein envisioned? And, how will Americans respond?

²⁵⁰ See Article 59 Entry into Force; Period for Rejection or Reservations', IHR (2005), *supra*. Prior to June 2007, States are encouraged to take appropriate measures to guarantee the full and effective implementation of the Regulations. This will include developing, strengthening and maintaining the public health capacities required under Annex 1 of the IHR(2005), and mobilizing the resources necessary for that purpose; adopting the necessary legal and administrative provisions and preparing for the use of the decision instrument (Annex 2 of the Regulations) for the assessment and notification of events occurring within their territory that may constitute a public health emergency of international concern. See Frequently Asked Questions About the International Health Regulations, No. 19, World Health Organization, at: (<http://www.who.int/csr/ihr/howtheywork/faq/en/index.html#dispute>).

²⁵¹ See Article '61 Rejection' and Article 62 Reservations', IHR (2005), *supra*.

²⁵² The IHR (2005) require States to notify WHO of all events that may constitute a public health emergency of international concern... and to respond to requests for verification of information regarding such events. This will enable WHO to ensure appropriate technical collaboration for effective protection of such emergencies and, under certain defined circumstances, inform other States of the public health risks that merit action on their part. See Frequently Asked Questions About the International Health Regulations World Health Organization, at: (<http://www.who.int/csr/ihr/howtheywork/faq/en/index.html>). The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations. See Article 12 Determination of a Public Health Emergency of International Concern', IHR (2005).

²⁵³ According to the regulations, States Parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible. The provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements. See Article 57 Relationship With Other International Agreements', IHR (2005), *supra*. But it will be interesting to see the relationship between these regulations and the TRIPS Agreement compulsory licensing provisions actually evolve.

²⁵⁴ The CBD entered into force during 1993.

²⁵⁵ It also recognizes the importance of preserving the biodiversity-related knowledge and innovations of indigenous communities. See Laurence R. Helfer, Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking, at pp. 26-27.

²⁵⁶ These provisions were actually intended to facilitate the following *quid pro quo*: the transfer of proprietary technologies to developing states for access to genetic resources... [B]io technology-poor developing countries sought financial benefits and technology transfers as incentives to conserve rather than exploit the genetic resources within their borders. Biodiversity-poor but biotechnology rich industrialized states, by contrast, sought to minimize benefits and transfers while maximizing access to those resources. *Ibid.*, at pp. 24-25.

²⁵⁷ *Ibid.*, at pp. 25-26.

²⁵⁸ TRIPS does not require protection of indigenous communities' traditional knowledge as such. Nor does the treaty require applicants seeking intellectual property protection to provide information about the origin of genetic resources... [N]othing in TRIPS requires sharing of financial or technological benefits of biodiversity-related patents and plant innovations with source countries or communities. Nor does TRIPS require its members to consider unwritten traditional knowledge as a form of prior art', thus permitting such knowledge to be patented in its original form. *Ibid.*, at p. 26.

²⁵⁹ CBD recognizes states' sovereign right to control genetic resources within their borders and to determine conditions of access to them. Access may be granted only upon mutually agreed terms and subject to the prior informed consent of the state providing the resources... [A]ccess by private parties seeking the genetic raw materials needed for future innovations... [m]ay be]... condition[ed]... upon a promise to provide compensation, technology transfers, or other benefits should those innovations prove commercially profitable. *Ibid.*, at p. 27.

²⁶⁰ Brazil is a member of the Like-Minded group of Mega-diverse Countries (LMMCs) which contain most of the world's biodiversity.

²⁶¹ According to at least one commentator, 'Biopiracy' is most commonly used to mean either the misuse of intellectual property (when patents or trademarks are erroneously issued) or restricting the access of foreign companies to genetic resources. Three years ago, the Japanese trademark office issued a trademark for *Acia, a fruit found in Brazil*. Marina Silva, the Brazilian minister of environment, has long-campaigned on the basis that this is biopiracy. That is a fallacy. Common names should not be patented as trademarks. This was contested and the trademark was withdrawn (emphasis added). See Alan Oxley, *That Phantom Menace*, TCS Daily (Mar. 21, 2006), at: (<http://www.tcsdaily.com/article.aspx?id=032106F>). The term 'biopiracy' has also been described as a political term which means that foreigners (mainly multinational companies, of course) obtain these products (even buy them in the local market), take them away and create blockbuster drugs that earn billions. See Alan Oxley, *Green Gold and Cargo Cults*, TCS Daily (Mar. 29, 2006), at: (<http://www.tcsdaily.com/article.aspx?id=032906A>).

²⁶² See Priya Shetty *Biodiverse Countries Call For Tighter Patent Rules*, Sci Dev.Net (2/25/05), at: (<http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=1954&language=1>).

²⁶³ The key to preventing the hijack⁴ of genetic resources is to establish contract arrangements where payments are made for access to the resources and the right to use them. Any government can introduce such a system. The pharmaceutical company Merck has pioneered one with the government of Costa Rica. It is simple and effective. The payment for access is negotiated and each government decides how much of the payment is provided to indigenous communities. See Alan Oxley, A Healthy Dose of Property Rights is Good Medicine, The Bangkok Post (Feb. 18, 2005), at p. 1, at: (<http://www.williams.edu/go/native/moreipr.htm>).

²⁶⁴ See Priya Shetty Biodiverse Countries Call For Tighter Patent Rules, *supra*.

²⁶⁵ This would certainly stop bio-prospecting because it would stop pharmaceutical industries in any country that adopted such a law. The cost of developing new drugs is too great to handle without secure rights to use the genetic materials (provided by contract arrangements) and inventions developed from them (provided by patents). No country aspiring to develop biotech industries could succeed if it diminished intellectual property rights as proposed by the mega-diverse countries. See Alan Oxley, A Healthy Dose of Property Rights is Good Medicine, *supra*.

²⁶⁶ There are several problems with this. First, no fabulous profitable drugs have been discovered from genetic resources from the forests or jungles. Most are the result of very expensive and laborious research. Second, who is the ultimate owner of a genetic resource? Every living organism is derived from something else. Is not an Indonesian researcher able to buy a Neem tree in India, bring it to Indonesia and use it for research without having each action approved by whoever is said in Indian law to be the owner?...It also undermines other important treaty obligations created by the Food and Agricultural Organisation (FAO). They allow intellectual property rights to be granted to developers of new seed varieties. They also create common and streamlined methods to give easier access for agricultural researchers to global data banks of agricultural genetic resources. *Ibid*.

²⁶⁷ *Ibid*.

²⁶⁸ The main business at this conference is not to protect biodiversity, but to endorse a return to the sort of economic philosophy that has impoverished many nations... [G]overnments in Africa and Latin America, including Brazil, and India propose an international treaty which will improve access⁴ (i.e. stop foreigners) to these genetic resource and increase benefits (by holding up patents and other intellectual property if any shard of a genetic resource is used in any

product patented), until they get their fair share... *The strategy is to nationalize the resource.* Environmental officials evidently are unaware that many of their governments [] nationalize[d] their economies in the past, triggering falls in the standard of living and impoverishment (emphasis added). See Alan Oxley, *Green Gold and Cargo Cults*, *supra*.

²⁶⁹ Whatever the specifics of ABS prove to be, a patent-based system is equivalent analytically to a long-run tax on biotechnological and pharmaceutical research and development investment. [T]he assumed long-run ABS tax... is 50 percent for the biotechnology subsector and 20 percent for the pharmaceutical subsector. See Timothy A. Wolfe and Benjamin Zycher, *Biotechnological and Pharmaceutical Research and Development Investment Under a Patent-Based Access and Benefit Sharing Regime*, Pacific Research Institute (May 2005), at pp. 1 and 10, at: (http://www.pacificresearch.org/pub/sab/health/2005/ABS_EU_LMMC.pdf).

²⁷⁰ Brazil's head of delegation, Hadil Fontes da Rocha Vianna, said the meeting produced a well-organized and structured basis to fulfill the Group's mandate to negotiate an international ABS regime... Elements (with brackets) for the international regime include: Access to genetic resources [*and derivatives and products*]; [Recognition and protection of] traditional knowledge associated with genetic resources [derivatives and products]; Fair and equitable benefit-sharing; [Disclosure of legal provenance/origin/prior informed consent and benefit sharing]; [Certificate of origin] [International certificate of origin/source/legal provenance]; Implementation, monitoring and reporting; [Compliance and enforcement]; Access to justice; [Dispute settlement mechanism]; Capacity building [and technology transfer]; [Institutional support]; [Non-Parties] (emphasis added). See Chee Yoke Ling, "New CBD Meeting Ends With Draft Elements of ABS Regime", *SUN S – South-North Development Monitor* (Feb. 7, 2006), Choike.org, at: (http://www.choike.org/nuevo_eng/informes/3946.html).

²⁷¹ At the COP8 in Brazil, Marina Silva, Brazil's Minister of the Environment, instilled a sense of responsibility to mainstream environmental issues into public policy, especially cross-cutting issues such as ABS... Brazil's President Luis Inácio Lula da Silva called for adopting an international regime on ABS, noting that biodiversity is our planet's greatest treasure and that opposition to fair benefit-sharing is a threat to life on earth... See *CBD COP-8 Highlights: Monday, 27 March 2006*, *Earth Negotiations Bulletin*, Vol. 9 No. 359, (Mar. 28,

2006) International Institute for Sustainable Development, at: (<http://www.iisd.ca/vol09/enb09359e.html>).

²⁷² ... [T]o ensure compliance with prior informed consent (PIC) and mutually agreed terms for access (MAT) which are obligations under the CBD. Several... countries such as *Brazil*... called for binding compliance measures; periodic monitoring; and user measures to prevent misappropriation and ensure compliance with PIC of countries of origin as well as PIC of indigenous and local communities... *Brazil*, Colombia and Malaysia were among developing countries that *disagreed*... [that] CBD was not the forum for discussing IPR issues... and said that IPR aspects of bio-diversity were the responsibility of CBD Parties (emphasis added). See Chee Yoke Ling, *New CBD Meeting Ends With Draft Elements of ABS Regime*, SUNS – South-North Development Monitor (Feb. 7, 2006), Choike.org, at: (http://www.choike.org/nuevo_eng/informes/3946.html).

²⁷³ *Brazil* saw the work of the CBD Parties and the TRIPS Council as complementary, with a group of developing countries at the WTO deeply engaged to move forward disclosure requirements' in the TRIPS Agreement. [*Brazil*] said IPR applications whose subject matter makes use of derivatives and products should disclose the country of origin, evidence that PIC has been complied with and show evidence of benefit sharing. There must be sanctions that affect the IPR in question when there is non-compliance, and the international regime should incorporate this binding requirement of disclosure in IPRs applications,' said *Brazil*, adding that the developed countries' proposals would not be effective in dealing with bio-piracy... There was also no agreement on the listing of organizations invited to address and/or continue their work on disclosure requirements in IPR applications... *Brazil* was not in favour of singling out WIPO as there were many other organizations that looked at the inter-relation between the CBD provisions and IPRs. [*Brazil*] said the CBD has received an excellent study by UNCTAD. It proposed the following wording: Invites relevant organizations such as FAO, UNCTAD, UNEP, UPOV, WIPO and WTO ...' *Ibid*. The following paragraph proposed by *Brazil* for COP8 to take note of, is also in brackets: Notes the progress in international discussions regarding disclosure of origin/source/legal provenance in intellectual property rights applications, in particular in the framework of the Doha round of negotiations of the World Trade Organization, and requests the Executive Secretary to renew the request for accreditations of the CBD as an observer at the WTO TRIPS Council.' *Brazil*, supported by

Malaysia and India, also *proposed the inclusion of* an additional operative paragraph that recommends that COP8: Reiterates the terms of Article 16 (5) of the Convention and Decision VII/19 D and notes that the international regime negotiations shall consider disclosure of origin/source/legal provenance in intellectual property rights applications' (emphasis added). *Ibid.*

²⁷⁴ The COP-8 meeting ended with an agreement... to pursue negotiations on an international regime, with a deadline of COP-10, to be held in 2010. See Tove Iren S. Gerhardsen, Decision On International Regime On Genetic Resources Postponed Until 2010, Intellectual Property Watch (4/4/06), at: (<http://www.ip-watch.org/weblog/index.php?p=260&res=1280&print=0>).

²⁷⁵ The urgency is heightened by the race against free trade agreements. *There is antagonism 'between the Convention on Biological Diversity and the imposition of a neo-liberal economic agenda' by the World Trade Organization (WTO) at the expense of natural resources*, according to the Brazilian Forum of Non-governmental Organizations (NGOs) and Social Movements for Environment and Development. Many environmentalists see the convention as an instrument for opposing the new rules on trade and patents that threaten biodiversity by subjecting everything, including life itself, to market criteria. The convention is a strategic mechanism for indigenous peoples, as the natural route for confronting the WTO, 'Brazilian activist Marcos Terena, coordinator of the indigenous representatives participating in COP8, told IPS (emphasis added). See Mario O'sava and Haider Rizvi Biodiversity: Key Decisions Few and Far Between at Conference, Globalinfo News.org (GIN), Inter Press New Service Agency (IPS) (Apr. 1, 2006) at: (<http://www.globalinfo.org/eng/reader.asp?ArticleId=42966>).

²⁷⁶ See The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity – Summary of Issues Raised and Points Made, Revised Summary Notes of the Council for Trade-Related Aspects of Intellectual Property Rights, World Trade Organization, IP/C/W/368/Rev.1 (2/8/06), at: (http://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf). This note... seeks to summarize the relevant material presented to the TRIPS Council, whether in written or oral form, and lists all the relevant documentation tabled in the Council since 1999... In accordance with the mandate given to the Secretariat, the note only contains issues raised and points made by delegations in the Council for TRIPS... This note is divided into three major sections. The first concerns general views on the relationship between the TRIPS Agreement and the

CBD[;] the second concerns patentability of genetic resources and the CBD[;] and the third concerns the TRIPS Agreement and prior informed consent/ benefit sharing. *Ibid.*, at p. 3.

²⁷⁷ According to WTO Director Pascal Lamy, ... [T]he Appellate Body of the WTO has repeatedly confirmed that WTO rules are not to be interpreted in isolation of other bodies of law. However, it is undoubted that more can be done. In fact, I would like to seize this opportunity to send a message to the membership of the WTO: We all agree that unilateral action, outside a country's jurisdiction, should be avoided. Let us lend our support, therefore, to multilateral environmental accords. The Doha Round, in which this issue is currently under negotiation, is a once in lifetime opportunity to confirm the need for mutual supportiveness. *Discussion in the WTO, that is specific to the relationship between the TRIPS Agreement and the Convention on Biological Diversity, is also taking place of course. In fact, I had a very productive meeting with the Executive Secretary of the CBD yesterday, Mr. Ahmed Djoghlaf, on the various interlinkages between the two legal regimes.* However, we were both cognizant of the fact that the membership of these regimes is not identical. *The issues of access to genetic resources, of prior informed consent and of benefit sharing are currently being explored in the WTO.* They are also being examined in WIPO – another important partner in the intellectual property domain. Our members continue to be divided on how best to address these issues, with some wanting an amendment of the TRIPS agreement, and others saying that there is no tension between the WTO and the CBD warranting such a change. The discussion must still run its course. Whatever its outcome, it is incumbent on all countries to use intellectual property rights in a manner that fosters biodiversity – all countries have a responsibility (emphasis added). See Lamy Urges Members to Support Environmental Accords, WTO News: Speeches – DG Pascal Lamy (5/30/06), at: (http://www.wto.org/english/news_e/sppl_e/sppl28_e.htm).

²⁷⁸ See Communication from Brazil, India, Pakistan, Peru, Thailand and Tanzania, Doha Work Programme – The Outstanding Implementation Issue on the Relationship Between the TRIPS Agreement and The Convention on Biological Diversity, supra, at p.1.

²⁷⁹ See Tove Iren S. Gerhardsen, Developing Countries Propose TRIPS Amendment On Disclosure, Intellectual Property Watch (6/1/06), at: (<http://ip-watch.org/weblog/index.php?p=323&res=1280&print=0>).

²⁸⁰ The purpose of the amendment is to establish a mutually supportive relationship between this Agreement and the Convention on Biological

Diversity, in implementing their obligations, Members shall have regard to the objectives and principles of this Agreement and the objectives of the Convention on Biological Diversity... Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge. See WT/GC/W/564 TN/C/W/41, *supra*, at pars. 1-2. See also Conversation with Rufus Yerxa, WTO Deputy Director-General, on the Doha Round, Presentation made at the Carnegie Endowment for International Peace, *supra*.

²⁸¹ See Brazil, India Get Developed Country Support For TRIPS Amendment On Biodiversity, IP-Watch (6/15/06) at: (http://www.ip-watch.org/weblog/index_test.php?p=332).

²⁸² The Norwegian proposal emphasized how The TRIPS Agreement and the Convention on Biological Diversity (CBD) can and should be implemented in a mutually supportive manner, and how the interaction between the two treaties would be enhanced by introducing *a mandatory obligation in the TRIPS Agreement to disclose the origin of genetic resources and traditional knowledge in patent applications*. It reasoned that such [a]n obligation under the TRIPS Agreement... would ensure transparency as regards the origin of biological materials that are to be patented. *This would make it easier for parties to enforce their rights to their own genetic resources when these are the subject of a patent application*, which in turn would make the CBD provisions on prior informed consent and benefit-sharing more effective. Furthermore, such a disclosure obligation would be a significant step towards giving effect to Article 16.5 of the CBD, which provides that the Contracting Parties should cooperate to ensure that intellectual property rights are supportive of and do not run counter to the objectives of the CBD. *A disclosure requirement would ensure that novelty criteria are met*, which accords with the basic intentions and principles of the patent system and increases its credibility. An equivalent disclosure obligation should apply where the claimed invention relates to or applies traditional knowledge, *even where the*

traditional knowledge is not directly linked to genetic resources. The CBD only applies to traditional knowledge linked to genetic resources. However, a general obligation to disclose any traditional knowledge upon which an invention is based would help to prevent patents being wrongfully granted... Norway supports the amendment of the TRIPS Agreement to introduce a mandatory obligation to disclose the origin of genetic resources and traditional knowledge in patent applications. Such a disclosure obligation should be introduced in a new Article 29bis and should provide that patent applications should not be processed unless the required information has been submitted (emphasis added). See The Relationship Between the TRIPS Agreement, The Convention on Biological Diversity and the Protection of Traditional Knowledge – Amending the TRIPS Agreement to Introduce an Obligation to Disclose the Origin of Genetic Resources and Traditional Knowledge in Patent Applications, Communication from Norway, WT/GC/W/566, TN/C/W/42, IP/C/W/473 (6/14/06), at pars. 1, 2 and 11, at: (http://www.ip-watch.org/files/Norway_Proposal.doc).

²⁸³ The Brazilian and Norwegian proposals differed in two important ways. The Norwegian proposal differs from the proposal by the major developing countries in that patents would not be revoked if incorrect or incomplete information has been given in the patent applications, which is identified after the patent is granted. The Norwegian proposal says this should be penalised outside the patent system. [And,] [b]y disclosure, the Brazil, China and India proposal includes disclosure of origin, prior informed consent and benefit sharing. But the Norwegian proposal calls for mandatory disclosure of origin as a binding international obligation, not the other areas. See Brazil, India Get Developed Country Support for TRIPS Amendment on Biodiversity, *supra*.

²⁸⁴ *Ibid.* A review of the Japanese proposal will reveal the following rational argument: [A]s a matter of legal rights and obligations, it is apparent that the CBD and the patent system *do not conflict with each other* and that they are mutually supportive... Regarding the impact of the patent system on the CBD, it is necessary to keep in mind that *the patent system grants patents that are only for inventions that meet certain requirements such as the requirements of novelty, inventive steps, and industrial applicability, but it does not grant rights for prior art. In other words, what has existed as public domain will remain as it is, and if countries providing/ providers of genetic resources and associated traditional knowledge can utilize those in the same manner as usual, and they will not come under the influence of the patent*

system... [I]t should be kept in mind that benefits (monetary and non-monetary benefits, including technologies subject to technology transfer), which are subject to benefit sharing, arise from the proper protection of intellectual property rights. To forbid granting of a patent to any living organism will deprive prospective applicants of opportunities to obtain benefits arising from inventions utilizing genetic resources and take away incentives for the technology development which might be subject to transfer, and, consequently, the opportunities for benefit sharing to the countries providing the genetic resources will also be lost. [T]he judgments of novelty and inventive steps are not associated with information about the country of origin, the country providing the resource, and the sources of genetic resources and related traditional knowledge. Moreover, the judgments of novelty and inventive steps are not associated with evidence based on prior informed consent relating to genetic resources and traditional knowledge or evidence of the sharing of benefits. The erroneous granting of a patent for an invention, which does not meet the requirements for novelty and inventive steps, cannot be prevented if information which is not useful for making judgments about novelty and inventive steps is provided... Even if a genetic resource collected in a specific place has its own specific characteristics, which differ from the characteristics of a resource collected in another place, and an invention was made by utilizing such specific characteristics, this does not sufficiently explain the necessity of imposing a new, additional obligation of disclosure on an applicant (emphasis added). See *The Patent System and Genetic Resources*, Communication from Japan World Trade Organization IP/C/W/472 (6/13/06), at pars. 1, 5, 7, 61, at: (<http://www.ip-watch.org/files/JapanProposal.doc>).

²⁸⁵ [S]ome developing countries have called for a harmonisation of the CBD and TRIPS. This has since become an outstanding implementation issue' and in the December Hong Kong WTO ministerial declaration, the WTO director general is requested to 'intensify his consultative process' and report to the Trade Negotiations Committee and the General Council, which will consider progress and 'take any appropriate action' by the end of July. *Ibid.*

²⁸⁶ A group of developing nations critical of IP's impact on development has worked alongside Brazil in multiple fora. They are known as the Friends of Development, and they include Bolivia, Cuba, the Dominican Republic, Ecuador, Egypt, Iran, Kenya, Sierra Leone, South Africa, Tanzania, and Venezuela.

²⁸⁷ Mr. Geoff Mulgan, one of the book's co-authors is Director of the Michael Young Foundation. See The Young Foundation –

Introduction, at: (<http://www.youngfoundation.org.uk/?p=2>). See also The Young Foundation – Staff- Geoff Mulgan, at: (<http://www.youngfoundation.org.uk/?p=32>). He was formerly the Founder and Director of the British think tank Demos, another socialist-minded brain-trust. See About Demos, at: (<http://www.demos.co.uk/aboutus/default.aspx>). A perusal of the website reveals science and technology as one of its primary foci. In particular, its program aims at opening up science and innovation policy. Among other publications, Demos issued a pamphlet during 2004 entitled, *See-Through Science: Why Public Engagement Needs to Move Upstream*, Demos (© 2004). It was authored by James Wilsdon, the Head of Demos' Science, Innovation and *Sustainable Development* Program and by Rebecca Willis, *Associate Director of Green Alliance and Vice-Chair of the UK's Sustainable Development Commission*. The pamphlet calls for the upstream engagement (involvement) of non-specialists in setting research priorities, as a result of the myriad scientific uncertainties surrounding new scientific discoveries and innovations. Predictably, it advocates in favor of open source methods, *the precautionary principle*, which it says stimulates rather chills innovation, *environment-centric sustainable development*, and *corporate social responsibility (CSR)*. See *See-Through Science: Why Public Engagement Needs to Move Upstream*, *supra*, at pp. 9, 23, 48-54, at: (<http://www.demos.co.uk/catalogue/paddlingupstream>).

²⁸⁸ Open source software is any computer software distributed under a license which allows users to change or share the software's source code. Source code is the human-readable version of a computer program – in order for a computer to understand a program it must be converted to a binary format which is not human-readable... While there are many different kinds of open source software, they all have one core similarity: they insist that the source code be made available whenever a piece of software is used, distributed, or modified. See Geoff Mulgan and Tom Steinberg, *Wide Open – Open Source Methods and Their Future Potential*, Demos (© 2005), at pp. 9-10, at: (<http://www.demos.co.uk/catalogue/wideopen>).

²⁸⁹ Open Source methods of development [are] volunteer powered, internet enabled, geographically dispersed. They embody a new way of creating knowledge that combines an open and democratic ethos with an extraordinary ability to produce work of high quality on a huge scale. For centuries, the pursuit of knowledge has been undertaken in ways that involve widely dispersed groups commenting on each others' work. The evolution of the Talmud in Judaism is one example, and the tradition of interpretation in Islam is another. Modern science has

developed through critical peer review in an open, expert and increasingly global community. Each shares the principle of making thought open, and using structured commentary to advance knowledge. *Each operates more like a gift economy than a market economy... In recent years, open source‘ has been applied to many areas that have nothing to do with software. There are now important new organizations involved in biosciences and pharmaceuticals that describe themselves, or are being described by others, as open source... The application of open source methods to wider areas of social and economic life is understandably attractive to many. The promise for the casual observer is of huge returns from relatively little investment, as well as a sense that non-professionals outside big corporations now have an unprecedented chance to beat the big beasts‘ at their own games (em phasis added).Ibid., at pp. 8-9.*

²⁹⁰ *Ibid.*, at p. 10

²⁹¹ [Miguel] de Icaza cofounded a startup company called Ximian in 1999 to bring Linux-based desktop tools to market. The company quickly became a major player in the open-source movement, and [during 2003,] Novell, a financially troubled software vendor best known for its corporate networking products, bought the startup. Novell hopes to use open source to stop the hemorrhaging of its customer base. Novell’s once vaunted Windows-oriented corporate networking software had been waging an increasingly vain battle against Microsoft’s own products... Novell hitched itself to the one approach making headway against Microsoft: open-source software. See David H. Freedman, *The Linux Revolution – Part I: Some Call Miguel de Icaza a Sellout. But the Mexican Open-Source Firebrand Says the Best Place to Continue the Battle Against Microsoft is Within a Big Corporation*, *Technology Review* (Sept. 2004), at p. 46; Wade Roush, *The Linux Revolution – Part II: Linux is Finally Offering Windows Users a Real Choice*, *Technology Review* (Sept. 2004), at p. 50.

²⁹² IBM CEO Sam Palmisano and company have decided *that IBM’s future will be best served by doing whatever it can to turn the basic software that runs computers into a commodity*. This strategy puts IBM squarely in opposition to Microsoft... The patent giveaway isn’t just a broad-side at rivals. It’s also a key part of IBM’s strategy to build the information networks of the future... By now, most software firms – including IBM, Microsoft, SAP and Oracle – have come to agree that an important step is greater openness and cooperation among each other. This includes embracing so-called open software, a communal body of code that individuals and companies develop at

their own expense and then share with each other freely... *IBM's idea is to give away its patents so that other firms can do much of the basic software plumbing on the cheap. At the same time, IBM wants to retain the more profitable parts of the business – for instance, business-management tools – for itself... We're trying to be right in the middle here and play it both ways',* says John Kelly an IBM executive who heads a task force on patent strategy. *If we can help the industry grow faster, we'll get at least our fair share of that growth'. No company has as much of a stake in open source as IBM ... Under Palmisano, IBM executives have come to realize that it needs to get its own software technology out into the world faster than it can by licensing it... Open standards would make it easier for IBM to mesh its software with other firms' software, but fear of patent infringement has been a big roadblock. Palmisano is especially keen for open standards to take hold in fast-growth industries like healthcare, which is why IBM waived its patent fees in October. IBM did the same for education, where standardized tools could make it easier to reach students in remote areas or emerging economies... Microsoft- whose core products such as Windows and Office constitute the plumbing that IBM is trying to turn into commodities – has responded by strengthening its patenting and enforcement. Guided by former IBM executive... Microsoft changed its intellectual property strategy two years ago from relying on copyrights to filing aggressively for patents (which offer greater protection, making it harder for open-source developers to reverse engineer a program). At the same time Microsoft has begun to cross-license its patents to giants like Siemens and Nokia... Its strategy is to make Windows into the preferred platform upon which to run open-source applications (emphasis added). See Karen Lowry Miller, *The New Big Blue Attitude*, *NewswEEK* (12/19/05), at pp. E8, E10 and E14.*

²⁹³ The natural opportunity for Microsoft is to become the platform company [for the internet]', says Nathan Myhrvold, Microsoft's chief technical officer until 2000. Just as Windows has become ubiquitous thanks to its role as the common platform on which other developers write their software, Microsoft's software could eventually play a wider role on the servers, handheld computers and other intelligent devices whose collective power will make up the computing power of the internet. All they need to do is sell the parts', says Mar. Myhrvold – potentially a vastly bigger market than the PC business that has come before. See Richard Waters, *Pondering The Future For Microsoft*, *Financial Times* (5/1/06), at p. 5.

²⁹⁴ See Geoff Mulgan and Tom Steinberg, *Wide Open – Open Source Methods and Their Future Potential*, *supra*, at p. 10.

²⁹⁵ A collaborative research project entitled OpenBusiness (<http://www.openbusiness.cc>) is currently being compiled by academic institutions based in *Brazil* (FGV Law School in Rio de Janeiro), *the United Kingdom* (Oxford University, London School of Economics and Michael Young Foundation) and *South Africa* (LINK Centre, at the University of the Witwatersrand in Johannesburg), to provide entrepreneurs, artists and creators with practical guides about how to incorporate Creative Commons open-content licenses and other open-content licenses into their business models. Ronaldo Lemos is the Director of the Center for Technology & Society at the Getulio Vargas Foundation (FGV) Law School in Rio de Janeiro. He is the project lead for the Creative Commons project in Brazil, and a member of the International Commons Board (emphasis added). See *The Future of Open Business and its Significance for Entrepreneurs: A Presentation and Discussion of Practical Examples from the United Kingdom, Brazil and South Africa*, a Presentation Made in Parktown, Johannesburg, South Africa (2/8/06), at: (<http://lists.ibiblio.org/pipermail/cc-za/2006-January/000021.html>). OpenBusiness is a collaboration between Christian Ahlert and his team at the Michael Young [Michael Young Foundation](#) in the UK, Heather Ford and Kerryn McKay from the [Link Centre](#) in South Africa, and Ronaldo Lemos from [FGV Law School](#) in Rio de Janeiro. All partners are involved with Creative Commons in their respective countries, namely the [United Kingdom](#), [Brazil](#) and [South Africa](#), the [Open Society Institute](#) [Soros Foundation (<http://www.soros.org/about>)], [Arts Council England](#) and [IDRC](#) in The project is supported by Canada. See *Creative Commons South Africa*, at: (<http://za.creativecommons.org/blog/archives/2005/10/14/open-business-model-launches-at-the-tate-britain-london>).

²⁹⁶ See Presentation made by Dr. Christian Ahlert, Senior Research Associate, Michael Young Foundation, London, at the *Workshop: Global Intellectual Property From a Brazilian Perspective*, *supra*.

²⁹⁷ In the setting and sharing of EU region-wide and external policies with other non-EU countries, there is often an unstated understanding between the EU Commission and the national EU member state governments that one or more member states will take the lead in promoting a given policy internationally. In the case of Europe's promotion of the (anti-empirical science) precautionary principle, it has been Germany, while in the case of Europe's promotion of universal access and open source (anti-IP) methods, it has been France.

²⁹⁸ [A]n international consortium dedicated to open-source infrastructure software, [including INRIA, the [French] national institute for research in computer science and control... [an industry consortium including French, Dutch, Canadian and even American companies]... and GMRC (Guangzhou Middleware Research Center), a leading Chinese research institute on middleware, today signed a memorandum of understanding²⁹⁸ to ensure the sustainable development of ObjectWeb and promote the adoption of open-source software by governmental organizations, technology providers and academia in China. *China and France announced their decision to leverage open-source software to expand Sino- French scientific and industrial cooperation on information technologies. More specifically, the category of software known as middleware was identified as a key enabling technology for development of the information society through services such as e-commerce, e-government and e-learning. Middleware also appears to be a central part of software infrastructures in a number of multi segment industries (e.g. telecommunications) and vertical industries (e.g. finance, transport, automotive, energy) (emphasis added). See ObjectWeb to Expand Intercontinental Collaboration on Industrial Open-Source Software*, ObjectWeb Press Release (5/13/05), at: <http://www.objectweb.org/phorum/read.php?admview=1&f=25&i=121&t=121>); <http://www.objectweb.org/phorum/download.php/25.127/PR-MOU-ObjectWeb-GMRC-final.pdf>).

²⁹⁹ One Newsweek article authored by IBM Chairman and CEO Sam Palisano tries to explain IBM's seemingly contradictory stand on innovation. He sums up the issues as being between open source and open standards, and between intellectual property and intellectual capital. *Open source is a method of tapping a community of experts to develop useful things. It began in software, but applies broadly, and is anything but anti-capitalist. It can raise quality at reduced costs, and vastly expands opportunities for profit. In a sense, open source fuels innovation much the way science fuels technology. Science is created by communities of experts, whose fundamental discoveries are typically made available to all, including individuals and companies that are able to capitalize on the new knowledge in novel ways... Open standards, in contrast, are not a methodology, but an underlying condition for economic or social progress because they make possible the free flow of capital, information and ideas... The Internet's founding protocols- http, html, etc.- are important open standards... Now, to intellectual property vs. intellectual capital...*

More and more of the innovation that truly matters today functions not only as intellectual property (the brilliant work of individuals), but as intellectual capital (a deep well of knowledge created collaboratively). As with open standards, this is about enlarging the pie and fostering innovation on top of what is available to all. And it's not about gizmos, but about new enterprise models— such as networkless telecoms, online auctions or real-time retail systems. Our intellectual-property laws, based on an earlier paradigm, will have to catch up (emphasis added). See Sam Palmisano, *The Information Puzzle*, *Newsw eek* (12/2/05), reproduced at Michael Dolan Dot Com: Linux, Law, Open Source, (12/7/05), at: (<http://www.michaeldolan.com/90>).

³⁰⁰ Some players in the pharmaceutical and agricultural biotechnology industries have a long tradition of commitment to aggressively closed intellectual property management practices, but others have an equally long tradition of commitment to open scientific communication and the public interest, while still others are simply trying to make a living and may well be willing to consider even a radical departure from the standard business model if an alternative model promises lower costs or increased profits. It may be that the most sympathetic audience for ideas about open source biotechnology will be researchers and institutions in developing countries and institutions that have their interests at heart. See Janet Hope, *Open Source Biotechnology?* Research School of Social Sciences, Australian National University (2003), at: (<http://rsss.anu.edu.au/~janeth/OSBiotech.html>). If an open source movement in the life sciences is going to take off, it may not come from the deep pockets of venture capitalists, who are skittish on how to glean returns on biotech even when they own all the intellectual property. Instead, it may be borne of the purse of federal funding agencies, which may see open source projects as a way to ensure that public monies result in public goods. See Kenneth Neil Cukier, *Open Source Biotech - Can a Non-proprietary Approach to Intellectual Property Work in the Life Sciences?* *The Acumen Journal of Life Sciences*, Vol. I, Issue 3(Sept/Oct 2003), at: (<http://cukier.com/writings/opensourcebiotech.html>).

³⁰¹ In recent years there has been an explosion of open and collaborative projects to create public goods. These projects are extremely important, and they raise profound questions regarding appropriate intellectual property policies. They also provide evidence that one can achieve a high level of innovation in some areas of the modern economy without intellectual property protection, and indeed excessive, unbalanced, or poorly designed intellectual property protections may be counter-productive. We ask that the World

Intellectual Property Organization convene a meeting in calendar year 2004 to examine these new open collaborative development models, and to discuss their relevance for public policy... See Letter dated, July 7, 2003, addressed to Dr. Kamil Idris, Director General World Intellectual Property Organization, at: (<http://www.cptech.org/ip/wipo/kamil-idris-7july2003.pdf>). Attached to the letter was an Appendix requesting that the findings of seven collaborative projects to create public goods in the following areas be considered: 1) internet governance; 2) free and open software; 3) internet documents; 4) the human genome project; 5) single nucleotide polymorphisms (SNPs); 6) open academic and scientific journals; and 7) global positioning satellites. *Ibid.*, at pp. 9-12

³⁰² Interestingly, extremists James Love and Ralph Nader, of the Consumer Project on Technology (CPTech) have long worked together to develop open source methods' as an international paradigm in both the health and information technology sectors. See James Love and Ralph Nader, What To Do About Microsoft, *Le Monde Diplomatique* (Nov. 1997), at: (<http://mondediplo.com/1997/11/nader>); James Love, Nader Colleague Responds, *Information Week* (6/13/02), at: (<http://www.informationweek.com/story/IWK20020613S0004>); Ralph Nader and James Love, Opinion: Ralph Nader Tells Feds to Stop Microsoft, *CNN.com* (11/11/98), at: (<http://www.cnn.com/TECH/computing/9811/11/nader.idg/index.html>); Ralph Nader and James Love, A Framework for ICANN and DNS Management, proposals presented by Ralph Nader to Governing the Commons: The Future of Global Internet Administration, a conference organized by Computer Professionals for Social Responsibility, (9/25/99), at: (http://www.eff.org/Infrastructure/DNS_control/ICANN_IANA_IAHC/19990927_nader_icann_coms.html); Ralph Nader and James Love February 18, 1999 Letter to Secretary of State Madeleine Albright Regarding NGO/State Dialogue on International HIV/AIDS and Intellectual Property, at: (<http://www.cptech.org/ip/health/cl/mafef181999.html>); Sabin Russell, New Crusade To Lower AIDS Drug Costs Africa's Needs at Odds With Firms' Profit Motive *San Francisco Chronicle* (5/24/99), at: (<http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/1999/05/24/MN104738.DTL>); CPT Urges Gore to Reverse Policy on South African Policies Regarding Access to HIV/AIDS Drugs, Other Medicines *Common Dreams News Wire* (4/9/99), at: (<http://www.commondreams.org/pressreleases/april99/040999i.htm>);

³⁰³ One intriguing possibility for future open-source development comes from medicine, an area where people can become passionate and where intellectual components can far exceed physical components... An ambitious doctor can network online with other researchers interested in disease X and, at the least, can quickly exchange data about the newest research techniques. In fact, there are already medical networks that pass around information about acute medical cases, using email and computers that can automatically send out patient files over a network and put X-rays into the overnight mail... Now the same doctor can farm out parts of the project to interested collaborators... Every breakthrough or improvement in the model could be posted online so that other participants could begin work on the next challenge. If a sample test is performed, data could be transferred to the Web simultaneously. Eventually a prototype could be developed and adopted by an established drug company (or perhaps even a non-profit company, funded by foundations, that specializes in distributing open-source drugs and selling them at minimal costs) that licenses the product with the FDA, runs it through the necessary tests, and then manufactures, distributes and sells it--keeping prices relatively low both because no company would have exclusive copyrights and because research costs (drug companies' largest expense) would be drastically reduced. See Nicholas Thompson, Reboot! - How Linux and Open-source Development Could Change the Way We Get Things Done, Washington Monthly (March 2000), at: (<http://www.washingtonmonthly.com/features/2000/0003.thompson.html>). Open-source biology surfaced in public debate... [during June 2004]... after a team of two lawyers (Stephen M. Maurer of U.C.-Berkeley and Arti Rai of Duke) and one scientist (Andrej Sali of U.C.-San Francisco) proposed an open-source drug discovery program to find cures for diseases that affect the world's poorest people. See Open-Source Drug Discovery Proposed for Neglected Diseases, Science & Intellectual Property in the Public Interest (6/18/04), at: (http://sippi.aaas.org/ipissues/updates/?res_id=317). See also Stephen M. Maurer, Arti Rai, and Andrej Sali, Finding Cures for Tropical Diseases: Is Open Source an Answer? (12/28/04), at: (http://salilab.org/pdf/136_MaurerBIOESSAYS2004.pdf) and (<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0010056>).

³⁰⁴ According to an article recently appearing within the Bulletin of the WHO, there is a potentially deadly gap between the information-rich and the information-poor. This gap is not the result of lack of technology or of money, but of a failure of imagination. We live in the

most information-rich era of history, when the Internet allows immediate global dissemination of crucial health information, and the inter-linking of online information creates an integrated, living body of information – the ultimate vision of which is the semantic web. What is preventing such a living web? For scientific and medical information, two obstacles are vested interests and traditions. Central to these traditions is the role of copyright, which was developed when the dissemination of work was on paper... Print is no longer the most efficient way to disseminate information. The Internet provides the means to revolutionize publishing in two crucial ways. First, it makes it possible to disseminate health information at no charge to anyone in the world with online access... Second, because the Internet allows not just ease of access but ease of reuse, an article's usefulness is limited only by a user's imagination. To allow this, the traditional role of copyright has to change. Instead of publishers using copyright to restrict use, authors can retain copyright and grant the public the right to creatively reuse their work. Licenses such as those developed by the Creative Commons, which facilitate rather than prohibit reuse, are used by the open-access publishers Public Library of Science (PLOS) and BioMed Central (BMC). The result is that: ... copyright can be used for what it is meant to in science, not to make the articles artificially scarce and in the process restrict their distribution, but instead, to ensure that their potential for maximum possible dissemination can be realized... Increasingly, funders of research also realize the benefit of an open-access model of publishing. The UK's Wellcome Trust mandates its funded authors to make their work publicly available; the United States National Institutes of Health are encouraging it, and increasing numbers of governments and funding bodies are signing up to declarations on open access. See Virginia Barbour, Paul Chinnock, Barbara Cohen and Gavin Yam ey, *The Impact Of Open Access On Public Health*, *Bulletin of the World Health Organization*, Vol. 84, No. 5, (May 2006), at pp. 337-424, at: (<http://www.who.int/bulletin/volumes/84/5/en>).

³⁰⁵ See Kenneth Neil Cukier, *Open Source Biotech - Can a Non-proprietary Approach to Intellectual Property Work in the Life Sciences?* *supra*. [T]he first seedlings of an open-source biotech movement are beginning to emerge in the field that melds both molecular biology and computing: *Bioinformatics*... BioBriks, an attempt to establish standardized, non-proprietary terms, tools and processes for DNA work. This, as much as anything, can free the biotech industry from an ungainly reliance on patented technologies. It's a matter of interoperability; the life sciences' equivalent of software

Application Programming Interfaces. BioBricks will make it more reliable and less expensive for researchers to assemble genetic sequences, by using standardized process and non-proprietary tools that are forever being improved upon by the community. The idea of copying one gene from one place to another - that goes away,' Dr. Knight [of the Massachusetts Institute of Technology]... says. It is a computer science problem.' In such a world, the base pairs that comprise strands of DNA are akin to digital bits, and just as computers modify those bits from scanner (the input) to printer (the output), so too will we be able to sequence and synthesize DNA. The central tool in both cases is the same - a computer - so it only makes sense that the same approach to the technology, via open source methods and practices, emerges in the life sciences as it did in computing. *Ibid.*

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³⁰⁷ Between these two types of licenses there exists a small constellation of alternatives and variations, and tension exists between the two ends of the spectrum. See Melise R. Blakeslee and Brian E. Ferguson, The Truths and Myths of Open Source Software, McDermott, Will & Emory, Mondaq (5/31/06), at: (http://www.mondaq.com/article.asp?articleid=40128&email_access=on).

³⁰⁸ *Copyleft* is a general method for making a program or other work free, and requiring all modified and extended versions of the program to be free as well. The simplest way to make a program free software is to put it in the public domain, uncopyrighted. This allows people to share the program and their improvements, if they are so minded. But it also allows uncooperative people to convert the program into proprietary software. They can make changes, many or few, and distribute the result as a proprietary product. People who receive the program in that modified form do not have the freedom that the original author gave them; the middleman has stripped it away. In the GNU project [Gnu's Not Unix], our aim is to give *all* users the freedom to redistribute and change GNU software. If middlemen could strip off the freedom, we might have many users, but those users would not have freedom. So instead of putting GNU software in the public domain, we 'copyleft' it. Copyleft says that anyone who redistributes the software, with or without changes, must pass along the freedom to further copy and change it. Copyleft guarantees that every user has freedom. Copyleft also provides an incentive for other programmers to add to free software... Copyleft also helps programmers who want to contribute improvements to free software to get permission to do that. These programmers often work for companies or universities that

would do almost anything to get more money. A programmer may want to contribute her changes to the community, but her employer may want to turn the changes into a proprietary software product. When we explain to the employer that it is illegal to distribute the improved version except as free software, the employer usually decides to release it as free software rather than throw it away. To copyleft a program, we first state that it is copyrighted; then we add distribution terms, which are a legal instrument that gives everyone the rights to use, modify, and redistribute the program's code *or any program derived from it* but only if the distribution terms are unchanged. [copies and derivatives of the source code to be made available on terms no more restrictive than those of the original license]. Thus, the code and the freedoms become legally inseparable. Proprietary software developers use copyright to take away the users' freedom; we use copyright to guarantee their freedom. That's why we reverse the name, changing 'copyright' into 'copyleft' (italicized emphasis in original, boldface emphasis added). See *What is Copyleft?*, GNU Project – Free Software Foundation, Inc. (5/25/06) at: (<http://www.gnu.org/copyleft/copyleft.html>).

³⁰⁹ *Ibid.*

³¹⁰ See *Explaining BSD*, at: (<http://www.lemis.com/bsdpaper.html>).

³¹¹ SCO Group has hit back at IBM's latest legal challenge in the row over intellectual property rights and the Linux operating system. In an amendment filed last week, IBM claimed that SCO violated the GNU General Public Licence (GPL). Based on this violation, IBM now argues that SCO has in turn violated IBM copyrights. See Robert Jacques, *SCO Slams IBM's GPL Linux Defence*, *Infomatics News* (9/30/03), at: (<http://www.infomaticsonline.co.uk/articles/print/2123380>). See also, Robert McMillan, *SCO: IBM Cannot Enforce GPL – Free Software Foundation is the Only Entity That Can Enforce the GPL*, *SCO Officials Say*, *IDG News Service* (10/27/03), at: (http://www.infoworld.com/article/03/10/27/HNScoenforce_1.html).

Since suing IBM in March over allegations that the company put SCO Unix source code into Linux, SCO has been countersued by both IBM and Linux distributor Red Hat. In response to IBM's claims that SCO was in violation of its own copyright restrictions, SCO argued that the GPL is unenforceable and void, barring IBM's claims. SCO went on to argue that the GPL violates the U.S. Constitution, copyright, antitrust and other laws, again barring IBM's claim s... Phil Albert, a software legal expert... called SCO's unconstitutional claim s weird, 'telling TechNewsWorld that it will be tough for SCO to argue that the GPL is not valid. Consistent with the Free Software Foundation's contentions

that SCO is also in violation of copyright for its own distribution of Linux under the GPL if the license is not valid, Albert said SCO is shooting [itself] in the foot' with its response to IBM's counterclaim. For SCO to say 'we're in possession, but the license is not valid and is unconstitutional' -- that leaves them in the position of copyright infringer,' Albert said. See Jay Lym an, SCO Claims Linux GPL Is Unconstitutional TechNewsWorld (10/28/03), at: (<http://www.technewsworld.com/story/31975.html>). See also Sean Michael Kerner, GPL Awaits Test in SCO Group/IBM Dispute , Enterprise (1/23/04), at: (<http://www.internetnews.com/enterprise/article.php/3302801>); IBM Goes For SCO Jugular in Test of GPL Validity , (8/19/04), at: (<http://www.linuxdevices.com/news/NS9902827613.html>). As noted above, SCO is involved in a number of other disputes besides its lawsuit with IBM. SCO is in litigation with Red Hat, Novell, AutoZone and Daimler Chrysler. See SCO v IBM , Wikipedia at: (http://en.wikipedia.org/wiki/SCO_v._IBM).

³¹² See Eric Raymond, OSI Position Paper on the SCO -vs.-IBM Complaint , Open Source Society Institute, at: (<http://www.opensource.org/sco-vs-ibm.html>).

³¹³ See Melise R. B lakeslee and Brian E. Ferguson, The Truths and Myths of Open Source Software , *supra*.

^{314*} Mr. Palmisano... is trying to reinvent the services industry by injecting disciplines of product development and delivery that are normally found in traditional product markets – and he is trying to do it on a global scale... Turning services, which by definition are delivered by people, into repeatable processes where IBM can get economies of scale, amounts to an organizational and cultural overhaul of significant scale... The attempt to remake IBM Global Services is based on a belief that there are more effective ways of using all of IBM's brain power, from its research and development arm all the way through to its consultants, to design and sell services. If you combine labour with IP [intellectual property], you get repeatable offerings', says... Mike Daniels... These days, IBMers talk about productising' services, turning them into clearly defined offerings that can be marketed and delivered in much the same way that new mainframe computers are... To create these repeatable services, IBM has set out to isolate and standardize many of the components that go into such assignments... Making processes repeatable effectively means baking' services into software: some of the work that was once done afresh by consultants on each assignment can be isolated and described in software, making it easier to apply the same processes to subsequent

projects. That has blurred the line between the services and software business models. It means revenue growth is no longer limited by the number of smart consultants IBM can throw at projects. *See* Richard Waters, *IBM Repackages Its Brain Power*, *supra*. * In other words, by commoditizing software produced for free by open source Linux or other programmers, IBM can not only earn higher profits from their labors, but also more readily reduce the salaries of employees and fees paid to consultants, whose management services and expertise would no longer be needed to recreate the wheel for each project. Thus, IBM's promotion of open source business methods and giving away of thousands of older patents is arguably disingenuous and self-serving; it will also be detrimental to its labor force in the longer term.

³¹⁵ Berkeley Software Distribution (BSD, sometimes called Berkeley Unix) is the Unix derivative distributed by the University of California, Berkeley, starting in the 1970's. The name is also used collectively for the modern descendants of these distributions. BSD was widely identified with the versions of Unix available for workstation-class systems. This can be attributed to the ease with which it could be licensed and the familiarity it found among the founders of many technology companies during the 1980's. This familiarity often came from using similar systems— notably DEC's Ultrix and Sun's SunOS— during their education. While BSD itself was largely superseded by the System V Release 4 and OSF/1 items in the 1990's (both of which incorporated BSD code), in recent years modified open source versions of the codebase (mostly derived from 4.4BSDlite) have seen increasing use and development. *See* Berkeley Software Distribution, Wikipedia at: http://en.wikipedia.org/wiki/Berkeley_Software_Distribution).

³¹⁶ *See* BSD License Wikipedia at: http://en.wikipedia.org/wiki/BSD_License).

³¹⁷ *See* Melise R. Lakeslee and Brian E. Ferguson, *The Truths and Myths of Open Source Software*, *supra*.

³¹⁸ *See* Copyright Policy *OpenBSD* at: <http://www.openbsd.org/policy.html>).

³¹⁹ The Berkeley Standard Distribution (BSD, first developed at the University of California, Berkeley) is one of the most widely respected UNIX implementations. BSD provides Mac OS X with the stability, performance, and compatibility for which UNIX is justly famous. Apple has enhanced BSD by adding Mach 3.0 technology based on the OSF/mk microkernel from the Open Software Foundation, providing memory management, thread control, hardware abstraction, and interprocess communication services. Apple has built on top of this rich

Mach/BSD heritage with a number of powerful innovations, including well-defined, future-proof kernel programming interfaces (KPIs) supporting dynamically loadable file systems, network extensions, and packet filters, as well as I/O Kit drivers. Such innovations enable Mac OS X to provide a wide range of services... See *Mac OS X for UNIX Users The power of UNIX with the simplicity of Macintosh*, at p. 3, at: (http://images.apple.com/macosex/pdf/MacOSX_UNIX_TB.pdf).

³²⁰ Two members of the FreeBSD core team, Jordan Hubbard and Mike Smith, have joined Apple... [According to Jordan,] ... Apple does fully understand the importance of FreeBSD and they don't want me or anyone else to stop working on it. FreeBSD doesn't compete with Apple's product offerings in any way and provides an excellent source of technology for them. Darwin is substantially based on FreeBSD 3.2 and Apple certainly doesn't want the technology transfer to end there or to be strictly one-way. Part of my mandate will in fact be helping Apple to be an even better Open Source citizen, increasing collaboration and strengthening relationships with FreeBSD and other Open Source projects.' See *Does Microsoft Run BSD code?*, *Daemon News*, *supra*.

³²¹ See *Does Microsoft Run BSD code?*, *Daemon News* (Aug. 2001), at: (<http://ezine.daemonnews.org/200108/dadvocate.html>); David Sims, Tim O'Reilly and Rael Dornfest, *Microsoft Plans Shared Source .NET*, *O'Reilly ONDotnet.com* (6/27/01), at: (<http://www.ondotnet.com/pub/a/dotnet/2001/06/27/dotnet.html>); Paula Rooney, *Microsoft's FreeBSD Move Aimed At Next Generation Of Developers*, *CRN Daily News* (6/27/01), at: (<http://www.crn.com/sections/breakingnews/breakingnews.jhtml;jsessionId=QYSIPZTRGWRD0QSNDLRCKH0CJUNN2JVN?articleId=18814901&requestid=482366>); See *Migrating Microsoft Hotmail From FreeBSD to Microsoft Windows 2000 Technical Case Study*, Microsoft TechNet at: (<http://www.microsoft.com/technet/interopmigration/case/hotmail/default.msp>).

³²² See George Kraft, *IBM TTS SDK now BSD-Licensed* (3/27/06), at: (<http://mail.gnome.org/archives/gnome-accessibility-list/2006-March/msg00048.html>).

³²³ Companies such as IBM have been at the forefront of the open source movement, not least because it may serve as a way to save money and effort, and perhaps, also compensate for lost revenues in other of its businesses. Starting in 1964, when IBM bet its future on the development of the 360 product family as the global standard for mainframe computers, it pushed vertical integration to the

extreme... The recession of the early 1990s had exposed the weaknesses of the closed system of innovation. For the first time since 1946 the company experienced three years of declining revenues, shrinking profit margins, and even losses in 1991- 1993. In response *IBM transformed itself from a hardware producer to a supplier of integrated solutions, with the objective of leveraging its broad portfolio of intellectual property (IP), not only to exclude rival firms but also to generate new and highly profitable sources of growth. IBM had to go beyond its own R&D and find the best technologies wherever they existed, combining them into integrated solutions. An important facilitator was the adoption of open standards in a variety of areas, including the Linux operating system and the Java programming language* (emphasis added). See Transnational Corporations and the Internationalization of R & D , United Nations Conference on Trade and Development (UNCTAD) World Investment Report, UNCTAD/WIR/2005 (Sept. 2005), at p. 169, at: http://www.unctad.org/en/docs/wir2005_en.pdf).

³²⁴ On January 10, 2005, U.S. patent leader IBM [announced]... it plans to donate 500 patents for free use by software developers, marking a major shift of intellectual property strategy for the world's top computer maker and a challenge to the high-tech industry. Jim Stallings, IBM's vice president in charge of intellectual property, said in an interview that the move was meant to encourage other companies to unlock patent portfolios in order to spur technological innovation... As the leading provider of computer services, IBM also stands to benefit from helping other companies make use of new technology developed under the open licensing program. The donation coincide[d] with an announcement by the U.S. Patent and Trademark Office that IBM topped the list of annual patent recipients for the 12th straight year, with 3,248 patents – or 1,314 more patents than No. 2-ranked Matsushita of Japan, known for its Panasonic brand. *IBM's move puts it at the vanguard of a movement to redefine patent laws in less restrictive ways. Critics of patent law reforms over the past decade say they have undermined the ability of software developers to innovate with the same level of freedom that led to the PC and Internet revolutions. But it also puts IBM at further loggerheads with rivals such as Microsoft, which argues that open source software development undermines corporate intellectual property rights.* It also contrasts with zealous patent defenders such as major pharmaceutical and media companies – big IBM customers. Open source refers to a method for developing software in which developers share the underlying code but compete to introduce specific innovations. It

contrasts with the proprietary model of creating software in which the underlying code is shielded by each company as trade secrets. The IBM move is meant to encourage other patent holders to donate their own intellectual property in order to form what the company refers to as a patent commons, 'a modern twist on shared public lands set aside under traditional laws (emphasis added).

See "IBM to Give Away 500 Patents - Move Marks Major Shift of Intellectual-Property Strategy", Reuters (1/11/05) cited at: (<http://www.msnbc.msn.com/id/6811975/from/RL.4>).

³²⁵ Dr. Nelson directs MIT's [The Massachusetts Institute of Technology's] patent transfer office. Rather than a law degree, hers is a PhD in organic chemistry. Her work has earned her respect among intellectual property lawyers, and world renowned among other universities that are keen to emulate MIT's successes... Open Source Bio tech?...I don't know what it means! 'The term is so broad, she says, it's meaningless. Similarly, she believes trying to adapt intellectual property approaches for different classes of technology, such as processes versus products, would be impossible. One man's infrastructure is another man's product or biotech company.' she says. Patents provide an incentive to invest; open-source negates this. Many firms won't want access to a tool if it can't have it exclusively. Free software and journal articles are small change compared with the immensity of the life sciences industry and the problem of hindered innovation. *Ibid.*

³²⁶ Over the past year – since a disastrous first-quarter performance in 2005 – IBM has been trying to put in place the organizational structure and processes to make its more rigorous approach to services work. See Richard Waters, IBM Repackages Its Brain Power, Financial Times (7/11/06), at p. 10. [T]he services business... which accounts for more than 50 percent of Big Blue's revenues – is now suffering sclerosis. Revenues, which grew by 2.5 percent last year, are likely to grow by about the same this year, with a further 3 percent in 2007 and 2008, according to estimates by Merrill Lynch... That has exposed an underlying weakness: IBM did not deliver on the original promise of services... the lack of a standardized approach led it largely to miss some of the hottest new markets in technology, such as security. See The Gravy Train Comes Off the Rails, Financial Times (7/11/06), at p. 10.

³²⁷ The US earnings season got off to a surprisingly rocky start as IBM ... and Intel on... reported earnings that fell short of expectations. The technology heavyweights blamed a variety of causes... Intel said... *the company's outlook for first quarter sales would be lower than*

expected. In spite of announcing a 16 per cent rise in net income for the fourth quarter, the chipmaker spooked investors by suggesting demand for desktop computers weakened toward the end of 2005. IBM's results were... stronger... with fourth-quarter profits up 13 per cent but revenues fell shy of Wall Street forecasts due in part to lower sales in its global-services business (emphasis added). See Dan Roberts and Richard Waters, High-tech Giants Fall Short of Forecasts, Financial Times.com (1/18/06), at: (<http://news.ft.com/cms/s/e3d9829a-87c6-11da-8762-0000779e2340.html>). Interestingly, only one month prior to the release of their earnings reports, IBM and Intel, had announced their participation in a new collaborative open source' research and development venture with a number of universities. Leaders from four information technology companies, seven American universities and the Ewing Marion Kauffman Foundation announced [recently] that *they ha[d] adopted first-of-a-kind guiding principles to accelerate collaborative research for open source software...* [According to]... Dr. John E. Kelly III, senior vice president of Technology & Intellectual Property for IBM [,] These principles are based on a balanced approach to IP management and should stimulate additional joint industry and university research projects' (emphasis added). See Twelve Leaders Adopt Principles to Accelerate Innovation, Press Release Ewing Marion Kauffman Foundation (12/19/05), at: (<http://www.kauffman.org/items.cfm?itemID=662>). This would seem to suggest that IBM migrated towards open-source collaborations because its software management consulting business was underperforming. IBM is not an eleemosynary [charitable] institution, *and it did this for good commendable motives of capitalist greed and a desire to dish its competitors, including Sun and Microsoft.* As industry observer Joel Spolsky noted, the myth' is that Lou Gerstner read [an open source] manifesto and decided he does not actually like capitalism,' whereas the reality is that IBM needs to commoditize enterprise software' so as to promote their consulting division and the best way to do this is by promoting open source' (emphasis added). See James V. DeLong, Peddling Dope: Open Source Drug Development, TechCentralStation.com (5/18/04), at: (<http://www.techcentralstation.com/051804C.html>). Actually, IBM's 1st quarter 2006 service and software revenues were recently reported to be flat, at best. See IBM Reports 2006 First-Quarter Results, Business Wire (4/18/06), at: (<http://news.moneycentral.msn.com/ticker/article.asp?Symbol=US:IBM&Feed=BW&Date=20060418&ID=5650471>); IBM Shares Down 71 Cents in Early Trade, Associated Press

(4/19/06), at: <http://news.moneycentral.msn.com/ticker/article.asp?Feed=AP&Date=20060419&ID=5650545&Symbol=US:IBM>).

³²⁸ A look back during 2005 reveals that both IBM and Sun Microsystems earnings fell short of analyst expectations also for the first quarter of 2005. The announcement from IBM followed poorer results from struggling rival Sun Microsystems Inc. and Unisys Corp., that together were the latest evidence that *big technology companies are having a harder time selling their goods and services to corporate clients*... A low point for IBM was its sales of its vaunted mainframe computers, which were down 16% from the year-earlier quarter. That hits the company's net income, because the expensive mainframes carry high profit margins... Chief Financial Officer Mark Loughridge... also placed the blame for the shortfall at the feet of the giant services organization, which accounts for about half the company's revenue. Those services encompass everything from handling a company's payroll operation and designing computer networks to basic consulting. Mr. Loughridge said IBM had execution issues' in services, and that the company was beginning restructuring efforts... (emphasis added). See Charles Forelle and Donald Clark, IBM Results Fall Short of Targets As Companies Slow Tech Spending, Wall Street Journal (4/15/05), at A1 and A4.

³²⁹ The rise of the Linux operating system and other open-source software is just one of the new forces that threaten to shake software giants such as Oracle. Others include software as a service' – the practice of running software on behalf of a customer and selling access to it under a monthly subscription fee... By allowing anyone to use and adapt their code free of charge and generally charging only for maintenance, open-source companies benefit from a low-cost approach to developing and distributing software that *threatens to disrupt established software empires*... Without control of their own intellectual property, open-source companies are vulnerable to seeing their products simply absorbed by companies such as Oracle, says Mr. Ellison. The reason I have a hard time writing checks for billions or hundreds of millions of dollars for things that are open source is that if we could this, other people do this too.' Those considerations seem also to have dissuaded Oracle from trying to buy one of the big Linux companies, at least for now. I don't see how we could possibly buy Red Hat... *I'm not going to spend \$5bn, or \$6bn, for something that can just be so completely wiped off the map*, he says (emphasis added). See Richard Waters, The Prophet of Oracle's Evolving Future, Financial Times Interview of Larry Ellison (4/17/06), at p. 6. In a

related article, Larry Ellison indicated that Oracle is considering launching its own version of the Linux operating system and has looked at buying one of the two companies that dominate the Linux world... to open a new front in Oracle's long rivalry with Microsoft. *Oracle wanted to sell a stack' of software that, like Microsoft, ranged from the operating system through to applications...* Like IBM, Oracle has counted on Linux – an open source systems whose code is open to anyone to view and adapt – to act as a counterweight to Microsoft's Windows. See Richard Waters, *Oracle Looks at Launching Version of Linux*, Financial Times (4/17/06), at p. 1.

³³⁰ [O]ne of the quandaries of open-source software [is] the degree to which companies such as Oracle, which depend on Linux to compete effectively against Microsoft, should co-opt it for their own ends... The open-source movement sprung up as a grassroots response to proprietary development of software by companies such as Microsoft. Linux, an operating system that runs on cheap Intel-based servers, competes head on with Windows... Many companies have adopted it as the foundation on which to run their database and applications software. Linux is distributed under open-source terms, which means that any contributor's work can be used free by anyone else... [Companies] which distribute versions of Linux [] cannot charge for the software itself[,] but make money by providing support and upgrades to make sure it works stably with other corporate software. Linux has become an ecosystem comprising not only open-source volunteers but also software companies and distributors. The benefit of being part of this ecosystem is that Linux is a cheap and open operating platform ... But ecosystems are delicate: they rely on all participants gaining something and not feeling that others are taking out more than they put in. The open-source ecosystem is particularly so because... no one holds intellectual property rights over Linux software or can charge for it per se, which curtails the profits that Linux distributors can make. See John Gapper, *A Threat To The Fragile Linux Ecosystem*, Financial Times (4/24/06), at p. 15.

³³¹ Apparently, IBM 's gamble to become a first-mover' has paid off insofar, as it has now pitted two former opponents of the open source movement (Microsoft and Sun Microsystems) against one another. In a recent article, Sun Microsystems Chairman Scott McNealy, a former opponent of open-source systems, now waxes poetic about them.

From time to time, forward thinkers posed the idea that less protection would be more beneficial – that building communities and sharing intellectual resources could create new marketplaces that would create

new economic opportunities. This concept has been slow to take off, given the traditional opportunity costs associated with sharing your ideas. For most, it has been easier and more intuitive to go it alone and keep the crown jewels locked up. While that model may have worked in the industrial age and flourished in the information age, it will be the 'kiss of death' in the participation age... There are many ways to be competitive in the participation age but the most successful approaches require companies to evolve their cultures and rethink their business models. For us, at Sun, that has meant open-sourcing our products – for example our operating system Solaris... See Scott McNealy, 'Share the Crown Jewels' and Create New Markets, *Financial Times* Comment (2/16/06), at p. 13. In light of this recent turnabout, one must question whether the same tactics have begun to be applied to the pharmaceutical industry. IBM, however, should not yet rejoice, as it appears to have been up-ended by its open source competitor Red Hat. Red Hat, the biggest distributor of the open source Linux computer operating system, recently acquired upstart JBoss, which makes application server software and other middleware that lets companies run their applications over the internet, directly rivalling IBM and Microsoft. JBoss was earlier this year a take-over target of Oracle. See Richard Waters, 'Red Hat Agrees to Buy Open Source Upstart', *Financial Times* (Apr. 11, 2006), at: <http://news.ft.com/cms/s/3ae18f7a-c8b7-11da-b642-0000779e2340.html>).

³³² Interestingly, Scott McNealy recently resigned as CEO of Sun Microsystems on April 24, 2006. See Richard Waters, 'McNealy Steps Down as Sun Microsystems' CEO', *FT.com* (4/24/06), at: <http://news.ft.com/cms/s/97dc99b8-d3d9-11da-b2f3-0000779e2340.html>). His resignation was reportedly triggered by Sun's poor operating performance, which was attributed to McNealy's overexpansion of Sun during the boom years, and his delay in launching Sun's Solaris computer operating system on low-cost servers that run the standardized X86 chips made by Advanced Micro Devices and Intel. The latter mistake helped to open the door to the Linux open-source operating system, which has become a popular choice for customers looking to escape the high prices of proprietary servers made by companies like Sun. See Richard Waters, 'McNealy Takes the Hits and a Backseat at Sun', *FT.com* (4/25/06), at: <http://news.ft.com/cms/s/97559726-d481-11da-a357-0000779e2340.html>);

³³³ It is arguable that the French government's challenge to the Apple iTunes platform on the grounds of lack of inter-operability and anti-

competitive practices is actually a form of disguised trade protectionism and forum-shopping' employed by French and even American competitors. The same is also likely true with respect to the EU Commission's longstanding case against Microsoft. The Commission has charged Microsoft with anti-competitive practices – namely its use of a closed proprietary operating system (e.g., the plumbing of the internet) protected by patents and copyrights, and its bundling of its own software products with it. In the Microsoft case, especially, foreign and American Microsoft competitors have provided the EU Commission with information adverse to Microsoft's legal and economic interests, much the same way they unsuccessfully provided information to the US Department of Justice several years ago. During 1998, Microsoft's competitors had assisted the U.S. Department of Justice in bringing an anti-trust case against Microsoft. Although the trial court ruled against Microsoft, the decision was later appealed and overturned by the DC Circuit Court of Appeals. The case was subsequently settled. For a summary of this case, See United States v. Microsoft, Wikipedia, at: (http://en.wikipedia.org/wiki/Microsoft_antitrust_case).

³³⁴ [T]he Brazilian government... [has]... undertaken four actions... regarding innovative [i]ntellectual property perspectives. The first is the adoption of *free* software, both by the government, as well as by the private sector. At the government level, *free* software has been adopted by several Ministries and governmental bodies, at the federal, state and city levels. The army is also adopting *free* software, as is the main data processing entity at the government, SERPRO (the Federal Data Processing Service). In the private sector, technology companies such as Itautec are investing in *free* software products, as is the case for IBM. Retail store chains, airlines, financial consulting companies and supermarkets are also using *free* software in Brazil. The second initiative... is the Creative Commons project. The Creative Commons project is a tool for creators and artists to license their creations so that society as a whole becomes entitled to exercise some rights over the work. It is a tool for *intellectual generosity*, as well as for the emergence of *open business models*. The Creative Commons licenses move from the strict All rights reserved' to a Some rights reserved' model. The artist and the creator are the ones who decide, on a voluntary basis, which rights he or she wants to reserve, and which rights he or she wants the society to be free to exercise (for instance, there are noncommercial sharing licenses, also non-derivative works licenses, and others)... Finally, [there are]... *the access to medicines initiative*... and also *the Development Agenda* proposed at the

World Intellectual Property Organization by Brazil and Argentina (emphasis added). See Remarks by Dr. Ronaldo Lemos, at the Workshop: Global Intellectual Property from a Brazilian Perspective', *supra*.

³³⁵ See Steve Kingstone, Brazil Adopts Open Source Software, BBC News (6/2/05), at: (<http://news.bbc.co.uk/1/hi/business/4602325.stm>).

³³⁶ See Carlos A. Ball, Why Is There No Free Trade in the Americas?, TCSDaily.com (2/25/04), at: (<http://www.tcsdaily.com/022504B.html>).

³³⁷ As an example, when the development agenda was proposed at WIPO, the US Trade Representative was having lunch with businessmen in Sao Paulo. Asked by the press about what his opinion was on the initiative, he was clearly unfavorable of it. The US Trade Representative's Office is responsible for the publication of the so-called Special 301 Report, which grades every country in terms of how much Intellectual Property was enforced during the previous year. Brazil was downgraded in the report published just after the development agenda proposal. The report leads to a series of unreasonable situations inside the country. Remarks by Dr. Ronaldo Lemos, at the Workshop: Global Intellectual Property from a Brazilian Perspective, University of Oxford Centre for Brazilian Studies (11/4/05), at: (<http://www.brazil.ox.ac.uk/confreports/IP%20report%20final3.pdf>).

³³⁸ See Julian Dibblell, We Pledge Allegiance to the Penguin, quoting Cultural Minister, and former pop star, Gilberto Gil, Wired Magazine (Nov. 2004) Issue 12.11 at: (<http://www.wired.com/wired/archive/12.11/linux.html>).

³³⁹ *Ibid.*

³⁴⁰ [A] model of development is, of course, more than a formula for increasing GDP. The development path a country chooses tells you not just about its economic sensibility but about the culture it envisions for itself (emphasis added). *Ibid.* It is said that Brazil's cultural attitude toward intellectual property is best reflected in the 1960's music-making approach of tropicalism which, in turn, is said to derive from Brazil's early history of *cannibalism*. In 1556, not long after the Portuguese first set foot in Brazil, the Bishop Pero Fernandes Sardinha was shipwrecked on its shores and set about introducing the gospel of Christ to the native heathens. 'The locals, impressed with the glorious civilization the bishop represented and eager to absorb it in its totality, promptly ate him. Thus was born Brazilian culture. Or so wrote the modernist Brazilian poet Oswald de Andrade, whose interpretation of the incident in a 1928 manifesto exalted the cannibals as symbolic role

models for all of his country's cultural practitioners. *Ibid.* Tropicalismo has actually been described as more of an *attitude*, a type of *cultural cannibalism*, than as a method. It entailed the limitless cutting, pasting and combining of different genres of music into a new synthesis of sound and expression. However, as noted by Brazil's Minister of Culture, Gilberto Gil, tropicalismo was also a political movement. It reflected not only a refusal to submit to the forces of economic imperialism ... [but also] a cannibalistic response of swallowing what they gave us, processing it, and making it something new and different. We saw the cultivating of new habits and manners from the outside as a way of nourishing ourselves, not just intoxicating ourselves. *Ibid.* And, the movement's ideas have become integral to Brazil's self-image. Those ideas are a feature of the country's intellectual landscape, name-checked regularly not just in doctoral dissertations but on television talk shows and Carnival floats. But what's most striking about those ideas... is how the globalizing drift of technology and economics is forcing a similar path on the rest of us. In the production of all manner of cultural goods - from music to software to scientific knowledge itself - the logics of networks, digital media, and global interdependence are telling us to loosen up. They're urging us to stretch our notions of authorship and creativity, to let hybridity and flux seep into the tools with which we craft our cultures and ourselves... Gil and his team, for instance, have coined a word to sum up Brazil's approach to intellectual property in the networked age. The idea, Gil says, is to *tropicalize*. *To make the digital world join in the samba* (emphasis added). *Ibid.*

³⁴¹ *Ibid.*

³⁴² It was actually conceived during the administration former Brazilian Prime Minister Fernando Henrique Cardoso (thought to be a supporter of market-based systems), under the watchful eye of former Health Minister and current Sao Paulo Mayor Jose Serra. It has been said that Serra... was *the man who set Brazil on its path toward IP independence*. *Ibid.* See also Andrew Stevens, José Serra Mayor of Sao Paulo, (http://www.citymayors.com/mayors/saopaulo_mayor.html).

³⁴³ In 1996, in response to Brazil's alarming rate of AIDS infection, the government of then-president Fernando Henrique Cardoso *guaranteed distribution of the new retroviral drug cocktails to all HIV carriers in the country*. Five years later, with the AIDS rate dropping, it was clear that the plan was wise but - *at the prices being charged for the patented drugs in the cocktail, utterly unsustainable...* [W]ith the drug patents standing between Serra and a functioning AIDS program, the problem took on a particular urgency. [Serra's] first approach was

to go to the key patent holders, the US pharmaceutical giant Merck and the Swiss firm Roche, and ask for a volume discount. When the companies said no, Serra raised the stakes. Under Brazilian law, he informed them, *he had the power in cases of national emergency to license local labs to produce patented drugs, royalty free*, and he would use it if necessary. Merck immediately caved, but Roche stood its ground until August 2001, when Serra prepared to make good on his threat by drawing up the required paperwork. It was the first time a poor country had even come close to breaking a drug patent - and Roche, stunned, returned to the bargaining table with a newly cooperative attitude. *In return for Serra's agreement to play nice, the drugmaker would reduce the price of its drug in Brazil to less than half what it was (and less than Brazil's cost to go it alone). This was a powerful lesson in the politics of intellectual property - and Brazil was fertile ground for it. As it happens, the open source community in Brazil has long been one of the most active*, with a half-dozen GNU/Linux versions and the world's first open source bank ATM network. That community is also undoubtedly among the most politically mobilized (emphasis added). See Julian Dibbell, *We Pledge Allegiance to the Penguin*, *supra*.

³⁴⁴ *The Ministry of Health of Brazil has declared the anti-retroviral drug Kaletra (Lopinavir/ ritonavir), manufactured by Abbott Laboratories, to be of public interest. As such, the Brazilian government will adopt obligatory licensing of the medication, in the case that the manufacturer does not provide the necessary requirements to guarantee the sustainability of the National STD/AIDS Program... With the declaration of public interest, the Brazilian government is applying the flexibility laid out in international norms and Brazilian legislation, without breaking a contract... The Brazilian National STD/AIDS Program is a worldwide benchmark for treatment of HIV carriers and has as its goals the universal and free access to all resources available for the treatment of the disease, and for prevention and diagnosis at public hospitals... Article 71 of Brazilian patent law (Law 9.279/96) provides for obligatory licensing in the case of public interest. Decrees 3201 of 1999, and 4830 of 2003, also consider those items related to public health to be of public interest (emphasis added). See The Government Declares Anti-retroviral Kaletra to Be of Public Interest and Will Produce it in Brazil, Ministry of Health of Brazil (6/23/05), at: <http://ww2.aegis.org/news/pr/2005/PR050651.html>);*

(<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/06-25-2005/0003950348&EDATE=>).

³⁴⁵ See Bush Touts Foreign HIV/AIDS Funding As Great Compassion 'And In Our National Interest', *Medical News Today* (2/7/06), at:

(<http://www.medicalnewstoday.com/medicalnews.php?newsid=37072>

). However, some scholars have even begun to doubt the power of aid packages by themselves to promote the degree of self-sufficiency in countries unwilling to emancipate themselves from the philosophy of welfare dependency. See *Five Debates on International Development - The US Perspective*, Presented by former Administrator, US Agency for International Development (USAID) Andrew Natsios, at the Overseas Development Institute, United Kingdom (10/12/05), at: (http://www.odi.org.uk/speeches/apgood_oct05/apgood_oct12/HLnatsios.pdf).

³⁴⁶ Kenya and *Brazil* joined forces to press donors and wealthy governments for more funds to develop treatments for neglected diseases that mostly affect poor people. The two nations said they would co-sponsor a resolution calling for such action at a meeting next week of the World Health Assembly (WHA) in Geneva at which global health priorities are to be addressed... *Guilherme Patriota, a representative of Brazil's foreign ministry*, said the resolution would give governments the opportunity to wake up from their slumber on essential health research and development. We have begun to move in the right direction but it is essential that we develop better and new health tools to improve the long-term health both of patients and economies of developing countries,' he said (emphasis added). See *Kenya, Brazil Press For Funds For Neglected Diseases* *Agence France Presse* (5/17/06), at:

(<http://www.todayonline.com/articles/118794print.asp>).

³⁴⁷ See, e.g. Brett D. Schaefer, *How Economic Freedom Is Central to Development in Sub-Saharan Africa*, Heritage Lecture #922, *supra*.

³⁴⁸ See Slavi Pachovski and Lawrence A. Kogan, *The Wolf and the Stork - How Brazil's Breaking of U.S. Drug Patents Threatens Global Trade and Public Health*, Institute for Trade, Standards and Sustainable Development (6/14/05), at: (http://www.itssd.org/White%20Papers/TheWolf_and_theStork-Brazil_snon-patentabilitylaw.pdf).

³⁴⁹ See *Workshop: Global Intellectual Property From a Brazilian Perspective*, University of Oxford Centre for Brazilian Studies

(11/4/05), at:
(<http://www.brazil.ox.ac.uk/confreports/IP%20report%20final3.pdf>).

³⁵⁰ See Janet Hope, *Open Source Bio technology?* *supra*.

³⁵¹ See Robin Bloor, *South America Wars to Open Source*, *The Register* (2/10/05), at:
(http://www.theregister.co.uk/2005/02/10/south_america_open_source)

³⁵² Remarks by Dr. Ronaldo Lemos, at the Workshop: Global Intellectual Property from a Brazilian Perspective, University of Oxford Centre for Brazilian Studies, *supra*. This sounds eerily similar to the French justification of cultural diversity.

³⁵³ The trend to Open Source in South America seems to be stronger than it is anywhere else. Almost all governments there seem to be setting an Open Source agenda... In Chile, Open Source is being deployed extensively in schools through the government's high school internet access network, Enlaces, which now implements the Edulinux system... In Venezuela, President Chavez issued a decree, in December 2004, mandating Venezuela's public administration to switch to Open Source in the course of the next two years. All ministries are required to come up with migration plans to meet the target date. Most interesting of all, perhaps, is Peru, where the government recently introduced a bill mandating the use of Open Source software by the state. It is an interesting development because the emphasis within the bill is specifically on the idea of openness. In Peru, Open Source in government is being viewed as a citizen's right... In South American countries, as in most other areas of the world, the government is by far the biggest purchaser of software. Thus the Open Source trend that is now established in the government sector across the continent will doubtless spur Open Source adoption in the private sector. See Robin Bloor, *South America Wars to Open Source*, *supra*.

³⁵⁴ During the week of August 22, 2005, Argentina and Brazil pledged... to join forces in producing generic drugs to treat AIDS, the latest step by the South American neighbors to cut costs and expand care for people infected with HIV. Officials provided few details of the agreement, such as how soon production might start. The two nations will begin by sharing information and technology and by bringing experts together... We are going to conduct ourselves in accordance with the public interest,' said Saraiva Felipe, [Brazil's newly appointed Health Minister]... [The] accord, however, should not be viewed as merely another aspect of [Brazil's successful] negotiating strategy, Argentine officials said. [T]he two nations will work together on drugs for other diseases, such as Chagas, that are no longer under patent.

Some of the medicines the Argentines and Brazilians have in mind often are overlooked or abandoned by private drug companies because they provide little profit, officials said. See Colin McMahon, Argentina, Brazil Pledge Alliance to Produce Generic AIDS Drugs, quoting Michael Weinstein, president of AIDS Healthcare Foundation, Chicago Tribune (8/25/05), at: (<http://www.ledger-enquirer.com/mld/ledgerenquirer/news/world/12472502.htm>).

³⁵⁵ During August 2005, officials from 11 Latin American nations reached a deal with 26 drug and diagnostic companies to lower the prices governments pay for anti-HIV drugs and tests. Among the signatories were Brazil, Mexico and Argentina, Latin America's three biggest pharmaceutical markets. *Ibid.* And more recently, during January 2006, Brazil's news agency reported that Representatives from 19 Latin American and Caribbean nations... [agreed to]... act as a bloc to try to reduce the price of AIDS medication... See 19-Nation Bloc to Negotiate Price of AIDS Drugs CNN World, *supra*.

³⁵⁶ According to the representative of one American HIV/AIDS advocacy group, Michael Weinstein, president of AIDS Healthcare Foundation, It's really been the Brazilian model that has gone a long way to opening up access to anti-retrovirals across the globe. *Ibid.*

³⁵⁷ See Julian Dibblell, We Pledge Allegiance to the Penguin, *supra*.

³⁵⁸ The UN General Assembly [Resolution 56/183](#) (21 December 2001) (endorsed the holding of the World Summit on the Information Society (WSIS) in two phases. The first phase took place in Geneva from 10 to 12 December 2003 and the second phase took place in Tunis, from 16 to 18 November 2005. See WSIS Executive Secretariat – Report on the WSIS Stocktaking, WSIS-05/TUNIS/DOC/5 (10/19/05), at: (<http://www.itu.int/wsis/docs2/tunis/off/5.pdf>).

³⁵⁹ For a history of the ITU, and its objectives, mandates and activities, See International Telecommunications Union – About US, at: (<http://www.itu.int/aboutitu/overview/index.html>).

³⁶⁰ The official U.S. position on how intellectual property rights relate to the issue of internet governance was articulated during August 2005 at the WSIS, by U.S. Special Representative John Marburger, the President's Science and Technology Adviser. *The United States attaches great importance to a comprehensive, effective and properly enforced intellectual property system and believes that any Information Society envisioned by the WSIS must clearly and explicitly recognize that such a system is essential to the Information Society because it creates an incentive for creativity and innovation. To that end, WSIS and its documents must recognize, respect and support the existing international intellectual property system.* The balance between owners

and users of intellectual property is an important underpinning of an effective intellectual property system. Existing international intellectual property agreements encompass and reflect the balance between owners and users of intellectual property. Indeed, this balance is struck so that intellectual property owners are encouraged to develop and disseminate their works and inventions to the public for use and enjoyment. The United States believes that the appropriate United Nations forum for dealing with intellectual property issues is the World Intellectual Property Organization (WIPO), which has regularly examined the interaction of cyberspace and intellectual property since the early days of the Internet (em phasis added). See Intellectual Property Rights - Comments of the United States of America on Internet Governance , Bureau of Economic and Business Affairs, U.S. Department of State (8/15/05), at: <http://www.state.gov/e/eb/rls/othr/2005/51063.htm>.

³⁶¹ The aim of the memorandum of understanding is to improve training and education in the use of FOSS. This software can be a way of closing the "digital divide" in computer-based technology between developing and industrialized nations. But to benefit from FOSS developing countries need to have the knowledge to use these programmes effectively. The agreement between Brazil and UNCTAD will help build expertise in Portuguese-speaking nations with the help of FOSS training experts. It will also involve sharing relevant training materials and resources. The MOU was signed by Gilberto Gil, Minister of Culture of Brazil, and Supachai Panitchpakdi, Secretary General of UNCTAD. See UNCTAD and Brazil Support Free and Open-source Software , UNCTAD at WSIS (11/16/05) at: http://www.unctadxi.org/templates/News_5797.aspx .

³⁶² See UNCTAD-ICTSD Capacity Building Project on IPRs , at: <http://www.iprsonline.org/unctadictsd/description.htm> . The project is producing a series of documents through a participatory process involving trade negotiators, national policy makers, as well as eminent experts in the field, the media, NGOs, international organizations, and institutions in the North and the South dealing with IPRs and development. *The published outputs are not intended to be academic exercises, but instruments that, in their final forms, will be the result of a thorough process of consultation* (em phasis added). *Ibid.*

³⁶³ See also, Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement, United Nations Conference on Trade and Development and the International Centre for Trade and Sustainable Development (Cambridge University Press May 2005), at:

(<http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>); Intellectual Property Rights: Implications for Development, UNCTAD-ICTSD Project on IPRs and Sustainable Development (August 2003), at: (http://www.ictsd.org/pubs/ictsd_series/iprs/PP/PP_1Intro.pdf).

³⁶⁴ The issue of intellectual property did not make the headlines during the concluding session of the five-year-long UN World Summit on the Information Society (WSIS) in Tunis. While the final Tunis documents make ample references to access they mainly refer to it in the context of access to infrastructure. Four points talk cautiously about the numerous challenges for expanding the scope of useful accessible information content (paragraph 15); about improving access to the world's health knowledge and telemedicine services (paragraph 90.g) and to agricultural knowledge" (90.i); and, finally, about supporting educational, scientific, and cultural institutions, including libraries, archives and museums, in their role of developing, providing equitable, open and affordable access to, and preserving diverse and varied content, including in digital form, to support informal and formal education, research and innovation (90.k). But concerns like the one presented by Alex Byrne, president of the International Federation of Libraries Association (IFLA), that *librarians all over the world see a growing imbalance of IP laws in favour of rights holders and to the detriment of the users' and about a shrinking of the public domain,* that in some respects increasingly was also barring access in developed countries, were a side issue in the plenary talks. Burne, like the representatives of the free software community, spoke in side events organised by NGOs, namely a panel organized by IP Justice on the World Intellectual Property Organisation (WIPO) and a panel organised by the Free Software Foundation on free and open source software... (emphasis added). See Monika Ermert, Intellectual Property Issues Kept Off WSIS Agenda, Intellectual Property Watch (11/30/05), at: (http://www.ip-watch.org/weblog/index.php?p=158&res=1024_ff&print=0).

³⁶⁵ See WSIS Declaration of Principles - Building the Information Society: A Global Challenge in the New Millennium WSIS-03/GENEVA/DOC/4-E (12/13/05), at Section B An Information Society for All: Key Principles', Subsection 6 Enabling Environment', Paragraph 42, at: (<http://www.itu.int/wsis/docs/geneva/official/dop.html>).

³⁶⁶ See WSIS Plan of Action WSIS-03/GENEVA/DOC/5-E (12/13/05) at Section C Action Lines, Subsection C3 Access to Information and Knowledge', Paragraph 10d, at:

(<http://www.itu.int/wsis/docs/geneva/official/poa.html>);
 (http://www.itu.int/dms_pub/itu-s/md/03/wsis/doc/S03-WSIS-DOC-0005!!PDF-E.pdf).

³⁶⁷ The WSIS Stocktaking Report describes several Brazilian government initiatives/programs that are actively promoting open source methods within Brazil. *See, e.g.*, WSIS Executive Secretariat – Report on the WSIS Stocktaking, WSIS-05/TUNIS/DOC/5, at pars. 15, 18, 20 and 21, at: (<http://www.itu.int/wsis/docs2/tunis/off/5.pdf>)

³⁶⁸ 8.2 *International and regional cooperation* 74. The European Commission, DG Information Society has a number of programmes in this area including... Access to cultural heritage‘ is a strategic objective of the Information Society Technologies (IST) priority area within the 6th EU R&D Framework Programme. It aims to develop advanced systems and services that help improve access to Europe's knowledge and educational resources (including cultural and scientific collections)... 75. The Steering Committee for Culture (CDCULT) of the Council of Europe also has a number of relevant programmes: Through the drafting of a Framework Convention on the Value of Cultural Heritage for Society,‘ the Steering Committee for Cultural Heritage (CDPAT) aims to provide countries with a cooperation structure and monitoring system that will allow them to adapt their policies to the context of a knowledge-based network economy. As a regional complement to UNESCO ‘s work on the protection of the diversity of cultural contents and artistic expressions,‘ the CoE defines principles and criteria governing the sustainable use of the cultural heritage resources, to establish a development scheme of benefit to society as a whole. The European Heritage Network is a European information service facilitating the achievement of various WSIS targets, including: connecting central government services and heritage agencies (31 participating countries in 2004); promoting access to public official information and scientific knowledge; creating online working instruments for the heritage community; encouraging European cultural content and respecting linguistic diversity; *developing R&D in the cultural field, together with open source, property and free software; and creating a basis for self-learning and life-long learning*... 76. UNESCO is the pre-eminent international organisation in this area. Its relevant programmes include: UNESCO Recommendation concerning the Promotion and Use of Multilingualism and Universal Access to Cyberspace that was adopted by UNESCO's General Conference at its 32nd session (30 September – 17 October 2003). *It proposes fostering universal access to digital resources and services*, and facilitating the preservation of their cultural

and language diversity (emphasis added). See WSIS Executive Secretariat – Report on the WSIS Stocktaking, WSIS-05/TUNIS/DOC/5, at pars. 74-76. *Ibid.*

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³⁷⁰ 7. Member States and international organizations should promote access to the Internet as a service of public interest through the

adoption of appropriate policies in order to enhance the process of empowering citizenship and civil society, and by encouraging proper implementation of, and support to, such policies in developing countries... 13. *Concerted efforts within the United Nations system should promote the sharing of information about and experience on the use of ICT-based networks and services in socio-economic development, including open source technologies*, as well as policy formulation and capacity-building in developing countries... 15. *Member States should recognize and enact the right of universal online access* to public and government-held records including information relevant for citizens in a modern democratic society... 17. *Member States and international organizations should encourage cooperative arrangements which respect both public and private interests in order to ensure universal access to information in the public domain without geographical, economic, social or cultural discrimination*... 19... *The development of human capital* for the information society, including an open, integrated and intercultural education combined with skills training in ICT, is of crucial importance. *ICT training should not be limited to technical competence but should also include awareness of ethical principles and values*... 23. Member States should undertake, in close cooperation with all interested parties, the updating of national copyright legislation and its adaptation to cyberspace, *taking full account of the fair balance between the interests of authors, copyright and related rights-holders, and of the public embodied in international copyright and related rights conventions* (emphasis added). See Recommendation concerning the Promotion and Use of Multilingualism and Universal Access to Cyberspace, Adopted by the UNESCO General Conference at its 32nd Session (Oct. 2003), at: (http://portal.unesco.org/ci/en/ev.php-URL_ID=13475&URL_DO=DO_TOPIC&URL_SECTION=201.html)

³⁷¹ The panel featured, among others, Richard Stallman, the founder of the free software movement. See *All's Well That Ends Well! The Tunis Agenda for the Information Society* and the *Tunis Commitment*, Summary Highlights, World Summit on the Information Society Newsroom (11/18/05), at: (<http://www.itu.int/wsis/tunis/newsroom/highlights/18nov.html>). See also UNDP-APDIP International Open Source Network, at: (<http://www.iosn.net>).

³⁷² For example, In November 2004, Brazil and Argentina alleged... that WIPO - even though... a UN Agency - was not acting in accordance with the Millennium Development Agenda goal. A

development agenda was co-sponsored by a group of other twelve countries, referred to as the Group of Friends of Development. The GFD proposed reforms at WIPO to guarantee a transparent, pro-development and balanced agenda for WIPO's mandate, governance, and *norm-setting*, as well as equal representation in the Organization's activities, and increase access to knowledge and technology, together with technical assistance programs to harmonize developing countries' legislation to the standard of developed countries (emphasis added). See Workshop: Global Intellectual Property From a Brazilian Perspective, University of Oxford Centre for Brazilian Studies (11/4/05), at: <http://www.brazil.ox.ac.uk/confreports/IP%20report%20final3.pdf>).

³⁷³ International lawyers often distinguish between hard' and soft' law. Such a distinction, it is said, has at least two meanings. First, the distinction may refer to the difference between rules of law meant to be followed and norms meant merely to set out preferred outcomes... Second, the distinction between hard' and soft' law may refer to the difference between formal sources of law (such as treaties) and instruments that are not formally legal sources (such as mutual declarations of government leaders issued at the end of a diplomatic conference). Such declarations may contain non-binding' statements of principle. See Mark W. Janis and John E. Noyes, *International Law – Cases and Commentary* (West Group © 2001), at 39.

³⁷⁴ Brazil and the European Union are now apparently seeking to require open source and royalty-free software interoperability' standards at the International Organization for Standardization (ISO). See Nicos L. Tsilas, The Threat to Innovation, Interoperability, and Government Procurement Options From Recently Proposed Definitions of Open Standards', *International Journal of Communications Law & Policy*, Special Issue, Global Flow of Information (Autumn 2005), at: http://www.ijclp.org/10_2005/pdf/ijclp_08_10_2005.pdf) (mandatory royalty-free licensing and unfettered sublicensing and prohibition of other reasonable licensing terms in favor of FRAND' – fair, reasonable and non-discriminatory); The European Interoperability Framework: An Industry Perspective, Business Software Alliance (Dec. 2005), at: http://www.politech-institute.org/review/articles/MULLER_Benoit_volume_3.pdf) (The requirement that a standard be irrevocably available on a royalty-free basis' [and] ... that standards licenses be irrevocable' and impose no constraints on re-use' of the standard [are] inconsistent with the licensing policies of every major standards organization, including those that require royalty-free licensing... BSA also has concerns with

statements in the EIF [European Interoperability Framework] regarding open-source software (OSS); Standards, Intellectual Property Rights (IPRs) and the Standards-Setting Process, World Intellectual Property Organization at: (http://www.wipo.org/sme/en/documents/ip_standards.htm); Patents & Open Standards, National Information Standards Organization (2003), at: (http://www.niso.org/press/whitepapers/Patents_Caplan.pdf) (patent policy rejects RAND – reasonable and non-discriminatory terms – and favors royalty-free licensing); Lawrence J. Bassuck, 'RAND *ex ante* and Open Source/Standard', Presented at CASRIP 2005 High Technology Protection Summit (7/22/05), at: (<http://www.law.washington.edu/Casrip/Summit/2005/Bassuk.pdf>); Matthew Clark, Standards and Intellectual Property Rights: A Practical Guide for Innovative Business (Crown © 2004), at: (<http://www.smartoptics.org/pdfs/Intellectualfinal1.pdf>).

³⁷⁵ See, e.g., Lawrence A. Kogan, 'Polluting the Future of the WTO', Institute for Trade, Standards and Sustainable Development, Inc. (July 2006), at: (<http://www.itssd.org/Publications/PollutingtheFuture.pdf>); Lawrence Kogan, 'EU Trade Protectionism Must Yield to Non-EU Market Access Demands', Institute for Trade, Standards and Sustainable Development, Inc. (July 2006), at: (<http://www.itssd.org/Publications/EU-Trade-Protectionism.pdf>).

³⁷⁶ See "Workshop: Global Intellectual Property From a Brazilian Perspective", University of Oxford Centre for Brazilian Studies (11/4/05), at: (<http://www.brazil.ox.ac.uk/confreports/IP%20report%20final3.pdf>).

³⁷⁷ See Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO: Appendix – Issues and Measures to be Considered, W/O/GA/31/11, Secretariat of the World Intellectual Property Organization (8/27/04), at pp. 7-8, at: (http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_11.pdf).

³⁷⁸ In order to ensure that development concerns are fully brought into WIPO activities, the Member States may consider the possibility of amending the Convention Establishing the World Intellectual Property Organization (1967). The amendment would explicitly incorporate the development dimension into WIPO's objectives and functions. Since Article 4 (Functions) of the WIPO Convention relates its Article 3 (Objectives), paragraph (i) of Article 3 of the WIPO Convention could be amended to read as follows: (i) to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other

international organization, fully taking into account the development needs of its Member States, particularly developing countries and least-developed countries' (emphasis in original). *Ibid.*, at p. 7. As background in support of the amendment sought, the proposal states the following: Technological innovation, science and creative activity in general are rightly recognized as important sources of material progress and welfare. However, despite the important scientific and technological advances and promises of the 20th and early 21st centuries, in many areas a significant knowledge gap as well as a digital divide continue to separate the wealthy nations from the poor. *Ibid.*, at Annex p. 2.

³⁷⁹ *Ibid.*, at p. 7. As background in support of the amendment sought, the proposal states the following: Technological innovation, science and creative activity in general are rightly recognized as important sources of material progress and welfare. However, despite the important scientific and technological advances and promises of the 20th and early 21st centuries, in many areas a significant knowledge gap as well as a digital divide continue to separate the wealthy nations from the poor... Intellectual property protection is intended as an instrument to promote technological innovation, as well as the transfer and dissemination of technology. Intellectual property protection cannot be seen as an end in itself, nor can the harmonization of intellectual property laws leading to higher protection standards in all countries, irrespective of their levels of development. The role of intellectual property and its impact on development must be carefully assessed on a case-by-case basis. IP protection is a policy instrument the operation of which may, in actual practice, produce benefits as well as costs, which may vary in accordance with a country's level of development. Action is therefore needed to ensure, in all countries, that the costs do not outweigh the benefits of IP protection. *Ibid.*, at Annex p. 2.

³⁸⁰ See Juliana César Nunes, Brazil Wants New Rules for Intellectual Property, *Brazzil Magazine* (9/29/04), at: (<http://www.brazzilmag.com//content/view/279/2>). The official referred to was Roberto Jaguaribe, the president of the Brazilian Institute of Intellectual Property (INPI).

³⁸¹ To the extent possible, the meetings will be convened in conjunction with the 2005 session of the Permanent Committee on Cooperation for Development Related to Intellectual Property. See General Assembly Decision on a Development Agenda, CP-Tech (10/4/04), at: (<http://www.cptech.org/ip/wipo/wipo10042004.html>). See also, Member States Agree to Further Examine Proposal on

Development, WIPO Press Release 396 (10/4/04) at: (http://www.wipo.org/edocs/prdocs/en/2004/wipo_pr_2004_396.html).

³⁸² See Geneva Declaration on the Future of the World Intellectual Property Organization, at: (http://www.soros.org/initiatives/information/news/wipo_20040929/wipo_declaration.pdf).

³⁸³ See Declaration on the Future of WIPO News and Announcement - Information Program, Open Society Institute & Soros Foundation Network (9/30/04), at: (http://www.soros.org/initiatives/information/news/wipo_20040929).

O SI's Information Program, together with the Consumer Project on Technology (CPTech), convened a group of experts to draft a declaration calling upon the World Intellectual Property Organization (WIPO) to adopt a fairer approach to intellectual property (IP) policymaking. The Geneva Declaration on the Future of WIPO arose from a workshop on the future of WIPO that was hosted by the TransAtlantic Consumer Dialogue on September 13 and 14, 2004, in Geneva, Switzerland. The drafters of the declaration— including academics and NGO representatives— are urging WIPO, the United Nations agency that oversees intellectual property, to seriously reconsider its agenda. *Ibid.*

We do not ask that WIPO abandon efforts to promote the appropriate protection of intellectual property, or abandon all efforts to harmonize or improve these laws. But we insist that WIPO work from the broader framework described in the 1974 agreement with the UN, and take a more balanced and realistic view of the social benefits and costs of intellectual property rights as a tool, but not the only tool, for supporting creativity intellectual activity. WIPO must also express a more balanced view of the relative benefits of harmonization and diversity, and seek to impose global conformity only when it truly benefits all of humanity. A one size fits all approach that embraces the highest levels of intellectual property protection

for everyone leads to unjust and burdensome outcomes for countries that are struggling to meet the most basic needs of their citizens. See

Geneva Declaration on the Future of the World Intellectual Property Organization, *supra*, at p. 2.

³⁸⁴ See Geneva Declaration on the Future of the World Intellectual Property Organization, at p. 1.

³⁸⁵ See Policy Brief on Intellectual Property, Development and Human Rights: How Human Rights Can Support Proposals for a World Intellectual Property Organization Development Agenda, Policy Brief 2, 3D (Feb. 2006) at: (http://www.3dthree.org/pdf_3D/3DPolBrief-

[WIPO-eng.pdf](#)); Human Rights and the Establishment of a WIPO Development Agenda, 3D Information Note 51 (June 2006), at: (http://www.3dthree.org/pdf_3D/3Dnote5_WIPO_June06.pdf).

³⁸⁶ On May 16, 2006, the delegate from Third World Network made a pointed

intervention to the... WIPO Advisory Committee on Enforcement (ACE)... which noted the absence of any consumer voices on the WIPO ACE panels. Today in its intervention, Brazil called for the consumer voice to be taken into consideration at these deliberations and requested that consumer organizations be represented in the WIPO ACE panels. The delegate (Paul Salmon) from the United States, however, opposed the inclusion of consumer groups on panels on the Advisory Committee on Enforcement as he noted that consumer groups did NOT fall into the mandate of the ACE which only mentions consultations with the private industry. Argentina took the floor to call for greater public interest NGO participation in this body; Brazil also reiterated its point that all stakeholder views be taken into consideration in the WIPO ACE. See Thiru Balasubramaniam, US Delegation Opposes Consumer Groups' Inclusion On WIPO ACE Panels, (5/17/06), at: (<http://fromgeneva.blogspot.com/2006/05/us-delegation-opposes-consumer-groups.html>).

³⁸⁷ The WIPO General Assembly (GA) specified that this committee would hold two one-week sessions and report any recommendations to the next GA in September 2006. The new forum's ability to influence WIPO policy, however, is yet to be determined. The 26 September - 5 October GA also decided to continue discussions on the draft Substantive Patent Law Treaty (SPLT) and a basic proposal for a treaty on the protection of the rights of broadcasting organisations. See WIPO Members Create New Forum to Discuss Development Agenda, Bridges Weekly Trade News Digest, Vol. 9, No. 33 (10/5/05), at: (<http://www.ictsd.org/weekly/05-10-05/story2.htm>).

³⁸⁸ See Proposal for the Establishment of a Development Agenda for WIPO: A Framework for Achieving Concrete and Practical Results in the Near and Longer Terms, Provisional Committee on Proposals Related to a WIPO Development Agenda, World Intellectual Property Organization (PCDA/1/5) (2/17/06), at: (http://www.wipo.int/edocs/mdocs/mdocs/en/pcda_1/pcda_1_5.pdf).

³⁸⁹ See Friends of Development proposal: Decision of the PCDA on the Establishment of a WIPO Development Agenda (6/23/06), at: (<http://lists.essential.org/pipermail/ip-health/2006-June/009771.html>).

³⁹⁰ As no consensus could be found on how to proceed, the FoD prepared a summary of their proposals and suggestions on how the

PCDA could arrive at concrete recommendations for action (PCDA/2/2, 23 June 2006). Their proposals dealt with issues including the establishment of pro-development rule-making principles; the reaffirmation of WIPO members' commitment to UN objectives and principles (including development-related ones); the adoption of guidelines for the provision of technical assistance; the functioning of the WIPO Secretariat; the promotion of alternative innovation models; the protection of the public domain and access to knowledge; and the incorporation of competition rules in the IP system.

³⁹¹ See WIPO General Assembly to Decide Future Work on a Development Agenda for WIPO, Press Release 453 (6/30/06), at: (<http://www.wipo.org/wilma/pressinfo-en/2006/msg00031.html>). The session is scheduled to take place from Sep 25, 2006 to Oct 3, 2006. See Conferences, Meetings and Seminars, World Intellectual Property Organization,, at: (http://www.wipo.int/meetings/en/details.jsp?meeting_id=10264).

³⁹² FoD leaders **Brazil and Argentina** described the chair's text as biased and unbalanced. They pointed out that the proposals reflected primarily those which were supported by Group B developed countries, and argued that the text was therefore effectively transforming the Development Agenda into an agenda of developed countries rather than developing ones. They added that the text was an example of precisely the kind of behaviour the proponents of the Development Agenda were trying to move away from with their call for a decision-making process that is not primarily driven by the interests of developed countries. Therefore, they said, it ought not to be the basis for any work in the PCDA... Negotiators from both **Brazil and Argentina** indicated that they had explicit instructions from their capitals to not continue the process on the basis of the chair's text. In light of the deadlock in the PCDA, they requested that all of the country proposals related to the Development Agenda be sent directly to the September General Assembly (emphasis added). See WIPO Development Agenda Meeting Breaks Down Over Chair's Text, Bridges Weekly Trade News Digest, Vol. 10, No. 24 (7/5/06), at: (<http://www.ictsd.org/weekly/06-07-05/story1.htm>).

³⁹³ The US government seems to be making such an attempt at the WIPO by moving to replace its senior representative at the WIPO, a former US ambassador to the WTO, with a senior official at the US Patent and Trademark office. See Frances Williams, Fears of Polarization If Bush Nominee Takes Top WIPO Post, FT.com (5/12/06), at : (<http://news.ft.com/cms/s/fcb83c38-e10e-11da-90ad-0000779e2340.html>).

³⁹⁴ It is common knowledge within the biotech and pharmaceutical industry sectors that at-or below-cost pricing of successful drugs is wholly inadequate to compensate such companies for the risks and financial losses they have incurred each year to bring those successful drugs to market. It also does not permit them to cover direct and indirect overhead and other expenses associated with such efforts, let alone, to earn a reasonable profit. In other words, at-or below cost pricing removes practically all incentive for such companies to innovate.

³⁹⁵ See, e.g. Chris Beyrer, Varun Gauri and Denise Vaillancourt, Evaluation of the World Bank's Assistance in Responding to the AIDS Epidemic: Brazil Case Study, The World Bank Operations Evaluation Department (2005), at p. 25, at: (http://www.worldbank.org/ieg/aids/docs/case_studies/hiv_brazil_case_study.pdf).

³⁹⁶ See, e.g., Pedro da Motta Veiga Brazil and the G-20 Group of Developing Countries - Managing the Challenges of WTO Participation: Case Study 7, at: (http://www.wto.org/english/res_e/booksp_e/casestudies_e/case7_e.htm).

³⁹⁷ See Slavi Pachovski and Lawrence A. Kogan, The Wolf and the Stork - How Brazil's Breaking of U.S. Drug Patents Threatens Global Trade and Public Health, *supra*.

³⁹⁸ See Natasha Metzler, Brazil Uses Compulsory Licensing Threat in Negotiations, Pharm Exec Direct (7/18/05), at: (<http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=170954>); Nadezhda Pitulova, Abbott Criticizes Brazil's Move to Copy Company's HIV/AIDS Drug, Scripps Howard Foundation Wire - infoZine, (6/29/05), at: (<http://www.infozine.com/news/stories/op/storiesView/sid/8701>); Nadezhda Pitulova, U.S. Delegation to Brazil Will Discuss Proposal to End Drug Patents, Scripps Howard Foundation Wire (6/16/05), at: (http://www.shfwire.com/story.phtml?action=show_story&id=1526);

Brazil, Abbott Reach Tentative Deal on Kaletra - Threat to Suspend Antiretroviral Patents in Abeyance for Now, 24 Biotechnology Law Report 581 No. 5 (©Oct. 2005 Mary Ann Liebert, Inc.), at p. 584.

³⁹⁹ See Mário Marconini, Brazil's Trade Policy 2004: The Good, The Bad, and the Uppity, View Point Brazil, Council of the Americas, Americas Society, Vol. I, Issue 3 (1/17/05), at: (<http://www.counciloftheamericas.org/coa/publications/ViewPointBrazil/ViewPoint%20Brazil%20Marconini%20Jan%20'05%20final.htm>).

⁴⁰⁰ *Ibid.*

⁴⁰¹ See Laurence Tribe, *American Constitutional Law*, (©Foundation Press 1978) at pp. 1-2.

⁴⁰² See Peter Goldsmith, Hamish Gow and Nesve Turan, Is it Safe? Post-Market Surveillance versus Ex-ante Signalling, Department of Agricultural and Consumer Economics, University of Illinois at Urbana Champaign (2002), at 5-6, at: (<http://www.ifama.org/conferences/2003Conference/papers/goldsmith.pdf>).

⁴⁰³ ...The notion that governmental authority has implied limits which preserve private autonomy predates the establishment of the American republic. During the 17th and 18th centuries, there evolved an American tradition of natural law, postulating that certain principles of right and justice... are entitled to prevail of their own intrinsic excellence. It was widely believed that these principles effectively reconciled governmental power with individual liberty by identifying their respective roles in society. In particular, each level and branch of government was thought to be confined to a sphere of authority defined by the nature and function of that level or branch and by the inherent rights of citizens. See Laurence Tribe, *American Constitutional Law*, at p. 427-428.

⁴⁰⁴ See Douglas W. Kmiec, The Takings Clause, WebMemo #843, an Excerpt From *The Heritage Guide to the Constitution* (9/16/05), at: (<http://www.heritage.org/Research/LegalIssues/wm843.cfm?renderforprint=1>).

⁴⁰⁵ The U. S. Patent Act (Title 35 U.S.C. 1 *et seq.*) governs the grant and protection of intellectual property rights in the United States. This statute not only provides any person who invents something the right to patent it, but also sets forth the criteria to determine whether or not an invention can be patented in the first place. See 35 U.S.C. 101, 102 and 103b.

⁴⁰⁶ *Lynch v. Household Finance Corp.*, 405 U.S. 538, 552 (1972), at: (<http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?navby=case&court=us&vol=405&invol=538>), citing J. Locke, *Of Civil Government* 82-85 (1924); J. Adams, *A Defence of the Constitutions of Government of the United States of America*, in F. Coker, *Democracy, Liberty, and Property* 121-132 (1942); 1 W. Blackstone, *Commentaries* *138-140. Congress recognized these rights in 1871 when it enacted the predecessor of 1983 and 1343 (3). We do no more than reaffirm the judgment of Congress today. *Ibid.* This decision, delivered by U.S. Supreme Court Justice Potter Stewart, reversed a Connecticut Federal District Court ruling which barred an individual citizen from challenging the validity of Connecticut state

garnishment statutes under the Equal Protection and Due Process Clauses of the Fourteenth Amendment, and from seeking declaratory and injunctive relief under 42 U.S.C. 1983 and its jurisdictional counterpart, 28 U.S.C. 1343 (3).

⁴⁰⁷ Article I, Section 8, Clause 8, of the Constitution of the United States.

⁴⁰⁸ See Prepared Remarks of James E. Rogan, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office at the Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy (2/6/02), at: (<http://www.ftc.gov/opp/intellect/rogan.htm>).

Although a patent allows an inventor to exclude others from using or selling the invention without permission, it is not a monopoly in the antitrust sense. While patents can encourage risk-taking and investment in new ideas, patent law also limits the advantage that a patent confers. An inventor does not have exclusive rights to his invention forever. Once the term of the patent expires, the invention is in the public domain and may be used or manufactured by anyone. This term limit also creates incentives for patent holders not to rest on their laurels: they must continue to innovate, since the advantage of patent protection is temporary. *Ibid.*

⁴⁰⁹ [T]he Patent Act... declares that patents shall have the attributes of personal property,' §261, including the right to exclude others from making, using, offering for sale, or selling the invention,' §154(a)(1)... Indeed, the Patent Act itself indicates that patents shall have the attributes of personal property [s]ubject to the provisions of this title,' 35 U. S. C. §261, including, presumably, the provision that injunctive relief may issue only in accordance with the principles of equity,' §283. This approach is consistent with our treatment of injunctions under the Copyright Act. Like a patent owner, a copyright holder possesses the right to exclude others from using his property.' *Fox Film Corp. v. Doyal*, 286 U. S. 123, 127 (1932); See also *Id.*, at 127–128 (A copyright, like a patent, is at once the equivalent given by the public for benefits bestowed by the genius and meditations and skill of individuals, and the incentive to further efforts for the same important objects' (internal quotation marks omitted)). *Ebay Inc., et al., v. MercExchange, LLC*, 547 U. S. ____ (2006), at p. 5.

⁴¹⁰ *James v. Campbell*, 104 U.S. 356, 358 (1882); *Hollister v. Benedict Mfg. Co.*, 113 U.S. 59, 67 (1885).

⁴¹¹ A patent for an invention is the grant of a property right to the inventor, issued by the United States Patent and Trademark Office. The right conferred by the patent grant is, in the language of the statute and

of the grant itself, the right to exclude others from making, using, offering for sale, or selling the invention in the United States or importing the invention into the United States. What is granted is not the right to make, use, offer for sale, sell or import, but the right to exclude others from making, using, offering for sale, selling or importing the invention. Once a patent is issued, the patentee must enforce the patent without aid of the USPTO. See General Information Concerning Patents, United States Patent and Trademark Office (Rev. Jan. 2005), at: (<http://www.uspto.gov/web/offices/pac/doc/general/#ptsc>).

⁴¹² The Restatement [of Torts, First] defines a trade secret as any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.' [Section] 757, Comment b... Because of the intangible nature of a trade secret, the extent of the property right therein is defined by the extent to which the owner of the secret protects his interest from disclosure to others... Information that is public knowledge or that is generally known in an industry cannot be a trade secret... If an individual discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret, his property right is extinguished... Trade secrets have many of the characteristics of more tangible forms of property. A trade secret is assignable... A trade secret can form the res of a trust... and it passes to a trustee in bankruptcy. *Ruckelshaus v. Monsanto, Co.*, 467 U. S. 986 (1984), 1001-1002 at: (<http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?court=US&vol=467&invol=986>).

⁴¹³ *Ruckelshaus v. Monsanto, Co.*, 467 U. S. 986 (1984), at: (<http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?court=US&vol=467&invol=986>).

⁴¹⁴ The District Court found that development of a potential commercial pesticide candidate typically requires the expenditure of \$5 million to \$15 million annually for several years. The development process may take between 14 and 22 years, and it is usually that long before a company can expect any return on its investment... For every manufacturing-use pesticide the average company finally markets, it will have screened and tested 20,000 others. Monsanto has a significantly better-than-average success rate; it successfully markets 1 out of every 10,000 chemicals tested. *Ibid.* Monsanto, like any other applicant for registration of a pesticide, must present research and test data supporting its application. The District Court found that Monsanto

had incurred costs in excess of \$23.6 million in developing the health, safety, and environmental data submitted by it under FIFRA ... The information submitted with an application usually has value to Monsanto beyond its instrumentality in gaining that particular application. Monsanto uses this information to develop additional end-use products and to expand the uses of its registered products. The information would also be valuable to Monsanto's competitors. For that reason, Monsanto has instituted stringent security measures to ensure the secrecy of the data. *Ibid.* It is this health, safety, and environmental data that Monsanto sought to protect by bringing this suit. The District Court found that much of these data contain or relate to trade secrets as defined by the Restatement of Torts and Confidential, commercial information.⁴¹⁵ *Ruckelshaus v. Monsanto, Co.*, 467 U.S. at

⁴¹⁵ *Ruckelshaus v. Monsanto, Co.*, 467 U. S. 986 at 987, 1004.

⁴¹⁶ Amendment V [1791], of the Constitution of the United States of America, Proposed by Congress, and Ratified by the Legislatures of the Several States Pursuant to the Fifth Article of the Original Constitution .

⁴¹⁷ See Roger Pilon, Protecting Private Property Rights from Regulatory Takings , Testimony Before the Subcommittee on Constitution Committee on Judiciary United States House of Representatives (2/10/95), citing James Madison, Property, 1 NATIONAL GAZETTE, Mar. 29, 1792, at 174. Reprinted in 4 LETTERS AND OTHER WRITINGS OF JAMES MADISON 480 (1865), cited in, at: (<http://www.cato.org/testimony/ct-pi210.html>).

⁴¹⁸ Amendment V of the citizens' Bill of Rights to the Constitution of the United States of America was passed by Congress on September 25, 1789, and later ratified December 15, 1791.

⁴¹⁹ [T]he federal government's power of eminent domain resides in, and is limited by, the Necessary and Proper Clause (Article I, Section 8, Clause 18), or by Congress's implied powers as confirmed by the Necessary and Proper Clause. *McCulloch v. Maryland*, [17 U.S. (4 Wheat.) 316 (1819)]; *United States v. Gettysburg Electric Railway Co.* [160 U.S. 668 (1896)]. Under this perspective, Congress may exercise the power of eminent domain only in order to effectuate one of its delegated powers. Similarly, the executive is limited to property takings allowable only under Article II executive powers, but they are far more restricted. *Youngstown Sheet & Tube Co. v. Sawyer* (1952). Inasmuch as James Madison came to support and propose a Bill of Rights because he realized the range of congressional power under the

Necessary and Proper Clause, and inasmuch as the Takings Clause is primarily his offering, such a reading has historical credence. See Douglas W. Kmiec, *The Takings Clause*, WebMemo #843, an Excerpt From *The Heritage Guide to the Constitution*, *supra*.

⁴²⁰ See Laurence Tribe, *American Constitutional Law*, at p. 463. The Fifth Amendment's guarantee that private property shall not be taken for a public use without just compensation was designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole.' *Armstrong v. United States*, [364 U.S. 40, 49](#) (1960).

⁴²¹ First, government might act with the deliberate aim of redistributing wealth. Second, it might also act so as to reallocate property, leaving the distribution of wealth intact but seeking, through a different arrangement of objects or resources, to generate more of some uniformly desired good or less of some uniformly disliked bad. And, third, it might act out of a conviction that a formerly tolerated use of property should now be deemed immoral or otherwise unacceptable. *Ibid.*... A [government] reply in terms of intentional redistribution [i.e., taking steps to redistribute a harm initially imposed by government action... because the person injured 'had more than his or her rightful share in the first place'] is least acceptable when other still more fortunate have been spared. A [government] reply in terms of prior notices [i.e., the injury 'involved nothing more than being forced to cease a practice that the individual should have realized was wrong] is least persuasive when no history of accumulating disapproval suggests that the individual really should have seen the handwriting on the wall. And a reply in terms of long-run gain to all is most suspect when made to someone in a situation of frequent disadvantage or exploitation, or when made by an agency with a programmatic goal of its own that is furthered by the injury inflicted. *Ibid.*, at p. 464... [W]e must deny government the power to... announce that all property acquired in the jurisdiction is held subject to government's limitless power to do with it what government wishes... or at least to give such an announcement legal effect, if we are to give content to the compensation clause... [T]he expectations protected by the clause must have their source outside the positive law of the state. Grounded in custom or necessity, those expectations achieve protected status not because the state has deigned to accord them protection but because constitutional norms entitle them to protection. See Laurence Tribe, *American Constitutional Law*, at p. 465.

⁴²² *Backus v. Fort Street Union Depot Co.*, [169 U.S. 557, 573](#), 575 (1898).

⁴²³ *Monongahela Navigation Co. v. United States*, [148 U.S. 312, 326](#) (1893).

⁴²⁴ The Supreme Court has ruled that the just compensation requirement applies not only to takings of a full fee simple interest in property, but also to lesser legally valid economic interests in property, including easements, leaseholds, and partial ownership rights. *United States v. Welch*, [217 U.S. 333](#) (1910); *United States v. General Motors*, [323 U.S. 373](#) (1945); *Bauman v. Ross*, [167 U.S. 548](#) (1897); *Sharp v. United States*, [191 U.S. 341, 351](#) -52, 354 (1903).

⁴²⁵ *Chicago B. & Q. R.R. v. Chicago*, [166 U.S. 226, 250](#) (1897); *McGovern v. City of New York*, [229 U.S. 363, 372](#) (1913).

⁴²⁶ *United States v. Miller*, [317 U.S. 369, 374](#) (1943); *United States ex rel. TVA v. Powelson*, [319 U.S. 266, 275](#) (1943).

⁴²⁷ *United States v. Miller*, supra; *United States v. 564.54 Acres of Land*, [441 U.S. 506](#) (1979); *United States v. 50 Acres of Land*, [469 U.S. 24](#) (1984); *United States v. Felin & Co.*, [334 U.S. 624](#) (1948); *United States v. Commodities Trading Corp.*, [339 U.S. 121](#) (1950); *Vogelstein & Co. v. United States*, [262 U.S. 337](#) (1923); *United States v. Cors*, [337 U.S. 325](#) (1949); *United States v. Toronto Navigation Co.*, [338 U.S. 396](#) (1949).

⁴²⁸ See 28 U.S.C. § 1498 (2000), which allows the U.S. government to use a patentee's invention without his permission (i.e., subject to a compulsory license) in exchange for paying reasonable and entire compensation. Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be action against the United States in the United States Court of Federal Claims for the recovery of his *reasonable and entire compensation* for such use and manufacture (emphasis added). *Ibid.*

⁴²⁹ *Ibid.* In the case of Brazil, it is highly unlikely that either Gilead or Abbott would have agreed to the extremely low price points ultimately negotiated with the Brazilian government for their newest HIV/AIDS drugs had they not been under extreme public pressure from NGOs plus the coordinated threat from the Brazilian government to issue a compulsory license and/or to abrogate drug patent protections. Indeed, it is arguable that Brazil's threats were intended to compromise investor confidence in the Brazilian markets for the purpose of causing, and actually had the effect of causing, a diminution in the market value of these companies' drugs and stock values. See Brazil, Gilead Agree AIDS Drug Price Cut Agence France Presse (5/9/06), at: http://news.yahoo.com/s/afp/20060509/hl_afp/brazilusaidsspharma_06

0509230740); Brazilian Health Ministry, Gilead Reach Price Reduction Agreement For Antiretroviral Tenofovir Medical News Today (5/15/06), at: (<http://www.medicalnewstoday.com/medicalnews.php?newsid=43339&nfid=crss>). Unfortunately, NGOs do not seem to care how far drug companies such as Gilead and Abbott have reduced their product prices, as long as the patients have to pay anything more than a demimis price. Under the mantra of universal access/open source/free-of-charge, NGOs have recently stepped up their activities in Brazil and other countries. In India, for example, NGOs have strenuously opposed Gilead's filing of an Indian patent application for its anti-HIV/AIDS drug tenofovir. See Amelia Gentlemen and Hari Kumar, AIDS Drug Provokes Patent Battle in India, International Herald Tribune, Asia-Pacific (5/11/06), at: (<http://www.ihf.com/articles/2006/05/10/news/aids.php>); Vineeta Pandey, Patent War: Will AIDS Cost You Dearer? DNA (5/13/06), at: (<http://www.dnaindia.com/report.asp?NewsID=1029053&CatID=2>); MSF Supports Opposition To Gilead's Tenofovir Patent Application in India: Tenofovir Patent Would Set Dangerous Precedent for Global Access to Newer Essential Medicines, Medicines Sans Frontieres Press Release (5/10/06), at: (<http://www.doctorswithoutborders.org/pr/2006/05-10-2006.cfm>); Activists: Deny Patent to Gilead, InsideBayArea.com (5/11/06), at: (http://insidebayarea.com/business/ci_3809511). The aid organization Doctors Without Borders said Wednesday that Gilead's HIV drug Viread shouldn't get a patent in India because that would limit the medicine's availability. *Ibid.* For fear of not being granted a patent, as a result of such clamor, Gilead was compelled to offer non-exclusive, voluntary licenses to generic manufacturers in India for the local Indian market as well as provision for manufacturers to export product to the 97 developing world countries included in Gilead's access program. See Gilead Offers Voluntary Licenses for Manufacturing of Viread in Developing World, Press Release (5/10/06) at: (http://www.gilead.com/wt/sec/pr_1147371459#uphere). AHF Applauds Gilead Sciences For Move To Increase Global Access to Affordable Drugs: AIDS Healthcare Foundation Calls On Other Drug Companies To Take Similar Steps and Remove Barriers To Access To Affordable AIDS Drugs For The Populations Most In Need In The World, PR Newswire (5/11/06), at: (<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/05-11-2006/0004360102&EDATE=>). Notwithstanding this generous offer, however, Indian NGO patent protests have continued. See US Drug

Company Accused Of Making HIV Meds Unaffordable In India Associated Press (5/14/06), at: (<http://www.365gay.com/Newscon06/05/051406hiv.htm>). This is the second patent application on an AIDS drug that is opposed by Indian NGOs. The first opposition was filed on 30 March 2006 by the INP, the Manipur Network of Positive People (MNP), and the Lawyers' Collective HIV/AIDS Unit to a patent application filed in the Kolkata patent office by Glaxo Group Limited for Combivir, a fixed-dose combination of two AIDS drugs (zidovudine/lamivudine, or AZT/3TC). See Sangeeta Shashikant Opposition to Drug Patents in India Highlights Access Fears Third World Network's South-North Development Monitor (5/15/06), at: (<http://www.cptech.org/ip/health/c/india/suns05152006.html>).

⁴³⁰ *James v. Campbell*, 104 U.S. 356, 358 (1881), at: (<http://laws.findlaw.com/us/104/356.html>).

⁴³¹ See also *Hollister v. Benedict Mfg. Co.*, 113 U.S. 59 (1885). It was authoritatively declared in *James v. Campbell*, 104 U.S. 356, that the right of the patentee, under letters patent for an invention granted by the United States, was *exclusive of the government of the United States as well as of all others, and stood on the footing of all other property, the right to which was secured, as against the government, by the constitutional guaranty which prohibits the taking of private property for public use without compensation*; but doubts were expressed whether a suit could be sustained, such as the present, against public officers, or whether a suit upon an implied promise of indemnity might not be prosecuted against the United States by name in the court of claims. If the right of the patentee was acknowledged, and without his consent an officer of the government, acting under legislative authority, made use of the invention in the discharge of his official duties, it would seem to be a clear case of the exercise of the right of eminent domain, upon which the law would imply a promise of compensation, an action on which would lie within the jurisdiction of the court of claims, such as was entertained and sanctioned in the case of *U. S. v. Great Falls Manuf'g Co.*, ante, 306, decided at the present term. And it may be that, even if the exclusive right of the patentee were contested, such an action might be brought in that court involving all questions relating to the validity of the patent; but as we have concluded to dispose of the present appeal upon other grounds, it becomes unnecessary to decide the question arising upon this defense. It is referred to only for the purpose of excluding any inference that might be drawn from our passing it over without notice (emphasis added). *Ibid.*, at p. 67.

⁴³² See also, *Leesona Corp. v. United States*, 599 F.2d 958, 963 (Ct. Cl. 1979) (where such an action is deemed a compulsory compensable license ‘in the patent, just compensation, a reasonable royalty’ for that license – another method of estimating the value lost – must be provided. A court should base compensation on what the owner has lost, not what the taker has gained). *Ibid.*, at pp. 964, 968-969); *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748, 767-775 (Ct. Cl. 1999) (a reasonable royalty is the amount a person who desires to manufacture, use, or sell a patented article would be willing to pay as a royalty and yet still be able to make a reasonable profit.’ To make this determination, courts should first look to an established royalty, and second, they should perform a hypothetical negotiation between the parties. The determination of a reasonable royalty’ can also be based on other factors, as was set forth in *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F.Supp. 1116, 1120 (S.D.N.Y. 1970)).

⁴³³ *Ibid.*, at pp. 501-502, citing *Murray’s Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 276 (1856).

⁴³⁴ [T]he [Supreme] Court established early in its consideration of [due process] that procedural due process was implicated *whenever government action seemingly conflicted with substantive individual rights* protected either by a constitutional guarantee more specific than due process, or by those settled usages and modes of proceeding existing in the common and statute law of England before the emigration of our ancestors, which were shown not to have been unsuited to their civil and political condition by having been acted on by them after the settlement of this country.’ *Ibid.*, at p. 507, citing *Tumey v. Ohio*, 273 U.S. 510, 523 (1927).

⁴³⁵ Barring emergency, at least the minimum content of the process due was largely unquestioned: notice and a hearing had to be accorded prior to any grievous government deprivation. *Ibid.*, at pp. 507-508.

⁴³⁶ Amendment XIV [1868], of the Constitution of the United States of America, Proposed by Congress, and Ratified by the Legislatures of the Several States Pursuant to the Fifth Article of the Original Constitution. It was passed by Congress on June 13, 1866, and later ratified on July 9, 1868.

⁴³⁷ Thus, apart from the specific declarations of the Bill of Rights – virtually all of which later came to be applied to states through the due process clause of the fourteenth amendment – there was no attempt to tie the invocation of due process protection to positive rules. See Laurence Tribe, *American Constitutional Law*, at p. 507.

⁴³⁸ *Ibid.*, at p. 508, citing *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923).

⁴³⁹ *Lingle v. Chevron, U.S.A., Inc.*, 544 U.S. ___, 125 S.Ct. 2074 (2005), at: (<http://supct.law.cornell.edu/supct/pdf/04-163P.ZO>).

⁴⁴⁰ The Takings Clause of the Fifth Amendment, made applicable to the States through the Fourteenth... provides that *private property shall not be taken for public use, without just compensation*. As its text makes plain, *the Takings Clause does not prohibit the taking of private property, but instead places a condition on the exercise of that power*... In other words, it is designed not to limit the governmental interference with property rights *per se*, but rather to *secure compensation* in the event of otherwise proper interference amounting to a taking. *Id.*, at 315. While scholars have offered various justifications for this regime, we have emphasized its role in bar[ring] Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole... (em phasis added). *Ibid*, citing *Armstrong v. United States*, 364 U. S. 40, 49 (1960); see also *Monongahela Nav. Co. v. United States*, 148 U. S. 312, 325 (1893).

⁴⁴¹ Our precedents stake out two categories of regulatory action that generally will be deemed *per se* takings for Fifth Amendment purposes. First, where government requires an owner to suffer a permanent physical invasion of her property—however minor—it must provide just compensation. See *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419 (1982) (state law requiring landlords to permit cable companies to install cable facilities in apartment buildings effected a taking). A second categorical rule applies to regulations that completely deprive an owner of all economically beneficial use of her property. *Lucas [v. South Carolina Coastal Council]*, 505 [U.S. 1003, 1114 (1992)]... at 1019 (emphasis in original). We held in *Lucas* that the government must pay just compensation for such total regulatory takings, ‘except to the extent that background principles of nuisance and property law ‘independently restrict the owner’s intended use of the property. *Id.*, at 1026– 1032. Outside these two relatively narrow categories (and the special context of land-use exactions discussed below), regulatory takings challenges are governed by the standards set forth in *Penn Central Transp. Co. v. New York City*, 438 U.S. 104 (1978). The Court in *Penn Central* acknowledged that it had hitherto been unable to develop any set formula ‘for evaluating regulatory takings claims, but identified several factors that have particular significance. *Id.*, at 124. *Primary among those factors are [t]he economic impact of the regulation on the claimant and, particularly, the extent to which the regulation has interfered with distinct investment-backed expectations* [(em phasis added)]. *Ibid*. In addition,

the character of the governmental action –for instance whether it amounts to a physical invasion or instead merely affects property interests through some public program adjusting the benefits and burdens of economic life to promote the common good –may be relevant in discerning whether a taking has occurred (emphasis added). *Lingle v. Chevron, U.S.A., Inc.*, 544 U.S. ___, 125 S.Ct. 2074 (2005).

⁴⁴² The *Lingle* decision has already prompted at least one legal scholar to debate the Court's holding that a takings' analysis should and does not incorporate a due process' analysis. The majority opinion believes that they are separate and independent of one another. Although a number of our takings' precedents have recited the substantially advances' formula m inted in *Agins* [v. *City of Tiburon*, 447 U.S. 255 (1980)] this is our first opportunity to consider its validity as a freestanding takings test. We conclude that this formula prescribes an inquiry in the nature of a due process', not a takings' test, and that it has no proper place in our takings' jurisprudence. There is no question that the substantially advances' formula was derived from due process, not takings', precedents. *Ibid.* The legal scholar argues that In *Lingle v. Chevron U.S.A., Inc.*, 125 S.Ct. 2074 (2005), the U.S. Supreme Court repudiated what had been recognized as the requirement that a land use regulation constitutes a taking unless it substantially advances' a legitimate government interest. *Agins v. City of Tiburon*, 447 U.S. 255 (1980). This paper restates the controversy and asserts that, contra to *Lingle*, the Court's takings tests remain based on substantive due process concepts, primarily under the rubric of fairness. It suggests that property rights-based takings analysis would be clearer, easier to administer, and more consistent with the language and meaning of the Takings Clause... Although the Supreme Court's *Lingle* opinion purports to reject substantive due process review as a tool in Takings Clause adjudications, its own takings jurisprudence is not based on property rights. See *infra* Part III. Instead, it is based on substantive concepts such as fairness and proportionality in burdens placed upon property owners. See Steven J. Eagle, *Lingle v. Chevron and its Effect on Regulatory Takings*, at pp. 1 and 5, at: (http://d2d.aliaba.org/files/thumbs/course_materials/SL012-CH09_thumb.pdf).

⁴⁴³ Although our regulatory takings jurisprudence cannot be characterized as unified, these three inquiries (reflected in *Loretto*, *Lucas*, and *Penn Central*) share a common touchstone. Each aims to identify regulatory actions that are functionally equivalent to the classic taking' in which government directly appropriates private property or ousts the owner from his domain. Accordingly, *each of these tests*

focuses directly upon the severity of the burden that government imposes upon private property rights [(emphasis added)]. The Court has held that physical takings require compensation because of the unique burden they impose: *A permanent physical invasion, however minimal the economic cost it entails, eviscerates the owner's right to exclude others from entering and using her property*, perhaps the most fundamental of all property interests [(emphasis added)]. See *Dolan v. City of Tigard*, 512 U. S. 374, 384 (1994); *Nollan v. California Coastal Comm'n*, 483 U. S. 825, 831-832 (1987); *Loretto, supra*, at 433; *Kaiser Aetna v. United States*, 444 U. S. 164, 176 (1979). In the *Lucas* context, of course, the complete elimination of a property's value is the determinative factor. See *Lucas, supra*, at 1017 (positing that *total deprivation of beneficial use is, from the landowner's point of view, the equivalent of a physical appropriation*) [(emphasis added)]. And the *Penn Central* inquiry turns in large part, albeit not exclusively, upon the magnitude of a regulation's economic impact and the degree to which it interferes with legitimate property interests. *Lingle v. Chevron, U.S.A., Inc.*, 544 U.S. ___, 125 S.Ct. 2074 (2005).

⁴⁴⁴ See also, *Pennsylvania Coal Co. v. Mohan*, 260 US 393 (1922), wherein the Court held that, a state law which prohibited the mining of coal in a manner that could cause subsidence of residence of the surface, amounted to a taking because it rendered the underlying mineral rights economically valueless.

⁴⁴⁵ *Compulsory licensing is the eminent domain of intellectual property*. It, too, allows the state to interfere with an individual's property as long as compensation is paid, and mandates that the amount of compensation be determined objectively, not subjectively. That is, even if the owner wants a higher license fee, he or she must settle for the fee an arbitrator considers reasonable (emphasis added). See Anupam Chander, *The New York Times and Napster: How The Supreme Court's Ruling In Favor Of Freelance Writers Could Keep Online Music Sharing Alive* FindLaw (7/30/01), at: (http://writ.news.findlaw.com/commentary/20010730_chander.html).

⁴⁴⁶ The U.S. Court of Claims has held that the taking of patent rights by the government was analogous to an eminent domain taking under the Fifth Amendment, *which requires just compensation to the victim* (emphasis added). *Leesona Corp. v. United States* at 968, *supra*. See also, Mark C. Lang, *What a Long, Strange TRIPS' It's Been: Compulsory Licensing From the Adoption of TRIPS to the Agreement on Implementation of the Doha Declaration*, 3 J. Marshall Rev. Intell. Prop. Law 331 (2004), at: (<http://www.jmls.edu/ripl/vol3/issue2/lang-middle.html>).

⁴⁴⁷ In *Ruckelshaus v. Monsanto, Co., supra*, The District Court had reasoned that [FIFRA] 3(c)(1)(D) *appropriated* Monsanto's fundamental right to exclude, and that the effect of that appropriation [had been] substantial. 564 F. Supp., at 566 (emphasis added), 467 U.S. 986, 987, . The Supreme Court agreed with this finding. *The District Court found that Monsanto had incurred costs in excess of \$23.6 million in developing the health, safety, and environmental data submitted by it under FIFRA... The information submitted with an application usually has value to Monsanto beyond its instrumentality in gaining that particular application. Monsanto uses this information to develop additional end-use products and to expand the uses of its registered products.* The information would also be valuable to Monsanto's competitors. For that reason, Monsanto has instituted stringent security measures to ensure the secrecy of the data... It is this health, safety, and environmental data that Monsanto sought to protect by bringing this suit (emphasis added). *Ibid.* Hence, the court found that just compensation was due. [A] subsequent applicant for registration may piggyback' its registration on the efforts of the initial applicant. The subsequent applicant must offer to compensate the initial applicant, and compensation is to be determined by binding arbitration if the parties cannot agree on a sum. 463 U.S. 1315, 1316 (1983), at: (<http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=us&vol=463&invol=1315>).

⁴⁴⁸ In *Ruckelshaus v. Monsanto, Co.*, 467 U.S. 986 (1984), the dispute focused on whether the U.S. Environmental Protection Agency could share otherwise confidential pre-market authorization data (including trade secrets) for pesticides generated and submitted at the substantial effort and expense of one private party inventor pursuant to the Federal Insecticide, Fungicide and Rodenticide Act, for the benefit of a subsequent pesticide applicant that had incurred little or no such effort or cost. The *Kelo* majority focused on the *Monsanto* Court's reasoning that one private party may benefit at the expense of another private party, where the most direct beneficiaries of these provisions were [all of] the subsequent [future] applicants... We found sufficient Congress' belief that sparing [prospective] applicants the cost of time-consuming research eliminated a significant barrier to entry in the pesticide market and thereby enhanced competition. *Susette Kelo, et al. v. City of New London*, 545 U.S. ____ (2005), citing *Ruckelshaus v. Monsanto, Co.*, 467 U.S. at 1014-1015.

⁴⁴⁹ In *Ruckelshaus*, The District Court had reasoned that [FIFRA] 3(c)(1)(D) *appropriated* Monsanto's fundamental right to exclude, and that the effect of that appropriation [had been] substantial. 564 F.

Supp., at 566 (emphasis added), 467 U. S. 986, 987. The Supreme Court agreed with this finding. *The District Court found that Monsanto had incurred costs in excess of \$23.6 million in developing the health, safety, and environmental data submitted by it under FIFRA... The information submitted with an application usually has value to Monsanto beyond its instrumentality in gaining that particular application. Monsanto uses this information to develop additional end-use products and to expand the uses of its registered products.* The information would also be valuable to Monsanto's competitors. For that reason, Monsanto has instituted stringent security measures to ensure the secrecy of the data... It is this health, safety, and environmental data that Monsanto sought to protect by bringing this suit (emphasis added). *Ibid.* Hence, **the court found that just compensation was due.** [A] subsequent applicant for registration may piggyback its registration on the efforts of the initial applicant. ***The subsequent applicant must offer to compensate the initial applicant, and compensation is to be determined by binding arbitration if the parties cannot agree on a sum*** (emphasis added). 463 U.S. 1315, 1316 (1983), at:

(<http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=us&vol=463&invol=1315>).

⁴⁵⁰ 545 U. S. ____ (2005). The decision is accessible at: (<http://www.law.cornell.edu/supct/pdf/04-108P.ZO>).

⁴⁵¹ The private property owners in this case refused the developer's offer to purchase their property at a lower than fair price, believing that this amounted to a taking for other than a public use.

⁴⁵² The Court cited *Berman v. Parker*, 348 U. S. 26 (1954), *Hawaii Housing Authority v. Midkiff*, 467 U. S. 229 (1984), and *Ruckelshaus v. Monsanto, Co.*, 467 U. S. 986 (1984), in support of this proposition.

Quite simply, the government's pursuit of a public purpose will often benefit individual private parties. For example, in *Midkiff*, the forced transfer of property conferred a direct and significant benefit on those lessees who were previously unable to purchase their homes. In *Monsanto*, we recognized that the most direct beneficiaries of the data-sharing provisions were the subsequent pesticide applicants, but benefiting them in this way was necessary to promoting competition in the pesticide market. 467 U. S., at 1014.14 The owner of the department store in *Berman* objected to taking from one businessman for the benefit of another businessman,. 348 U. S., at 33, referring to the fact that under the redevelopment plan land would be leased or sold to private developers for redevelopment.¹⁵ Our rejection of that contention has particular relevance to the instant case: The public end

may be as well or better served through an agency of private enterprise than through a department of government, or so the Congress might conclude. We cannot say that public ownership is the sole method of promoting the public purposes of community redevelopment projects.. *Id.*, at 34.

⁴⁵³ In *Ruckelshaus v. Monsanto, Co., supra*, the dispute arose under the Federal Insecticide, Fungicide and Rodenticide Act. The Court reviewed whether the U.S. Environmental Protection Agency could share otherwise confidential pre-market authorization data (including trade secrets) for pesticides generated and submitted at the substantial effort and expense of one private party inventor for the benefit of a subsequent pesticide applicant that had incurred little or no such effort or cost. Appellee Monsanto Company, an inventor, developer, and producer of various kinds of chemical products, including pesticides, is one of a relatively small group of companies that invent and develop new active ingredients for pesticides and conduct most of the research and testing with respect to those ingredients. *Ibid.* The *Kelo* Court noted how the *Ruckelshaus* Court had upheld the EPA statute, emphasizing that while one private party may benefit at the expense of another private party, the most direct beneficiaries of these provisions were [all of] the subsequent [future] applicants. We found sufficient Congress' belief that sparing [prospective] applicants the cost of time-consuming research eliminated a significant barrier to entry in the pesticide market and thereby enhanced competition. *Susette Kelo, et al. v. City of New London, supra*, citing *Ruckelshaus v. Monsanto, Co.*, 467 U.S. at 1014-1015.

⁴⁵⁴ See e.g., Lawrence A. Kogan, Terminating Global Warming, Energy Dependence or Private Property Rights?, Institute for Trade, Standards and Sustainable Development (7/6/06), at: (<http://www.itssd.org/Publications/Terminating-Global-Warming.pdf>).

⁴⁵⁵ Vermont and the District of Columbia have proposed legislation that would allow them to issue compulsory drug licenses to patent holders under the eminent domain process. Under these bills, states would then contract with a generic manufacturer to produce the drug, paying the drug company a reasonable royalty— a proposed four percent— on each sale. The competition would facilitate the public good by offering state residents cheaper drugs.

Legislators have also drafted the Model State Pharmaceutical Eminent Domain Act to help other states considering a similar move. The act calls for compulsory licenses in instances where state officials declare that the public health and safety would be improved— but doesn't specify guidelines for determining that standard. The Vermont bill has

some guidelines, like whether the drug is essential for maintaining health or life,' the cost of the drug in relation to the cost in other countries and to average resident-income levels, as well as unspecified extenuating circumstances.' See Tam sen Valoir, Legal: State Compulsory Licenses, Pharmaceutical Executive (11/1/05), at: (<http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=197791>). See also Tim Shorrock, Capital Appropriations: One Man's Plan For High-Concept Health Care Legislation Mother Jones (July/Aug. 2005), at: (http://www.motherjones.com/news/outfront/2005/07/capital_appropriations.html).

⁴⁵⁶ In *Reid v. Covert*, 354 U.S. 1 (1957), the Court rejected the idea that when the United States acts against citizens abroad it can do so free of the Bill of Rights. The United States is entirely a creature of the Constitution ... *When the Government reaches out to punish a citizen who is abroad, the shield which the Bill of Rights and other parts of the Constitution provide to protect his life and liberty should not be stripped away just because he happens to be in another land. The language of Art[icle] III, [Section] 2 manifests that constitutional protections for the individual were designed to restrict the United States Government when it acts outside of this country, as well as here at home...* This Court and other federal courts have held or asserted that various constitutional limitations apply to the Government when it acts outside the continental United States. While it has been suggested that only those constitutional rights which are fundamental protect Americans abroad, *we can find no warrant, in logic or otherwise, for picking and choosing among the remarkable collection of Thou shalt nots' which were explicitly fastened on all departments and agencies of the Federal Government by the Constitution and its Amendments* (emphasis added). *Reid v. Covert*, 354 U.S. 1 (1957) at 6-9, at: (<http://www.constitution.org/ussc/354-001a.htm#f3#f3>).

⁴⁵⁷ *Mitchell v. Harmony*, 54 U.S. 115 (1851), at 135-136, at: (<http://www.justia.us/us/54/115/case.html>).

⁴⁵⁸ The Court previously ruled that the Fifth Amendment takings clause had prohibited a U.S. military officer from unjustifiably appropriating the personal property of a U.S. citizen merchant-trader who, while doing business in Mexico during the onset of the US-Mexican War, had inadvertently ventured into a cross-border combat zone. *Our duty is to determine under what circumstances private property may be taken from the owner by a military officer in a time of war. And the question here is, whether the law permits it to be taken to insure the success of any enterprise against a public enemy which the commanding officer*

may deem it advisable to undertake. And we think it very clear that the law does not permit it. The case mentioned by Lord Mansfield, in delivering his opinion in *Mostyn v. Fabrigas*, 1 Cowp. 180, illustrates the principle of which we are speaking. Captain Gambier, of the British navy, by the order of Admiral Boscawen, pulled down the houses of some sutlers on the coast of Nova Scotia, who were supplying the sailors with spirituous liquors, the health of the sailors being injured by frequenting them. The motive was evidently a laudable one, and the act done for the public service. Yet it was an invasion of the rights of private property, and without the authority of law, and the officer who executed the order was held liable to an action, and the sutlers recovered damages against him to the value of the property destroyed. *This case shows how carefully the rights of private property are guarded by the laws in England; and they are certainly not less valued nor less securely guarded under the Constitution and laws of the United States* (emphasis added). *Mitchell v. Harmony*, 54 U.S. 115 (1851), at 135-136, at: (<http://www.justia.us/us/54/115/case.html>).

⁴⁵⁹ Article VI, Section 2 of the Constitution of the United States, otherwise known as the Supremacy Clause, provides that, This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land .

⁴⁶⁰ *Reid v. Covert*, 345 U.S. 1 (1957).

⁴⁶¹ The records of the Virginia Ratifying Convention contain specific discussions of the scope of the treaty power. These discussions confirm that the Framers did in fact envision limitations on the treaty power. Anti-Federalists like Patrick Henry charged that under the proposed Constitution, the treaty-makers could make any treaty... as they please. In response, Federalist defenders of the Constitution strenuously denied that the treaty power was unlimited. Madison stated, for example: The exercise of the power must be consistent with the object of the delegation... The object of treaties is the regulation of intercourse with foreign nations, and is external.' He further explained that the Founders had not specified the proper subject matters of treaties in order to preserve flexibility, not because the power was unlimited. Consistent with this view, Edmund Randolph remarked that, **neither the life nor property of any citizen, nor the particular right of any State, can be affected by a treaty**'... And perhaps, most broadly, George Nicholas stated that no treaty could be made which shall be repugnant to the spirit of the Constitution, or *inconsistent with the delegated powers*.' Thus, when the question of the treaty power's

scope was specifically discussed, the Founders did express the view that it was subject to constitutional limitations (italicized emphasis in original; boldface emphasis added). See Curtis Bradley, *The Treaty Power and American Federalism*, *supra*, at p. 413 and ns. 125-126 at: ([http://eprints.law.duke.edu/archive/00001184/01/97_Mich. L. Rev. 390 \(1998-1999\).pdf](http://eprints.law.duke.edu/archive/00001184/01/97_Mich._L._Rev._390_(1998-1999).pdf)) citing *The Debates in the Convention of the Commonwealth of Virginia*, reprinted in 3 Elliot's Debates at p. 513 (Jonathan Elliot ed., 2nd ed. 1888). Justice Story stated in his constitutional law treatise that though the *[treaty] power* is thus general and unrestricted, it is not to be so construed as to destroy the fundamental laws of the [nation-]state; and *cannot supersede or interfere with any other of [the Constitution's] fundamental provisions*' (emphasis added). *Ibid*, at pp. 416-417, citing 3 Joseph Story, *Commentaries on the Constitution of the United States* Sec. 1502 (1833).

⁴⁶² By the supremacy clause, both statutes and treaties are declared . . . to be the supreme law of the land, and no superior efficacy is given to either over the other.' As statutes may be held void because they contravene the Constitution, it should follow that treaties may be held void, the Constitution being superior to both. And indeed the Court has numerous times so stated. The treaty is... a law made by the proper authority, and the courts of justice have no right to annul or disregard any of its provisions, unless they violate the Constitution of the United States'... It need hardly be said that a treaty cannot change the Constitution or be held valid if it be in violation of that instrument.' *Reid v. Covert*, 345 U.S. 1 (1957) at 16, citing *Doe v. Braden*, 57 U.S. (16 How.) 635, 656 (1853); *The Cherokee Tobacco*, 11 Wall. (78 U.S.), 616, 620 (1871) ;*Geofroy v. Riggs*, 133 U.S. 258, 267 (1890); *United States v. Wong Kim Ark*, 169 U.S. 649, 700 (1898); *Asakura v. City of Seattle*, 265 U.S. 332, 341 (1924).

⁴⁶³ [T]he treaty power is understood as being subject to the individual rights protections of the Constitution . . . See Curtis Bradley, *The Treaty Power and American Federalism*, 97 *Mich. L. Rev.* 390 (1998-1999), *supra*, at p. 393, citing *Boos v. Barry*, 485 U.S. 312, **324** (1988) ([I]t is well established that no agreement with a foreign nation can confer power on the Congress, which is free from the restraints of the Constitution.' *Reid v. Covert*, 354 U.S., 1, 16 (1957). See 1 *Restatement of Foreign Relations Law of the United States* 131, Comment a p. 53 (Tent. Draft No. 6, Apr. 12, 1985) ([R]ules of international law and provisions of international agreements of the United States are subject to the Bill of Rights and other prohibitions,

restrictions or requirements of the Constitution and cannot be given effect in violation of them ')).

⁴⁶⁴ *Reid v. Covert*, 345 U.S. 1, 18.

⁴⁶⁵ Presumably, the Bush administration has taken its obligation seriously, even as it has agreed to ratify a recently proposed WTO waiver of TRIPS Agreement requirements (Articles 31(f) and (h)). See Implementation of Paragraph 110 of The General Council Decision of 30 August 2003 On The Implementation Of The Doha Declaration On The TRIPS Agreement And Public Health Council for Trade-Related Aspects of Intellectual Property Rights (IP/C/41) (12/6/05). The USTR has insisted that an exporting WTO Member government that issues a compulsory license for purposes of providing pharmaceuticals to an importing government lacking pharmaceutical manufacturing capacity must pay the U.S. IP rights holder(s) adequate remuneration... taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. *Ibid.* at Annex To The Protocol Amending The TRIPS Agreement, *Article 31bis*, pars 1 and 2.

⁴⁶⁶ See Emma Aisbett, Larry Karp, and Carol McAusland, Regulatory Takings and Environmental Regulation in NAFTA's Chapter 11, (10/25/05), at: http://are.berkeley.edu/courses/EEP131/old_files/lectureNotes/CarolEmmafragment.pdf). Although we draw much of our motivation from NAFTA, there are currently over 2200 bilateral investment treaties (BITs) globally... [a]lmost all of [which]... contain expropriation clauses similar to that in NAFTA, as do the recently signed Central American - Dominican Republic Free Trade Agreement (CAFTA-DR) and the draft Free Trade Agreement of the Americas (FTAA)... *Ibid.*, at p. 1 and fn #1.

⁴⁶⁷ Bilateral Investment Treaties (BITs) and multilateral investment agreements (including Chapter 11 of NAFTA, the North America Free Trade Agreement) seek to promote foreign direct investment by offering foreign investors increased security and transparency. *These treaties require that hosts compensate investors in the event of expropriation or (possibly) regulatory actions that diminish the value of the investment.* (emphasis added). See Emma Aisbett, Larry Karp, and Carol McAusland, Regulatory Takings and Environmental Regulation in NAFTA's Chapter 11, (2/20/06), at pp. 1-2, at: <http://are.berkeley.edu/~karp/iiasubmitfeb06.pdf>).

⁴⁶⁸ See Thomas Walde and Abba Kolo, Multilateral Investment Treaties and Environmental Expropriation of Foreign Investment, Alexander's Gas & Oil Connections - Speech (1998?), at:

(<http://www.gasandoil.com/goc/speeches/waelde2.htm>). This paper addresses protection of the environment through regulation of foreign investment and how to reconcile it with investment protection obligations under Multilateral Investment Treaties (MITs). Specifically, where to draw the line between legitimate non-compensable regulation aimed at protecting the environment, or human, animal or plant life or health', on one hand, and a regulation which is tantamount' to expropriation requiring compensation, on the other? This question has recently become important for a number of reasons. Firstly, concern over the environment - from the activities of multinational corporations in particular and international trade and investment generally - is now on top of the economic policy agenda of governments, financial institutions, and business leaders. Secondly, the previously socialist/statist attitude to foreign investment popularly expressed through the New International Economic Order (NIEO) in the 1970s - but which has lost its appeal - has been reincarnated in the environmentalist movement, with the environmental cause being used as a Trojan horse by statist/bureaucrats, protectionists, environmentalists and others who oppose globalisation and continuing trade and investment liberalisation. *Ibid.*

⁴⁶⁹ The original aim of Chapter 11 was to promote investment, particularly in Mexico, by providing increased security and transparency to foreign investors... The most familiar argument for including an expropriation clause in an investment treaty is that it solves the hold-up problem. The hold-up problem occurs when the host wants to expropriate the assets of foreign investors after they sink their up-front costs. Wary of holdups, investors may forego investment in the first place. Signing a treaty with an expropriation clause is one way a government can pre-commit not to expropriate foreigners' assets. Markusen (2001) discusses the costs and benefits of commitment for developing countries wishing to gain from Foreign Direct Investment (FDI). The hold-up problem occurs where the host attempts to capture rent from a project. Even when the host's objective is to solve a legitimate public problem, and not to capture rent, it may behave inefficiently when the investor is a non-citizen. Consider environmental regulations that decrease a firm's profits, which investors may label *creeping expropriation* or *regulatory takings*. *When a government weighs the benefits and costs of a new regulation, it may ignore the regulation's impact on profits repatriated by foreigners*. Consequently, when viewed from a global welfare perspective, governments may regulate foreigners' activities with excessive zeal. *By forcing governments to compensate investors for any costs arising from*

regulation, expropriation clauses can induce cost-internalization, eliminating excess regulation and thereby promoting investment. Cost-internalization is the leading justification among legal scholars for U.S. Fifth Amendment's compensation mandate. See Emma Aisbett, Larry Karp, and Carol McAusland, Regulatory Takings and Environmental Regulation in NAFTA's Chapter 11, (10/25/05), *supra* at pp. 1-2.

⁴⁷⁰ *Ibid.* at p. 1.

⁴⁷¹ *Ibid.*, at p. 6.

⁴⁷² In *Ethyl Corporation vs. Canada*, a U.S. company with business interests in Canada claimed that a law banning importation and interprovincial trade in MMT, a chemical substance which formed part of the company business operation in Canada amounted to expropriation of its investment. No ban on local manufacture of the product was, however, imposed. The parties were able to reach a settlement with the company accepting \$13 million in compensation from the Canadian government for lost trading opportunities, a lift on the ban and a public statement regretting the ban which was based on unsubstantiated scientific facts. *Ibid.*, at fn #4. In *Metalclad vs. Mexico*, a U.S. company filed a complaint with the IC SID claiming the expropriation of its waste disposal plant by a state authority in Mexico which prevented the company from operating the plant on environmental grounds. *Ibid.* The Tribunal ruled that it would *not* need to inquire into the motivation or intent of a challenged measure, in order to determine whether it amounted to an expropriation. In other words, it did not see the merit in carving out an exception for the exercise of so-called police-powers. In *S.D. Myers, Inc.*, a U.S. company threatened to file a complaint against Canada for its ban on the export of PCB, a waste material, on health and environmental grounds. The ban was lifted after 15 months but the company demanded compensation for lost of business during the ban. *Ibid.* The *Metalclad* and *S.D. Myers* decisions held governments to requirements for transparency and for least trade-restrictiveness – key trade law principles. Environmentalist extremists and socialist-minded state-centrist governments, however, have argued that this is an overly broad interpretation of the NAFTA Chapter 11 provisions. See Private Rights Public Problems; A Guide To NAFTA's Controversial Chapter On Investor Rights, International Institute For Sustainable Development and World Wildlife Fund (2001), at: (http://www.iisd.org/pdf/trade_citizensguide.pdf).

⁴⁷³ *Ibid.* One such recent case is *Methanex Corp. v. United States of America*... On August 3, 2005, the Tribunal issued a Final Award,

dism issing all of Methanex's claim s. The Tribunal dism issed the expropriation claim on the grounds that the MTBE ban was the result of due process and for the public good: ...as a m atter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process and, which affects, inter alios, a foreign investor or investment is not deemed expropriatory and com pensable... (UNCITRAL Tribunal, p. 278). *Ibid.*, at p.8.

⁴⁷⁴ The extent of protection that the Fifth Am endm ent provides property owners is a matter of debate, but thus far U.S. courts have rejected the doctrine of regulatory takings... Som e Chapter 11 plaintiff arguments... appear to construe NAFTA as an endorsement of the doctrine of regulatory takings for international investments. These plaintiff arguments have prompted public complaints that the expropriation clause amounts to an end-run around U.S. and other nations' dom estic law . Som e observers believe regulatory takings claims such as *Methanex v. U.S.* are an unintended consequence of the expropriation clause. Daniel Price, the lead U.S. Chapter 11 negotiator, rejects this view, stating 'The parties did not stumble into this [interpretation]...This was a carefully crafted definition'... The legal community is still debating whether the NAFTA case history validates fears that NAFTA establishes a regulatory takings doctrine... See Emma A isbett, Larry K arp, and Carol M cAusland, *Regulatory Takings and Environmental Regulation in NAFTA's Chapter 11*, (2/20/06), *supra*, at p. 4.

⁴⁷⁵ In this paper, we assess the efficiency, equity, and investment promotion impacts of a police powers carve-out. Since many of the NAFTA cases involve environmental regulations, our model uses an environmental setting; however *the tension between expropriation and nondiscrimination clauses arises for a variety of regulatory problems*. Similarly, even though our modeling choices are guided by characteristics of the legal environment created by NAFTA, *our results are applicable to the many hundreds of similar bilateral and multilateral investment agreements containing expropriation and non-discrimination clauses* (em phasis added). *Ibid.*, at p. 3.**It therefore appears that these and other commentators have provided legal cover for foreign governm ents bent on using a police power carve-out', not otherw ise subject to a 'just com pensation' requirem ent, to justify their imposition of strict precautionary principle-based health and environmental regulations. Europe, then, should be delighted!

⁴⁷⁶ An argument in favor of expropriation clauses is that they solve several post-investment moral hazard problems such as hold-ups. However, we show that expropriation clauses can also interact with co-

existing National Treatment clauses in a manner that hinders investment. We show that a police powers carve-out for environmental regulation can recover some of these investment opportunities and may promote welfare... U.S. courts (for example) have largely rejected the theory of regulatory takings. If international tribunals accept this doctrine by adopting a broad interpretation of expropriation, the investor-to-state provision of BITs would give foreign investors rights not enjoyed by domestic investors. Foreign investment would then create more risk for the host (relative to domestic investment), because the need to provide compensation makes regulating foreign investment more costly. The requirement of National Treatment makes it difficult for the host to require a side-payment in order to offset this additional risk. Thus, even though a strict definition of expropriation and a requirement of National Treatment both solve incentive problems when viewed individually, their combination can create inefficiencies... Compensation rules that are applied to regulatory actions have distribution as well as efficiency effects. Conditional on the investment already being made (i.e. ex post), *the host bears all risks associated with the project and may even incur losses. For example, a particular project might be discovered to create environmental damages that require costly mitigation. If this occurs under a strict definition of expropriation, the host suffers environmental damage and/or costly cleanup, or it regulates and pays compensation to the foreign firm.* The prospect that a host nation is left bearing all the risk from overseas investment is ***at the heart of public dissatisfaction with the expropriation clauses*** in modern investment agreements. One solution is for the host to be exempted from paying compensation when its actions are a legitimate use of the host's police powers to protect the public good. ***That is, governments might be granted a police powers carve-out from the expropriation clause*** (emphasis added). See Emma Aisbett, Larry Karp, and Carol McAusland, Regulatory Takings and Environmental Regulation in NAFTA's Chapter 11, (10/25/05), *supra*, at pp. 2-3.

⁴⁷⁷ See Article 8(G) and (I) Expropriation', IISD Model International Agreement on Investment for Sustainable Development, International Institute for Sustainable Development, (April 2005) at p. 17 at: (http://www.iisd.org/pdf/2005/investment_model_int_agreement.pdf). At least one legal expert has tried to point out to the Model Agreement's authors that these provisions will actually discourage investments in developing countries. With respect to expropriation, under the model agreement, if a country expropriates property through a series of regulations, and states that the regulations are for the public

good, *the property owner does not have to be compensated*. But by definition, all expropriation is for the public good – and just because an action is for the public good does not relieve the government of the obligation to provide fair market compensation... I do not believe that this model agreement will encourage investment (emphasis added). See Comments of Daniel M. Price, at the Introductory Workshop on the International Institute for Sustainable Development's Model International Agreement on Investment for Sustainable Development - Globalization, International Law and the Future of International Investment Treaties Carnegie Endowment for Peace (5/15/05), at: (<http://www.carnegieendowment.org/events/index.cfm?fa=eventDetail&id=808>).

⁴⁷⁸ Presidential Executive Order 12630 recognized that governmental actions that do not formally invoke the [eminent domain] condemnation power, including regulations, may [in fact] result in a taking for which just compensation is required (emphasis added). See Presidential Executive Order 12630 - Governmental Actions and Interference With Civil Constitutionally Protected Property Rights, 53 FR 8859 (3/15/88), at: (http://www.blm.gov/nhp/news/regulatory/EOs/eo_12630.html). Section 3(b) of E.O. 12630 provides that ... [R]egulations imposed on private property that substantially affect its value or use, may constitute a taking of property. Further, governmental action may amount to a taking even though the action results in less than a complete deprivation of all use or value, or of all separate and distinct interests in the same private property and even if the action constituting a taking is temporary in nature (emphasis added). *Ibid.* It also established broad guidelines for government agencies to follow in order to render that assessment. Section 1(c) provides that, The purpose of this Order is to assist Federal departments and agencies in undertaking such reviews and in proposing, planning, and implementing actions with due regard for the constitutional protections provided by the Fifth Amendment and to reduce the risk of undue or inadvertent burdens on the public fisc resulting from lawful governmental action. Interestingly, E.O. 12630 also set forth a standard to determine whether environment, health and safety (EHS) regulations so affect the value and/or beneficial use of private property as to be deemed a 'taking' for public use that is also entitled to 'just compensation'. Generally speaking, these guidelines required officials to consider whether governmental actions' and policies' could have takings' implications before rather than after they are pursued, i.e., to perform a takings impact assessment' where there is a high probability that a government action or policy could affect the

use of any real or personal property. This E.O. predates the current international debate about whether expensive socialist-style regulations based on the nonscientific principle of precaution (‘better safe than sorry’) should also be adopted as the basis for U.S. regulation. Nevertheless, it eerily seems to have anticipated it. Section 3(c) of Presidential Executive Order 12630 provides that, ... ***the mere assertion of a public health and safety purpose is insufficient to avoid [having the regulation deemed] a taking... Actions... asserted to be for the protection of public health and safety, therefore, should be undertaken only in response to real and substantial threats to public health and safety, be designed to advance significantly the health and safety purpose, and be no greater than is necessary to achieve the health and safety purpose*** (em phasis added).

⁴⁷⁹ Specifically, through the 1988 Executive Order 12630... the administration sought to initiate a national level process analogous to environmental impact assessments (BIAs) called takings impact assessments (Folsom, 1993). Under this procedure, all government agencies were required to conduct an analysis of the anticipated impact of proposed laws, rules, and regulations on private property rights. This order was promoted by its advocates as a prudent look before you leap’ action, like EIAs. Its advocates maintained that the intent of the order was to clarify the impact of proposed governmental action so that legislators and agency heads could then decide if the social benefits of laws, rules, and regulations outweighed the costs to private individuals. According to skeptics, the order was actually intended to (1) provide publicly researched data to the adversaries of new regulations, and (2) cause the public machinery to slow down in its development and promotion of new rules, regulations, and laws (em phasis added). See Harvey M. Jacobs, The Politics of Property Rights at the National Level – Signals and Trends, Commentary, Journal of the American Planning Association, Vol. 69, No. 2 (Spring 2003), at: (<http://www.law.georgetown.edu/gelipi/papers/jacobs.pdf>).

⁴⁸⁰ However, E.O. 12630 contains some questionable language that may have discouraged or curtailed the ability of federal agencies to vigilantly assess whether international treaty terms under negotiation could amount to a taking’. See E.O. 12630 Sections 2(a)(2) and 2(c)(2), which provide that Actions taken... in preparation for or during treaty negotiations with foreign nations neither qualify as Policies that have takings implications, nor as Actions, within the meaning of Section 1 the E.O. See, e.g., 64 F.R. 68113-68114 (12/6/99), at: (<http://www.fws.gov/policy/library/99fr68113.html>).

⁴⁸¹ **A 2003 U.S. General Accounting Office study found, however, that the takings impact assessment guidelines had been virtually abandoned during the Clinton era.** These guidelines were subsequently updated to reflect more recent case law following a 2003 review by the U.S. General Accounting Office which found that federal agencies had conducted few takings implications assessments, pursuant to Executive Order 12630. *See* Regulatory Takings: Implementation of Executive Order On Government Actions Affecting Private Property Use, United States General Accounting Office Report to the Chairman, Subcommittee on the Constitution, Committee on the Judiciary, House of Representatives (Sept. 2003), at: (<http://www.gao.gov/new.items/d031015.pdf>). *Although the executive order's requirements have not been amended or revoked since 1988, the four agencies' implementation of some of these requirements has changed over time as a result of subsequent guidance provided by the Office of Management and Budget (OMB). For example, the agencies no longer prepare annual compilations of just compensation awards or account for these awards in their budget documents because OMB issued guidance in 1994 advising agencies that this information was no longer required. According to OMB, this information is not needed because the number and amount of these awards are small and the awards are paid from the Department of the Treasury's Judgment Fund, rather than from the agencies' appropriations. Regarding other requirements, agency officials said that they fully consider the potential takings implications of their regulatory actions, but provided us with limited documentary evidence to support this claim.* For example, the agencies provided us with a few examples of takings implications assessments because, agency officials said, these assessments are not always documented in writing or retained on file. In addition, our review of the agencies' rulemakings for selected years that made reference to the executive order revealed that relatively few specified that a takings implication assessment was done and few anticipated significant takings implications (emphasis added). *Ibid.*, at p. 2.

⁴⁸² *At least one think tank has noted how [federal] agencies [could have] easily circumvent[ed] E.O. 12630 simply by routinely finding no takings implications' each time they perform the Takings Implication Assessment' required by the Attorney General's guidelines for implementing the Order. *See* William G. Laffer, Realistic Options for Reducing the Burden of Excessive Regulation, (1/19/93), at: (<http://www.heritage.org/Research/Regulation/CM15.cfm>). This is likely to have actually occurred, as certain March 1993 documents of the Clinton Administration's Health Care Task Force and Working

Group seem to reveal. Those documents show how some or all of the requirements of E.O. 12630 could have been waived in order to federally fund procurement of low-cost patented medicines for U.S. domestic alcohol and drug programs and for the International Monetary Fund (IMF)'s Heavily Indebted Poor Countries (HIPC) Initiative. Federal Government Implementation of Health Reform ... This arrangement permits tasks to be defined over time and under an expedited process. The consumer information and **HIPC support** master contracts would be awarded by March 1994. The ADP would be awarded by December 1994... Executive Orders may be required in the following areas to expedite rulemaking: Designation of a lead agency to prepare rules, Legal basis to suspend the normal comment period and to issue an interim final rule, **Waiver of all or some of the requirements for rulemaking in E.O. 12291, 12498, 12606, 12612, 12630, 12778.** OMB will amend the Uniform Regulations agenda to include the regulations for health care reform (emphasis added). See Excerpts from Clinton Administration Health Care Task Force and Working Group Documents, Box Nos. and 1767, at pp. 64 and 236, (3/28/03) at: (<http://www.aapsonline.org/judicial/taskforc.pdf>).

⁴⁸³ *In fact, this same think tank discovered how the Clinton Administration and its supporters had virtually tried to rescind E.O. 12630. See Todd F. Gaziano, The Use and Abuse of Executive Orders and Other Presidential Directives (2/21/01), at: (<http://www.heritage.org/Research/LegalIssues/LM2.cfm>). Apparently, supporters believed that it represented an effort to undermine public health and environmental regulations through the back door by promoting an exaggerated and inaccurate version of regulatory takings doctrine... Because the Executive Order so severely misstated the law, it was difficult to avoid the conclusion that the true purpose of the Executive Order was not to enforce the Constitution, but rather to attack regulatory protections. **On April 2, 1993, a number of prominent law scholars wrote to President Clinton urging him to rescind executive Order 12630** (emphasis added). See, e.g., Testimony of John D. Echeverria, Executive Director Georgetown Environmental Law & Policy Institute, Georgetown University Law Center, at the Oversight Hearing Based on the Report of the General Accounting Office on the Implementation of Executive Order 12630, Before the Subcommittee on the Constitution Committee on the Judiciary, U.S. House of Representatives (10/16/03), at pp. 4-5, at: (<http://www.law.georgetown.edu/gelpi/papers/2003testimony.pdf>). See also, Folsom, R. E., Executive Order 12630: A President's Manipulation of the Fifth Amendment's Just Compensation Clause to

Achieve Control Over Executive Agency Regulatory Decisionmaking, *Boston College Environmental Affairs Law Review*, 20 *B.C. Envtl. Aff. L. Rev.* 639, 650–659 (1993). Apparently, Clinton Administration supporters of stronger environmental regulation and weaker private property rights had also been speaking to *French government representatives* about how [t]he *economic and legal literature on property seems, ultimately, to come down in favor of the position taken by those who see private property as necessarily secondary to social needs* (emphasis added), consistent with the 1940's teachings of Wisconsin ecologist Aldo Leopold. See Harvey M. Jacobs, Social Conflict Over Property Rights: Environmental Thought, Environmental Action, and the Uncertain Future of the New Private Property Rights Movement in the U.S., Paper prepared for presentation at the international conference Property Rights and Environment, Aix-en-Provence, France, 27-29 June 1996, **under the patronage of the French Minister of the Environment**, Madame Corinne Lepage, and organized by the Centre d'Analyse Economique, University of Aix-Marseille III, at pp. 2, 10-16, at: (<http://www.environnement-propriete.org/english/1996/pdf-download/Jacobs.pdf>).

⁴⁸⁴ See Lawrence A. Kogan, Precautionary Preference: How Europe's New Regulatory Protectionism Imperils American Free Enterprise, Institute for Trade, Standards and Sustainable Development, Inc. (July 2005); Lawrence A. Kogan, Exporting Europe's Precaution: How Europe's Risk-Free Agenda Threatens American Free Enterprise, Washington Legal Foundation, (Nov. 2005), *supra*.

⁴⁸⁵ Outside of America, countries use weak intellectual property laws as a means of facilitating the theft of advanced technologies. The United States did that. We stole technology from England, France, Europe, on a mass scale, 200-plus years ago. Germany did the same thing to England. Japan did the same thing to Europe and the United States in the mid-1950s. And China is following that same path. See Bay Fang, Interview with Pat Choate, quoting Pat Choate, *U.S. News & World Reports* (6/20/05), at: (<http://www.usnews.com/usnews/biztech/articles/050620/20eeguru.htm>).

⁴⁸⁶ On December 5, 1791, Hamilton submitted to Congress his Report on Manufactures, which outlined why and how the United States could achieve economic equality with Europe and an industrial self-sufficiency. Build a strong U.S. industrial base, he wrote... To become a true equal of Europe, Hamilton proposed that the United States follow Europe's lead and erect a tariff wall behind which the American market could develop and American manufacturers could prosper. This, he

argued, was the only way to confront Europe's manufacturing subsidies, its high tariffs on U.S. imports, and its repeated pattern of dumping goods at artificially low prices in the U.S. market to kill America's infant industries... Behind this tariff wall, the government could provide the protections of a strong patent system, giving inventors and investors a government-guaranteed right to the exclusive use of their innovations for a fixed period. To accelerate national development, Hamilton also wanted to encourage the migration of skilled foreign workers to America. They would bring badly needed abilities and state-of-the-art technology to the new nation... Hamilton's message to potential immigrants was loud and clear: bring your nation's industrial secrets to America, gain citizenship, get a patent, be honored and become wealthy. See Pat Choate, *HOT PROPERTY: The Stealing of Ideas in an Age of Globalization*, *supra*, at pp.25-26.

⁴⁸⁷ *Ibid.*, at p. 29.

⁴⁸⁸ *Ibid.*, at pp. 29-30.

⁴⁸⁹ Congress authorized the appointment of a commissioner of patents, who was empowered to reject applications that lacked novelty, and gave inventors the right of appeal that would be heard by impartial but skilled arbitrators. The act also provided for a major library of scientific works and clerks, technicians, and examiners who could compare applications with existing technology to ensure that they were truly advances. Also the patent went to the first person to create the advance, and with it the right for the exclusive use of that creation for fourteen years from the date the patent was issued. *Ibid.*, at pp. 32-33.

In 1842, the system was strengthened further when Congress expanded the laws to cover new and original designs for manufacture'. Finally, the United States had a patent system that truly encouraged novelty and rewarded merit. With a patent on a commercially attractive idea, inventors could assure investors that for a set time only they could exploit their new creation. *Ibid.*, at p. 33. [T]he Patent Act of 1836 marked another divide in U.S. economic history. By making patents real, the legislation unleashed the innovative capacities of an entire nation on a scale never before attempted. Regardless of social position, education, or economic condition, any citizen who invented something novel and useful could be awarded exclusive rights for its use and commercialization. Many of the ideas that were pouring forth represented fundamental breakthroughs that profoundly changed the way the U.S. economy worked. Each advance led to a host of improvements and a demand for other goods and services that, in turn, produced entirely new industries. *Ibid.*, at p. 34.

⁴⁹⁰ At least temporarily, America thus became, by national policy and legislative act, the world's premier legal sanctuary for industrial pirates. *Ibid.*, at p. 33.

⁴⁹¹ The following examples are illustrative of this practice: Samuel Slater & automated spinning machines – Britain, *Ibid.*, at pp. 26 and 30; Cabot Lowell & the power loom – Britain, *Ibid.*, at pp. 30-31; Thomas Edison & films – France, *Ibid.*, at pp. 73-74; US government & chemical inventions/ processes, and seizure of U.S. filed patents upon declaration of war, WWI – Germany, *Ibid.*, at p. 104.

⁴⁹² *Ibid.*, at pp. 99-100.

⁴⁹³ Many... German patent owners had filed either misleading or incomplete information in their applications. *Ibid.*, at p. 104... Germany preferred patents to tariffs as a means of protecting its industries, thereby avoiding the risk of provoking other nations into raising tariffs and stifling German exports. *Ibid.*, at p. 105... Germany adopted a mercantile trade strategy, raising tariffs against imports while providing cash bonuses to industries that exported German-made goods. *Ibid.*, at p. 110... As German trade expanded, the banks forced the companies they ruled into cartels... similar businesses were brought together to control the production, pricing, and marketing of products... [to]... eliminate[e] domestic competition [and to]... reduce costs, lower business risks, and raise prices... To gain the scale of research and production it needed... to meet its economic and military aspirations... the nation had to dominate the global markets its industries supplied, which often meant nothing less than mounting a coordinated attack on rival foreign producers. To succeed, Germany technology and production processes had to be superior to any competitor's. When other nations had better technology, the German government assisted its companies in stealing it... If another nation's nascent industry threatened a vital German interest German economic forces had to quickly destroy it. *Ibid.*, at p. 111.

⁴⁹⁴ Beginning in the mid-1870's, the German government issued fifteen-year patents on chemical innovations, but only to those who built and operated a facility in Germany that incorporated the patented improvement. By this method, the Germans effectively denied patents to virtually every foreign chemical maker, none of which wanted to take on the cartel in its home country. At the same time, German corporations could take a foreign technology not patented in Germany, even if it might have been patented elsewhere, and use it with impunity in their German factories. *Ibid.*, at p. 117.

⁴⁹⁵ In the United States, German companies used a fourfold patent strategy. First, they refused to license their patented technology to any

U.S. companies except under the most extraordinary circumstances. Nor did the Germans share their technology in any way... They erected corporate and government barriers to industrial espionage, used only German workers in their key positions, and only rarely built factories in other nations... Second, the Germans hired skilled and politically well connected American lawyers who filed thousands of patent applications on behalf of their clients... Anyone who infringed on one of those German-owned, U.S. issued patents faced protracted, expensive litigation in the United States. *Ibid.*, at p. 118... Third, even when the German companies described their technology in their patents, they generally omitted vital details, identified false steps, or concealed key ingredients that often could be purchased only in Germany. This violated the legal requirement that a patent contain sufficient information that someone skilled in the field could replicate whatever was patented. The Germans even filed bogus patents whose sole purpose was to misdirect research and investment by competitors. *Ibid.*, at pp. 118-119. ...[Fourth,] [b]ecause the Germans held a virtual monopoly on the global production of dyes, their government used their patents instead of tariffs for protection against imports... Germany set low tariffs on imported dyes, while seeking reciprocally low tariff concessions in the United States and elsewhere for the export of German dyes... But the German patent scheme smothered foreign producers that they had no product to export into Germany's domestic market. When a U.S. chemical maker independently invented a new way of making an existing product and secured a U.S. patent, the Germans would try to lure the inventor or company into a consortium, often with the threat of ruinous dumping if the U.S. manufacturer refused. *Ibid.*, at p. 119.

⁴⁹⁶ . Cartels, subsidies, and protectionism were as central to the Japanese way as profits were to American capitalism... MITI's control was total and its officials had no hesitation to use it, often giving foreign patent holders a Hobson's choice: Either license your patents in Japan for almost nothing or MITI will keep you out of Japan's markets. *Ibid.*, at p. 140... Implicit was the threat that the Japanese would take the technology and use it without either getting a license or paying a royalty, leaving the patent holder with nothing... In the late 1950's, for instance, MITI officials told IBM to either license its basic patents on computer technology to Japanese companies at no more than a 5 percent royalty or face MITI opposition to all its Japanese operations. IBM capitulated, licensing its technology and subject itself to MITI's 'administrative guidance' in the Japanese market... Using IBM's technology, Japanese companies entered the global computer

industry... Japan was mining U.S. technology; often Japan's techniques were largely invisible to all but the victims. *Ibid.*, at p. 143.

⁴⁹⁷ Patent flooding' was a particularly successful, and largely imperceptible, means of stripping foreign patents from their owners. When a foreigner filed a desirable patent application with Japan's patent agency, administered by MITI, rival Japanese companies soon flooded' that office with dozens, even hundreds, of nuisance patent requests, all of which were closely associated with the foreign application. *Ibid.*

⁴⁹⁸ The goal of the patent flooder is to surround the target company's technology with patents and patent applications, so that the target company cannot commercially exploit its technology without the risk of infringing the flooder's rights. The flooder may not be able to exploit its claimed inventions without running afoul of the target company's patent rights, but neither can the target company exploit its own technology without the risk of infringing on the flooder's claims to variations and uses of that technology. The flooder uses this 'gridlock' to negotiate a license to the target company's technology, offering in return licenses to technology claimed in the flooder's patent applications and patents. See Sri Krishna Sankaran, Patent Flooding in the United States and Japan, *IDEA: The Journal of Law and Technology* (40 IDEA 393) (2000), at p. 1-2, at: (http://www.idea.piercelaw.edu/articles/40/40_3/13.Sankaran.pdf).

Patent flooding should be defined as a technique in which a patent applicant: 1) claims the inventions of another; or 2) files patent applications that a reasonable person would believe are not allowable or, if allowed, invalid. As a result of a patent flood, the target company cannot commercially exploit its own technology without the risk of infringing the intellectual property rights of the patent flooder. *Ibid.*, at p. 19.

⁴⁹⁹ *Ibid.*, at p. 2.

⁵⁰⁰ See U.S. General Accounting Office, Intellectual Property Rights: U.S. Companies' Patent Experiences in Japan, 94 (GGD-93-126) (1993). Patent flooding, according to a U.S. General Accountability Office (GAO) survey, victimized one of every eight companies filing patent applications in Japan as recently as the early 1990's. See Pat Choate, *HOT PROPERTY: The Stealing of Ideas in an Age of Globalization*, at pp. 143-144.

⁵⁰¹ Japan's patent system was at once a defensive, offensive, and strategic tool of national development. Japan uses patents to: (1) exclude foreign goods; (2) examine the innards of proprietary foreign technology; and (3) strip patents from their foreign owners. The GAO

listed many tricks the Japan Patent Office used, such as: delaying approval of foreign patents for years; limiting the scope of protection; allowing rivals to examine and comment on patent applications; and erecting unworkable enforcement mechanisms. In other words, Japan's patent system offered foreign inventors government-managed intimidation. *Ibid.*, at pp. 146-147.

⁵⁰² *Ibid.*, at p. 148.

⁵⁰³ Sematech in Austin, Texas, [was] formed to pursue semiconductor research. Congress also established another highly visible R&D consortium in Ann Arbor, Michigan – the National Center for Manufacturing Sciences (now called the Association for Manufacturing Technology). [This center grew into a \$200 million a year research organization that U.S. corporations jointly funded with federal and state governments. *Ibid.*, at p. 150.

⁵⁰⁴ *Ibid.* The U.S. and the European Union, which was also experiencing similar technology 'mining' by the Japanese, initiated negotiations to create a new treaty and new rules to guide international collaborative research on intelligent manufacturing systems. The U.S. and Europe invited Japan to participate, which it did, as did Australia, Canada, and Korea. ... On the night before the negotiations concluded in 1994... [Edward] Miller... president of the National Center for Manufacturing Sciences [above]...received a private message from a major U.S. corporation that would give Japan a unique advantage... Japanese law requires the grant of a royalty-free patent license to the government whenever any research or development program that creates intellectual property is supported by one yen or more of Japan's public funds. Thus any patents or copyrights flowing from a collaborative project with a Japanese company automatically are shared with the government, which can then license them to other Japanese corporations. To collaborate with one meant sharing the technology with all. Miller bargained for acceptance of a provision that allowed any nation or corporation to stop the involvement of any company that had taken Japanese funds, directly or indirectly, that would result in the Japanese government granting licenses to anyone other than the research participants. In short, representatives of other nations could blackball any Japanese corporation if it were going to share with its government any patents or copyrights created out of a joint project. *Ibid.*, at pp. 150-152.

⁵⁰⁵ China is using its unprecedented access to some of the world's most advanced technology as a means of leapfrogging into the modern industrial age. China has been able to use this technology to upgrade its industries and to become globally competitive in a short span of

time... [Through the] process of absorbing [foreign] technology and using it to compete with the technology's original owners and creators... China's goal is to become competitive and to dominate all industries. While China already dominates in some low-technology sectors, China's goal is to dominate not only in low-technology sectors, but also in high-technology sectors. Unlike Japan or Korea, China does not intend to abandon lower-level technology sectors as it moves up the technology ladder. See Counterfeiting and China's Economic Development, Written Testimony of Professor Daniel C.K. Chow, at p. 3, Before the U.S.-China Economic and Security Review Commission, Hearing on Intellectual Property Rights Issues and Imported Counterfeit Goods (June 7-8, 2006).

⁵⁰⁶ With its joint venture model, the Chinese government has moved its industrial infrastructure from the nineteenth century to the twenty-first century in less than two decades. In the process, China is getting the knowledge and capacity it needs to become the world's manufacturing center. See Pat Choate, *HOT PROPERTY: The Stealing of Ideas in an Age of Globalization*, at p. 172.

⁵⁰⁷ China needs jobs. To get those jobs, China needs foreign technology. To get the foreign technology, China needs foreign investment. To get the foreign investment, the Chinese government has introduced a host of national development initiatives. Each is built on a grand four-part long-term development strategy. *Ibid.*, at p. 170.

⁵⁰⁸ For those companies that do decide to do business in China, the unfortunate reality is that they all must expect intellectual problems eventually. The problem may originate from suppliers or other Chinese manufacturer. It may come from former employees. *It may even come from state-sponsored reverse-engineering programs.* In March [2006], China's railway ministry proudly announced two new, high-speed railway lines. Government officials announced that the new railways would use only Chinese technology. How did China achieve this Great Leap Forward in transportation technology? Railroad minister Liu Zhijun explained it to the Chinese press: *Our technology is a re-innovation on the basis of assimilating advanced technologies of foreign countries.* 'Re-innovation', whether by the state or by other local businesses, is a fact of life in today's China (emphasis added). See Testimony of the Honorable Dave McCurdy, President and CEO, Electronic Industries Alliance, before the U.S.-China Economic & Security Review Commission Hearing on China's Enforcement of Intellectual Property Rights and the Dangers of the Movement of Counterfeited and Pirated Goods into the United States at p. 4 (June 7-8, 2006).

⁵⁰⁹ Just like the United States and Japan before it, China is using all the usual means – licensing, theft, piracy, intimidation, spies, and cooperation – to get the technology it needs. China has also adopted a system of joint venture, an old and established tool for securing foreign intellectual property, and has elevated it to an art form. With joint ventures, China reduces its need to steal or expropriate foreign intellectual property because foreign corporations share it as a condition of doing business there... In 2002, economists at Lehman Brothers... projected that China would have the world's second largest economy by 2030. But that projection will not be realized unless China can continue to: a. [G]et the basic foreign technology; b. [C]reate the capacity to develop proprietary technology domestically; and c. [C]ontrol these core technologies worldwide. *Ibid.*, at pp. 170 and 172.

⁵¹⁰ For decades China has been targeting Western technologies, initially seeking military and other secrets, but more recently concentrating much of its effort on technologies and intellectual property designed to drive its rapidly expanding economy... Thousands of American companies are among those attracted by China's cheap labor and growing market for consumer goods. Based on population, China's market is three times larger than the European Union and four times the size of the United States. Its economy is growing at an average of 8 percent a year. Many of the products are particularly vulnerable to reverse engineering, design infringement, and counterfeiting due to inadequate protections in China of intellectual property rights... It has been said that the right to counterfeit goods is engrained in China's culture. Former premier Deng Xiaoping promoted the philosophy of: 'Let foreign things serve China.' This perspective continues today and China generally views counterfeiting and other violations of intellectual property not as a serious offense, but as a major source of income, taxes, and employment. See *The Developing U.S.-China Relationship: Analysis of China's Weak Intellectual Property Rights Protection and Enforcement*, Written Testimony of Dr. Neil C. Livingstone, at pp. 1-2, Before the U.S.-China Economic and Security Review Commission, Hearing on Intellectual Property Rights Issues and Imported Counterfeit Goods (June 7-8, 2006).

⁵¹¹ China is now our third-largest trading partner. Last year American firms exported \$42 billion in goods and services to China, and exports rose 40% in the first quarter of this year, with high-tech products such as medical and scientific equipment and semiconductors among the fastest-rising major products... We have seen some small indications that the Chinese government is taking intellectual property more

seriously. There has been progress – a very tiny amount – but not nearly enough. The truth is that China has no strong tradition of protecting intellectual property rights. Until it does, the abundant rewards of trade with China will always be tempered by equally abundant risks. The concerted effort begun by the Chinese government in recent months to encourage homegrown innovation and lessen the country's economic development reliance on imported technology is in some ways a double-edged sword. On the one hand, it is encouraging that the government wants China to develop its own commercial technologies, because *the most effective way to foster true enforcement of IPR protection is for domestic entrepreneurs and small businesses to have a real stake in the system. It is impossible for someone to take enforcement seriously if they have nothing of their own to protect.* Encouraging innovation rather than mandating technology and standards is a definite step in the right direction of lowering non-tariff trade barriers... As a new market and an ever more important trading partner, China holds great promise. But there are still many challenges that U.S. companies face in doing business there. Sometimes the opportunities outweigh the risks; other times, firms run into serious trouble in China. In every case, the Chinese market will never meet its full potential until it is governed by a sound and transparent legal system, particularly in terms of intellectual property rights. See Testimony of the Honorable Dave McCurdy, President and CEO, Electronic Industries Alliance, before the U.S.-China Economic & Security Review Commission Hearing on China's Enforcement of Intellectual Property Rights and the Dangers of the Movement of Counterfeit and Pirated Goods into the United States *supra*, at pp. 1 and 4.

⁵¹² The foreign investor puts up the capital, patents, copyrights, trademarks, know-how, and overseas distribution. In most circumstances, the local Chinese partner keeps half the equity in the new enterprise. Any improvements in technology and any new patents, trademarks, or copyrights developed in China by the joint venture belong to the new enterprise. In exchange, China contributes an unlimited supply of low-wage, competent, compliant workers. The foreign corporations are allowed to serve their markets from Chinese-based factories that operate under the most limited public regulation of labor, production, pollution, and health and safety standards. Products from these ventures are often banned in China, leaving that market to state or locally-owned enterprises. Despite China's invitation to foreign companies to come and invest, the Chinese government has reserved entire sectors of its economy for state-owned enterprises. Other sectors

belong to China's private entrepreneurs. Foreign investors can participate in the rest on terms that China dictates. See Pat Choate, *HOT PROPERTY: The Stealing of Ideas in an Age of Globalization*, at p. 178. Foreign corporations also use local managers and engineers to operate their factories, teach the Chinese how to apply their technology, and follow the government's economic dictates. Through this, China gains know-how quickly. *Ibid.*, at p. 172. ... As foreign companies become increasingly dependent on Chinese manufacturing for their worldwide production, they will come under correspondingly more pressure to make available and then share ownership of their foreign distribution systems. Eventually, just as the Japanese and Koreans did, the Chinese will establish brand trademarks that become known worldwide, which they will sell through these joint distribution networks. Finally, the Chinese, just like the Japanese before them, will no longer need foreign corporations or their networks. *Ibid.*, at p. 183.

⁵¹³ ... [T]he [E]lectronic Industries Alliance [EIA] published in April [2006] a best practices guide entitled *Protecting Intellectual Property Rights in China* and sent it to senior executives at each of our nearly 1,300 member companies. The guide was a collaboration between EIA and the China Alliance, which is a partnership of four North American law firms... with a collective team of legal experts on China... **I think the most important message of the guide... is that in many ways there are no markets in China** (italicized emphasis in original) (boldface emphasis added). See Testimony of the Honorable Dave McCurdy, President and CEO, Electronic Industries Alliance, before the U.S.-China Economic & Security Review Commission Hearing on China's Enforcement of Intellectual Property Rights and the Dangers of the Movement of Counterfeited and Pirated Goods into the United States at pp. 3-4, *supra*.

⁵¹⁴ Some who have studied the lack of success experienced by large U.S. law firms in China have labeled the promise of Chinese market share 'fool's gold'. See, e.g.,: Jason Lohr, Gold Mountain or Fool's Gold?, Asia Business Law (4/4/06), at: (<http://asiabizlaw.blogspot.com/2006/04/gold-mountain-or-fools-gold.html>); Kelly Schmitt, Law Firms Pressured to Serve China on the Cheap, The Recorder (12/14/05), at: (<http://www.law.com/jsp/article.jsp?id=1134468312985>).

⁵¹⁵ See Pat Choate, *HOT PROPERTY: The Stealing of Ideas in an Age of Globalization*, at p. 174.

⁵¹⁶ China offers more than an enormous pool of cheap labor light manufacturing. It has a large pool of engineers and technicians available for more advanced work, many educated in the United States.

The Chinese Academy of Engineering reports that as of the late 1990's China had more than 2.1 million trained engineers, including 600,000 senior-level people. This is a significant reservoir of technical talent. Most of these engineers are available at roughly 10 percent of the salaries of their American, Japanese, or European counterparts. *Ibid.*, at p. 173.

⁵¹⁷ Angela Merkel, German chancellor, will urge China to drop rules that force foreign companies to transfer proprietary technologies and designs to Chinese competitors. These forced transfers' top a list of complaints that German business has asked Ms. Merkel to raise with Wen Jiabao, the Chinese premier, during her first visit to Beijing. The complaints, to be published today [May 22, 2006] by BDI, the industry federation, include the difficulties foreign companies face in obtaining redress before Chinese courts in intellectual property infringement cases. See Bertrand Benoit, *Merkel To Grill China On Forced Transfers*, *Financial Times* (5/22/06) at p.1.

⁵¹⁸ See Pat Choate, *HOT PROPERTY: The Stealing of Ideas in an Age of Globalization*, at pp. 171-172. China is developing its capacity to import raw materials and export finished goods. COSCO, the Chinese state-owned shipping company is now working with port authorities on both the west and east coasts of the United States to expand their capacity to handle far greater imports and exports with China. In 2002... COSCO opened a route to Boston. Within one year, the volume of goods shipped from the Boston port to Asia doubled, while the import volume from Asia to Boston increased fourfold. Equally significant, China has replaced the United States as the transport manager for the Panama Canal. The governments of Panama and China have had extensive negotiations on the construction of new locks for the canal, sufficient to carry the giant cargo ships that China envisions for the future. China is ensuring that it will be able to get the world's raw materials to its factories and its finished goods to world markets. China will eventually try to control the principal retail outlets that market its products in other nations. China's growing monopoly on the manufacture of goods that foreign retailers sell provides the business advantage required in such negotiations and takeovers. Viewed from China's perspective, as the products it makes come to dominate U.S. and other markets, why should not the Chinese share in the profits made by Wal-Mart, Kmart, JCPenney, and other retailers that sell its good, or even take them all if it can? This is the way capitalism works. *Ibid.*

⁵¹⁹ There is actual anecdotal evidence that China's domestic propaganda machine promotes industrial stealth of foreign technologies

by warning local industries that the Chinese government's protection of foreign intellectual property rights, if permitted, would lead to foreign company monopolies in China. On one of my trips to China, I had the chance to sit in on a speech made by a local Qingdao official of the State Intellectual Property Office. Since he was speaking to an auditorium of local businessmen and Chinese government officials, perhaps, I should have expected the candor with which he spoke, but my jaw dropped when I heard off-message rhetoric that enforcement of trademark, patent and copyright laws could lead to monopolies by foreign multinationals, that different economic development levels call for different standards of enforcement, and that better enforcement could not come at the expense of domestic innovators. That is not the language we hear from Vice Minister Wu Yi and other Beijing officials working to improve China's record. See Testimony of the Honorable Dave McCurdy, President and CEO, Electronic Industries Alliance, before the U.S.-China Economic & Security Review Commission Hearing on China's Enforcement of Intellectual Property Rights and the Dangers of the Movement of Counterfeited and Pirated Goods into the United States at p. 5. *supra*.

⁵²⁰ Some experts believe that China's IPR violation conundrum is caused not by the attitude of Chinese officials, but rather by limitations on state capacity. It is my considered opinion that the majority of Beijing's elite decision makers genuinely *believes in the importance of protecting intellectual property rights, even if it is for nationalistic or other self-interested reasons (i.e., economic growth, the strategic payoffs form a vibrant innovative – and protected – knowledge base, etc.)*. Insofar as this problem persists, much of the reason is due to limitations on state capacity: China's top leadership can only expend the necessary resources to sustain two or three major campaigns over the long term. That explains the paradox of why China can regulate the most intimate behavior of 1.3 billion people through its stringent population control policy but cannot crackdown in a sustained manner on a problem as seemingly straightforward and obvious as copyright piracy (emphasis added). See Andrew C. Mertha, Testimony to the US-China Economic and Security Review Commission, Hearing on Intellectual Property Rights Issues and Imported Counterfeited Goods (June 8, 2006), at p. 1.

⁵²¹ See *Surging With Self-Confidence and Ambition - India and Globalization*, Financial Times Special Report (1/26/06), at p. 1.

⁵²² The surge in interest is recent. Portfolio investors, aided by low US interest rates, have pumped 25 percent more cash into the Indian stock market over the past two years than in the preceding 11 years put

together... This has helped push the Sensex share index up by more than 50 percent in 12 months. *Ibid.*

⁵²³ International venture capital groups are increasingly shifting focus from China to India after years of reduced exposure to the subcontinent. According to... professional services firm Ernst & Young... E & Y, international venture capital investors are likely to step up investments in India during the next 12-18 months as technology companies such as Microsoft, Intel and Cisco Systems continue to expand R & D capacity in the country... Mark Wiseman, at JP Morgan Asset Management, said: 'I think China will do well on the service and manufacturing side but will have trouble with the areas that involve research and development and intellectual property.' See Florian Gimbel, 'Venture Capital Targets Growing Indian Technology Market', *Financial Times* (5/2/06), at p. 23.

⁵²⁴ Its share [of world trade] could quadruple in a decade, according to McKinsey, if the myriad infrastructural and regulatory hurdles to global competitiveness facing manufacturers are lifted. Its potential to attract more foreign direct investment is also considerable, given that existing flows are small both in absolute terms and as a percentage of GDP. India received less than one-tenth of the \$60 billion of FDI that went to China in 2004. This could increase rapidly if market deregulation and liberalization make further progress. *Ibid.*, referencing comments made by a representative of the management consulting firm of McKinsey & Co.

⁵²⁵ Why then, might a reasonable analyst anticipate a surge in India? There are three broad reasons: first, Indian demography is relatively favorable; second, India has better institutions than China; third, India has more room to improve its policies and investment performance... Unfortunately, India has done a particularly poor job of absorbing its labor force into productive employment... The much vaunted information technology sector employs just 1 [million] – a drop in the Indian Ocean. Unused labor is not an advantage, but a terrible burden. It is true, again, that India has a number of institutional advantages over China: a well-developed private sector; a relatively entrenched legal system; a stable democracy; and freedom of speech. The World Bank... gives India a modestly better score on the control of corruption and the rule of law. But it gives a worse one on regulatory quality and government effectiveness. Of the latter, there can be little doubt: China's ability to mobilize resources remains far greater than India's, as demonstrated in its vastly superior performance in provision of infrastructure. See Martin Wolf, 'What India Must Do to Catch Up

With and Possibly Outpace China , Financial Times Comment (2/15/06), at p. 13.

⁵²⁶ Indeed, according to at least one Indian entrepreneur, The young in India are inheritors of a centuries-old and vigorous entrepreneurial gene, which, mercifully, colonialism and socialism have failed to quell. The entrepreneurial mentality, once fired, is contagious; it creates a herd mentality, like gold prospecting... The most telling evidence of this vigorous gene is that several Indians, unknown just 15 years ago and not inheritors of a family business, are now listed in the Forbes list of global billionaires. See R. Gopalakrishnan, India's Path to Liberalisation: India has never followed the normal patterns of capitalism and democracy, but its entrepreneurial spirit is flourishing , World Business (May 2006), at p. 13.

⁵²⁷ Economists and analysts have habitually derided India's inability to attract FDI. This single-minded obsession with FDI is as strange as it is harmful. Academic studies have not produced convincing evidence that FDI is the best path to economic development compared with responsible economic policies, investment in education, and sound legal and financial institutions. In fact, one can easily think of counter examples. Brazil was a darling of foreign investors in the 1960's but ultimately let them down... An economic litmus test is not whether a country can attract a lot of FDI, but whether it has a business environment that nurtures entrepreneurship, supports healthy competition and is relatively free of heavy-handed political intervention. In this regard, India has done a better job than China. From India emerged a group of world-class companies ranging from Infosys in software, Ranbaxy in pharmaceuticals, Bajaj Auto in automobile components and Mahindra in car assembly. This did not happen by accident... With few exceptions, manufacturing facilities for which China is famous are products of FDI, not of indigenous Chinese companies. Yes, Made in China labels are still more ubiquitous than Made in India ones; but what is made in China is not necessarily made by China. Soon, Made in India will be synonymous with Made by India and Indians will not just get the wage benefits of globalization but will also keep the profits – unlike so many cases in China. See Yasheng Huang, What China Could Learn From India's Slow and Quiet Rise , Financial Times Comment (1/24/06), at p. 13.

⁵²⁸ Under the old patent regime, drugs patented in other countries could be analyzed and manufactured without paying royalty. This provision served to nurture the development of an indigenous pharmaceutical industry and by the 1990s Indian drug companies had become the fourth largest in the world when ranked by volume of drugs

produced. See Kranti Kumara, "India adopts WTO patent law with Left Front support", World Socialist Website (April 2005), at: (<http://www.wsws.org/articles/2005/apr2005/indi-a16.shtml>).

⁵²⁹ To understand why India, among other developing countries, has resisted full entry into the international patent regime for more than thirty years, we need to understand the perfectly rational, but time-bound and ultimately parochial arguments that justified India's refusal to grant product patents on foods, agro-chemicals, and pharmaceuticals. In the 1950s and 1960s, there came a growing recognition that the classical arguments for the benefits of a patent system might not apply to the case of many developing countries, and a counter-argument, made most forcefully in the work of Edith Penrose, was advanced to provide the ammunition for many developing countries – most prominently India – to abandon at least in part the patent regimes inherited from their colonial rulers. The counter-argument rests on the premise that a developing country lacks sufficient scientific and technical capability to produce economically significant patents on its own. If this is the case, granting exclusivity in the domestic market has little impact on domestic innovation. Moreover, if the developing country's market is but a small share of the world market, a grant of exclusivity has little impact on the incentives of foreign inventors. Under such conditions, patents granted to foreigners and practised in the domestic market simply transfer wealth from domestic consumers to foreigners. This conclusion holds whether the patented goods (or goods produced with patented processes) are imported or licensed to domestic producers. Thus, in a country with little indigenous capacity to invent, the patent system yields increased rents to foreign inventors without producing significant domestic benefits. See Presentation by Richard C. Levin, Patents in Global Perspective, Sir Purshotamdas Thakurdas Memorial Lecture at the Indian Institute of Banking and Finance (Jan. 2005), at: (http://www.domain-b.com/economy/general/2005/20050112_perspective.html).

⁵³⁰ It was such perfectly logical reasoning that led India, in 1970, to eliminate product patents on food, agro-chemicals, and drugs. India stopped short of completely eliminating the patent system, presumably because it recognized that domestic inventive capacity was not entirely absent. Thus, patents on other types of products and patents on manufacturing processes were retained. This approach proved ideal for the development of an indigenous capacity to copy drugs and chemicals invented and patented abroad, and to produce them with processes that could be patented domestically. Given that the cost structure of such

products, especially pharmaceuticals, involves very large up-front investments for development and testing and very low costs of production, Indian firms had the advantage of "free riding" on the development of new drugs and producing them at a small fraction of the cost of their imported, brand-name equivalent. Before long, India developed a large and efficient domestic pharmaceutical industry, supplying the domestic market with generic drugs at low prices and, eventually, exporting them to other developing nations in Asia and Africa that, like India, did not offer patent protection to pharmaceutical products (em phasis added). *Ibid.*

⁵³¹ See e.g., Jo Johnson, India Accused of Losing Nerve Over Its Reform Plans, *Financial Times* (7/10/06), at p. 3. Indian business leaders have lamented the government's loss of nerve over plans to sell small stakes in publicly owned companies, seen as the latest sign of backsliding in a reform programme that has lost momentum and credibility... Since large public investments are required in critical areas such as education, health and infrastructure, the government could face major resource constraints without disinvestments', the CII [Confederation of Indian Industry] warned, pointing to slower economic growth. *Ibid.* See also, India's Rude Awakening – The Privatization Debacle is a Serious Economic Setback, Editorial, *Financial Times* (7/10/06) at p. 14; Jo Johnson, Indian PM Caves in to Critics on Privatization Plans, *Financial Times* (7/7/06), at p. 2.

⁵³² See U.S. Country Commercial Guide – Brazil, U.S. Commercial Service (2005), at p. 28; U.S. Country Commercial Guide – Brazil, U.S. Commercial Service (2006), at p. 6.

⁵³³ See U.S. Country Commercial Guide – Brazil, U.S. Commercial Service (2005), at p. 28.

⁵³⁴ The GOB (Government of Brazil) has threatened to break patents for imported HIV/AIDS medication, saying generic equivalents can be produced in Brazilian laboratories. Often the intention to break patents is announced after pharmaceutical industries refuse to negotiate price reductions, indicating that the threat is being used as a bargaining chip. See U.S. Country Commercial Guide – Brazil, U.S. Commercial Service (2006), at p. 7.

⁵³⁵ See Statistics and Developments on the Intellectual Property Right situation in Brazil, U.S. Commercial Service – Market Research Report – Brazil (12/20/05).

⁵³⁶ *In Brazil, the adoption of intellectual property mechanisms follows a particular logic, conducive with a specific level of technological and industrial development.* The country takes advantage of the (now almost minimal) degree of freedom offered by the international

agreements for the conformance of rights (the TRIPs Agreement, for example) to undertake a more equitable implementation at national level. Since the nineties, Brazil has promoted a broad and deep revision in various legal instruments (Industrial Property Law, Copyright Law etc), as well as inaugurating certain dispositions (Plant Variety Law, Regulation for the Access to Biological Resources etc).. *Intellectual protection in the biomedical field differs from the protection in the agricultural field due to the distinctive nature and dynamics of each of these fields. In health biotechnology the patents perform a fundamental role.* The agents organize themselves to achieve protection (especially simultaneous protection: patents and trademarks) and try to extend to the utmost the term of the protection achieved. On the other hand, the logic of the developing countries is disturbed by the dilemma of prices and the access to technologies. Is it possible then, to conciliate intellectual protection and guarantee access by the population to advanced technology at costs compatible with the local reality? ***Safeguards such as compulsory licensing are vital, however, it must be seen that these are short term measures of limited scope*** (emphasis added). See Claudia Inês Chamas, Andreia Azevedo, Sérgio Salles-Filho, Sérgio Paulino de Carvalho, 'The Dynamics of Intellectual Protection for Biotechnology in Brazil' (April 2005) at p. 2, Presented as part of the 'IPR, Industrial Dynamics & Markets for Knowledge Segment' of the Triple Helix 5 Conference on the Capitalization of Knowledge: Cognitive, Economic, Social & Cultural Aspects (5/19/05), at pp. 9-10, at: (http://www.triplehelix5.com/pdf/A196_THC5.pdf).

⁵³⁷ The Decree n. 9,313 of November 13, 1996 assured all patients infected by HIV *free access to all medication necessary to their treatment*... Currently 15 antiretrovirals (ARVs) are made available by the Ministry of Health, with eight of them already produced locally. Some are not protected by patents, having being commercialized before Law n. 9,279. *Those having patent protection increase therapy costs considerably. Access to medicines has since become increasingly expensive.* The strategy for maintaining the antiretroviral access policy has various dimensions: systematic follow-up of patents in force, as well as in the public domain, in this field of knowledge; *negotiations with the suppliers; use of the [TRIPS] safeguards*; local production and import of generic medicines; intensification of local R&D activities to try to close the technological gap; and adjustments in the legal procedures to facilitate access measures (emphasis added). See Claudia Ines Chamas, 'Developing Innovative Capacity in Brazil To Meet Health Needs', pp., 75-111, at pp. 98-99, in Sibongile Pefile,

Zezhong Li, Wan Ke Chen Guang, Claudia Chamas, and Hiro Bhojwani, *Innovation in Developing Countries to Meet Health Needs – Experiences of China, Brazil, South Africa and India*, The Centre for Management of IP in Health R&D MIHR, Country Reports for Submission to the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) (April 2005), at: (<http://www.who.int/intellectualproperty/studies/MIHR-INNOVATION%20EXPERIENCES%20OF%20South%20Africa.%20CHINA.%20BRAZIL%20AND%20INDIA%20MIHR-CIPIH%20REPORTS%2014-04-05.pdf>).

⁵³⁸ This policy continues to be advanced by NGOs. *See* AIDS: Expenses Reignite Discussions Over Patents, *GLOBAL*, (4/16/06).

Non-governmental organizations fear that within two years the government will not be able to maintain the national AIDS program, which serves as a worldwide reference for the distribution of free medicines for 170,000 people who are in need of treatment. The reason is that the greater efficacy of treatment has lengthened patient survival, while at the same time the number of HIV infected persons does not stop growing. For the first time, the Ministry of Health will spend R\$1 billion (roughly \$454 million USD) this year to purchase medicines, which has reignited the discussion about compulsory licensing. *Ibid.*

⁵³⁹ *Ibid.*, at pp. 105-106.

⁵⁴⁰ *See* Patents: Time of Crisis, Time of Change, Abifina Informa Newsletter Edition 214, Associação Brasileira das Industrias de Química Fina, Biotecnologia e suas Especialidades (Jan. 2006) at: (<http://www.abifina.org.br/informaNoticia.asp?cod=62>).

⁵⁴¹ One recent article appearing within a socialist publication argues in favor of Brazil's adoption of colonial America's policy of protectionism. It also cites among other works, articles prepared by the former vice-president of a prominent Brazilian trade association and a former Brazilian finance minister. The keynote speech given by Brazilian President Fernando Henrique Cardoso, at the Third Summit of the Americas held April 20 [2001] in Quebec City, Canada, hit the entire Anglo-American establishment like a bath of ice water, by attacking the premise that a Free Trade Area of the Americas (FTAA) is the only direction for nations to go... At the conclusion of his speech, President Cardoso surprised his listeners with an unexpected reference: At the dawn of the 19th Century, men like Thomas Jefferson and the Luso-Brazilian diplomat Correa Serra already dreamed of an American System '... The reference to American System' is not fortuitous, or merely a rhetorical turn of phrase, but rather reflects the

intense discussion ongoing about *the protectionist policies associated with Alexander Hamilton, in the early industrialization of the United States*. For example, sociologist Helio Jaguaribe, known as the only Brazilian member of the Club of Rome... stated in an April 21 television interview with journalist Roberto Davila that, the FTAA constituted national suicide', and acknowledged the nationalist resurgence which he, like President Cardoso in the past, had mocked. To the surprise of many, Jaguaribe went back in history to state that the industrial power of the United States derived from the tariff model of Hamilton and McKinley.' *Another example of this debate over the need to return to a protectionist system is seen in an article by Nelson Brasil de Oliveira, vice-president of the Brazilian Association of Chemical Industries (ABIFINA), which was published in the Feb. 16 issue of O Globo newspaper.* In his article entitled 'Cairu and Hamilton', he polemicalizes against the liberal ideas championed by Cairu Viscount José da Silva Lisboa, an apologist for Adam Smith. Cairu was responsible for the free trade agreements and the opening up of Brazil's ports to England in 1808, which made Brazil at its birth, a colony and slave plantation. De Oliveira contrasts Viscount Cairu to his contemporary, U.S. Treasury Secretary Alexander Hamilton, responsible for the explosive economic growth achieved by the United States in the 19th Century, starting from the same economic level at which Brazil found itself at that time'... [F]ormer Finance Minister Antonio Delfim Netto is also participating. In a signed article published Feb. 28 in the newspaper *Valor Econômico*, and also titled 'Cairu and Hamilton', Delfim Netto looks at the lives of Hamilton and Cairu, and refers to Hamilton's immortal *Report on Manufactures*, presented to the U.S. Congress on Dec. 5, 1791. It is a small jewel of political cunning and economic knowledge, which dialogues with, and combats, Adam Smith. *The polemic continued with an interview with Delfim Netto, published in the April 2001 monthly bulletin of ABIFINA...* In Brazil, we are experiencing a highly curious situation. We train our professionals with American texts, which teach 'a supposed economic theory to be applied in underdeveloped countries, but which has very little to do with reality in those countries. If we observe the U.S.A. once again, we will verify that, until the Second World War, the bulk of the income of the American Treasury came from customs tariffs. And further: the United States practiced a strongly protectionist policy against England... The United States was created with the clear awareness that it would have to realize its own development, and that free trade did not exist in reality.' *Delfim concludes that with regard to Brazil, instead of simply accepting the ideology they sell us, what we*

should do is copy the example that they give us in defense of their national interest' (em phasis added). See Silvia Palacios and Lorenzo Carrasco, Alexander Hamilton's Specter Stalks Brazil , Executive Intelligence Review Internet Edition (5/11/01), at:

(http://www.larouchepub.com/other/2001/2819e_brazilhamilton.html).

⁵⁴² Stanford University economist Paul Romer's 1990 paper, Endogenous Technological Change sets forth the New Growth Theory' of economics. It was presented at the First International Conference of the Institute for the Study of Free Enterprise Systems, sponsored in part by the Smith Richardson Foundation and by supporters of then Buffalo, NY congressman and U.S. presidential contender, Jack Kemp. [I]t was in this unlikely setting that the concept of intellectual property was, if not exactly 'discovered', then formally characterized for the first time in the context of growth theory, embedded in an aggregate-level model of the economy, describing knowledge as both an input and an output of production, in a way that permitted economists to take account of its significance... [I]t showed how, by opening markets to new knowledge, trade policy could affect not just welfare (as had long been argued) but the rate of growth itself. The economics of creating ideas were very different from those of making things, because ideas, from intellectual property to the most basic research, could be copied practically without cost and used by any number of persons at the same time. ***Thus, innovations – the various new sets of instructions' that arose and the entrepreneurs who put them to use – were the key to growth...*** It was true that assembling old materials in new ways always required additional human capital... and more physical capital... [H owever,] [*p*]eople cooked up the new instructions in the hope of making money, then either kept secret some aspects of them, patented them, or used the advantage of their newfound knowledge to keep going forward to create still more new knowledge' (em phasis added). See David Warsh, *Knowledge and the Wealth of Nations – A Story of Economic Discovery, supra*, at pp. 290 and 293.

⁵⁴³ See Evaluation of MIF Projects – Market Functioning: Promotion of Competition and Consumer Protection MIF/GN-78-14, Office of Evaluation and Oversight, OVE, Multilateral Investment Fund, the Inter-American Development Bank (Dec. 2003), Executive Summary at p. ii. The Bank describes such projects as promoting 'second generation' institutional reforms... aimed at enhancing the capacity of the State to perform its regulatory functions appropriately [to] ensure the sustainability of [prior macroeconomic] market reforms... The confluence of interests between the government and the private sector

with respect to these reforms is even more apparent in the connection with competitiveness. The current conception is based on a comprehensive vision of the business environment, including such factors as the quality of macroeconomic policy, the availability of financial resources, infrastructure and human capital services, *and the capacity of enterprises and think tanks to innovate* (emphasis added).

Ibid.

⁵⁴⁴ *Ibid.*, at p.18.

⁵⁴⁵ *Ibid.*, at p. 19.

⁵⁴⁶ *Ibid.*, at p. 20.

⁵⁴⁷ One core feature of intellectual property is that it can help differentiate products. This is a key factor in the marketing challenges faced by [small and medium enterprises] SMEs. Brand names, patents, and designs can help to position a product on the market because they make it possible to distinguish its specific characteristics from those of competing products and to locate it in specific segments... An adequate grasp of intellectual property... may... [also]... increase the... commercial... value of an enterprise in the eyes of potential investors. *Alternatively, the intellectual property assets can be used as collateral security to obtain external funding.* Many entrepreneurs, especially the owners of small businesses, are unaware of the value of brand names, designs, and patents. Proper valuation of those assets can raise the value of an enterprise in the event of a sale, merger, or acquisition ... Intellectual property... [can also be used]... to access new markets, export, or to open branches... Franchising is an instrument that allows a business to expand by granting a brand name license together with authorization to use specific know-how and an agreement to provide ongoing technical assistance... In short, franchising is a commercial expansion tool based exclusively on the sale of intellectual property rights (emphasis added). *Ibid.*, at pp 20-21.

⁵⁴⁸ In Brazil, the Arab food chain 'Habib'... ranked one of the most outstanding enterprises in Latin America by Global Finance magazine... has a vast network of 200 outlets created over the past 14 years [1989-2003]... A report by the Brazilian Franchising Association states that the [franchise] business grew 12 percent in 2002. Annual billing increased from US\$ 8.3 billion in 2001 to approximately US\$ 9.3 billion in 2002. Together, franchising operations have generated 350,000 jobs in the country as a whole. *Ibid.*, at pp. 21-22. A very recent study focused on how franchise operating systems can help to establish respect for intellectual property rights and rule of law in developing countries. [F]ranchise operating systems can serve many of the same functions as a rule of law while franchise networks can be

wonderfully supportive social institutions... The franchise business model is all about brand protection. International franchise consultants are quick to point out that entrepreneurs abroad do not strictly buy and sell franchises'. They license a brand'. It is in the self-interest of everyone associated with a franchise network – the franchisor, master franchisee and local franchisee – to protect the brand which delivers ongoing mutual value. Proliferating MicroFranchises throughout an economy will be an effective way to educate large numbers of people about the benefits of IPP as local owners work to protect and strengthen their co-owned

brands. See Kirk Magelby, *MicroFranchises as a Solution to Global Poverty* at pp. 31-32, at: (<http://www.nextbillion.net/files/Micro%20Franchises%20as%20a%20Solution%20to%20Global%20Poverty.pdf>); (<http://www.omidyar.net/group/poverty/file/7.35.11055472357/get/Micro%20Franchises%20as%20a%20Solution%20to%20Global%20Poverty.pdf>).

⁵⁴⁹ Hernando De Soto is the best-selling author of *The Other Path: The Economic Answer to Terrorism (1989)* and *Mystery of Capitalism: Why Capitalism Triumphs in the West and Fails Everywhere Else (2000)*. He is also founder/director of Peru's Institute for Liberty and Democracy, a champion of market economics and property rights. According to Dr. De Soto, in Peru there indeed exists a private sector, but it exists largely on the basis of competing for government favors, contracts, and privileges, and its economic approach is to try to exclude or marginalize competitors--not by out-producing them in quantity, quality, or prices, but through political means, from legislation to outright use of the many resources of legal coercion at the disposal of a modern state... The informal economy is much closer than the formal to what we call a market economy. Not only does it not function on the basis of political favors, but it often functions in spite of a government opposition incited by participants in the formal economy... We pointed out that the problem which both formals and informals had to face was not a class struggle' but rather how to handle the intrusion of the government in the activities of all businessmen in Peru... [T]he difference between the institute's agenda of granting official property rights to their land to the informals and the old left-wing idea of agrarian reform' [is that] *Agrarian reform is a process by means of which government assigns lands to the peasants*. But when we talk about titling and registering those who have already occupied the lands, the squatters,' we are talking about a different phenomenon. The squatters have already created their own revolution. They do not need

anybody, neither a party nor a government agency, to carry out a revolution for them ... Private property constitutes a formidable bastion against socialism ... (emphasis added). See Dario Fernandez-Morera, Reason Online Interview with Hernando de Soto, (?), at: (<http://reason.com/DeSoto.shtml>).

⁵⁵⁰ Dr. De Soto, in effect, works with heads of state to implement institutional reforms that give the poor access to formal property rights for their real estate holdings and businesses along with the tools to release the capital locked up in those assets... Extralegal is something that cannot be readily used as a guarantee to obtain credit, invest, or make accountable by a third party. The under-the-table economy is part of the extralegal sector... If they own assets, these assets are not working for them because they are not registered; they cannot borrow against their assets to create wealth... Once you're in the legal system, you become more interested in the political system '... [M]icrocredits will only work if the borrower has something to lose by not paying back their loan, and they will only have something to lose if they have title deed, legal ownership of their house, their car, their family farm, whatever.' See Kenneth Rapoza, Interview: Peruvian Economist Hernando de Soto, World Press Review (Oct. 15, 2003), at: (<http://www.worldpress.org/Americas/1602.cfm>).

⁵⁵¹ Some of the region's shortcomings with respect to innovation have to do with the enterprises themselves. Innovation tends to be informal, since only 15.7 percent of enterprises have a formal in-house R&D facility. Another aspect of informality is that most enterprises have no idea how much they invest in R&D. Another problem is lack of coordination among enterprises and the other generators of innovation. Empirical data in the region suggest limited and inadequate cooperation among the companies themselves and among the business community, universities, and research institutions. This constitutes a bottleneck for the generation of new knowledge and for determining enterprises' innovation needs. See Evaluation of MIF Projects – Market Functioning: Promotion of Competition and Consumer Protection *supra*, at p. 20.

⁵⁵² [A]vailable evidence indicates that technology markets (essentially licensing transactions) are expanding rapidly, in particular in the United States and in the ICT and biopharmaceutical sectors. This expansion reflects a shift toward more open innovation processes that make firms more eager to use licensing to gain access to needed inventions in a timely fashion and to generate additional revenues from inventions they do not plan to exploit themselves. It has been facilitated by governments, which are encouraging universities and other public

research organisations to enter patent markets, licensing inventions to the private sector and engaging in more co-operative research with industry. Expansion is further fuelled by globalisation, as reflected in increased international licensing of technology. While the majority of licensing transactions remain within affiliated groups of companies, evidence suggests that the share of open trade between unaffiliated firms is increasing. See Intellectual Property as an Economic Asset: Key Issues in Valuation and Exploitation, EPO-OECD-BMWA Conference Summary Report, Organisation for Economic Co-Operation and Development (6/30-7/1/05), at p. 6.

⁵⁵³ *Ibid.*, at pp. 5-6.

⁵⁵⁴ *Ibid.*, at p. 5.

⁵⁵⁵ *Ibid.*, at p. 7.

⁵⁵⁶ It is highly context-dependent and relates to the ability of a firm to extract the value from its patents through competent management, as well as on the particular market environment facing a patent holder. Differences across sectors are driven by factors such as patent strength, market structure, technology characteristics, company strategies and firm size. Firms exploit the value of their patents through multiple channels. Firms capture the value of their patents not only by embedding protected inventions in new products, processes and services while excluding competitors from the market place, but also by using patents as a source of additional revenue (e.g., via royalties from outward licensing) and a mechanism for accessing technology (e.g., via cross-licensing and inward licensing). Increasingly, they view their patents as assets that can provide markets with information about their technological capabilities and enhance their bargaining power in various types of transactions, such as establishing joint ventures, negotiating mergers and acquisitions, and accessing financial markets. Different strategies are followed by firms in different industries, often reflecting differences in innovation processes and markets: cross-licensing to get freedom of action and access to complementary technologies, direct licensing to extract royalty revenues, asset in mergers and acquisitions, exclusive rights on leading products, etc. In some low-margin, high-volume industries, such as ICT manufacturing, firms increasingly license their patents to generate revenues that finance R&D and innovation. Start-up firms find licensing an effective means improving the commercialisation prospects of their inventions, as well as of attracting financing from venture capitalists and banks.

Ibid., at p. 6

⁵⁵⁷ *Ibid.*, at p. 11, paraphrasing Ruud Peters, Chief Executive Officer at Philips Intellectual Property and Standards. By way of contrast, In the

1970s a company's strategic effort was typically based on investing in product development and manufacturing with the objective of making better products at lower cost. Success was based on manufacturing high-volume products at low prices. *Ibid.*

⁵⁵⁸ *The utility of patents to companies varies among industrial sectors. Patents are perceived as critical in the drug and chemical industries. That may reflect the nature of R&D performed in these sectors, where the resulting patents are more detailed in their claims and therefore easier to defend.* In contrast, one study found that in the aircraft and semiconductor industries patents are not the most successful mechanism for capturing the benefits of investments. Instead, lead time and the strength of the learning curve were determined to be more important. *The degree to which industry perceives patents as effective has been characterized as . . . positively correlated with the increase in duplication costs and time associated with patents.*⁴ *In certain industries, patents significantly raise the costs incurred by non-patent holders wishing to use the idea or invent around the patent – an estimated 40% in the pharmaceutical sector, 30% for major new chemical products, and 25% for typical chemical goods – and are thus viewed as important.* However, in other industries, patents have much smaller impact on the costs associated with imitation (e.g. in the 7%-15% range for electronics), and may be considered less successful in protecting resource investments (emphasis added). See Wendy H. Schacht and John R. Thomas, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984

(The Hatch-Waxman Act), Congressional Research Service, Order Code RL30756 (Updated 1/10/05), at p. 5, at: (<http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL3075601102005.pdf>).

⁵⁵⁹ The six motives for patenting are the following: commercial exploitation of the innovation, licensing, cross-licensing, prevention from imitation, blocking rivals, and reputation. The most important reasons for patenting are the commercial exploitation of the innovations and the prevention from imitation. *In other words, inventors and organisations patent because they seek exclusive rights to exploit economically.* By patenting the inventions around they prevent others to imitate their valuable innovations. Another reason for patenting is to block competitors that might patent similar innovations, which suggests that patents are important for competitive reasons more than for evaluating or motivating people working in the organization (emphasis added). See Study on Evaluating the Knowledge Economy:

What Are Patents Actually Worth? – The Value of Patents for Today's Economy and Society, Tender n° MARKT/2004/09/E, Final Report for Lot 1 for the European

Commission, Directorate-General for Internal Market (5/9/05), at p. 44., at:

(http://ec.europa.eu/internal_market/indprop/docs/patent/studies/patents_tudy-report_en.pdf).

Different types of employers have different motivations to patent. [C]ommercial exploitation of a patent is more important for small and medium firms... Licensing is more important for private and public research organizations, including universities... Cross-licensing is an important reason for patenting for large firms. Large and medium firms also consider prevention from imitation and blocking rivals as important motives to ask for patent protection. Finally reputation is an important reason to patent for public research organizations and universities. *Ibid.*, at p. 45. The report, furthermore, cites the findings of at least one 2003 study which concluded that patents have the greatest positive incentive effect on research and development (in the sense that an increase in the premium generates a positive a substantially positive response in R&D) in pharmaceuticals, biotechnology, medical instruments, and computers. In semiconductors and communications equipment the premium and the incentive effect are much lower, although still positive and not negligible. *Ibid.* at p. 14, citing Ashish Arora, Marco Ceccagnoli, Wesley M. Cohen, R & D and the Patent Premium, National Bureau of Economic Research Working Paper No. 9431 (Jan. 2003), at: (<http://papers.nber.org/papers/W9431>). [T]here are technologies in which the probability of inventing valuable patents is higher than in others. If we consider the innovations that are worth more than 10 million Euros, the technological sectors with the highest share of patents in this class are: Pharmaceuticals & Cosmetics (17.48%), Semiconductors (12.81%), Organic Fine Chemistry (13.07%), Chemical, Petrol & Basic Material Chemistry (12.54%), and Material Processing, Textile & Paper (9.90%). *Ibid.*, at p. 30.

⁵⁶⁰ An important, and sometimes overlooked, feature of farm policy is that agriculture is a technologically dynamic sector. Agriculture is in the midst of two ongoing technological revolutions -- crop genetics and livestock industrialization -- and is in the early stages of a third -- gene modification through recombinant DNA. These technological changes have a number of implications. First, the evolution of large agrobusiness firms devoted to life science has generated substantial industrial concentration and vertical integration in the sector. Second, while research in agricultural product development is increasingly

undertaken in the private sector, the relationships between public research agencies and private firms in establishing basic scientific results are growing in complexity. Third, there is increasing product innovation through the development of new plant and animal varieties, biologically based inputs for agriculture, and crop-based nutritional and pharmaceutical goods. Taken together, these factors mean that the *industry places growing reliance on formal means of protecting new technologies, including intellectual property rights (IPRs), and there are strong interests pushing for further strengthening and international harmonization in this regard. There are three major forms of IPRs that affect such protection and the willingness to invest in agricultural technologies. These are patents on life forms, plant variety rights, and geographical indications.* Also relevant is competition policy, including the treatment of exhaustion (parallel imports) (emphasis added). See Keith E. Maskus, *Intellectual Property Rights in Agriculture and the Interests of Asian-Pacific Economies*, Discussion Paper No. 59, Institute of Economic Research Hitotsubashi University, Tokyo, Japan (Dec. 2004), at pp. 1-2, at: (<http://hi-stat.ier.hit-u.ac.jp/research/discussion/2004/pdf/D04-59.pdf>); (<http://www.fordschool.umich.edu/rsie/Conferences/CGP/Mar2004Papers/Maskus.pdf>).

⁵⁶¹ See Public Health, Innovation and Intellectual Property Rights, Report on the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), World Health Organization, at pp. 32-33, *supra*.

⁵⁶² IPRs in the pharmaceutical industry rely mainly on two instruments, patents and data exclusivity. Patents are usually given for 20 years from the day the patent is accepted by the national patent office. For most innovations, holding a patent is equivalent to holding a marketing authorization and market exclusivity for a certain period of time, until a newer, better alternative is introduced. For NCEs, however, having a patent can be quite disconnected from having marketing authorization. In fact, it is ten years, on average, before a newly patented medicine reaches the patient's bedside. After receiving a patent, the innovator must prove the safety and efficiency of the new drug to the regulatory authority. In order to prove safety and efficiency of a new drug, pre-clinical and clinical tests must be performed. The results of tests on animals and humans are systematically reported in the registration dossier prepared for the regulatory authority. Because of the large investment in money and time needed to successfully gain marketing approval through clinical trials, the data generated during testing phases is kept confidential and cannot be exploited by potential

competitors for a certain number of years. This protection is referred to as both data protection and data exclusivity... *For most drugs, patent protection goes beyond data protection. However, if the testing period has been extremely long, or if the drug does not have full patent protection, data exclusivity can be the only form of IP* (em phasis added). See Corinne Sauer and Robert M. Sauer, Reducing Barriers to the Development of High Quality, Low Cost Medicines - A Proposal for Reforming the Drug Approval Process, IPN Working Papers on Intellectual Property, Innovation and Health (©2005), at: (<http://www.who.int/intellectualproperty/submissions/Sauerbarriers.pdf>).

⁵⁶³ Return of capital' is essentially a return of one's actual cost (outlay) investment in a capital asset' - i.e., a long-term asset that is not bought or sold in the normal course of business. In a broader sense, it can be viewed as a return on invested capital, including both contributed equity and incurred debt, or return on investment', or ROI, [which] is a useful means of companies or corporate divisions in terms of efficiency of management and viability of product lines. See John Downes and Jordan Elliot Goodman, Finance and Investment Handbook, Barrons (© 1987) at pp. 199 and 431.

⁵⁶⁴ Return of sales' is essentially net pretax profits as a percentage of net sales... [figured after returns, allowances, and discounts]...a useful measure of overall operational efficiency when compared with prior periods or with other companies in the same line of business. *It is important to recognize, however, that a return on sales varies widely from industry to industry* (em phasis added). *Ibid.*, at p. 431.

⁵⁶⁵ IPRs are crucial in pharmaceutical innovation because of the high cost of innovation relative to the cost of imitation. Patent protection and data exclusivity provide innovators with a period of market exclusivity that allows them to recoup their large initial investments and earn a profit. Without such protection, innovative products would be quickly imitated at a very low cost, rendering the original R&D effort worthless... [A]mong the 118 new chemical entities (NCEs) introduced to the market between 1990 and 1994, only 30% of them had a present value of net revenue that exceeded their R&D costs. For the median drug, the cost of R&D was not recovered. It was only among the few high selling drugs, known as blockbusters, that the return to R&D was substantial (five times greater than the return to all other drugs). This wide range of returns in new drug investment led the authors to conclude that R&D effort in the pharmaceutical industry is mainly driven by the search for a blockbuster. In fact, research-based pharmaceutical companies need to have some top selling drugs in order

to cross-subsidize other R&D investments. Legislative enactments that weaken IPRs and lower the price of blockbusters, without lowering their costs of development, could cause a cascading reduction in pharmaceutical innovation. *Ibid.*, at p. 8.

⁵⁶⁶ For R & D – and innovation in general – the most relevant types of intellectual property are patents and trade secrets. *Trade secrets may in fact be even more important than patents for a country to be able to attract FDI in R&D.* To the extent that the R&D process involves sensitive information, TNCs will always seek to protect trade secrets against disclosure. A 1994 survey of 1,478 R&D labs in the United States manufacturing sector found that trade secrecy was effective for 51% of innovations, while the corresponding figure for patents was only 35% (em phasis added). See Transnational Corporations and the Internationalization of R & D , United Nations Conference on Trade and Development (UNCTAD) World Investment Report, UNCTAD/WIR/2005 (Sept. 2005), at p. 209, at: (http://www.unctad.org/en/docs/wir2005_en.pdf).

⁵⁶⁷ As a condition for registering pharmaceutical products, national authorities normally require registrants to submit data relating to a drug's quality, safety and efficacy as well as to its physical and chemical characteristics.

⁵⁶⁸ In addition to test data, national authorities require information on the quantitative and qualitative composition and other attributes of the product, as well as on manufacturing methods. Marketing approval is generally granted for a specific drug used for a specific therapy. Changing the composition of the drug, combining it with other drugs in a single product or selling the drug for a different therapeutic purpose requires new approval. See Carlos María Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement , The South Centre (2002), at pp. 17, at: (<http://www.southcentre.org/publications/protection/protection.pdf>).

⁵⁶⁹ For example, in *Ruckelshaus v. Monsanto, Co.*, the U.S. Supreme Court noted the District Court's finding that Monsanto had incurred costs in excess of \$23.6 million in developing the health, safety, and environmental data submitted by it under FIFRA ... The information submitted with an application usually has value to Monsanto beyond its instrumentality in gaining that particular application. Monsanto uses this information to develop additional end-use products and to expand the uses of its registered products. The information would also be

valuable to Monsanto's competitors. *Ruckelshaus v. Monsanto, Co.*, 467 U.S. at ___.

⁵⁷⁰ See Alfred Adebare, Data Exclusivity: The Implications for India, LexCounsel India (11/22/05), at: (http://www.articlealley.com/article_16562_18.html).

⁵⁷¹ *Ibid.*

⁵⁷² Pursuant to U.S. law, a trade secret is a protectable intellectual property right that meets the following definition: information, including a formula, pattern, compilation, program, device, method, technique, or process that: (i) derives independent economic value, actual or potential, from not being generally known, and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. See The Uniform Trade Secrets Act, Sec. 1(4)(1985), 14 U.L.A. 286 (Supp. 1987). Factors that should be considered when ascertaining whether information is covered under this definition are set forth within the U.S. Restatement of Torts (Sec. 757 comment b (1939)). Trade secrets may include pending patent applications. See Robert C. Dorr and Christopher H. Munch, Protecting Trade Secrets, Patents, Copyrights and Trademarks, Wiley Publications (© 1990), at pp 4 and 9. [The Uniform Trade Secrets Act (UTSA) essentially codifies the basic principles of common law trade secret protection '...The UTSA has been adopted by most states. In addition to injunctive relief, the UTSA provides for the award of monetary damages, including exemplary damages. Reliance on the UTSA may be compelling because it codifies a broad enough definition of trade secret that: 1) comports with the Restatement (Third)... of Unfair Competition §39 (1995); and 2) covers a wider array of categories of information beyond what is contemplated by federal statutes like [the Freedom of Information Act] FOIA. See Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation, RX for the Defense (Winter 2004), at p. 23, at: (<http://www.orrick.com/fileupload/298.pdf>). That restatement defines trade secret' as any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others. *Ibid.*

⁵⁷³ See Meir Perez Pugatch, Intellectual Property and Pharmaceutical Data Exclusivity in the

Context of Innovation and Market Access, Presentation made at the ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable

Access to Essential Medicines (10/12-10/16/04), at: (http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio_3.pdf). The underlying logic of data exclusivity *suggests* that it is an expression of trade-secrets, and that as such, data exclusivity should be independent of patents. Compared with patents, the market power of data exclusivity is, in theory, less restrictive, mainly because it does not legally prevent other companies from generating their own registration data (em phasis added). [D]ata exclusivity is becoming increasingly dominant as an additional IP layer of protection which affects both research-based and generic-based companies... Trade retaliation policy tools are also currently being used by the US and the EU against developing countries, such as Israel, Turkey and India, in which the absence of data exclusivity legislation results in a serious commercial clash between research-based multinational pharmaceutical companies and powerful local generic-based companies that are often perceived as national champions'... [S]ince data exclusivity is a new form of protection, there are still significant disagreements on what this form of IP protection encompasses. *Ibid.*

⁵⁷⁴ According to the U.S. Supreme Court, patent application shall include a full and clear description of the invention and of the manner and process of making and using it' so that any person skilled in the art may make and use the invention. *Kweanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974). The information contained in a patent application is kept by the Patent and Trademark Office as a trade secret as long as the application is pending... [H]owever,] ... [t]he day the patent is printed by the Government Printing Office, all trade secrets contained therein become public knowledge ... Issued patents are good examples of technical information that no longer constitutes trade secrets... When a chemical composition falls within this category, it is a wise business decision to protect the chemical formulation as a trade secret and not publicly disclose it in an issued patent. *See Dorr and Munch* at p. 6.

⁵⁷⁵ *See Dorr and Munch* at pp. 5-6. Prior the enactment of the Uniform Trade Secrets Act (USTA) the definition of trade secret was narrowed down by the courts with respect to information submitted to regulatory authorities. For example, in *Public Citizen Health Research Group v. Department of Health and Human Services*, 704 F.2d 1280 (D.C. Cir. 1983), the federal circuit court defined a 'trade secret' as a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. As a result of the *Public Citizen*

court's ruling, the U.S. Food and Drug Administration amended its operative regulations to read as follows: a trade secret: may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process... This requirement means that sensitive information, like marketing projections, customer or supplier lists, or pricing information, not directly related to the productive process, would not be deemed to be trade secret. Rather, these categories would fall under the definition of confidential commercial or financial information, found in 21 C.F.R. §20.61(b), and risk being afforded a reduced level of protection. See Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, *Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation*, *supra*, at p. 22

⁵⁷⁶ For example, whenever a company submits information to the FDA... [several] statutory and regulatory provisions ostensibly provide reassurance that any confidential information will be protected. Still, the protections afforded in these provisions require companies to properly designate their information as trade secret, or confidential. See Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, *Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation*, *supra*, at p. 22; Robert C. Dorr and Christopher H. Munch, *Protecting Trade Secrets, Patents, Copyrights and Trademarks*, *supra*, at p. 31.

⁵⁷⁷ For instance, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §331(j), prevents: [t]he using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information... concerning any method or process which as a trade secret is entitled to protection... Additionally, 18 U.S.C. §1905 prohibits government officials and employees from publishing, divulging, disclosing or making known, to any extent not authorized by law, a wide array of confidential information, except as provided by law. Violators of this provision will be subject to fines, and even possible imprisonment. However, these punitive provisions do nothing to undo the probable economic damage of disclosure of a trade secret that a company would suffer. FDA regulations also prohibit the disclosure of trade secret information: Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or

confidential commercial or financial information are not available for public disclosure (em phasis added). See Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation , RX for the Defense (Winter 2004), at p. 21, at: (<http://www.orrick.com/fileupload/298.pdf>).

⁵⁷⁸ *Ibid.*, at p. 22.

⁵⁷⁹ [U]nder 21 C.F.R. §20.83, the FDA will disclose information pursuant to a final court order, even if that information is otherwise not available for public disclosure[;]21 C.F.R. §20.86 permits the release of confidential information in an administrative proceeding or a court proceeding, where data or information are relevant to that proceeding[;] [T]he FDA ... is authorized to release trade secrets and commercial or financial information to other federal government departments and agencies if the FDA satisfies certain provisions of the United States Code. One such provision is Section 331(j) of Title 21, which permits disclosure of trade secrets to courts when relevant in any judicial proceeding[;] [and] [T]he FDA Commissioner also has the discretionary authority to disclose otherwise exempt information based on a finding that disclosure would be in the public interest, promote the objectives of the act and the agency, and is consistent with rights of individuals to privacy, the property rights of persons in trade secrets, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities (em phasis added). *Ibid.*, at p. 23.

⁵⁸⁰ The Federal Trade Secrets Act covers only the specific criminal acts of federal employees. See Dorr and Munch at p. 9, citing The Federal Trade Secrets Act, 18 U.S.C. Sec. 1905 (Supp. 1988).

⁵⁸¹ See Restatement First of Torts, comment b (1939). The Restatement.. historically was relied upon by courts and federal agencies when considering whether to withhold confidential information from production. See Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation , at p. 22.

⁵⁸² The elements of that tort of are: '(1) an economic relationship between [the plaintiff and some third person] containing the probability of future economic benefit to the [plaintiff], (2) knowledge by the defendant of the existence of the relationship, (3) intentional acts on the part of the defendant designed to disrupt the relationship, (4) actual disruption of the relationship, [and] (5) damages to the plaintiff proximately caused by the acts of the defendant.' *Buckaloo v. Johnson* 14 Cal.3d 815, 827 (1975). See The Lectric Law Library's Lexicon

On Intentional Interference With Prospective Economic Advantage , at: (<http://www.lectlaw.com/def/i084.htm>).

⁵⁸³ *Ibid.*, citing *Youst v. Longo* 43 Cal.3d 64, 71 (1987). In New Jersey, [w]hat is actionable is the luring away, by devious, improper and unrighteous means, of the customer of another.' *Printing Mart-Morrison v. Sharp Elecs. Corp.*, 563 A.2d 31, 36 (N.J. 1989). A complaint based on tortious interference must allege facts *that show some protectable right* – a prospective economic or contractual relationship. Although the right need not equate with that found in an enforceable contract, *there must be allegations of fact giving rise to some 'reasonable expectation of economic advantage.'* *Id.* at 37 (emphasis added); see *Democratic State Comm. v. Bebchick*, 706 A.2d 569, 573 (D.C. 1998) (In order to survive a motion to dismiss on a claim of intentional interference with prospective economic advantage a plaintiff must allege business expectancies, not grounded on present contractual relationships, but which are commercially reasonable to anticipate.); *Walker v. Sloan*, 529 S.E.2d 236, 242 (N.C. Ct. App. 2000) ([T]o state a claim for wrongful interference with prospective advantage, the plaintiffs must allege facts to show that the defendants acted without justification in inducing a third party from entering into a contract with them which contract would have ensued but for the interference.) See *United Educational Distributors, LLC v. Educational Testing Service*, (SC CA 2002), at: (<http://www.law.sc.edu/ctapp/3436.htm>).

⁵⁸⁴ For the most part, the expectancies' thus protected have been those of future contractual relations, such as the prospect of obtaining employment, or employees or the opportunity of obtaining customers. In such case[] there is a background of business experience on the basis of which it is possible to estimate with some fair amount of success both the value of what has been lost [e.g., prospective profits] and the likelihood that the plaintiff would have received it if the defendant had not interfered. See William L. Prosser, *Handbook of the Law of Torts*, 4th ed., Interference With Prospective Advantage' Sec. 130, West Publishing Co., at pp. 949-950, (© 1971).

⁵⁸⁵ [F]ree competition... proverbially is the life of trade. So long as the plaintiff's contractual relations are merely contemplated or potential, it is considered to be in the interest of the public that any competitor should be free to divert them to himself by all fair and reasonable means. *Ibid.*, at p. 954. Though trade warfare may be waged ruthlessly to the bitter end, there are certain rules of combat which must be observed. The trader has not a free lance. Fight he may, but as a soldier, not as a guerilla.' In the interests of the public and the

competitors themselves, boundaries have been set by the law, and numerous practices have been marked out as unfair competition, for which, in general, a tort action will lie in favor of the injured competitor, although very often the tort is given some other name. *Ibid.*, at p. 956, citing Hammond, J., in *Martell v. White*, 185 Mass. 255, 260, 69 N.E. 1085, 1087; Grismore, *Are Unfair Methods of Competition Actionable at the Suit of a Competitor*, 33 Mich. L. Rev. 321 (1935).

⁵⁸⁶ See Black's Law Dictionary Special Deluxe Fifth Edition at p. 93 (© 1979) West Publishing Co. at p. 1371. The torts of intentional interference with contractual relations, with lawful business, and with prospective business advantage are closely related. . . The general wrong involved in each tort consists of intentional and improper methods of diverting or taking away ongoing or prospective business or contractual rights from another, which methods are not within the privilege of fair competition. See 45 Am. Jur. 2d Interference § 36 (1999).

⁵⁸⁷ [A] method was said to be an unfair method if its does not leave to each actual or potential competitor a fair opportunity for play of his contending force engendered by an honest desire for gain. *California Rice Industry v. Federal Trade Commission*, C.C. A. 9, 102 F.2d 716, 721. *Ibid.*, at p. 1372.

⁵⁸⁸ See Dorr, and Munch, *supra*, at p. 104.

⁵⁸⁹ The term 'appropriation' is defined as To make a thing one's own; to make a thing the subject of property; to exercise dominion over an object to the extent, and for the purpose, of making it subserve one's own proper use or pleasure. See Black's Law Dictionary, *supra* at p. 93.

⁵⁹⁰ The term 'misappropriation' has been defined as the taking and use of another's property for [the] sole purpose of capitalizing unfairly on good will and reputation of [the] property owner. *Ibid.*, at p. 901.

⁵⁹¹ *Ibid.*, at p. 108.

⁵⁹² See Dorr and Munch, *supra*, at p. 111.

⁵⁹³ See *supra*.

⁵⁹⁴ See Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, *Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation*, *supra*, at p. 24.

⁵⁹⁵ See also Andrew Beckerman-Rodau, *Are Ideas Within The Traditional Definition of Property? A Jurisprudential Analysis*, *supra*, at pp. 12-21.

⁵⁹⁶ See Public Law 98-417.

⁵⁹⁷ The Hatch-Waxman Act also created mechanisms to address concerns that regulatory requirements for FDA approval of a drug prior to marketing often meant that the owner of a patent associated with a drug did not enjoy the full benefit conferred by that patent. Provisions were included to [enable such owners to submit a regulatory filing under certain circumstances to] extend the patent as compensation for some of the regulatory activities. These provisions are not discussed in this white paper. See Wendy H. Schacht and John R. Thomas, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 (The Hatch-Waxman Act), Congressional Research Service, Order Code RL30756 (Updated 1/10/05) at p. 33, at: (<http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL3075601102005.pdf>).

⁵⁹⁸ *Ibid.*, at p. 23. *They also received the ability to file for a patent term extension to compensate for any regulatory delays they encountered in the approval process. See discussion, *infra*, concerning the Bolar Amendment.

⁵⁹⁹ The 1984 Act created a new type of application for market approval of a pharmaceutical. This application, termed an Abbreviated New Drug Application (ANDA), may be filed at the FDA. An ANDA may be filed if the active ingredient of the generic drug is the bioequivalent of the approved drug. An ANDA allows a generic drug manufacturer to rely upon the safety and efficacy data of the original manufacturer. *Ibid.*

⁶⁰⁰ The 1984 Act defines an NCE drug as an approved drug which consists of active ingredients, including the ester or salt of an active ingredient, none of which has been approved in any other full NDA. *Ibid.*, at p. 24.

⁶⁰¹ *Ibid.*, at pp. 24-25. The FDA will not consider applications for a generic version of a new chemical entity for five years after approval of the original. This applies even if there is no patent on the drug. According to the [Congressional Budget Office] CBO, however, this may, in actuality, add more than five years because abbreviated drug applications often take more than 30 months, on average, for approval. Added together, this may provide over seven years of market exclusivity. The Food and Drug Administration also is permitted to grant a three year exclusivity period if a new drug application (or supplemental application) necessitates additional clinical investigation. These situations include new dosage forms for already approved drugs, a new use for a drug, or for over-the-counter marketing of a drug. *Ibid.*, at p. 34.

⁶⁰² *Ibid.* ... [T]he 1984 Act extends market exclusivity if the FDA accepts a new claim for an existing pharmaceutical. For example, Bristol-Myers Squibb repositioned Excedrin as Excedrin Migraine with the same active ingredients. Similarly, J&J/McNeil produces Motrin Migraine Pain as well as Motrin. The argument has been made that the brand name drug companies are creating improved drug entities based on their original invention. When approved by the FDA, the changes made permit three years of exclusivity on the marketing of the pharmaceutical if a new patent is not forthcoming and an additional 20 years if a patent issues. If the original drug is removed from the market, however, a generic for that pharmaceutical cannot be introduced. *Ibid.*, at p. 35.

⁶⁰³ Scientific experiments conducted the term of an original manufacturer's patent were often permitted as an exception to patent infringement. However, not until the Bolar Amendment was adopted in 1984 within the United States that clinical trials conducted to provide the basis for a generic drug's subsequent regulatory approval were allowed to escape infringement of an existing patent. The Bolar provision is contained within 35 U.S.C. § 271(e)(1). It states that [i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products. This provision is accessible at: (http://www4.law.cornell.edu/uscode/html/uscode35/usc_sec_35_0000_0271----000-.html). The Bolar type defense originated from the U.S. case of *Roche v Bolar [Pharmaceuticals]* (733 F.2d 858, 221 USPQ 937), in which it was decided that a generic pharmaceutical company was not permitted to conduct tests on a patented compound prior to patent expiry, even if such tests were conducted in order to fulfill regulatory requirements for securing marketing authorization. Following this decision, U.S. patent law was amended to include an exemption to permit such experiments. See Licensing Update - IPR in Business, Licensing Executives Society Britain and Ireland (Dec. 2005), at: (<http://www.les-bi.org/articles/december05.htm>).

⁶⁰⁴ The U.S. generic drug industry considers the Bolar Amendment a critical U.S. provision that allows for the development, testing and experimental work required for the registration of a generic medicine during the patent period of the original product. The purpose of this provision is to ensure that generic medicines enter the market immediately *after patent expiry* to improve access and encourage

competition (emphasis added). See Statement of Kathleen Jaeger, Generic Pharmaceutical Association, Arlington, Virginia, to the Committee on Ways & Means, U.S. House of Representatives (2004), Hearing Archives at: (<http://waysandmeans.house.gov/hearings.asp?formmode=view&id=1876>).

⁶⁰⁵ In an attempt to launch immediately upon patent expiry, Bolar carried out tests on the patented active ingredient during the term of the patent for the purposes of obtaining marketing approval from the FDA. The U.S. court in that case held that such tests constituted an infringement of the relevant patent. The U.S. government reacted very quickly to this recognizing that the position as it existed was in fact hindering the, potentially lucrative, generics market. The government therefore included the so called Bolar provision in the 1984 Hatch-Waxman Act. This Act contained other provisions designed to accelerate and facilitate generic entry while also providing protection for the owner of the pioneer patent. The purpose behind the inclusion of this provision was explained [by] Congress, as being: Promotion of speedier entry by generic drugs, by streamlining the development and approval process, in order to make available more low cost generic drugs, ' whilst at the same time protecting the interests and preserving the incentives for continued innovation if the patent-holding pioneer branded drug manufacturers. *In exchange for the rights afforded to generic companies under the Bolar provision, originator companies in the U.S. received the right to obtain an extension of the patent term to compensate for the loss of time between patent approval and exploitation as a result of the regulatory approval process* (emphasis added). See Marjan Noor and Camilla Smith, EU Strikes Balance With New Bolar Provision, *Managing Intellectual Property* (July/Aug. 2005), at: (<http://www.managingip.com/default.asp?page=10&PUBID=34&ISS=17580&SID=524273>).

⁶⁰⁶ There are currently efforts underway in the United Kingdom to amend the UK Patents Act of 1977 to include a Bolar provision. (Proposed Section 60(5)(h) of the UK Patents Act of 1977 (30/10/05)). These efforts seek to provide the same protection against liability for patent infringement to clinical work undertaken during a drug's patent term *to secure market authorization* for a generic drug (emphasis added). See Licensing Update - IPR in Business, Licensing Executives Society Britain and Ireland, *supra*; See also Marjan Noor and Camilla Smith, EU Strikes Balance With New Bolar Provision, *supra*.

⁶⁰⁷ [B]y introducing a Bolar provision in Article 10(6) of Directive 2004/27, it was hoped that the situation would be leveled across the EU in allowing generics companies to conduct development work on drugs during their patent period. Unfortunately the wording used in the Directive means that some ambiguity remains in terms of the extent and type of such development work. In fact differences of interpretation persist between the national patent laws of UK, Germany and Poland. See Confusion Still Surrounds EU Bolar Provision, Pharmaceutical and Healthcare Newsletter, Baker & McKenzie (March 2006), at: <http://www.bakernet.com/newsletters/Article.asp?ArticleID=8298&EditionID=1213&URL=%2Fnewsletters%2Fnewsletter.asp&NLID=9>.

⁶⁰⁸ As a result of the 1984 Act, generic firms now enter the market much more rapidly after patent expiration and enter in abundant numbers.' Prior to the law, 35% of top-selling drugs had generic competitors after patent expiration; now almost all do. In addition, the time to market for these generic products has decreased substantially. *Ibid.*, at p. 31, citing Henry G. Grabowski and John M. Vernon. Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act, *Journal of Law and Economics*, (Oct.1992) at p. 334.

⁶⁰⁹ ... The portions of the legislation that have accelerated the introduction of generic products have affected the brand name firms in various ways that may or may not influence innovation in the industry. The Congressional Budget Office found that originator drugs lose more than 40% of their market, on average, to generic versions after a patent expires. This is combined with research that indicates the rate of market share decline is increasing. Studies by Grabowski and his colleagues indicate that while these brand name drugs lost more than 31% of their market share (per unit) in the year between 1989 and 1990, during the first six months of 1993, 50% of market share was lost. The larger blockbuster drugs lost up to 90% of sale revenue within one year of the expiration of the patent. *Ibid.*, at p. 32.

⁶¹⁰ ... Despite the ability of the FDA to offer market exclusivity, some experts argue that the 1984 Act ... has also significantly curtailed the expected revenues to innovative firms from the latter phases of their drug's life cycle.' According to CBO, despite this period of exclusivity, most of the average cost of drug development cannot be recouped. CBO found that the increase in generics has led to an average \$27 million (or 12%) decrease in the total return to a new drug (not including antibiotics not covered by the 1984 Act). The average market price declines even though the cost of the innovator drug increases because generics make up a larger share of the market. This

has occurred at the same time that R&D costs and time to market have increased. *Ibid.*, at p. 35, citing Henry Grabowski.

⁶¹¹ See: Mark S Cohen and Tal Frieman, Data Exclusivity in Israel, Business Briefing: Pharmagenetics 2003, at: (http://www.touchbriefings.com/pdf/15/pg031_r_cohen.pdf).

⁶¹² [T]est data must only be protected if national authorities require their submission for obtaining marketing approval of pharmaceuticals or agrochemical products... *Data voluntarily submitted by an applicant, or in excess of what is required for approval, are not subject to protection under Article 39.3* (em phasis added). See Carlos Maria Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement, *supra*, at p. 27..

⁶¹³ Based on the different meanings that different countries could ascribe to the term 'new chemical entity', it is possible that it could encompass not only new chemical molecules, but also new applications (uses) for existing molecules (second indications, etc.) that vary among different nation's regulatory frameworks.

⁶¹⁴ The categorization of test data as a subject matter of intellectual property does not mean that Article 39.3 puts their protection on the same footing as other intellectual property rights. See Carlos Maria Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement, *supra*, at p. 27.

⁶¹⁵ *Ibid.*, at p. 29.

⁶¹⁶ See Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement, United Nations Conference on Trade and Development and the International Centre for Trade and Sustainable Development, *supra*, at Chapter 28 'Undisclosed Information', at p. 521, at: (http://www.iprsonline.org/unctadictsd/docs/RB_2.28_update.pdf).

⁶¹⁷ The obligation established under Article 39.1 is limited to the protection of undisclosed information against unfair competition as provided in Article 10bis of the Paris Convention... Unfair competition rules supplements in some cases the protection of industrial property rights, such as patents and trademarks. Unlike the latter, however, the protection against unfair competition does not entail the granting of exclusive rights. National laws must only provide for remedies to be applied in cases where dishonest practices have occurred. *Ibid*; See also, Carlos María Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement, *supra*.

⁶¹⁸ Foreign direct investment (FDI) has become more important than trade for delivering goods and services to foreign markets: in 2003, the sales of foreign affiliates (US\$ 18 trillion) were twice as large as exports (US\$ 9 trillion). In addition to integrating markets, FDI also integrates production activities internationally through the corporate production systems established by transnational corporations (TNCs). Such deep integration 'constitutes, in many ways, the productive core of the globalizing world economy. See Karl P. Sauvant, *New Sources of FDI: The BRICs – Outward FDI From Brazil, Russia, India and China*, *Journal of World Investment & Trade*, vol. 6 (October 2005), pp. 639-709 at:

(http://www.cpii.columbia.edu/documents/JWIT_New_Sources_of_FDI_The_BRICs_KPS_article.pdf). Mr. Sauvant is Executive Director of the Columbia Programme on International Investment. Its website url is: (<http://www.cpii.columbia.edu/pubs>).

⁶¹⁹ See Kamal Saggi, *Trade, Foreign Direct Investment, and International Technology Transfer: A Survey*, The World Bank Development Research Group (May 2000), at p.17.

⁶²⁰ See Tim Büthe and Helen Milner, *The Politics of Foreign Direct Investment into Developing Countries: Increasing FDI through Policy Commitment via Trade Agreements and Investment Treaties?* Circulation Draft (3/24/05), at (http://polisci.ucsd.edu/calendar/ButheMilner_FDI_24mar05.pdf), at p. 2.

⁶²¹ *Ibid.*

⁶²² FDI involves the acquisition or creation of productive capacity, which implies a long-term perspective and inherently involves at least some assets that are highly specific to the location and cannot be moved in the short run without considerable loss. *Effective property rights safeguard such investments* (emphasis added). *Ibid.*, at p. 9.

Once the MNC undertakes a foreign direct investment, some bargaining power inevitably shifts to the host country, because the investment is by definition not perfectly mobile and depends upon local property rights. *Ibid.*, at p. 1.

⁶²³ [S]ince few developing countries have well established property rights regimes... [p]otential foreign investors should therefore be expected to be weary about committing significant investments to any developing countries. Although outright expropriation of foreign investments has become much less likely over time, it remains a possibility. More important, however, are the myriad mechanisms that exist for changing the terms of an investment and thus reducing its profitability and/or changing its ownership. *Governments can pose far*

more subtle threats to property rights through changes in taxation, tariffs, and fees, as well as government toleration of crime and intellectual property theft (em phasis added). *Ibid.*

⁶²⁴ *Ibid.*, at pp. 9-10. In this regard, the study found strong empirical [anecdotal] support for the centrality of property rights concerns. In a survey of its members in the late 1990s, the U.S. chamber of commerce found property rights to rank first among the factors noted by U.S. businesses as important to their allocation of investment abroad (U.S. Chamber, "12 Rules for Investors"). And this does not appear to be just an American preoccupation: In a series of interviews with German senior managers—conducted by one of us in 2000-2002, on, inter alia, the factors that make for a good investment climate in a given country, interviewees tended to distinguish first between countries where physical and intellectual property is essentially secure and countries where it is not. For the latter category, in which interviewees tended to include countries outside Western Europe and North America, measures that would enhance property rights guarantees were always the first concern (em phasis added). *Ibid.*, at p. 40.

⁶²⁵ International institutions may allow governments to make more credible commitments. Why? In our view, international institutions, while certainly not determining government behavior, affect the incentives that governments face when choosing between alternative policies by changing the relative cost of the policy choices (making some more costly than they would be in the absence of the institutions... [P]articipation in international agreements, treaties and organizations that institutionalize the country's commitment to property rights and a liberal economic policy should make this commitment more credible (em phasis added). *Ibid.*, at pp. 12 and 13.

⁶²⁶ See also Kim Sokchea, Bilateral Investment Treaties, Political Risk, and Foreign Direct Investment, International University of Japan (2006), at p. 8, at: (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=909760). The study analyzes the effects of bilateral investment treaties on foreign investment in... 10 Asian countries from 1984 to 2002... [T]his study provides evidence that BITs play a significant role in stimulating the inflows of investment... BITs can function as a credible framework to promote FDI, and countries with higher political risk seem to be better able to receive more FDI with BIT ratification. While the effects of BITs with OECD countries are not likely to depend on the quality of political condition, those of BITs with non-OECD countries might be likely to... As BITs are viewed as the commitment of a host country to provide a stable legal framework to investors, signing BITs is a signal

to not only signatory countries, but also the international business community. The result concludes that the commitment is credible even with BITs signed with non-OECD countries although conditional on BITs signed with OECD countries. Thus, a message to a developing country is that a BIT is really worth negotiating, signing, ratifying, and complying. In addition, using 2004 political risk data, the study provides evidence that an additional BIT ratified raises FDI inflows by an average of 2.3 percent in South, East, and South-East Asian nations... Lastly, the overall findings in this study add to the literature on the determinants of FDI. As shown in the empirical results, the market size, political stability, the quality of infrastructure, wage, the degree of openness, APEC membership are the important factors for stimulating FDI inflows. *Ibid.*, at pp. 30-31.

⁶²⁷ See Transnational Corporations and the Internationalization of R & D , United Nations Conference on Trade and Development (UNCTAD) World Investment Report, UNCTAD/WIR/2005 (Sept. 2005), at pp. 33-34, at: http://www.unctad.org/en/docs/wir2005_en.pdf).

⁶²⁸ [There is now] evidence on the response of U.S. multinationals to a series of well-documented IPR reforms by developing countries in the 1980s and 1990s. Our results indicate that U.S.-based MNCs expand the scale of their activities in reforming countries after IPR reform, and this effect is disproportionately strong for affiliates whose parents rely strongly on patented intellectual property as part of their global business strategy. See Lee Branstetter, Ray Fisman, Fritz Foley, and Kamal Saggi, Intellectual Property Rights, Imitation, and Foreign Direct Investment: Theory and Evidence , National Bureau of Economic Research (NBER) (Aug. 2005), at p. 1, at: <http://faculty.smu.edu/ksaggi/IPR-LEE.pdf>). A prior 1999 study had found that international trade flows consisting of knowledge-intensive or high technology products rose sharply following the enactment of intellectual property reforms by developing countries , but not as much as for manufacturing trade flows. See Carsten Fink & Carlos A. Primo Braga, How Stronger Protection of Intellectual Property Rights Affects International Trade Flows, The World Bank, Policy Research Working Paper Series 2051, (1999), at p. 2.

⁶²⁹ Each reform can be classified according to whether or not it expanded and strengthened patent rights along five dimensions. These dimensions include: 1) an expansion in the range of goods eligible for patent protection, 2) an expansion in the effective scope of patent protection, 3) an increase in the length of patent protection, 4) an improvement in the enforcement of patent rights, and 5) an

improvement in the administration of the patent system. While the 16 patent reforms are not identical, there is a surprising degree of similarity in these reforms, with 15 out of 16 exhibiting expansion of patent rights along at least 4 of the 5 dimensions described. These are the kind of substantive reforms that are likely to have a material impact on intrafirm technology transfer... See Lee Branstetter, Raymond Fisman, and Fritz Foley, Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence From U.S. Firm-Level Panel Data, National Bureau of Economic Research (NBER) Working Paper # 11516 (July 2005), at p. 14, at: (<http://weblog.ipcentral.info/IPRs%20&%20Tech%20Trans.pdf>).

⁶³⁰ *Changes in the value of licensing payments could reflect changes in the volume of technology transferred or merely changes in the price charged for that technology.* Analyzing changes in the R&D expenditures of affiliates is helpful in distinguishing between these two possibilities. *Ibid.*, at p. 6. [Prior studies reveal that]... co-location of R & D with foreign manufacturing facilitates the transfer of knowledge and prototypes from the firm's home location to actual manufacturing.' Viewed in this light, affiliate R&D and technology transfer from the parent may be considered complements. Given this complementary relationship, IPR reform should also prompt an increase in R&D spending (em phasis added). *Ibid.*, at p. 7. In addition to reporting extensive information on measures of parent and affiliate operating activity including R&D expenditures, multinationals must also report the value of royalties paid by affiliates to parents for the sale or use of intangible property. *Royalty payments are reported at the affiliate level, and they include payment for industrial products and processes, which capture technology licensing fees, as well as franchise fees, fees for the use of trademarks, and payments for other intangibles* (em phasis added). *Ibid.*, at p. 9. Section 482 of the U.S. tax code requires affiliates to make royalty payments for intrafirm technology transfer and to ascribe a value to these transfers that would be equivalent to what the firm would charge an unaffiliated party. These legal reporting requirements *meaningfully constrain the discretion the firm can exercise in reporting transfers*, as demonstrated by a number of high profile legal cases (em phasis added). See Lee Branstetter, Raymond Fisman, and Fritz Foley, Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence From U.S. Firm-Level Panel Data, National Bureau of Economic Research (NBER) Working Paper # 11516 (Jan. 2005), at p.10. *****(Presumably, this was an earlier version of the July study cited above).

⁶³¹ See Lee Branstetter, Raymond Fisman, and Fritz Foley, Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence From U.S. Firm-Level Panel Data (July study), *supra*, at pp. 1, 2 and 25.

⁶³² See Alireza Naghavi, Strategic Intellectual Property Rights Policy and North-South - Technology Transfer, Fondazione Eni Enrico Mattei, NOTA DI LAVORO 18.2005 (Jan. 2005), at pp. 1 and 21, at: (<http://www.feem.it/NR/rdonlyres/CCCC4C73-1C23-41AC-9046-A1463A39EE51/1440/1805.pdf>).

⁶³³ See Belay Seyoum, The Impact of Intellectual Property Rights on Foreign Direct Investment, citing United Nations Center for Transnational Corporations, World Investment Report (New York: UNCTC, 1993), *supra*, at 57.

⁶³⁴ *Ibid.*

⁶³⁵ See Dermot Leahy and Alireza Naghavi, Intellectual Property Rights and Entry into a Foreign Market: FDI vs. Joint Ventures, NOTA DI LAVORO 97.2006 (June 2006), at: (<http://www.feem.it/NR/rdonlyres/B1B45A6F-70BD-4B77-BEEB-928ED383851D/2051/9708.pdf>).

⁶³⁶ *Ibid.*, at pp. 31-33.

⁶³⁷ See Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment and Technology Transfer*. International Finance Corporation, Discussion Paper No. 19, The World Bank (1994), at p. vii, at: (<http://www.bvindicopi.gob.pe/colec/emansfield2.pdf>).

⁶³⁸ *Ibid.*, at p. 19.

⁶³⁹ *Ibid.*, at p. 20.

⁶⁴⁰ See Carlos A. Primo Braga and Carsten Fink, The Relationship Between Intellectual Property Rights and Foreign Direct Investment, 9 *Duke J. of Comp. & Int'l L.* 163 at 172 (Fall 1998).

⁶⁴¹ *Ibid.*

⁶⁴² *Ibid.*, at 174.

⁶⁴³ *Ibid.*, at pp. 175-176.

⁶⁴⁴ *Ibid.*, at p. 180.

⁶⁴⁵ See Kamal Saggi, Trade, Foreign Direct Investment, and International Technology Transfer: A Survey, The World Bank Development Research Group (May 2000) at p. 17.

⁶⁴⁶ *Ibid.* at pp. 37 and 39. A more recent (2004) study drew similar conclusions with respect to how developing country adoption of various levels of copyright protections impacted the FDI flows of companies operating within the U.S. feature film and video industry. See Phillip McAlman, Foreign Direct Investment and Intellectual

Property Rights: Evidence from Hollywood's Global Distribution of Movies and Videos *Journal of International Economics* 62 (2004) 107 – 123. Due to the technological characteristics of its output, the chief issue facing Hollywood studios is the internalization question (FDI or license) rather than the location question (export or produce abroad). So, the main decision that a studio has to make is whether its presence in a foreign market is most profitable in the guise of an affiliate or an agent. *Ibid.*, at p. 109. ... While Hollywood studios are likely to service a foreign market through an affiliate if the standards are either low or high, they are more likely to enter into a licensing agreement if a country offers a moderate degree of IPR protection. This pattern characterizes Hollywood's behavior in both feature film distribution and video distribution markets. *Ibid.*, at pp. 121-122). This study was notable because it examined the impact of such protections at the *firm* rather than at the aggregate industry level, which enabled it to take into account the idiosyncrasies of each industry sub-sector.

⁶⁴⁷ [I]n theory a strengthening of patent rights in developing countries could reduce or expand access to foreign technologies. The former problem would arise essentially because of enhanced market power on the part of technology developers, who could choose not to offer certain technologies or to raise access fees. It would be exacerbated by the higher cost of imitation in recipient countries. *However, stronger IPRs may be expected also to reduce the costs of reaching and enforcing contracts, while raising the returns to FDI and licensing, thereby expanding the aggregate flows of technology.* While the empirical evidence on this issue remains somewhat murky, *the preponderance of results from econometric studies suggests the impact could be large and positive in developing economies with the ability to absorb technology. In this regard, developing countries may wish to focus resources on improving their absorptive capacities through improved governance, strengthened education programs, targeted technology inducements, and competition policies.* Turning to substitution effects, standard economic theory argues that as a country's IP regime is strengthened, multinational enterprises would choose to shift away from FDI and toward licensing at the margin. Again, there is evidence to support this claim. However, we have put forward a simple model focusing on the relative impact of IPRs on reducing contracting costs in FDI and licensing. We find that the standard prediction holds only in sectors with rapid innovation rates, which presumably are higher-technology industries. In lower-technology industries it is more likely that stronger patents would induce firms to shift toward greater use of FDI and lesser use of licensing. To the

extent that lower-income developing countries hope to attract FDI in such sectors, which presumably are more important in the medium term as a means of exploiting comparative advantage in international trade, strengthened IPRs would have this additional benefit (emphasis added). See Keith E. Maskus, Kamal Saggi and Thitima Puttitanun, Patent Rights and International Technology Transfer Through Direct Investment and Licensing Revised Draft (6/28/04), at p. 23, at: (http://spot.colorado.edu/~Emaskus/papers/MSP-paper_6-04.doc).

⁶⁴⁸ My conversations with managers and researchers in China also indicate that many of the labs are developing specific technologies which are later integrated into large R&D projects for global applications... For instance, AutoMovie, a video-editing technology developed at Microsoft Research (MSR) Asia in Beijing, was later integrated into Movie Maker, a feature of the new Windows XP. Other examples at MSR Asia include the Mobile HTML Optimizer used in FrontPage and the Ink Parsing technology used in Tablet PC. See Minyuan Zhao, Conducting R & D in Countries with Weak Intellectual Property Rights Protection (July 2004), at p.1 and fn1, at: (<http://www.isnie.org/ISNIE04/Papers/zhao%20paper.pdf>).

⁶⁴⁹ *Ibid.*

⁶⁵⁰ ... [This] study directly illustrates the arbitrage framework: institutional gaps across countries can be an important source of opportunity for firms possessing the right capabilities. Just as globalization is not for every firm, neither is establishing R&D centers in China and India. To take full advantage of such opportunities, a firm must have the ability to efficiently transfer, integrate and further develop knowledge on a global basis... In the face of international competition, a firm's competitive advantage resides not only in its proprietary knowledge and resources, which may be vulnerable to imitation, but also in its dynamic organization that matches the internal resources with the external environment. See Minyuan Zhao, Conducting R & D in Countries with Weak Intellectual Property Rights Protection, at pp. 21-22.

⁶⁵¹ *Ibid.*, at pp. 1-2. MNEs are substituting internal organization for external IPR protection in countries with poor institutional environments. Firms with closely-knit internal technology structures can thereby take advantage of the underutilized human capital in weak IPR countries without exposing themselves to excessive risk. *Ibid.*, at p. 21.

⁶⁵² *Ibid.*, at pp. 2-3.

⁶⁵³ *Ibid.*, pp. 2-3, 10.

⁶⁵⁴ *Ibid.*, at p. 4.

⁶⁵⁵ *Ibid.*, at p. 12. There is no direct measure for the internalized value of technologies, but value can be proxied by usage. Technologies whose values are highly dependent on internal resources are more likely to be utilized within the firm ... Presumably, the more a patent is cited by the same firm, the more its value is being retained inside the firm boundary. Because I am more interested in the firm as an integrated organization, any citations that occur among affiliated entities are considered self-citations. *Ibid.*, at p. 13.

⁶⁵⁶ *Ibid.*, at p. 21.

⁶⁵⁷ See Transnational Corporations and the Internationalization of R & D , United Nations Conference on Trade and Development (UNCTAD) World Investment Report, UNCTAD/WIR/2005 (Sept. 2005), at p. 22, at: http://www.unctad.org/en/docs/wir2005_en.pdf).

⁶⁵⁸ Some developing countries like **Brazil**, China and India have attracted significant amounts of FDI in R&D; despite being perceived as having relatively lax IPR regimes. *There are four main reasons why IPR protection may have a limited impact on the location of TNC R&D:* [(1)] R&D may be conducted for a completely different market. For example, it has been noted that IPR issues for TNC R&D labs in China are mostly handled in the home country as these labs work on technologies aimed at world markets. Since a patent gives its assignee a monopoly on both production and sales, the TNC can protect its intellectual property by obtaining patents in the countries for which the product was developed rather than in the country where the R&D is undertaken. [(2)] A technology may be highly firm-specific and thus of limited value to others. For example, if different technologies developed by a firm are complementary to one another and can only be used jointly, a particular innovation in the host economy may have little value on its own. TNCs may structure their international R&D activities so that a foreign affiliate in a country with weak IPR protection undertakes only R&D with strong complementary elements. [(3)] TNC R&D in a host economy may deal with technologies that are too advanced for local competitors to copy and use commercially. [(4)] Certain types of technology involve tacit and uncodifiable elements that are difficult for outsiders to imitate without intimate knowledge gained by working with that specific technology (emphasis added). *Ibid.*, at p. 164.

⁶⁵⁹ The extent to which international technology flows would increase as a result of strengthening IPRs depends importantly on the state of access to technological information. Such access is determined by a variety of factors. Impediments may come from many sources in the

recipient country, including weak domestic absorption capacities, poor infrastructure, restrictions on inward technology, trade, and investment flows, and inadequate regulatory systems. In this context, strengthening intellectual property (IP) protection could play a positive and important role in mitigating the costs such factors raise for investors and thereby expanding technology flows. It should be evident from this brief description, however, that *simply strengthening IPRs alone cannot suffice to improve access significantly. Rather, the intellectual property regime needs to be buttressed by appropriate infrastructure, governance, and competition systems in order to be effective* (emphasis added). See Keith E. Maskus, Kamal Saggi and Thitima Puttitanun, Patent Rights and International Technology Transfer Through Direct Investment and Licensing, *supra*, at pp. 2-3.

⁶⁶⁰ National innovation systems are comprised of a number of different components that come together to facilitate scientific research, the creation of new technologies and the application of these technologies into an economy... The ultimate goals of any innovation system are to 1) spur technological innovation and 2) ensure that innovation is used to enhance economic growth...[T]he way an innovation system is organized can have a very significant impact upon both the rate of technological innovation and the impact such innovation has on economic growth... In most cases, innovation systems are comprised of three main components: 1) laws/policies/culture (institutional environment), 2) organizations and 3) the relationship between and among organizations and the institutional environment (linkages). See Bruce Lehman and Eric Garduño, Technology Transfer and National Innovation, Presentation at the International Conference on Technology Transfer, Intellectual Property Rights and Business Policy, Sao Paulo, Brazil (3/25/04 - 3/26/04).

⁶⁶¹ Brazil ha[s] a huge capacity to innovate. There are tremendous resources being devoted to scientific research and innovation in Brazil and much of the capacity to innovate is located in public research organizations – primarily universities and government funded laboratories and research institutes. *Unfortunately, the capacity in these organizations to add value to the Brazilian economy has largely been untapped... Most of these public research organizations have few ties with industry and conduct their research without seeking to find industrial applications of their work.* Technology transfer, in this context the establishment of a system to efficiently move the products of research from public research organizations to the private sector, could bring much needed benefit to Brazil's ability to adopt, adapt and create innovative products and services which can be used in industrial

application and thereby benefit the Brazilian economy (emphasis added). See Bruce Lehman and Eric Garduño, *Technology Transfer and National Innovation*, *supra*..

⁶⁶² Brazil lacks both an effective patent system and sufficient local experts knowledgeable in how to obtain, enforce, and license rights in important markets such as the United States and Europe. As was recently reported in *The Washington Post*, Brazilian scientists at the University of So Paulo were successful in decoding the genome of a grape-killing pest that had threatened California's \$2.7 billion wine industry. California vintners welcomed the discovery and persuaded the U.S. and state departments of agriculture to support the Brazilian research. Unfortunately, the funding agreement with the University of So Paulo provided that there would be no patents on this research. The result: Brazilian science will get nothing except good press, when it might otherwise have been compensated by the very markets that could and should have paid for its discoveries. If the University of So Paulo were located in the United States, the outcome might have been very different. In the United States, research conducted at universities funded by government dollars is automatically reviewed for patenting. If the research had taken place, for example, at the University of California, the innovations would have been patented and the resulting royalties would have been added to the \$250 million a year in patent licensing income the university already receives. With technical assistance in designing and implementing a comparable IP mechanism, Brazil could open its doors to a whole new source of national wealth stemming from research efforts.

See Bruce Lehman, *Key Report Sends Developing Countries a Distorted Message on IP Rights*, *Legal Times* (11/25/02), reproduced at: <http://lists.essential.org/pipermail/ip-health/2002-November/003763.html>).

⁶⁶³ Many experts believe that the current Brazilian patent system is broken'. Since 1999, all patent applications for pharmaceutical products or processes must be analyzed first by ANVISA (the National Agency of Sanitary Surveillance), which must give its *prior consent* before INPI issues a patent. Since *prior consent* was not initially defined, some misunderstandings between ANVISA and INPI arose in the past, resulting in further delays. To help solve this issue, during the patent application for any pharmaceutical product or process, the two organizations agreed that ANVISA would give consent before INPI issues its final decision... Currently [however], Brazil's patent office, the National Institute for Industrial Property (INPI), has amassed a backlog of more than 120,000 patent applications and an estimated

580,000 trademark applications. Some specialists estimate that the patent application backlog will reach approximately 155,000 by the end of 2005. *See* Statistics and Developments on the Intellectual Property Right situation in Brazil, U.S. Commercial Service – Market Research Report – Brazil (12/20/05). *See also* U.S. Speaker [Bruce Lehman] Cites Benefits of IPR, Embassy of the United States, Brasilia, Brazil (3/24/04) at: (<http://www.embaixada-americana.org.br/index.php?action=materia&id=2316&submenu=1&itemmenu=10>).

⁶⁶⁴ The eminent point is the conclusion of the revision of the Industrial Property Code (Law No. 5.772 of December 21, 1971) which, after passionate debate and intense dispute between Brazil and the United States regarding the question of pharmaceutical patents, resulted in the new Law No. 9.279 of May 14, 1996. The new Law follows the precepts of the Trade-Related Aspects of Intellectual Property Rights Including Counterfeit Goods (TRIPS) and, on the contrary to the former Code, does not incorporate anymore the character of not-patentable of substances, material, blends or food products, chemical pharmaceutical products and medicines of any kind, as well as the respective processes for their obtainment or modification. Other highly relevant measures were the approval of the Law for the Protection of Cultivars, Copyright Law and Computer Software Law. The trade-related agreements resulting from the Uruguay Round Agreements Act (GATT) were incorporated to the Brazilian legislation through decree No. 1.355, of December 30, 1994. Among those agreements, the TRIPS Agreement deserves to be especially emphasized. *See* Claudia Ines Chamás, Management of Intangible Assets at Brazilian Universities, Paper Presented at the DRUID Summer Conference on Industrial Dynamics of the New and Old Economy - Who is Embracing Whom?, Copenhagen/Elsinore (June 6-8, 2002), at pp. 5-6, at: (<http://www.druid.dk/conferences/summer2002/Papers/CHAMAS.pdf>).

⁶⁶⁵ Prior to the present law for industrial property, (law n. 9.279, passed in 1996 and in effect since May, 1997), Brazil had already reformulated its legislation concerning the subject, instituting the Industrial Property Code, through Law n. 5.772 of 21 December, 1971. This Code prohibited the patenting of chemical products; food and chemical-pharmaceutical products or processes and species of micro organisms. Due to clause 27 of the TRIPs Agreement, the new Industrial Property Law of 1996 started to recognise these fields as patentable matter, having, however, opted for a *sui generis* protection –

Plant Variety Protection – for plants. The new Brazilian legislation thus adopted the minimum levels of protection stipulated in the TRIPs Agreement. Further relating to the TRIPs Agreement, Brazil introduced a new legislation for Author's Rights (Authorship Rights Law (Law n. 9610/98), Computer Programs (Law n. 9.609 of 1998) and Plant Variety Protection Law (Law n. 9.456 of 1997). See Claudia Inês Chamas, Andreia Azevedo, Sergio Salles-Filho, Sérgio Paulino de Carvalho, The Dynamics of Intellectual Protection for Biotechnology in Brazil (April 2005) at p. 2, Presented as part of the 'IPR, Industrial Dynamics & Markets for Knowledge Segment' of the Triple Helix 5 Conference on the Capitalization of Knowledge: Cognitive, Economic, Social & Cultural Aspects (5/19/05), at: http://www.triplehelix5.com/pdf/A196_THC5.pdf).

⁶⁶⁶ See Comments Made by Roberto Jaguaribe, of the Brazilian Ministério do Desenvolvimento, Indústria e Comércio Exterior, at Session Three: Inter-Ministerial Working Group on IP (G IPI), of the Third Meeting of the Commission on Intellectual Property Rights, Innovation and Public Health, Commission on Intellectual Property Rights, Innovation and Health, World Health Organization, Brazil (1/31/05-2/4/05), at: <http://www.who.int/intellectualproperty/events/meeting3/en/index1.html>).

⁶⁶⁷ See Comments Made by Claudia Chamas, at the Third Meeting of the Commission on Intellectual Property Rights, Innovation and Public Health, Commission on Intellectual Property Rights, Innovation and Health, World Health Organization, at *supra*.

⁶⁶⁸ See Paulo Buss and Trindade Lima, The Oswaldo Cruz Foundation: 100 Years, at: <http://www.who.int/tdr/publications/tdrnews/news65/oswaldo-cruz.htm>).

⁶⁶⁹ See Claudia Ines Chamas, Management of Intangible Assets at Brazilian Universities, at p. 8, *supra*.

⁶⁷⁰ See Comments made by Geraldo Barbosa, Jr., president of the Brazilian unit of Becton Dickinson & Co., (the world's largest manufacturer of hypodermic syringes), at the Third Meeting of the Commission on Intellectual Property Rights, Innovation and Public Health, Commission on Intellectual Property Rights, Innovation and Health, World Health Organization, at *supra*. The problem... [can be]... described as... poorly drafted language in the 1996 patent law which has gone on to hinder efforts by Fiocruz in this area. Furthermore... Dr. Barbosa stated that 95% of patents were not useful

when it comes to technology transfer and over the past 35 years only seven technology transfers have been successfully concluded. *Ibid.*

⁶⁷¹ See Arthur Vasconcellos, Amcham Brazil's Position on the Importance of Industrial Property Protection in Brazil (July 2005).

⁶⁷² The very poor operational conditions and the lack of qualified personnel at the INPI also contribute to the limited use of the industrial property system in Brazil. The Institute is currently undergoing a process for restructuring the organization, which has demonstrated great difficulty in analysing and granting patents in any reasonable time. See Claudia Ines Chamas, Developing Innovative Capacity in Brazil To Meet Health Needs, pp. 75-111, at p. 95, in Sibongile Pefile, Zezhong Li, Wan Ke Chen Guang, Claudia Chamas, and Hiro Bhojwani, Innovation in Developing Countries to Meet Health Needs – Experiences of China, Brazil, South Africa and India, *supra*.

⁶⁷³ ... We praise the INPI's recent advances of hiring examiners in 2004 and the available budget resources required for the improvement of the INPI. We are sure that the solution of problems currently faced by the INPI will certainly represent a strong encouragement to innovation and investments in the country. This will result in job creation, increase in tax collection, greater technological qualification and dissemination of knowledge, creating a virtuous cycle that will contribute to increase Brazil's competitiveness and raise the country's human development level. *Ibid.* Yet, this problem is likely to take considerable time to reverse. According to the report, as of July 2005, there was a backlog of 580,000 trademarks and 120,000 patents, with a respective approval time of 10 and 12 years, respectively. *Ibid.*

⁶⁷⁴ In compliance with its mission to contribute constructively with public policies, Amcham Brazil offers its reflections: (i) Backlog reduction – Intellectual property protection requires greater agility from the INPI in the examination of trademark and patent processes, which may be achieved by means of: a) Regulation of internal analysis processes; b) Development of resolution on deadlines by instituting administrative silence; Previous examination, with urgent review, of those patents already approved in European and American Patent and Trademark offices; and c) Definition of the criteria used for the analysis of accumulated applications. (ii) Human Resources Improvement: a) Hiring 450 new employees already requested by the MDIC (Ministry of Development, Industry and Foreign Trade); and b) Balancing job and salary plan with other efficient federal agencies. (iii) Financial and administrative autonomy: a) transforming the INPI into a Patent and Trademark Regulatory Agency. *Ibid.*

⁶⁷⁵ Mr. Evandro S. Didonet, Minister Counselor and Deputy Chief of Mission, Embassy of Brazil (Wash. DC), recently confirmed that INPI had hired approximately 400 new examiners to address the substantial patent backlog in Brazil. Mr. Didonet made this comment as a recent panel participant in Washington, DC on February 8, 2006 – IP in the Balance: The State of American Intellectual Property Policy’, co-sponsored by USA for Innovation and Technet.

⁶⁷⁶ See Claudia Ines Chamas, Developing Innovative Capacity in Brazil To Meet Health Needs, pp. 75-111, at p. 93, in Sibongile Pefile, Zezhong Li, Wan Ke Chen Guang, Claudia Chamas, and Hiro Bhojwani, Innovation in Developing Countries to Meet Health Needs – Experiences of China, Brazil, South Africa and India, *supra*.

⁶⁷⁷ In the two last decades, Brazil went up from 27th to 18th place in the world ranking for science and technology. There were 1.887 articles published in periodicals indexed by the Institute for Scientific Information (ISI) in 1981, which corresponds to 0.44% of the world output; but by 2001, this number had risen to 10.555 articles, or, 1.44% of the world total. The number of articles in the medical and biomedical areas has increased and represents 40% of world and 36% of Brazilian production. In Brazil, medical research with a production of 7.365 articles in the period from 1997-2001 (0.9% in this area worldwide) occupies 23rd place in the world ranking and third in the internal ranking, which represents 16.9% of the total articles indexed for the country on the basis of the ISI Standard. The biomedical area showed slightly higher production than the medical area, with 8.366 articles for this period (0.9% in this area worldwide). With this output Brazil takes 21st place in the world ranking for this area and second place internally, representing 19.0% of all the country’s articles indexed on the basis of the ISI Deluxe. In opposition to the increase of scientific publications, Brazilian participation in world patent grants (0.2%) remains very low and reinforces the necessity of developing specific incentive programs for technological research. See Claudia Inês Chamas, Andreia Azevedo, Sergio Salles-Filho, Sérgio Paulino de Carvalho, The Dynamics of Intellectual Protection for Biotechnology in Brazil (April 2005), *supra* at pp. 6-7.

⁶⁷⁸ Implementing the IPR policy within EM BRAPA has been a major challenge. The new legal background requires a dramatic change in the management of the Corporations human resources. There are new opportunities and chances to stimulate scientific production through the distribution of royalties derived from proprietary technology. The new legislation, however, interferes with researchers’ deeply rooted behavioral values, such as their need to publish and make readily

available all research results. Keeping visitors away from laboratories and caring about the confidentiality of some sets of data have caused tremendous changes in the daily routine of researchers. A few scientists have easily jumped on the new bandwagon, but for most, it will be some time before they can fully adjust. See Maria Jose Amstalden Sam paio, Perspectives From National Systems and Universities, Chapter 4, in Intellectual Property Rights in Agriculture – The World Bank’s Role in Assisting Borrower and Member Countries, Uma Lele, William Lesser, and Gesa Horstkotte-Wessler, eds., The World Bank (1999), pp. 44-51, at p. 49, at: (<http://www.bvindexcopi.gob.pe/colec/ufile.pdf>).

⁶⁷⁹ ... Brazilian health biotechnology has not been as successful as it should have been, especially in transferring scientific knowledge into products...A major contributor to this problem is the lack of linkages among biotechnology firms. As one respondent noted, There is no coordination among enterprises. They are more worried about their own problems than about trying to generate some kind of synergy that could develop business everywhere.’ Cooperation between firms and the actors most active in health biotechnology research, such as the universities and research institutes, has also been limited. These actors generally lack mutual understanding, do not trust each other and operate in very different cultural environments. Consequently, the considerable research capacity within the public research system in health biotechnology is not exploited to its full potential by the industrial sector. See Marcela Ferrer, Halla Thorsteinsdóttir, Uyen Quach, Peter A Singer & Abdallah S Daar, The Scientific Muscle of Brazil’s Health Biotechnology, Commentary, Nature Biotechnology, Vol. 22, Supp. (Dec. 2004), at p. DC-11, at: (<http://www.utoronto.ca/jcb/home/documents/Brazil.pdf>).

⁶⁸⁰ On [the] federal level, one notes an increase in the percentage of investments in research and development through the implementation of Sectorial Funds for the support of technological development that will allow financing strategic projects and sectors in Brazil. The funds will come in part from royalties, in part from taxes charged from privatised companies and some special sectors. The first of these funds, destined to the oil and gas sector, began to operate in 2000... The resources are independent from the federal budget. According to the Ministry of Science and Technology, the Sectorial Funds are not only aimed to increment the funds destined to R & D but to mobilise intensely the chain of production, knowledge and technological innovation, creating goods and services for the wellbeing of the Brazilian population... Today the country spends 1,4% of its gross

domestic product in science and technology. The goal is to achieve 2% in 2005. In Brazil, 70% of resources for research come from the government and the rest from the private enterprise. See Claudia Ines Cham as, Management of Intangible Assets at Brazilian Universities , at p. 12.

⁶⁸¹ Pursuant to ... the capitalist economic model... [technological innovation is promoted and linked to economic growth]... by ensuring technological innovation makes its way into economic production – or in other words, innovation must be adopted by private firms and built into either their means of producing products and services, or are built into the products and services themselves. See Bruce Lehman and Eric G arduño, Technology Transfer and National Innovation , *supra*.

⁶⁸² See Maria José Amstalden Sampaio, Brazil: Biotechnology and Agriculture to Meet the Challenges of Increased Food Production , in Persley, G. J. and Lantin, M. M. (eds.), Presented at Agricultural Biotechnology and the Poor', An International Conference on Biotechnology, Consultative Group on International Agricultural Research - The World Bank (2000), pp. 76-79, at pp. 76-77, at: (<http://www.cgiar.org/biotech/rep0100/Sampaio.pdf>).

⁶⁸³ Brazilian biotechnology became basically restrict[ed] to the Empresa Brasileira de Pesquisa Agropecuária (Embrapa) and the Fundação Oswaldo Cruz (Fiocruz), institutions that act, respectively, on the agricultural area and human health, supported mainly by *public* financing. See Maria G. Derengowski Fonseca, José Maria da Silveira and Sérgio Salles-Filho, Recent Biotechnology Development: Challenges and Opportunities to the Consolidation of its Knowledge "Building Blocks" (©2000), at p. 10, at: (<http://in3.dem.ist.utl.pt/downloads/cur2000/papers/S22P03.PDF>).

⁶⁸⁴ *Until the mid-1990s, Brazil did not allow patenting of pharmaceutical or biopharmaceutical products.* This restriction discouraged industrial development in health biotechnology and *promoted the copying of innovations from other countries* (emphasis added). See Marcela Ferrer, Halla Thorsteinsdóttir, Uyen Quach, Peter A Singer & Abdallah S. Daar, The Scientific Muscle of Brazil's Health Biotechnology , *supra*, at DC-11.

⁶⁸⁵ See Maria Jose Amstalden Sampaio, Perspectives From National Systems and Universities , Chapter 4, in Intellectual Property Rights in Agriculture – The World Bank's Role in Assisting Borrower and Member Countries , *supra*, at p. 46. EM BRAPA determined some years ago that advanced biotechnology and the development of transgenic crops, microorganisms, and even domestic animals, would play a central role in its goal of providing for increased sustainability

and competitiveness of agriculture/agribusiness in Brazil. This would, in turn, contribute to the country's development and poverty alleviation. *The increasing use of proprietary technology in agricultural R&D requires careful case-by-case analysis. Although responding to the new IPR scenario, EMBRAPA continues to study and produce non-proprietary technologies that will be transferred to farmers and other clients without constraint. In fact, most of EMBRAPA's technologies fall into this category. **Maintaining trade secrets in agriculture is inappropriate in most cases**, because major research projects are not impacted by the IPR ruling... (em phasis added). *Ibid.*, at p. 49.*

⁶⁸⁶ See Comments Made by Roberto Jaguaribe, of the Brazilian Ministério do Desenvolvimento, Indústria e Comércio Exterior, at Session Three: Inter-Ministerial Working Group on IP (GIPD), of the Third Meeting of the Commission on Intellectual Property Rights, Innovation and Public Health, *supra*.

⁶⁸⁷ See Marcela Ferrer, Halla Thorsteinsdóttir, Uyen Quach, Peter A Singer & Abdallah S Daar, The Scientific Muscle of Brazil's Health Biotechnology, *supra*, at p. DC-10.

⁶⁸⁸ The debate around use of public resources for research, obviously not only of interest for the public sector but also for the industry and the service sector, is taking place late in Brazil. This is for sure a consequence of the development pattern adopted by the country in the course of the last five decades. However, the question must be examined at this very moment, when the Brazilian industry needs to make use of research and technology to conquer and maintain positions at highly competitive markets. It is necessary to create a[] favourable atmosphere for innovation, so that companies invest more in research and

development and universities and research institutions contribute to this process through the training of personnel and research of interest for the society. See Claudia Ines Chamás, Management of Intangible Assets at Brazilian Universities, at p. 22.

⁶⁸⁹ See Brazil's New Beat: Social Challenges, Economic Progress: The Two Faces of Intellectual Property in Brazil, *Knowledge @ Wharton* at:

(<http://knowledge.wharton.upenn.edu/index.cfm?fa=viewArticle&id=1339&specialId=42>).

⁶⁹⁰ Back during 2000, for example, Bill 3,533/2000 [was] under analysis at the Brazilian National Congress.

The Bill create[d] a summary approval processes, but also contain[ed] a period of exclusivity for the undisclosed data of five or two years,

depending on whether the product include[d] new chemical or biological entities' or not. The protection period [was] provided from the grant of the registration or from the date of the first disclosure of the data anywhere (whichever occurs first). During the protection period, the authority shall not use the undisclosed data in connection with third parties' applications for marketing approval, except when authorized by the originator of the data. *See Baker & McKenzie, LLP, Data exclusivity protection in Latin America*, *Managing Intellectual Property, Supplement - Patent Yearbook 2001*, at: (<http://managingip.com/?Page=17&ISS=12699&SID=473117>).

⁶⁹¹ *See* Law No. 10.603 (17.12.02). The Law protects against the unfair commercial use of results of tests or data presented to the competent authorities by companies when they are seeking to obtain approval for the commercialization of pharmaceutical veterinary products, fertilizers, and other similar products. The information protected by the law is only that which is the product of elaborate investigation and effort on behalf of the company and that has commercial value only if it is not made public. The authorities are prohibited from using the results of tests presented by companies in favor of third parties and from making public the results of tests provided by companies, except when such publicity is necessary to protect the public. The protection extends: (a) in the case of products that use new chemical or biological products, for ten years from the granting of the registration, or until the first public release of the information in any country, whichever happens first and provided that a minimum of one year of protection is guaranteed, or (b) in the case of products that do not use new chemical or biological products, for five years. A new chemical or biological entity is any molecule or organism not yet registered in Brazil, which may be analogous or homologous to another entity, without regards to its purpose or use. *See Intellectual Property - Brazil: Protection of Confidential Information*, *Inter-American Trade Report Vol. 10, No. 1 (Jan. 2003)*, at p. 14, at: (<http://www.natlaw.com/bulletin/2003/0301/trene03.pdf>). *See also* Bruno Falcone, *Patents - Exclusive Commercialization Rights*, *Dannemann Siemsen News No. 009 (June 2005)* at pp. at: (http://www.dannemann.com.br/files/dsnews_200506_en.pdf).

⁶⁹² *See* Special 301 Priority Watch List Office of the United States Trade Representative (5/3/04), at: (http://www.ustr.gov/Document_Library/Reports_Publications/2004/2004_Special_301/Special_301_Priority_Watch_List.html).

⁶⁹³ *See* Maria Auxiliadora Oliveira, Gabriela Costa Chaves & Ruth Epsztejn, *Chapter 8: Brazilian Intellectual Property Legislation*,

Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health, WHO/PAHO Collaborating Center for Pharmaceutical Policies, National School of Public Health Sergio Arouca, Oswaldo Cruz Foundation, [Jorge Bermudez](#) and [Maria Auxiliadora Oliveira](#), Eds., *supra*, at pp. 157-58.

⁶⁹⁴ See [Claudia Ines Chamas](#), Developing Innovative Capacity in Brazil To Meet Health Needs, pp. 75-111, at p. 80, in [Sibongile Pefile](#), [Zezhong Li](#), [Wan Ke Chen](#) [Guang](#), [Claudia Chamas](#), and [Hiro Bhojwani](#), Innovation in Developing Countries to Meet Health Needs – Experiences of China, Brazil, South Africa and India, *supra*.

⁶⁹⁵ *Ibid.*, at p. 105.

⁶⁹⁶ HIV vaccine researchers really have to learn to crawl and walk at the same time. We need to understand more about the basic science of HIV/AIDS to produce a vaccine, but we do not have the luxury of time. *Because HIV/AIDS is a global emergency and a complex problem we have to try unorthodox solutions. We could argue endlessly about which of the different strategies currently underway in HIV vaccine research will work or not, but no one knows for sure. The difficulty is in how to move forward quickly with multiple approaches, knowing that we cannot wait for the results of one trial before starting the next...* There are groups such as the Global Vaccine Enterprise, with which I have been peripherally involved, who are trying to coordinate initiatives to ensure minimal overlap and repetition. But as well as coordination, there needs to be healthy competition, because researchers are only human, and like to compete... *In Brazil... [a]lthough the availability of free treatment makes some people more complacent about taking risks it does not hamper enthusiasm for vaccine development... The main factor limiting research in most developing countries is personnel.* At our research centre we have developed a system that has enabled us to grow steadily over the last few years... One of our biggest challenges is identifying young individuals who want to do research. Because Brazil has no real tradition of research, people do not know or think about it. *Research is not part of our culture, and there's only a small market for it.* To tackle this we have established a close relationship with various schools at the Federal University of Rio de Janeiro and we're trying to recruit fresh nurses, pharmacists and physicians from them... *The issue of intellectual property rights is a major area of contention – they can be used either to inhibit or motivate development. Creating incentives for development is a trick that so far, on a small scale, the International AIDS Vaccine Initiative (IAVI) has mastered quite well by funding vaccine development on the condition that resulting vaccines would be*

made available in the developing world at a 'reasonable price'. But on a larger scale, the world has to reconcile the need for financial rewards – which motivate companies to make new products – with the rights of people to be treated with whatever drugs and vaccines exist (emphasis added). See Mauro Schechter Vaccine Research Needs to Cover All Bases, Science and Development Network Opinions (7/20/05), at: <http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierReadItem&type=3&itemid=412&language=1&dossier=22&CFID=2371531&CFTOKEN=46442459>).

⁶⁹⁷ The Portuguese version of Law 10,973 is accessible at:

http://www.presidencia.gov.br/ccivil/_Ato2004-2006/2004/Lei/L10.973.htm).

⁶⁹⁸ A rough English translation of the law is set forth as an attachment to this white paper.

⁶⁹⁹ See Maria Beatriz Amorim Páscoa, In Search of an Innovative Environment – The new Brazilian Innovation Law (2004), at: http://www.wipo.org/sme/en/documents/brazil_innovation.htm).

⁷⁰⁰ The Technological Innovation Law is based on three axes: the constitution of a proper environment for strategic partnerships among universities, technological institutes and private companies; to stimulate the participation of science and technology institutions in the process of innovation; and the incentive to innovation within the companies. See Innovation Law Approaches Research Centers to Companies, <http://www.inmetro.gov.br/english/news/abdi.asp>).

⁷⁰¹ See Chap. I., Art. 2 V. STIs are the agen[ts] or entit[ies] of the public administration [i.e., of the national Government of Brazil, and of the governments of the Brazilian States, the Federal District and the Cities of Brazil]. See also Chap. II, Art. 3.

⁷⁰² See Chap. II, Of the Stimulation to the Environment – Construction of Specialized and Cooperative of Innovation, Brazil Technical Innovation Law.

⁷⁰³ See Chap. III, Of the Stimulation to the Participation of the ICT [Public Scientific and Technological Institution] in the Innovation Process, Brazil Technical Innovation Law.

⁷⁰⁴ See Chap. IV, Of the Stimulation to the Innovation in the Companies Brazil Technical Innovation Law.

⁷⁰⁵ See Chap. II, Art. 4;

⁷⁰⁶ See Chap. III, Art. 8. [T]he bill aims to: 1[)] Encourage the public and private sectors to share staff, funding and facilities such as laboratories... In addition, the Law allows STIs to negotiate the use of their laboratories with SMEs. This possibility will certainly facilitate

higher degrees of R&D among small companies that otherwise would not have the conditions (equipment, tools, lab materials, etc.) to develop and implement innovative projects. See Maria Beatriz Amorim Páscoa, In Search of an Innovative Environment – The New Brazilian Innovation Law, *supra*.

⁷⁰⁷ See Chap. IV, Art. 20. The bill also Allow[s] funding by private companies to public institutions to carry out research on their behalf. See Maria Beatriz Amorim Páscoa, In Search of an Innovative Environment – The New Brazilian Innovation Law, *supra*.

⁷⁰⁸ See Chap. III, Art. 6, Secs. 1-5. Section 5 seems to provide STIs with the authority to grant only *non-exclusive* licenses if it is in the *public interest* to do so. See also Maria Beatriz Amorim Páscoa, In Search of an Innovative Environment – The New Brazilian Innovation Law, *supra*. With this new regulation, STIs are able to accelerate the process of licensing and selecting the best partners. In addition, the Law allows STIs to negotiate the use of their laboratories with SMEs. This possibility will certainly facilitate higher degrees of R&D among small companies that otherwise would not have the conditions (equipment, tools, lab materials, etc.) to develop and implement innovative projects. *Ibid*.

⁷⁰⁹ See Chap. III, Art. 9.

⁷¹⁰ See Chap. III, Arts. 9 and 10.

⁷¹¹ See Chap. III, Arts. 14-15. For the first time, researchers will be paid for the time they work on these partnerships. See Fernanda Veneu, Brazil Adopts Innovation Law (12/20/04), SciDev.Net at: (<http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=1809&language=1>).

⁷¹² See Chap. III., Arts. 16-17. See also, See Maria Beatriz Amorim Páscoa, In Search of an Innovative Environment – The new Brazilian Innovation Law, *supra*.

⁷¹³ See Chap. V., Art. 22. See also, Maria Beatriz Amorim Páscoa, In Search of an Innovative Environment – The new Brazilian Innovation Law, *supra*.

⁷¹⁴ See Chap. I, Art. 2 I.

⁷¹⁵ See Chap. IV, Art. 19.

⁷¹⁶ See Chap. IV, Art. 21. Chapter IV of the Innovation Law ... makes it possible for public funding agencies to transfer *non-refundable resources* to private companies, which is currently prohibited. It is worth noting that *the allocation of public funds is contingent upon the firm investing a determined amount of its own resources in the research project...* In addition, there is a special requirement for funding agencies to promote specific programs to stimulate innovative

projects in micro and small enterprises (emphasis added). Maria Beatriz Amorim Páscoa, *In Search of an Innovative Environment – The New Brazilian Innovation Law*, *supra*.

⁷¹⁷ See Chap. III, Art. 6 Sec. 7, which provides the STIs with the right to use or exploit innovative creations developed through the R&D collaborations on a royalty-free basis. See also Chap. III, Art. 12, which cedes full authority to the STIs to control, and perhaps, prohibit, any and all disclosures of knowledge acquired from R&D collaborations, even in the form of IPR filings.

⁷¹⁸ See Chap. III, Art. 13, which guarantees STIs, at the very minimum, a creative minimum participation of 5% and principle of 1/3 in the economic profits gained [as a result of] licensing and technology transfers [that yield commercial products or processes]. Even the WHO recognizes that, drug discovery and development is a complex, lengthy, and costly activity. Widely quoted figures for a sample of medicines produced by the industry suggest that the average cost of developing a new drug is US\$ 800 million, or even much more. These figures... include the cost of success and failure, and the cost of capital. See Public Health, Innovation and Intellectual Property Rights, Report on the Commission on Intellectual Property Rights, Innovation and Public Health World Health Organization, *supra*, at p. 30.

⁷¹⁹ See Chap. III., Arts. 6, 9, 15-16.

⁷²⁰ See Chap. V, Art. 22, Sec. 3, which provides that the independent inventor will commit itself by means of contract, to share the gained economic profits with the industrial exploration of the protect[ed] [patented] invention.

⁷²¹ The legal right of ‘copyright’ is referred to in the following provisions: Chap. II, Art. 5; Chap. III, Art. 9, Secs. 2-3, Art. 13, Sec. 2, Art. 16 VI, Art. 17 I and Art. 18. The legal right of patent is referred to only once in the statute. See Chap. V, Art. 22, chapeau. Does this suggest an unstated Brazilian government preference for the use of copyrights, which provide less IPR protection than patents, to promote science and technology innovations?

⁷²² See Claudia Ines Chamás, *Management of Intangible Assets at Brazilian Universities*, *supra* at p. 9. [T]echnology transfer is meant to harness already existing scientific research being conducted in public research organizations. As such, there must first be strong research universities and government laboratories to draw from and these organizations must already be well funded to conduct their research. See Bruce Lehman and Eric Garduño, *Technology Transfer and National Innovation*, *supra*.

⁷²³ Due to the approval in November 2003 of the new Industrial, Technological and Foreign Trade Policy, this is an opportune political moment for building a favourable environment for research, technology and high risk business. The Policy sees biotechnology and the pharmaceutical industry as priorities. Amongst the strategies that may be adopted, we can cite: (i) better liaison between the investment policies and those for research and innovation in health; (ii) development of the capital market with attention to the technologically-based companies; (iii) an objective regulatory legal goal, with the definition of simple and facilitating rules that allow the integration of research, production and market; (iv) incentive for local business cultural changes, with emphasis on long-term investment in technology; (v) emphasis on the diffusion of entrepreneurship; (vi) better coordination of commercial, technological and health policies together with state purchasing power; (vii) modernization and expansion of the public and private laboratories, (viii) development of strategies for increasing corporate R&D; (ix) selection of niches for investment (vaccines, biopharmaceuticals, phytopharmaceuticals, pharminochemicals, generic medicines, neglected diseases, etc.); and (x) improvement of conditions for long-term funding. See Sibongile Pefile, Zezhong Li, Wan Ke Chen Guang, Claudia Chamas, and Hiro Bhojwani, *Innovation in Developing Countries to Meet Health Needs – Experiences of China, Brazil, South Africa and India*, supra, at p. 105.

⁷²⁴ *Chile already fulfils a number of framework conditions to boost innovation activity. Macroeconomic performance has been strong, with stable inflation and low real interest rates. FDI legislation is relatively investor-friendly. Product market regulations are reasonably pro-competition. Chile's liberal trade regime also facilitates access to foreign technology embedded in imported capital goods and inputs, which are important conduits for the diffusion of technology. Nevertheless, Chile's innovation performance leaves much to be desired by OECD standards, and even in relation to countries with comparable levels of income. The paper argues that the level of R&D spending is low and heavily reliant on government funds, owing in part to the fact that risk and venture capital markets are relatively underdeveloped in Chile. At the same time, innovation policy is formulated and implemented in a fragmented manner, which is not conducive to longer-term, strategic planning. Skilled workers and researchers are also in short supply (emphasis added). See José-Miguel Benavente, Luiz de Mello and Nanno Mulder, *Fostering Innovation in Chile*, *Organization for Economic Cooperation and**

Development (OECD) Economics Department, Working Papers No. 454 ECO/WKP (2005) 41 (10/27/05), at p. 4.

⁷²⁵ See Maria Beatriz Amorim Páscoa, In Search of an Innovative Environment – The new Brazilian Innovation Law, *supra*.

⁷²⁶ As of 1999, The Brazilian public [had] little understanding of the importance of IPR, and as a consequence, [was] not yet organized to deal with it. Actions urgently needed in Brazil, many of which would benefit from the assistance of the World Bank would include... See Maria Jose Amstalden Sampaio, Perspectives From National Systems and Universities, Chapter 4, in Intellectual Property Rights in Agriculture – The World Bank's Role in Assisting Borrower and Member Countries, at p. 50.

⁷²⁷ Paulo Skaf, president of the São Paulo Industries Federation, told the *Gazeta Mercantil* that the project represents a solid guarantee for Brazilian industry. This is an important step to participate competitively on the international market,' he said... The executive director of the National Association of Innovative Enterprises in Research and Development, Ovídio Ávila... [believes] the industrial sector would only be satisfied once they knew the details of [how] the law will be implemented. See Fernanda Veneu, Brazil Adopts Innovation Law, *supra*.

⁷²⁸ Since the passage of the Brazil's patent law in 1996, the pharmaceutical industry invested more than \$2.1 billion leading to the creation of jobs, increased tax revenues, increased exports and strengthened GDP. A recent KPMG study indicates significant increases in fixed assets (351%), R&D investments (474%), employment (35% or 6,131 jobs), taxes (152%), and revenues from exports (1,359%) in the period 1996-2000.

See Data Exclusivity – A Competitive Advantage in Biosciences Environment, Pharmaceutical Association of Malaysia (PHAMA) (2005), at pp.5-6, at: http://www.phama.org.my/pdf_document/DATA%20EXCLUSIVITY.pdf.

⁷²⁹ The Brazilian innovation system, at its best, has traditionally been like the German system with respect to the investment into university education and public research laboratories. However, Brazilian government protection of local firms from international competition from trade and investment, an ISI [import substitution innovation] strategy common in the developing world in the post-war era, and Brazilian firm strategic focus on the internal market has prevented Brazilian innovative capabilities to meet the innovation experiences of Korea and Taiwan. The Brazilian reforms of recent years... are shifting

their national innovation system toward an American model: Subsidize research; *provide intellectual property rights incentives*; encourage public-private cooperation toward technology commercialization (emphasis added).⁷²⁹ See Michael P. Ryan, *Brazil's Quiet Bio-Medical Innovation Revolution: Drugs, Patents and the 10/90 Health Research Gap*, Creative and Innovative Economic Center (Feb. 2006), at pp 15-16, at: (http://www.law.gwu.edu/NR/rdonlyres/A4C5FD97-7A82-4793-BEE9-A9ADA1EFB117/0/CIEC_Brazil_study.pdf).

⁷³⁰ *Ibid.*, at p. 11.

⁷³¹ *Ibid.*, at pp. 11-12.

⁷³² After several decades of implementation of regional policies, France seems to be reaping the benefits of its efforts to promote a more balanced distribution of population and activities throughout the country. Western and southern regions are catching up, several large cities are now developing more rapidly than the capital region and many rural areas are showing signs of vitality. Nevertheless, this new balance remains fragile, *with many regions lagging in terms of competitiveness, reflected by their inability to put to full use their manpower, entrepreneurial capacities and potential for firm co-operation*. The main goal of the [French] government's regional policies is now to strengthen economic performance in regions...[T]he priority is on innovation and engaging new markets. This strategy, underpinned by the poles of competitiveness programme launched in 2004, should pay off *provided that the government avoids building complex assistance systems and a multitude of support measures* (emphasis added). See OECD Territorial Reviews – France, OECD Publishing (2006), at: (http://www.oecdbookshop.org/oecd/print_results.asp?lang=EN&pge=forthcoming&SF1=VersionCode&ST1=P&SF2=AvailabilityCode&ST2=50,%2055&PL=50).

⁷³³ France's attempts to bridge the country's widening gap with the U.S. and other European countries in high-tech industries are not going far enough, the government was warned yesterday [April 25, 2006]. The Organization of Economic Cooperation and Development issued a critical assessment of President Jacques Chirac's drive to create poles of competitiveness, bringing together business and academics in 66 regional clusters with state funds and tax breaks to encourage innovation. See Martin Arnold, *France Still Trailing in High-Tech Research*, Financial Times, *supra*.

⁷³⁴ See *Innovation and Entrepreneurship in the Information Society – ESPRIT - Final Report of the 5-Year Assessment of ESPRIT*,

CORDIS (1997), at; (<ftp://ftp.cordis.europa.eu/pub/esprit/docs/carneiro.pdf>).

⁷³⁵ European industry is far less specialised in high technology products than are its American or Japanese competitors. While such products do represent half of Germany's exports, this performance (which is comparable to that of the United States, but is much less than Japan's 70%) remains exceptional in Europe. In the information technology (IT) sector, European industry is both weak in terms of hardware and software products and stagnant in terms of computer services. Despite significant growth in production and exports, its competitiveness has diminished and the trade deficit is now of one third of the production. See ERCIM Views on Information Technology in Europe, the Preparation of the 5th Framework Programme and the Revision of the Maastricht Treaty, European Research Consortium for Informatics and Mathematics (July 1996), at: (<http://www.ercim.org/publication/policy/5thFP.html>).

⁷³⁶ Community funding of IT R & D began in 1984. During the first decade, the programme has been essentially aimed at closing the gap between Europe's information technologies industries and those of the US and Japan.

The strategy changed radically with the launching of the Fourth Framework Programme in 1994 which recognised the increasingly critical role played by IT in the competitiveness of all industry... This report urges radical changes in the organisation and design of ICT programmes... Two priorities have been identified and addressed in the Panel's recommendations... **The need to merge the ACTS, Telematics and ESPRIT programmes...** the objectives of these separate programmes would be better achieved if they were brought together in a single programme that covers all aspects of ICT required by the Information Society... **The need to achieve much swifter commercial applications of research results.** The panel has concluded that ESPRIT's programme... has made a vital contribution to promoting cross-border collaboration between small and large industries, universities and research institutes. However, the programme could be even more effective if - in addition to activities such as best practice, first-user actions and assessments - *better mechanisms were established for ensuring the commercial exploitation of results* (italicized emphasis added). See Innovation and Entrepreneurship in the Information Society - ESPRIT - Final Report of the 5-Year Assessment of ESPRIT, *supra*, Executive Summary at pp. 4-6..

⁷³⁷ The new ICT programme must emphasise the need for Europe to become more innovative by stimulating the development of innovative applications using emerging and enabling technologies. *Ibid.*, Recommendations, at p. 12. The programme must encourage industry to develop and bring ICT applications to the market in shorter time. It must emphasise collaborative efforts in commercial exploitation and facilitate a market-driven approach by shortening the life of projects so that time-to-market periods are between 1-2 years. *Ibid.*, at p. 14.

⁷³⁸ In March 2000, EU heads of state and government agreed on an ambitious goal: making the EU the most competitive and dynamic knowledge-based economy in the world... by 2010... capable of sustainable economic growth with more and better jobs and greater social cohesion ‘...

⁷³⁹ [I]t is unclear whether... industrial bootstrapping policies [creating home-grown standards and know-how, and using domestic demand as a springboard] will pay off. [This] thinking lay behind Esprit, Europe’s information technology research programme in the 1980’s; despite big public subsidies it yielded little worthwhile innovation. See Guy De Jonquieres, To Innovate, China Needs More Than Standards, Financial Times Editorial (7/13/06), at p. 11.

⁷⁴⁰ On 22-23 March 2005, the Spring Council discussed the Commission’s mid-term review of the Lisbon strategy for economic, social and environmental renewal. More focus on growth and employment, simplification and national ownership via national action plans are the key elements to relaunch the Lisbon reforms agenda. See Relaunch of the Lisbon Strategy, EurActiv at: (<http://www.euractiv.com/en/innovation/relaunch-lisbon-strategy/article-131891>).

⁷⁴¹ The European Union’s record on innovation is so poor that it would take more than 50 years to catch up with the US, according to a survey presented by the European Commission yesterday... The innovation gap between the EU25 and Japan is increasing and the one between the EU and US is close to stable,’ the report notes. *It adds that it would take more than 50 years to close the gap between the average EU performance and the current US level* (emphasis added). See Tobias Buck, EU is 50 Years Behind the US for Innovation’, Financial Times (1/13/06), at p. 2.

⁷⁴² The president of Eurochambres (The Association of European Chambers of Commerce and Industry), one of Europe’s largest trade associations, recently wrote to the Financial Times about Europe’s poor innovation record. The letter referenced the FT article noted above, as

follows; Sir, Your article... on the European Union's performance across a range of indicators such as the number of science and engineering graduates, patents, and research and development spending, is alarming, yet the gap with the US may also be underestimated. Concerning R&D investment per capita, Eurochambres estimates that the current EU level was reached by the US 23 years ago. Looking forward, and depending on the scenario one accepts as likely, we estimate that will take the EU until 2123 to reach US levels of R&D investment, and then only if EU investment exceeds that of the US by 0.5 percent a year (emphasis added). See Pierre Simon, Letter to the Editor, Financial Times (1/20/05), at p. 12. Perhaps, it is just coincidence, but the 23-year gap to which Mr. Simon refers roughly corresponds to the number of years since the enactment of the Bayh-Dole Act.

⁷⁴³ Long Term Research (LTR) is one of the domains of ESPRIT. Its objectives are to ensure that, at any time, the potential for the next wave of innovation is maintained. However the main users of this domain i.e., universities and research institutes are often complaining about: the lack of funds as a result of which a number of good proposals cannot be funded the fact that several promising fields (multimedia, hyperfrequencies, AsGa, etc) are not properly covered the small share allocated to purely blue sky research the emphasis on industrial relevance so that a commonly found feeling is, that LTR is increasingly short term oriented. As one of the key objectives for the fifth FP would be to provide an effective contribution to the creation of a European Information Society, more consideration should be give to long term research. See Jean-Michel Chasseriaux, Long Term Research in ESPRIT in the Perspective of the 5th Framework Programme, The European Scene - ERCIM News No. 29 (April 1997), at: (http://www.ercim.org/publication/Ercim_News/enw29/chasseriaux2.html).

⁷⁴⁴ European research is of high quality but it remains insufficient in quantity as witnessed by the stagnation in overall R&D expenditures (2% of GNP) at a lower level than the one observed in the United States (2,6%) or Japan (2,8%); its weakness in human potential: 35 researchers for 10 000 working people, as opposed to 70 in the United States and Japan; a negative specialisation index' for scientific publications and patents in the IT sector. In addition, this performance seems to be deteriorating: Europe's share of scientific publications and patents filed in electronics in the United States and Europe dropped between 1981 and 1993 in favour of the fast developing Asian economies while that of the United States remained stable. In addition,

while American (IBM, Hewlett-Packard, Motorola) or Japanese (NEC, Canon, Fujitsu...) firms set up laboratories in Europe, the European computer industry invests much less (2,000 MECU in 1991) than its American (9,800 MECU) or Japanese (3,500 MECU) competitors. Between 1980 and 1990, the ratio of research expenditure to the volume of production fell from 7.2 to 6.4% in Europe while it went from 3.5 to 7.6% in Japan and from 12.2 to 17.8% in the United States. See ERCIM Views on Information Technology in Europe, the Preparation of the 5th Framework Programme and the Revision of the Maastricht Treaty, European Research Consortium for Informatics and Mathematics, *supra*.

⁷⁴⁵ A lot can be done with the available technology on the path towards the information society but many problems still remain, and although, in the short term significant economic gains can be obtained by the direct use of technology developed elsewhere, in the long term, the exchange of research results will become indispensable for the acquisition of new knowledge and it will therefore be necessary to produce one's own results. See Jean-Michel Chasseriaux, Long Term Research in ESPRIT in the Perspective of the 5th Framework Programme, The European Scene – ERCIM News, *supra*.

⁷⁴⁶ Europe's universities, taken as a group, are failing to provide the intellectual and creative energy that is required to improve the Continent's poor economic performance. Too few of them are world-class centres of research and teaching excellence. Many are desperately short of resources. The picture is not uniformly bleak... But European institutions are not well placed to compete in what has become a global competition for talent. See Richard Lambert, Six Steps to Revitalise Europe's Higher Education, Financial Times (6/5/06), at p. 15,

⁷⁴⁷ The Commission's annual innovation scoreboard indicates that the EU is still losing ground on the United States and Japan, but some member states are outperforming the two major global competitors. See Innovation Gap Between EU and US Still Growing, EurActive (11/25/04), at: (<http://www.euractiv.com/en/innovation/innovation-gap-eu-us-growing/article-132730>).

⁷⁴⁸ See Commission Staff Working Paper – European Innovation Scoreboard 2004 – Comparative Analysis of Innovation Performance, Commission of the European Communities SEC(2004) 1475 (11/19/04), at p. 4, at: (<http://register.consilium.eu.int/pdf/en/04/st15/st15189.en04.pdf>).

Countries that combine a very high innovation performance with moderate GDP performance are particularly concerned by these results.

The Swedish government recently created a Growth Policy Institute⁷⁴⁹ to provide advice for the integration of innovation and growth policies. Europe has taken similar steps with the *Lisbon agenda* and the creation of the Competitiveness Council'. *Ibid.*, at p. 13. After the 2002 Communication concerning an Industrial Policy in the Enlarged Europe', the European Commission launched several policy initiatives to improve the competitiveness of specific sectors, such as the textile, pharmaceutical, and aerospace industries. *It is now widely recognised that the horizontal competitiveness policy laid down in the Lisbon agenda must be complemented by sector specific policies. This is particularly true in the area of innovation because the patterns and mechanisms of innovation differ widely by sector.* The development of sector specific innovation policy instruments will need to be explored in the years to come (emphasis added). *Ibid.*, at p. 16.

⁷⁴⁹ The Framework Programme (FP) is the European Union's main instrument for funding research and development. It will be fully operational as of 1 January 2007 and will expire in 2013. It is designed to build on the achievements of its predecessor towards the creation of the European Research Area, and carry it further towards the development of the knowledge economy and society in Europe... Support will be given to the whole range of research activities carried out in trans-national cooperation, from collaborative projects and networks to the coordination of national research programmes. International cooperation between the EU and third countries is an integral part of this action. This action is industry-driven and organised in four sub-programmes: **Collaborative research** will constitute the bulk and the core of EU research funding **Joint Technology Initiatives** will mainly be created on the basis of the work undertaken by the European Technology Platforms **Coordination of non-Community research programmes**, [and] **International Cooperation** (emphasis in original) See Towards FP7: Your Gateway to the Preparation of the Seventh Framework Programme - Frequently Asked Questions, Cordis at: (<http://cordis.europa.eu/fp7/faq.htm>).

⁷⁵⁰ The core of this program is as follows: (1)... Through its support for research at the frontiers of knowledge, applied research and innovation, the Community seeks to promote synergies in European research and thus provide a more stable foundation for the European Research Area. This will make a positive contribution to the social and economic progress of all Member States. *The central role of research was recognised by the European Council of Lisbon which highlighted knowledge and innovation as the key, setting itself a new strategic goal for the next decade: to become the most competitive and dynamic*

knowledge-based economy in the world, capable of sustainable economic development and aiming at full employment with more and better jobs and greater social cohesion. (3) *The seventh Framework Programme is central to achieving the Lisbon strategic goal of Europe becoming the most competitive and dynamic knowledge-based economy in the world.* The triangle of knowledge - education, research and innovation - is a principal tool for achieving this goal. (4) *The central role of knowledge and intangible goods in the production of economic, social and cultural wealth was recognised by the Lisbon European Council. In the knowledge-based society, innovation and knowledge production, far from flowing top-down, are widely distributed throughout society and **are increasingly achieved by bottom-up processes.*** It is an aim of the Community to mobilize and strengthen all these research and innovation capacities. (5) In line with the Lisbon strategy, the European Council of Barcelona set the target of raising European research efforts to 3% of EU GDP, two thirds of which should come from private investment. (6) To that end, many Member States, and European industry, must step up their research efforts in order to help make the promotion of research under the Seventh Framework Programme a success. (7) The overriding aim of the whole Seventh Framework Programme must be to contribute to the European Union becoming the world's leading research area. This requires the Framework Programme to be strongly focused on promoting and investing in world-class research (emphasis added). See Amended Proposal for a Decision of the European Parliament and the Council, concerning the 7th framework programme of the European Community for research, technological development and demonstration activities (2007-2013) , COM (2006) 364 final (6/28/06), at pp. 4-5, 2005/0043 (COD), 2005/0044 (CNS), at: (ftp://ftp.cordis.europa.eu/pub/fp7/docs/ec_fp7_amended_en.pdf). See also Proposal for a Decision of the European Parliament and of the Council, concerning the seventh framework programme of the European Community for research, technological development and demonstration activities (2007 to 2013) COM(2005) 119 final (4/6/05), 2005/0043 (COD), 2005/0044 (CNS), at: (<http://cordis.europa.eu/documents/documentlibrary/2461EN.pdf>).

⁷⁵¹ The objective of the 'Ideas' programme proposed for FP7 is to enhance the dynamism, creativity and excellence of European research at the frontier of knowledge... to be implemented by a European Research Council (ERC)... The Ideas programme will thus become a trans-European mechanism to support creative scientific research designed to generate completely new knowledge opening up new

venues for technological progress and new solutions for social and environmental problems. See Towards FP7: Your Gateway to the Preparation of the Seventh Framework Programme - Ideas - A European Research Council to Support Basic, Frontier Research , at: (<http://cordis.europa.eu/fp7/ideas.htm>). Highly trained, qualified researchers are needed to advance science and underpin innovation, and to attract and sustain public and private investment in research... FP7's Specific Programme on People aims to improve the quality of the human potential in the European R&D and technology sector while at the same time increasing the number of researchers and other people working in the RTD sector. It aims to do this by stimulating people to enter into research professions, encouraging European researchers to stay in Europe and making Europe more attractive for the best researchers from around the world. At the same time, training and career development of researchers will be actively supported. See Towards FP7: Your Gateway to the Preparation of the Seventh Framework Programme - People - Human Potential and Science Careers , at: (<http://cordis.europa.eu/fp7/people.htm>). The Capacities programme proposed for FP7 aims to enhance research and innovation capacities throughout Europe and to ensure their optimal use. Within the strategic approach of the Capacities programme, support will be available for new research infrastructures as well as for measures intended to ensure the optimal use of existing research infrastructures... This specific programme also aims to support the coherent development of policies, complementing the Cooperation programme, and contributing to Community policies and initiatives to improve the coherence and impact of Member States policies... The objective of the Capacities programme with regard to SMEs is to strengthen the innovation capacity of European small and medium-sized enterprises and their contribution to the development of new technology based products and markets. This will be achieved by helping them outsource research, increase their own research efforts, extend their networks, better exploit research results and acquire technological know-how . See Towards FP7: Your Gateway to the Preparation of the Seventh Framework Programme - Research Capacities - Infrastructures, SMEs, Regions and Potential , at: (<http://cordis.europa.eu/fp7/capacities.htm#2>).

⁷⁵² The primary goal of the PatVal-EU survey was to gather information on the economic value of the European patents. The PatVal-EU survey, however, produced other interesting and unique data on: *the characteristics of the inventors*, like their age, the educational and work background, the institutions to which they are

affiliated; *the process that led to the innovation* such as the sources of knowledge used in the research process, and the setting up of formal or informal collaborations among individual inventors and organisations; *the motivations to patent and the use of property rights*, such as the licensing behaviour of firms, the strategic reasons to patent, etc. The combination of this information provides a good understanding of the relationship between the input and the output variables in the innovation process, and it helps derive policy implications for the European innovative and economic performance (emphasis in original). See Study on Evaluating the Knowledge Economy: What Are Patents Actually Worth? – The Value of Patents for Today’s Economy and Society, *supra*, at pp. 24-25.

⁷⁵³ The study, among other things, ranked the sources of knowledge used by different types of inventors to develop patent-based innovations, in descending order, as follows: 1) firm users; 2) patent literature; 3) science literature; 4) firm’s competitors; 5) participation in technical conferences and workshops; 6) interactions with a firm’s suppliers; and 7) university and non-university research laboratories.

The knowledge provided by the university and non-university research laboratories is at the bottom of the ranking in most of the micro technological classes... [except] in Biotechnology [where] they rank first together with the scientific literature... There are, for example, technologies like Telecommunications, Semiconductors and Information Technology where the scientific literature and the participation in conferences and meetings are of primary importance as sources of knowledge for developing the patent. There are sectors like Optics, Organic fine chemistry, Macromolecular Chemistry and Polymers, Pharmaceuticals and Cosmetics, Materials and Metallurgy, Food Chemistry, and Chemical and Petrol industry where the scientific and patent literature is the most important source of knowledge...

Ibid., at pp. 59-60.

⁷⁵⁴ See e.g., Future Patent Policy in Europe, Preliminary Findings: Issues for Debate, European Commission (June 2006), at: (http://ec.europa.eu/internal_market/indprop/docs/patent/preliminary_findings_en.pdf). The consultation was launched on 16 January 2006 with the aim of collecting stakeholders' views on the patent system in Europe. *Ibid.*, at p. 1. Industry generally (representatives such as UNICE, MEDEF but also sectoral associations as well as individual companies) insists on the need to develop a comprehensive innovation policy in Europe in order to respond to challenges from the US, Japan and emerging economic powers such as China and India, which all

have in recent years invested substantial effort in making innovation policy a top priority. *Ibid.*, at p. 9.

⁷⁵⁵ Asia and the US are leading the way in the rush to secure commercial returns from nanotechnology, with Europe lagging behind... In nanoelectronics, the area in which commercialization is most advanced, 51 percent of patent families' (groups of related patents) were filed by Japanese companies and organizations [see discussion about Japanese patent pooling', *supra*], compared with 24 percent by US and just 8 percent by European applicants... Of the 30 leading patent applicants in nanoelectronics, 18 are based in the Far East, 10 in the US, and just two in Europe: Philips and Infineon. The leaders in this field are Fujitsu of Japan, with 62 patent families, and Samsung of South Korea, with 56. While large corporations lead Asian patenting in nanoelectronics, activity in the US is led by universities and start-up companies. See Clive Cookson, Asia and US Lead Way on Nanotech Patents, *Financial Times* (5/8/06), at p. 4.

⁷⁵⁶ 1... (iv) ***Intellectual property and patent policy issues must not be subjugated to, for example, competition law or other public interests. Patent law already incorporates an adequate balance of interests. In designing the future patent system, the Commission should pay attention to the promotion of innovation and the improvement of the competitiveness of the European industry, which are at the core of the patent system.*** Other objectives, such as environment, are better dealt with in other bodies of the law ... 2... Patentability should continue to be limited to technical solutions, for example those implemented in computer programs, and not reduced or expanded (for example to include business methods)... 4... For companies, which base their protection on copyright, the patent system can appear less important. ***Because of the remaining confusion about the possibility of patenting software solutions and of the high cost of patenting in Europe, fewer companies opt for patent protection than copyright protection. Copyright thus remains the most common system of protecting computer programs. However there are great advantages to the patent system in terms of effectiveness of the protection and creation of value (patents are a valuable asset for companies). We don't think that all the different IPR protection systems can be compared since they are not protecting the same aspects of software and they do not reward the same investments,*** as exposed in the European Software Association paper on IPR. All forms of IPR protection systems are important to our industry if we are to continue to innovate and develop. IPR protection systems, including patents, are in our best interest. We are therefore very interested in participating in any effort to contribute to an

improved patent system in Europe (emphasis added). See European Software Association: Response to the European Commission's Consultation on the Patent System in Europe *supra*, at pp. 2-3.

⁷⁵⁷ Review of inventive step in the UK *The need for an inventive step requirement in a system designed to protect innovation is evident, but a balance must be struck between 'the patentee and those of the public at large, and between consistency and harmonisation* (The Inventive Step Requirement in UK Patent Law and Practice - UK Patent Office Publication). Recently, however, *the balance has seemed skewed, as an increase in the grant of 'trivial patents' has heightened discussion surrounding the fundamental purpose and effectiveness of UK patent law, although inadequate examination might also be to blame. Seeking to restore the equilibrium*, the UK Patent Office opened a consultation on the Inventive Step requirement in UK patent law and practice in February this year. At its heart, the consultation seeks to address whether: [1] the inventive step requirement for patentable inventions in the United Kingdom is right for inventors, the public at large, and the UK economy? [2] there are too many 'trivial patents' being granted? *Or whether ... [3] innovation and competitiveness are best served by easy patenting with low hurdles?*... See Julian Hitchcock and Jonathan Greenwood, Reinventing the Patent - Part 1, Cambridge Network (6/6/06), at: http://www.cambridgenetwork.co.uk/POOLED/ARTICLES/BF_NEWSART/VIEW.ASP?Q=BF_NEWSART_206078).

⁷⁵⁸ I will go for one big last push for the Community patent,' he told a 12 July public hearing in Brussels on the future patent policy in Europe... The day before, in an 11 July speech in Finland, McCreevy said, 'Over the coming year, I will intensify my efforts to improve the industrial property environment in Europe.' The push for a Community patent will happen some time during his term, he said, which ends in late 2009. But exactly when this push will take place is yet to be decided. I need the time to be ripe,' he told a group of journalists at the event. The commissioner said in Finland that the Community patent remains a central plank in the work of filling the gaps in terms of the legal framework for intellectual property... Meanwhile, McCreevy is ready to move forward now with the proposed European Patent Litigation Agreement (EPLA)... This could mean the setting up a European patent court with jurisdiction to deal with infringement and revocation actions concerning European patents, according to the European Patent Organisation Working Party on Litigation... Referring to the proposed EU software patent directive that the European Parliament dramatically voted down last summer, McCreevy said there

would be no new legislation in this area during his time at the Commission as the time is not right... McCreevy said patent policy decided in different fora does European business no good,' and Europe must retain its competition vis-à-vis growing economies such as those in Asia. McCreevy will focus on intellectual property and patents in particular, such as industrial patents, he said (emphasis added). See Tove Iren S. Gerhardsen EU Commissioner To Boost IP Focus, Seek Last Push For Community Patent Intellectual Property Watch (7/13/06) at:

<http://www.ip-watch.org/weblog/index.php?p=363&res=1280&print=0#comments#comments>).

⁷⁵⁹ Innovation, creativity and strict recognition of patents, rather than anti-dumping measures and protectionism, are the best way for European companies to meet the challenge from China and other low-cost manufacturers, says... Mario Moretti Polegato... the chairman of Geox, Italy's biggest shoe company. See Tony Barber, 'Patents Are Key' To Taking On China, Financial Times (7/25/06), at p. 2.

⁷⁶⁰ As noted above, even the EU is far behind the US as concerns hard investments in technology R&D, innovation (commercialization) and human capital, and the gap between the two regions continues to grow. Apparently, Europe's governance institutions are now paying the price for having made poor policy choices in the past that have been influenced mostly by political (civil society and protectionist) considerations. Together with the new challenges posed by emerging economies such as Brazil, China and India during the past decade, as concerns agricultural and capital goods (manufacturing) and services outsourcing, Europe has increasingly found itself, metaphorically speaking, between a rock and hard place – in both economic and technology terms. This perhaps explains why Europe has felt the need to promote a global negative 'paradigm of sustainable development premised on Europe's slow growth welfare state economic/political model, especially among impressionable developing countries, that seemingly emphasizes fair' over free' trade. For the difference between fair' trade and free' trade, See Daniel W. Drezner, U.S. Trade Strategy Free Versus Fair: Critical Policy Choices, Council on Foreign Relations, *supra*. Europe's knowledge conundrum may even explain the rationale underlying European intransigence during the recent Doha round negotiations that largely contributed to its collapse.

⁷⁶¹ [T]he average EU adult is significantly less educated than adults in other industrialized countries: he or she has spent some two years less

studying than the US citizen and one year less than the Japanese. This is not due to enlargement... but to the fact that in most of Europe the generalization of secondary education took place much later than in the US. A large part of the EU population has completed only primary education and less than 20 percent (against 40 percent in the US or Japan) has reached tertiary level. See Jean Pisani-Ferry, Europe's Eroding Wealth of Knowledge, *Financial Times* (8/23/06), at p. 9.

⁷⁶² See Clive Cookson, Asia and US Lead Way on Nanotech Patents, *Financial Times* (5/8/06), at p. 12.

⁷⁶³ Resource abundance, thought in the 1950s to be a good thing for development if a country had it, is now understood to too often result in weak political and governmental institutions... and these institutions have become appreciated as absolutely key to development... *Ibid.*, at p. 14.

⁷⁶⁴ *Ibid.*, at pp. 13-14.

⁷⁶⁵ See Haig Simonian and Daniel Dombey, Bolivia to Refuse Energy Payouts – Morales Warns Foreign Investors Over Contracts, *Financial Times* (5/12/06), at p. 1. Evo Morales, the Bolivian president, has ruled out compensating foreign energy companies that face changes to their contracts as a result of a controversial nationalization policy announced earlier this month and warned big landowners that they were next in his sights. *Ibid.*

⁷⁶⁶ *Ibid.*, at p. 14, citing Mancur Olson, The New Institutional Economics: The Collective Choice Approach to Economic Development. In Christopher Clague eds., *Institutions and Economic Development*, pp. 37-66. Baltimore, MD: John Hopkins University Press (1997), and Douglass C. North, Institutions and Economic Growth: An Historical Introduction, *World Development* 17:1319-1332 (1989).

⁷⁶⁷ Vicente Fox, the president of Mexico... delivered a salvo against the leftwing policies of Venezuela and Bolivia, warning that protectionism and nationalization could damage the prospects of Latin America as a whole... Mr. Fox said, when asked about the rise of economic nationalism in the region... I can say if something has not worked well in Latin America, its precisely populism, demagoguery, deception, which only hurt the process of development and impoverish people even more... I hope Latin American countries reaffirm our willingness to open up markets for trade and investment'. See Daniel Dombey, Fox Warns Leftist Policies Will Harm Latin America, *Financial Times* (5/12/06), at p. 5.

⁷⁶⁸ Bolivia's President Evo Morales has long advocated increasing state control over... Latin America's second largest reserves of natural

gas... By nationalizing, the Bolivian leader appears intent on shoring up his government's popularity ahead of elections in July to an assembly that will rewrite the constitution... Politically, this is a very astute move', said Jose Mirtenbaum of Gabriel Rene Moreno University in Santa Cruz. Evo is trying to correct some of his failures in other policy areas, such as coca, education and health'. Internationally, nationalization brings Mr. Morales closer to Mr. Chavez and Fidel Castro, the Cuban president.. For the region, Mr. Morales' decision has two consequences. First, it is a slap in the face for Brazil, Petrobras, the Brazilian state-owned company, is the biggest operator in Bolivia and has bent over backwards to develop good relations with the government.. Critics have been quick to attack President Luiz Inacio Lula da Silva's diplomats, pointing at that failure to influence the government in Bolivia has followed lack of success in boosting Brazil's image on the world stage, such as the costly but unsuccessful campaign to win a seat on the [UN] Security Council. Second, Mr. Morales' decision will make regional politics in general more polarized. Mr. Chavez and the lure of his resource-based populism seems to cast an ever longer shadow over the string of elections in the region over the next few months. See Richard Lapper and Hal Weitzman, Chavez Casts Long Anti-American Shadow In Region, Financial Times (5/3/06), at p. 6. See also, Daniel Dombey and Haig Simonian, South America's Leftist Duo Defy Europe, FT.com (5/12/06), at: (<http://news.ft.com/cms/s/a036befc-e1cd-11da-bf4c-0000779e2340.html>). Celso Amorim, Brazil's foreign minister, demanded that Bolivia provide compensation to Petrobras – which has invested more than \$1.5bn in the country since 1996. There are legal instruments which support the investments of Petrobras in Bolivia and those will be used if we don't arrive at a satisfactory solution, he said. *Ibid.*

⁷⁶⁹ [Foreign]... investors... hungry for returns [] are disregarding the risks posed by a wave of radical populism that is sweeping [the Latin American] region... Ollanta Humala, a radical nationalist [candidate in Peru], is widely tipped to emerge as eventual victor. He has promised to an end to neo-liberal' policies and regularly attacks foreign companies... Hugo Chavez, Venezuela's radical anti-American leader, may be deploying revenues from the western hemisphere's largest oil reserves in order to sow the seeds of what he calls 21st-century socialism '... Evo Morales, [the] radical indigenous leader [of Bolivia]... has confirmed plans to nationalize the gas industry... Nestor Kirchner, Argentina's radical president, has nationalized a foreign utility, imposed price controls and sacked Roberto Lavagna, his

market-friendly finance minister. Last year, his government negotiated a deal to restructure defaulted debt. So draconian were its terms that it seemed guaranteed to exclude the country from fresh borrowing on international capital markets... And, in Brazil, leftwing president... Lula da Silva is maintaining his commitment to conservative fiscal and monetary policy – although that is starting to look more threadbare following the resignation last week of the fiscally orthodox Antonio Palocci as finance minister amid the latest of a series of corruption scandals. With Mr. Lula facing an election this year, the appeal of easing spending controls could increase, especially since his economy has grown at only around 2 percent a year since his election in 2002. It is a perfect time populism. It will be more and more difficult for Brazil to resist’, says Christian Stracke, analyst with the independent Credit Sights. See Richard Lapper, Why Investors Are Deaf to the Latin American March of the Populists, Financial Times (4/6/06), at p. 11

⁷⁷⁰ Bolivia yesterday [on May 1, 2006,] ordered its military to seize natural gas fields controlled by foreign investors as the 100-day old government of Evo Morales signaled it was putting into effect a campaign pledge to nationalize the sector. The natural gas industry in Bolivia... is dominated by international energy companies, including Brazil’s Petrobras, Repsol of Spain, Total of France, and BF and BP of the UK. Together, they have invested about \$3.5 billion in the country in the past decade... [The]... sign[ed] nationalization decree... stated that the state recovers ownership, possession, and total and absolute control of these resources’. *The intervention will heighten investor fears about property rights in the energy sector*, and Mr. Morales’ willingness to pursue a leftwing agenda... The decree is the latest action signaling a more hostile approach to foreign investors (emphasis added). See Hal Weitzman, Bolivia Set To Seize Its Foreign-Run Gas Fields, Financial Times (5/2/06), at p. 1. Yesterday’s forced nationalization of the country’s oil and gas fields has fuelled fears about Mr. Morales’ attempts to centralize power through the election of an assembly to rewrite Bolivia’s constitution and his close ties to Hugo Chavez, Venezuela’s president... Mr. Chavez... convoked his own constituent assembly in 1999 to shore up his power and weaken Congress... [C]ritics see [Morales’ actions] as a bid by the ruling Movement to Socialism (MAS) to tighten its grip on power. See Hal Weitzman, Energy Nationalization Fuels Fears Over Morales, Financial Times (5/2/06), at p. 3.

⁷⁷¹ The decision to impose tough new contracts on international oil companies closely mimics actions taken by Venezuela, the fifth-largest oil exporter, earlier this year. The populist government of Hugo Chávez

gambled that international oil companies needed its oil too much to walk away. By and large, it was right. Virtually all the major oil companies reluctantly signed up to the new contracts. But in Bolivia's case, its confrontation with international oil companies may prove less successful. Venezuela's huge oil reserves are too attractive for oil companies to pass up and international companies have invested tens of billions of dollars developing them. Bolivia's case is very different. The country is rich in natural gas – it has South America's second-largest gas reserves. But it has a small domestic market for the fuel and needs foreign partners to provide markets for that gas. Whereas oil can be shipped into a global, fungible market, commercialising gas is far more complex. Pipelines must carry it to neighbouring countries or expensive liquefaction plants built to ship it overseas. Even then, companies often depend on the marketing might of international oil companies to sell their LNG. Foreign companies have also invested far less in Bolivia, around \$3.5bn in total, making it easier for them to walk away from the country if the terms become too unattractive... Because Brazil is a major destination for Bolivian gas, the country is also expected to work out a deal with Petrobras, the Brazilian state oil company. Bolivia needs to sell the gas and Brazil needs it for its growing consumption, said Lucrecia Tam, Latin America energy analyst at Deutsche Bank in New York. Petrobras is the most qualified candidate with a captive Brazilian market and a pipeline connecting the two countries. 'But some companies are likely to leave, analysts said. Bolivia has already a bad reputation among oil companies and some of them are now going to leave the country, said Anouk Honoré, natural gas analyst at the Oxford Institute for Energy Studies. See Thomas Catan and Javier Blas, 'Oil Groups May Escape Brunt of Bolivia Decree', FT.com (5/3/06), at: (<http://news.ft.com/cms/s/9a44ed0c-d9f8-11da-b7de-0000779e2340.html>).

⁷⁷² See Richard Lapper, 'Leftist Trend Tarnishes Boom', Financial Times (4/10/06), at p. 4, citing Michelle Billig, analyst at PIRA, a New York-based energy consultancy. ... Latin America is at the forefront of another development. Governments – driven by pressure from poorer voters who feel they are missing out on the prosperity – are seizing a bigger share of the action... Peru... Venezuela... Bolivia... Argentina... Ecuador... In the short term, all this is expected to be even better for [mining commodities] prices. If operating conditions deteriorate, companies are less likely to want to make the investments that would eventually increase supply and bring price back into line... Nationalists... argue

that by increasing revenues they can increase spending and resolve pressing social problems. They accept that private companies may no longer be prepared to make the same kind of capital commitments, but expect their own nationalized companies, such as Petrobras or state concerns from outside the region to make up for any shortfall. *Even so some critics argue that the region will – like it has in the past – lose out by restricting its access to multinationals' capital and technology* (emphasis added). *Ibid.* [T]here is tangible chatter... that [Peruvian nationalist candidate] Mr. [Ollanta] Humala threatens to reverse the economic progress of recent years... [A]mong young entrepreneurs in Lima's upmarket districts there is trepidation about the next government's policy towards their business interests... Mr. Humala's candidacy has made it more likely that... young Peruvians... will want to leave their country. See Hal Weitzman, *Whoever Takes Power in Peru, Children of Rich and Poor Alike Dream of Leaving*, *Financial Times* (4/15-4/16/06), at p. 3.

⁷⁷³ Lucent Technologies Inc.'s Bell Labs, the birthplace of the transistor and the laser, has been through a decade of turmoil during which it was reduced to a third of its size. Now, some of its scientists are warily embracing a former submarine officer and entrepreneur as perhaps the laboratory's best hope of maintaining its relevance. Jeong Kim took over last year with a direct plan for saving the storied laboratory: Make it profitable. Among his first moves, he set more of its scientific stars to work on breakthrough technologies that could turn quickly into businesses – the opposite of the pure research many live for. In earlier days, Bell Labs' scientists might have rejected Mr. Kim's commercial approach to science. Not now. See Sara Silver, *With Its Future Now Uncertain, Bell Labs Turns to Commerce*, *Wall Street Journal* (8/21/06), at p. A1.

⁷⁷⁴ The American liberal-regulatory political economy has proved superior to the versions of corporatist political economy established in Europe and Japan with respect to creating technological innovation, introducing it into the marketplace, encouraging sector-leading high-tech firms, and producing higher economic growth. Americans led innovation in computers and software, the Internet, composites, and materials, drugs, crops, and foods, and biotechnology...U.S. technological leadership owes to several identifiable strengths, including public financing of basic research through private universities and public laboratories; strong patent rights that have encouraged the commercialization of basic technologies into the marketplace; easily established start-up enterprises; adaptable, flexible organizations; flexible labor markets; MBA-educated, professional managers; and

risk-taking, innovative financial markets (emphasis added). See Michael P. Ryan, Brazil's Quiet Bio-Medical Innovation Revolution: Drugs, Patents and the 10/90 Health Research Gap, at pp. 12-13.

⁷⁷⁵ Two events, PVP [plant variety protection] and biotechnology, have greatly increased attention to intellectual property protection and management. LGCs [land grant colleges] now routinely review their new intellectual properties to determine the best way to handle them and still serve the public... [I]ndividual sponsors of LGC research efforts usually request exclusive access to any intellectual properties developed through the use of their funds. In some instances, sponsors, will provide proprietary information to the researcher and demand confidentiality. Even federal **research support relates to intellectual property, because every government-sponsored project carries the Bayh-Dole requirements of disclosing all inventions, providing the government with a license, and diligently seeking industrial licensing for inventions...** During the 1980's, a number of changes occurred that created an intellectual property awareness. One of these changes was the passage of the Bayh-Dole Act by the U.S. government, which gave universities the right to license technologies developed under federal funding (emphasis added). See Frederic H. Erbisch, United States Land-Grant Colleges, in Intellectual Property Rights in Agriculture – The World Bank's Role in Assisting Borrower and Member Countries, World Bank Report 19836, Uma Lele, William Lesser, and Gesa Horstkotte-Wesseler Eds. (Sept. 1999) at pp. 67 and 69, at: (http://www-wds.worldbank.org/servlet/WDSContentServer/WDSP/IB/1999/11/19/000094946_99110605305246/Rendered/PDF/multi_page.pdf).

⁷⁷⁶ A more recent World Bank report on the subject, however, suggests that IPRs can and should have only a limited role in least developed country plant breeding activities, at least, until the proper enabling environment has been created. Predictably, it nowhere mentions the Bayh-Dole Act. See Intellectual Property Rights: Designing Regimes to Support Plant Breeding in Developing Countries, Agricultural and Rural Development Department, World Bank, Report No. 35517-GLB (2006) at: (http://siteresources.worldbank.org/INTARD/Resources/IPR_ESW.pdf). Brazil, it must be remembered, is no longer a developing country – rather, it is an *emerging* economy.

⁷⁷⁷ [S]everal studies have shown that technological innovation and the scientific research on which it is based are responsible for more than half of the nation's productivity growth in the past 50 years. See University Technology Transfer of Government-Funded Research Has

Wide Public Benefits, Association of American Universities (1998), at: (<http://www.aau.edu/research/TechTrans6.3.98.html>). However, even with the U.S.' current advantage in R & D, experts well recognize that much more needs to be done to maintain that advantage in the future. See Caroline Daniel and Edward Aiden, Bush Puts Stress on Research Spending - \$50 Billion Pledged to Meet Threat From China and India, Financial Times (2/1/06) at p. 1.

⁷⁷⁸ Although Bayh-Dole certainly contributed to the increase in the commercialization of federally funded inventions, there were two other events which also played a role. One was a 1980 [U.S.] Supreme Court decision in *Chakrabarty v. Diamond* [447 U.S. 303 (1980)] that microorganisms were patentable subject matter which facilitated the patenting and licensing of biotechnology. Many of the university inventions which produced millions of dollars in royalties relate to biotechnology. The other was the creation of the Court of Appeals for the Federal Circuit in 1982. All appeals from patent suits are heard by this court instead of the regional circuit courts where previously many patents were found to be invalid. A single appeals court added to the stability of patent law since review by the Supreme Court was rare. This probably increased the value of patents and resulted in the tripling of the number of patent applications filed in the United States. See The Bayh-Dole Act- 23 Years Later, - High-level Seminar on Intellectual Property Rights Issues Related to Public Research Institutions Organization of Economic Cooperation and Development (OECD), Beijing, China (April 22-23, 2004), at: (<http://www.oecd.org/dataoecd/27/30/31858046.pdf>).

⁷⁷⁹ See 35 U.S.C. Sections 200-212, CHAPTER 18- PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE, accessible at: (http://www4.law.cornell.edu/uscode/35/usc_sup_01_35_10_II_20_18.html). See also 37 CFR 401, Title 37--Patents, Trademarks, and Copyrights, CHAPTER IV--ASSISTANT SECRETARY FOR TECHNOLOGY POLICY, DEPARTMENT OF COMMERCE, PART 401--RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS, accessible at: (http://www.access.gpo.gov/nara/cfr/waisidx_99/37cfr401_99.html).

⁷⁸⁰ On February 10, 1982, the Office of Management and Budget issued OMB Circular A-124 to provide guidance to federal agencies regarding implementation of the Bayh-Dole Act. This Circular established standard patent rights clauses for use in federal funding

agreements. It also set up standard reporting requirements for universities electing title to inventions. On February 18, 1983, a Presidential Memorandum on Government Patent Policy⁷⁸¹ was issued... [that]...directed federal agencies to extend the terms and provisions of the Bayh-Dole Act to all government contractors, with a follow-on amendment to the Federal Acquisition Regulations to assure that all federal R&D agencies would implement the Act and the Memorandum. On November 8, 1984, the original Bayh-Dole statute was amended by P.L. 98-620. New language was added to remove term limitations placed on exclusive licenses under the original Act. In addition, the Department of Commerce was designated as the federal agency responsible for overseeing the implementation of the Bayh-Dole Act and for monitoring the granting of exceptions to the rules. On March 18, 1987 (52 FR 8552), all of the relevant provisions--the Bayh-Dole Act, the amendment, OMB Circular A-124, and the Presidential Memorandum--were finalized and consolidated in a rulemaking published by the Department of Commerce-- appearing at 37 CFR Part 401. See *The Bayh-Dole Act - A Guide to the Law and Implementing Regulations*, Council on Governmental Relations (Sept. 1999), at: (<http://www.ucop.edu/ott/bayh.html>).

⁷⁸¹ Technology transfer--the transfer of research results from universities to the commercial marketplace for the public benefit--is closely linked to fundamental research activities in universities. Although a handful of U.S. universities were moving science from the laboratory to industrial commercialization as early as the 1920s, academic technology transfer as a formal concept, is said to have originated in a report entitled *Science - The Endless Frontier* that Vannevar Bush wrote for the President in 1945. At that time, the success of the Manhattan Project had demonstrated the importance of university research to the national defense. Vannevar Bush, however, also recognized the value of university research as a vehicle for enhancing the economy by increasing the flow of knowledge to industry through support of basic science. His report became instrumental in providing a substantial and continuing increase in funding of research by the federal government. It stimulated the formation of the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Office of Naval Research (ONR). Due to the success of these and other agencies, the funding of basic research by the federal government is now considered to vital to the national interest. *Ibid.*

⁷⁸² See *University Technology Transfer of Government-Funded Research Has Wide Public Benefits*

Association of American Universities (1998), at: (<http://www.aau.edu/research/TechTrans6.3.98.html>). The Act effectively authorized universities to grant corporations exclusive licenses to federally financed inventions (basic research and development) that were languishing in government archives. The Act's authors correctly believed that if companies gained exclusive rights in federally funded inventions, they would undertake the investments necessary to commercialize them.

⁷⁸³ [The]... [p]revailing view in the Academy prior to the advent of the Bayh-Dole Act... [was that]... [a] researcher that accepted corporate support was diverted from his basic research to serve corporate interests. Because the researcher had accepted corporate money his research would no longer be directed to the seeking of new knowledge but by the money-driven need to solve current problems in the real world, even to the development of products and processes to a market-ready condition. See William Swiggart, Bayh-Dole Act & the State of University Technology Transfer in 2003, Panel Presentation at the 4th Annual Conference, Princeton Entrepreneurs' Network, Campus of Princeton University (May 29, 2003), at: (http://cello.abora.com/articles/Bayh_Dole_act.doc), based in part on a speech by Howard W. Bremer delivered November 11, 2001.

⁷⁸⁴ The U.S. government got involved in funding university research heavily during WWII. A consensus developed after the war ended that the U.S. should maintain technological leadership in order to continue to enhance its military capabilities. As more and more technology was developed with government money by private companies, universities and nonprofit organizations, more and more of it began to be locked up in government patents. *Ibid.* In other words, The law allows universities and small businesses to own their inventions made under Government research contracts and grants. Previously, the Government owned those inventions

although the contractors and grantees could request rights. See The Bayh-Dole Act- 23 Years Later, - High-level Seminar on Intellectual Property Rights Issues Related to Public Research Institutions Organization of Economic Cooperation and Development (OECD), *supra*.

⁷⁸⁵ See The Bayh-Dole Act – A Guide to the Law and Implementing Regulations, Council on Governmental Relations, *supra*. In the 1960s and 1970s, there was great concern that too little federally funded research was being commercialized. Tight restrictions on licensing, varying patent policies among federal agencies, and the lack of exclusive manufacturing rights for government-owned patents made

product development a risky proposition for companies. In 1980, only five percent of government-owned patents resulted in new or improved products. See University Technology Transfer of Government-Funded Research Has Wide Public Benefits Association of American Universities, *supra*.

⁷⁸⁶ See Howard Bremer, THE BAYH-DOLE ACT: Impact on University Research and Intellectual Property Ownership Rights, Presentation Made at the Rensselaer Polytechnic Institute (12/2/03), at: (http://www.rpитеchnology.com/files/bayh_dole.pdf).

⁷⁸⁷ See The Bayh-Dole Act – A Guide to the Law and Implementing Regulations, Council on Governmental Relations, *supra*, citing U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled Technology Transfer, Administration of the Bayh-Dole Act by Research Universities dated May 7, 1998. For example, by 1978, NASA had waived title to the private contractor to less than 4% of the more than 30K inventions that had been reported to it by its contractors. See William Swiggart, Bayh-Dole Act & the State of University Technology Transfer in 2003, Panel Presentation *supra*.

⁷⁸⁸ See William Swiggart, Bayh-Dole Act & the State of University Technology Transfer in 2003, Panel Presentation, *supra*.

⁷⁸⁹ See Howard Bremer, THE BAYH-DOLE ACT: Impact on University Research and Intellectual Property Ownership Rights, *supra*.

⁷⁹⁰ See University Technology Transfer of Government-Funded Research Has Wide Public Benefits Association of American Universities (1998), *supra*.

⁷⁹¹ See The Bayh-Dole Act – A Guide to the Law and Implementing Regulations, Council on Governmental Relations, *supra*. From the beginning, it was obvious that economic interests rather than academic science interests were the driving forces for the change in government policy. As early as October 1963, President Kennedy had issued a Presidential Memorandum and Statement of Government Policy. This memorandum marked the beginning of an intense discussion about the effect that government patent policy had on commercial utilization of federally sponsored inventions, on industry participation in federally sponsored R & D programs, and on business competition in the marketplace. It was not until industry, academe and the government recognized that their individual interests could be reconciled in the pursuit of commercialization that passage of the Bayh-Dole Act became possible and ended years of debate. *Ibid*. See also Presidential

Memorandum and Statement of Government Patent Policy, issued October 10, 1963. Published in the *Federal Register*, Vol. 28, No. 200.

⁷⁹² See William Swiggart, Bayh-Dole Act & the State of University Technology Transfer in 2003, *supra*. This created an economic partnership triangle among the federal government, universities and private industry, encouraging the commercialization and utilization of therapeutic applications that arise from research in universities and similar institutions funded by the federal government. See Clifton Leaf, The Law of Unintended Consequences, *Fortune Magazine* (9/19/05), at: (<http://www.fortune.com/fortune/fortune75/articles/0,15114,1101810,0.html>).

⁷⁹³ See The Bayh-Dole Act – A Guide to the Law and Implementing Regulations, Council on Governmental Relations, *supra*.

⁷⁹⁴ See Bruce Lehman and Eric Garduño, Technology Transfer and National Innovation, Presentation at the International Conference on Technology Transfer, Intellectual Property Rights and Business Policy, Sao Paulo, Brazil (3/25-3/26/04).

⁷⁹⁵ The provisions apply to all inventions conceived or first actually reduced to practice in the performance of a federal grant, contract, or cooperative agreement. 35 U.S.C. 201(b) and (e). This is true even if the Federal government is not the sole source of funding for either the conception or the reduction to practice. See The Bayh-Dole Act – A Guide to the Law and Implementing Regulations, Council on Governmental Relations, *supra*.

⁷⁹⁶ 35 U.S.C. 202(c)(1).

⁷⁹⁷ 35 U.S.C. 202(c).

⁷⁹⁸ 35 U.S.C. 202(c)(2).

⁷⁹⁹ 35 U.S.C. 202(c)(3).

⁸⁰⁰ 35 U.S.C. 209(a) and (f).

⁸⁰¹ The term small business firm means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. See 35 U.S.C. 201(h).

⁸⁰² 35 U.S.C. 209 (c).

⁸⁰³ 35 U.S.C. 204.

⁸⁰⁴ 35 U.S.C. 202(c)(4); 35 U.S.C. 209(d)(1).

⁸⁰⁵ 35 U.S.C. 202(d); If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated thereunder. See 37 C.F.R. 401.9. In

other words, a University has [the] right to retain title – interpreted to mean that title was with the University ab initio. If [the] University declines title [it] will vest in government through the specific funding agency. See Howard Bremer, THE BAYH-DOLE ACT: Impact on University Research and Intellectual Property Ownership Rights, *supra*.

⁸⁰⁶ 35 U.S.C. 202(c)(7)(B) and (C).

⁸⁰⁷ Agencies may decide, for compelling reasons, that title should be vested in the federal government. Such decisions must be consistent with provisions within the Bayh-Dole Act and made in writing before entering into a funding agreement with a university. The agency must also file a Determination of Exceptional Circumstances (DEC) with the Department of Commerce. The NIH, for instance, has issued several DEC's for programs where NIH determined it was necessary to protect rights in intellectual property obtained from third parties. See The Bayh-Dole Act – A Guide to the Law and Implementing Regulations, Council on Governmental Relations, *supra*.

⁸⁰⁸ 35 U.S.C. 203(a).

⁸⁰⁹ 35 U.S.C. 203(a)(1).

⁸¹⁰ 35 U.S.C. 203(a)(2).

⁸¹¹ 35 U.S.C. 203(a)(3).

⁸¹² With the passage of the Bayh-Dole Act, colleges and universities immediately began to develop and strengthen the internal expertise needed to effectively engage in the patenting and licensing of inventions. In many cases, institutions that had not been active in this area began to establish entirely new technology transfer offices, building teams with legal, business, and scientific backgrounds. Evidence of this is reflected in the fact that the membership of the Association of University Technology Managers (AUTM) increased from 200 in 1990 to 800 in 1999. 691 in 1989 to 2,178 in 1999. In 1979, the year before passage of the Bayh-Dole Act, the Association counted only 113 members. See The Bayh-Dole Act – A Guide to the Law and Implementing Regulations, Council on Governmental Relations, *supra*.

⁸¹³ See Howard Bremer, THE BAYH-DOLE ACT: Impact on University Research and Intellectual Property Ownership Rights, *supra*.

⁸¹⁴ Before passage of the Bayh-Dole Act, fewer than 250 patents were issued to U.S. universities each year. Sixteen years later in 1996, universities received more than 2,000 new patents, executed nearly 2,200 licensing agreements, and received royalty income from licensing of \$242 million. See University Technology Transfer of

Government-Funded Research Has Wide Public Benefits Association of American Universities (1998), *supra*.

⁸¹⁵ Since 1980, American universities have witnessed a tenfold increase in the patents they generate... See W. Mark Crowell and James C. Greenwood, 'The Law of Unintended Consequences' vs. 'The Most Inspired Piece of Legislation in the U.S. in the Last 50 Years', *Fortune Magazine* (9/19/05), at:

(<http://www.autm.net/news/dsp.newsDetails.cfm?nid=63>).

⁸¹⁶ [F]rom its inception in 1984 through fiscal year 2001, the Columbia University Licensing Office generated \$1 billion of cumulative revenue through the licensing of university developed technology (much of this was from a single drug patent). See William Swiggart, *Bayh-Dole Act & the State of University Technology Transfer in 2003*, *supra*, citing from a presentation (unpublished) made by Frank Carrigan, Columbia University Science and Technology Ventures, at May 30, 2002 PrincetonEN.org National Conference.

⁸¹⁷ Academic institutions were granted more than 8,000 U.S. patents between 1993 and 1997 for technologies discovered by their researchers. See *The Bayh-Dole Act – A Guide to the Law and Implementing Regulations*, Council on Governmental Relations (Sept. 1999), *supra*.

⁸¹⁸ [T]he Bayh-Dole Act... provides a strong incentive for university-industry research collaborations. At the national level, industry support for research and development at universities represents less than 7% of the total funding of university-based research. While small compared to the 60% provided by federal agencies, this private investment in the creativity of universities, including professors, students and staff, drives a form of technology transfer that is increasingly important to industry. The investment by industry rests on a secure footing because it is based on the principles and provisions of the... Act. *Ibid*.

⁸¹⁹ Bayh-Dole has also contributed significantly to economic development. Between 1980 and 2004, U.S. universities, hospitals and research institutes combined spun out 4,543 companies based on licenses from those institutions. Two-thirds of these companies are still operating -- a high survival rate. Yet the process of creating and funding a new company is extraordinarily difficult because academic technologies are early-stage, unproven and high-risk. In gathering data for the fiscal year 2004 AUTM Licensing Survey, respondents reported that almost 50% of new spin-out companies received funding from individuals: the entrepreneur, the professors' friends and family, and individual angel investors. Venture capitalists financed fewer than 20% of spin-outs... In addition, more than 200,000 Americans are directly

employed in the biosciences field. This number does not include the hundreds of thousands of jobs and billions of dollars of economic impact this industry has had on the U.S. economy since Bayh-Dole was enacted. See W. Mark Crowell and James C. Greenwood, 'The Law of Unintended Consequences' vs. 'The Most Inspired Piece of Legislation in the U.S. in the Last 50 Years', *supra*.

⁸²⁰ In 2002... [a Fortune Magazine article quoted a study of the AUTM [The Association of University Technology Managers] allegedly reporting that]... North American academic institutions spent over \$200 million in litigation (though some of that was returned in judgments) -- more than five times the amount spent in 1991... [Actually] ... the Licensing Survey[']s... definition... [of]... Legal Fees Expenditures'... is in fact *the amount that academic institutions spent to obtain patent protection. This protection creates intellectual property from research results so institutions can license the results to industry for development.* The definition of Legal Fees Expenditures' explicitly excludes litigation costs. Further, Legal Fees Reimbursement'... shows that more than 40% of patent costs are reimbursed by licensees. *The correct interpretation of the data is that the universities, which spent \$38 billion on research in fiscal year 2003, made a net investment of around \$120 million -- just 0.3% of their research expenditures -- to turn scientific results into intellectual property that could be licensed to companies for commercialization* (emphasis added). *Ibid.*

⁸²¹ Having seen the results, America's trading partners have been quick to follow suit... Countries around the world are expressing their agreement by adopting laws similar to the Bayh-Dole Act. Germany, Korea and Taiwan are the most recent countries allowing academic institutions, as opposed to individual professors, to own inventions resulting from research in their labs. In Japan, the government is privatizing the entire university system in part because they want Japanese universities to become economic catalysts, like their U.S. counterparts. The British and Canadian governments have established pools of funds to accelerate the commercialization of university research. (In the U.S., universities fund commercialization themselves without government support.) *Ibid.*

⁸²² *Ibid.*

⁸²³ See 109TH CONGRESS 1ST SESSION H. CON. RES. ___ (12/14/05), Expressing the sense of the Congress regarding the successful and substantial contributions of the amendments to the patent and trademark laws that were enacted in 1980 (Public Law 96-517; commonly known as the Bayh-Dole Act'), on the occasion of

the 25th anniversary of its enactment at:
<http://www.autm.net/docs/HConRes319.PDF>)
<http://www.autm.net/docs/HConRes319.PDF>).

⁸²⁴ The life sciences industry is said to include organizations in the fields of biotechnology, pharmaceuticals, biomedical technologies, nutraceuticals, cosmeceuticals, food processing, environmental and biomedical devices. *See* Bitpipe, at: (<http://www.bitpipe.com/tlist/Life-Sciences-Industry.html>). It has been alternatively described as including the medical device, bio-tech, biomedical, pharmaceutical and healthcare industries. *See* Life Science Industry Council, at: (<http://www.elinc.org>).

⁸²⁵ This is broad category including many industry sectors. The OECD has attempted to provide a description of ICT. *See* A Proposed Classification of ICT Goods, OECD Working Party on Indicators for the Information Society, Organization for Economic Cooperation and Development (2003), cited at Information, Communication Technology (ICT) Sector, OECD Glossary of Statistical Terms, at: (<http://stats.oecd.org/glossary/detail.asp?ID=3038>). *See also* (http://unstats.un.org/unsd/cr/registry/docs/i31_ict.pdf). ICT goods are those that are either intended to fulfil the function of information processing and communication by electronic means, including transmission and display, OR which use electronic processing to detect, measure and/or record physical phenomena, or to control a physical process. ICT goods are defined by the OECD in terms of the United Nations Harmonized System. *See* OECD Glossary of Statistical Terms, at: (<http://stats.oecd.org/glossary/detail.asp?ID=6274>).

⁸²⁶ According to Brazil's Department of Civil Aviation (DAC), Brazil holds the world's third largest business aviation fleet, surpassed only by the US and Mexico. The total Brazilian fleet registered with DAC is approximately 17,000 aircraft, including airplanes and civil and military helicopters. Embraer is the fourth largest aircraft manufacturer in the world... *See* Gary Sands, Brazil's Airline Sector Is No Flight of Fancy, Brazil Magazine (5/2/05), at:

(<http://www.brazilfile.com/content/view/9018/76>). Embraer is Brazil's largest aerospace company, with 34 years of experience in designing, developing, manufacturing, selling and providing after-sales support for the global aircraft market. It is also Brazil's second-largest exporter. On February 17, 2006, Embraer announced that it expected demand in Asia and the Middle East for between 150 and 200 Super Tucano military training planes during the next five years. The world's fourth-largest maker of commercial planes will present the plane for the first time in Asia next week at the Asian Aerospace 2006 show in

Singapore. Last month, Embraer said its Chinese joint venture won a contract to sell five ERJ 145 LR planes to China Eastern Airlines. *See Embraer Sees Asian, Mideast Military Plane Demand*, Reuters (2/17/06), at: <http://today.reuters.com/business/newsarticle.aspx?type=basicIndustries&storyID=nN17313863&imageid=&cap=>. Aside from Embraer, São Paulo is home to other important companies such as Helibrás, a helicopter manufacturer, and Avibrás, manufacturer of military products. These big corporations have been encouraging the development of modern technology-based companies that offer world class products. São Paulo's aerospace activities comprise three lines: The aircraft industry, engaged in the manufacturing of airplanes, helicopters and their structural parts, engines and components and parts, radiocommunication and navigation equipment, on-board systems and air traffic equipment. The defense industry which, apart from airplanes for several types of military missions, also operates in the integration of systems and in the manufacturing of equipment, parts, and non-guided and intelligent weapons. The space industry, focused on the manufacturing of small satellites and their parts, cargo equipment such as payloads, rocket sounding and runway trailers, and several types of systems and their parts. *See Portal do Governo do Estado de Sao Paulo – Economic Sectors – Aerospace Industry* (2003), at: <http://www.investimentos.sp.gov.br/idiomas/english/setores/aeroespacial.htm>).

⁸²⁷ Petrobras, currently Brazil's largest company with net revenues of US\$ 32 billion (R\$ 95.7 billion) in 2003, is seeking to become a major global energy firm with objectives to both internationalize its operations as well as to dramatically increase production and refining within Brazil. Oil exploration and production (E & P) is expected to account for 70% of Petrobras' annual investments... [in, for example,]... offshore and onshore equipment and services, including flexible pipes, oilwell completion systems, pumps, valves, drill pipes, subsea services and others... Petrobras has also recently discovered a giant non-associated gas field with 70 billion m³ in estimated reserves capable of producing 10 million m³/day. This amount represents approximately 30% of Brazil's proven gas reserves which are currently estimated at 231 billion m³. *See Adriana Lieders, Note -A New Chapter in Brazil's Oil Industry: Opening the Market While Protecting the Environment*, 13 *Georgetown International Environmental Law Review* 781 (2001). Petrobras has announced that in May 2005, it posted a monthly average production of 1.729 million barrels of oil per

day (bpd) in Brazil, 21.1% more than the volume produced in May 2004 (1.428 million bpd). This result is also 1.5% up on volume for April of this year (1.704 million bpd) and 15.8% above the average for last year (1.493 million bpd). See Press Release: Petrobras Breaks a New Monthly Oil Production Record in Brazil (6/30/05), at: (http://www.oilvoice.com/Petrobras_Breaks_a_New_Monthly_Oil_Production_Record_in_Braz/3839.htm). Petróleo Brasileiro S.A., Brazil's state-controlled oil company, said fourth-quarter profit jumped 92 percent as higher fuel prices increased revenue. Consolidated net income at Rio de Janeiro-based Petrobras rose in the quarter to 8.14 billion reais (\$3.85 billion) or 1.86 reais a share, compared with 4.24 billion, or 97 centavos a share, a year earlier, the company said in a statement to the country's securities regulator. The company, which doubled revenue since 2001, is counting on rising sales to finance most of a \$56 billion, five-year plan to almost double output worldwide by 2010 to 3.4 million barrels a day, about the same as Mexico produces today. The company, which is discovering more than 13 barrels of new oil for each barrel it extracts, aims to become a net exporter of oil by the end of this year. See Jeb Blount, Petrobras 4th Qtr Net Soars on Prices, Lower Costs, Bloomberg (2/17/06), at: (http://www.bloomberg.com/apps/news?pid=10000086&sid=ai2fv18NsC2g&refer=latin_america).

⁸²⁸ See Remarks By U.S. Commerce Deputy Secretary David A. Sampson, cited in U.S.-Brazil Cooperation On Trade Is Crucial, Says U.S. Official - Commerce Department Outlines Areas for Closer Cooperation, U.S. Department of State International Information Programs (1/27/06), at: (<http://usinfo.state.gov/wh/Archive/2006/Jan/27-588350.html>).

⁸²⁹ The number of Brazilian pharmaceutical companies may actually be much larger than the number herein provided, according to an April 2005 report submitted to the WHO Commission on Intellectual Property Rights, Innovation and Public Health. Today, according to data from Intercontinental Medical Statistics, Brazil possesses 551 companies in the pharmaceutical area (laboratories, distributors and exporters) and holds 11th place in the ranking of the pharmaceutical world market. See Claudia Ines Chamas, Developing Innovative Capacity in Brazil To Meet Health Needs, pp. 75-111, at p. 82, in Sibongile Pefile, Zezhong Li, Wan Ke Chen Guang, Claudia Chamas, and Hiro Bhojwani, Innovation in Developing Countries to Meet Health Needs - Experiences of China, Brazil, South Africa and India, *supra.*

⁸³⁰ See U.S. Country Commercial Guide 2006 – Brazil (January 2006), at p. 26, at: (http://www.focusbrazil.org.br/ccg/PDF_Files/Brazil%20Country%20Commercial%20Guide.pdf).

⁸³¹ According to Brazil's Pharmaceutical Industry Syndicate (SINDUSFARMA), total Brazilian imports of pharmaceutical products in 2004 were approximately US\$1.8 billion. This reflects a 12% increase over the previous year's level. [See potential discrepancy in reported figures with the number reported to the WHO (approx. 50%) from FEBRAFARMA trade association and the number reported by USG from SINDUSFARMA.].

Ibid. See also Background Document for 3rd Commission Meeting, Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization (1/31/05 – 2/4/05), at: (<http://www.who.int/intellectualproperty/events/BackgroundPaper.pdf>), citing the Brazilian Federation of Pharmaceutical Industry (FEBRAFARMA) (1/19/05), at: (<http://www.febrafarma.org.br/areas/economia/economia.asp?area=tc>).

⁸³² See Claudia Ines Chamas, Developing Innovative Capacity in Brazil To Meet Health Needs, pp. 75-111, at p. 83, in Sibongile Pefile, Zezhong Li, Wan Ke Chen Guang, Claudia Chamas, and Hiro Bhojwani, Innovation in Developing Countries to Meet Health Needs – Experiences of China, Brazil, South Africa and India, *supra*.

⁸³³ See U.S. Country Commercial Guide 2006 – Brazil (January 2006), at p. 26.

⁸³⁴ See Antonio Costa, A View of the Brazilian Pharmaceutical Industry, Pharmaceutical Engineering (Jan.-Feb. 2004), Vol. 25, No. 1, reprinted in Country Profile – A Look at the Pharmaceutical Industry in Brazil, Pharmaceutical Engineering, International Society for Pharmaceutical Engineering (ISPE) (Jan-Feb 2005), at p. 3.

⁸³⁵ The Brazilian pharmaceutical market also includes a network of public laboratories (at federal, state and municipal levels) united by ALFOB. With a production capacity estimated at 11 billion pharmaceutical units per year, the 18 laboratories supply around 10% of the purchases made by the Ministry of Health. They are important players in the government's health policy, both as public medicine providers and price regulators. See Sibongile Pefile, Zezhong Li, Wan Ke Chen Guang, Claudia Chamas, and Hiro Bhojwani, Innovation in Developing Countries to Meet Health Needs – Experiences of China, Brazil, South Africa and India, *supra*, at p. 83.

⁸³⁶ *Ibid.* Brazil imports 80% of raw material used in pharmaceutical products. See *Improvement in the Quality Control of Raw Pharmaceuticals*, U.S. Commercial Service Brazil Market Research (Oct. 2005), at p. 1.

⁸³⁷ See Claudia Ines Chamas, *Developing Innovative Capacity in Brazil To Meet Health Needs*, pp. 75-111, at pp. 81-83, in Sibongile Pefile, Zezhong Li, Wan Ke Chen Guang, Claudia Chamas, and Hiro Bhojwani, *Innovation in Developing Countries to Meet Health Needs – Experiences of China, Brazil, South Africa and India*, *supra*. ... The Brazilian pharmaceutical market in 2004, was divided up as follows: Brazilian companies 36%; American 23%; German 16%; Other – (presumably China, India, others) 14%; Swiss 11%. The ten largest laboratories in terms of billing (comprising approx. 45.2% of the Brazilian market), 15.2% were Brazilian, French 5.8%, German 8.2%, Swiss 9.2%, American 6.8%. See *Improvement in the Quality Control of Raw Pharmaceuticals*, U.S. Commercial Service Brazil Market Research, at p. 5.

⁸³⁸ See *Improvement in the Quality Control of Raw Pharmaceuticals*, U.S. Commercial Service Brazil Market Research, at p. 5.

⁸³⁹ Although the API industry in China is continuing to develop rapidly, it still lags behind its Indian counterpart. Today, China continues to be mostly a supplier of older, off-patent molecules, while Indian API manufacturers often focus on newer, still-patented molecules. As a result of the introduction of product patents in India this January, we may however see increased interest in older molecules by Indian API manufacturers, though the full impact of this change is difficult to determine at this time... [T]he number of Indian and Chinese API manufacturers who have reached Newport's Established category, reserved for companies that Newport believes have been able to supply API to regulated markets for some time, has increased. While India still has more Established companies than China, the latter saw a bigger increase. Today, Newport rates 19 Indian and 12 Chinese API manufacturers as Established, as compared to 18 in India and 8 in China about one year ago. See Kate Kuhrt, *Where China and India Fit in the Global Active Pharmaceutical Ingredients (API) Supply Chain*, Thomson Scientific Knowledge Link Newsletter (June 2005), at: (<http://scientific.thomson.com/news/newsletter/2005-06/8279854>).

⁸⁴⁰ China [possesses many] strengths in APIs [:] Highly skilled in extraction and purification of herbs and botanicals; Highly skilled in fermentation of microorganisms; Very competitive in synthesis of intermediates and the finished API; Becoming competitive in R-DNA biologics. See Andrew Chen, *Sell Your Active Pharmaceutical*

Ingredients in the U.S., Slideshow Presentation made at the 10th Annual Conference of the Chinese Biopharmaceutical Association, USA (Rockville, MD – 6/18/05), at p. 15, at: (http://www.dwt.com/practc/life_sciences/SellPharmUS/SellPharmUS_files/frame.htm#slide0052.htm).

⁸⁴¹ Active Pharmaceutical Ingredients (API) are active chemicals used in the manufacturing of drugs. They are otherwise referred to as Bulk Drug Substances. See Active Pharmaceutical Ingredients (API), at: Drug Development-Technology.com at: (<http://64.233.179.104/search?q=cache:PpdCfQmS-M4J:www.drugdevelopment-technology.com/glossary/active-pharmaceutical-ingredients.html+active+pharmaceutical+ingredients+defined&hl=en&gl=us&ct=clnk&cd=1>). Definition of an API: For purposes of manufacturing and marketing, FDA regulations define an API/drug substance to mean a component of a drug that is intended to furnish pharmacological activity in the diagnosis or treatment of disease. 21 CFR 210.3(a)(7); 314.3. See also Guidance for Industry Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) (Aug. 2001), at: (<http://www.fda.gov/cder/guidance/4286fnl.pdf>).

⁸⁴² [T]he member companies of ALANAC [Associação dos Laboratórios Farmacêuticos Nacionais, Brazil] make finished dosage forms of medicines. This group of national laboratories has great capacity in Brazil to produce medicines where no patent issues exist and knowledge on manufacturing is available. See Comments of Mr. Dante Alario Jr., President & Director, ALANAC, Stakeholder Meetings, Pharmaceutical Manufacturers, at the Third Meeting of the Commission on Intellectual Property Rights, Innovation and Public Health, Commission on Intellectual Property Rights, Innovation and Health, World Health Organization, Brazil (1/31/05-2/4/05), at: (<http://www.who.int/intellectualproperty/events/meeting3/en/index1.html>).

⁸⁴³ ... [S]o many of the APIs [active pharmaceutical ingredients] used in Brazil come from India and China, and... there is very little integration between producers of APIs and producers of finished dosage products. Firms in the association are ready to expand production, both in terms of numbers of APIs as well as the quantities of each API. One issue with expansion, according to Dr. Mansur, is the lack of support for R&D in Brazil in relation to formulation of APIs.

The multi-national corporations do not buy APIs from Brazil. As a result, Brazilian firms have decided to develop APIs where a market existed already i.e. they have focused on ARVs due to domestic government demand. One possible way forward may be to provide guaranteed markets rather than providing financial support or grants to do R&D. This suggestion has grown out of previous difficulties in securing sales to the government because it would not follow through with a contract after asking firms to do R&D on the cost of production for ARV APIs. This is not sustainable: real commitments or contracts are needed if firms are going to stay in business. *See* Comments of Dr. Ramy Mansur, ABAFINA, at the Third Meeting of the Commission on Intellectual Property Rights, Innovation and Public Health, Stakeholder Meetings, Raw Chemical Manufacturers, *supra*.

⁸⁴⁴ *See* Patents: Time of Crisis, Time of Change, Abifina Informa Newsletter Edition 214, Associação Brasileira das Industrias de Quimica Fina, Biotecnologia e suas Especialidades (Jan. 2006) at: (<http://www.abifina.org.br/informaNoticia.asp?cod=62>).

⁸⁴⁵ *See* Marcela Ferrer, Halla Thorsteinsdóttir, Uyen Quach, Peter A Singer & Abdallah S Daar, The Scientific Muscle of Brazil's Health Biotechnology, Nature Biotechnology, Vol. 22, Supplement (Dec. 2004), at p. DC 9, at: (<http://www.utoronto.ca/jcb/home/documents/Brazil.pdf>).

⁸⁴⁶ *Ibid.*, at p. DC 10; Biotechnology companies are engaged in a variety of activities. Such as plant and micro-propagation improvement, production of bio-pesticide inoculates, food, pulp, and embryos and disease diagnosis... According to Embrapa, the main biotechnology applications in agriculture, include the following areas: Vegetal production and silviculture: genetic improvement, propagation, growth and nutrition; Animal production, aquaculture and fishing: genetic improvement, sanitation, and nutrition; Agro-industry: fermented products, biomass, and food processing, energy and equipment production; Environment: Bio monitoring, bio-recuperation of degraded ecosystems, Handling of waste and pollutants, and biologic control of diseases. *See* Vania Resende, The Biotechnology Market in Brazil, STAT-USA Market Research Report (3/12/03), at: (<http://strategis.ic.gc.ca/epic/internet/inimr-ri.nsf/en/gr114487e.html>).

⁸⁴⁷ ABRABI – The Brazilian Association of Biotech Companies, was established in 1986 *with the objective to promote the development* of the biotechnology in Brazil and to forward the companies's interests. Today, we defend the use of the genetic technology in agriculture, health, environment and industry and the access to biodiversity, aiming at the transformation of biotechnology into economic activity. We have

the objective to foster Biobusinesses, generating the creation of companies, jobs and taxes. We intend to bring to ABRABI the multiple players required for the development of the industry, as the Research, Development & Innovation institutes, the suppliers of equipment and inputs, the investors, the patent lawyers, the small innovative companies, the pharmaceutical industry, the agrobusiness, the bio informatics firms, the specialists of the government and the congress with the objective to stimulate the discussion and the cooperation... - We developed the web site "Brazilian Market of Biotechnology" (www.biotecbrasil.org.br) that it aims to stimulate the businesses of the area, listing all agents involved in biotechnology, the economic turnover, the job market and other informations... **ABRABI** has the goal to stimulate the development of the BIOTECHNOLOGY and the BIOBUSINESS in Brazil and Latin America. See *What's ABRABI*, English Translation at: (<http://www.abrabi.org.br/quemsomos.htm>).

⁸⁴⁸ See Marcela Ferrer, Halla Thorsteinsdóttir, Uyen Quach, Peter A Singer & Abdallah S. Daar, *The Scientific Muscle of Brazil's Health Biotechnology*, at p. DC 8.

⁸⁴⁹ *Ibid.*

⁸⁵⁰ ... The use of biotechnology to exploit natural resources of the Amazon rain forest is a strategic priority for the country's technological progress. The vast opportunities in the Amazon are attracting companies and researchers from all over the world. See: Vania Resende, *The Biotechnology Market in Brazil*, *supra*. [O]ne of the projects that has received attention from the government and from the largest Brazilian pharmaceutical laboratory (Laboratorios Ache) that includes the phytotherapeutic agents due to the diversity of Brazilian flora. See Renato Pimazzoni, *Professional Profile*, in *Country Profile - A Look at the Pharmaceutical Industry in Brazil*, *Pharmaceutical Engineering*, International Society for Pharmaceutical Engineering (ISPE) (Jan-Feb 2005), at p. 7.

⁸⁵¹ Until Achéflan, other plant-based anti-inflammatory drugs on the Brazilian market ha[d] been prepared from imported plants, including some from Africa. The herb in Achéflan has traditionally been used by Brazilians to make medicinal infusions, often sold at fairs. See *Brazil's New Beat: Social Challenges, Economic Progress: The Two Faces of Intellectual Property in Brazil*, *Knowledge @ Wharton* at: (<http://knowledge.wharton.upenn.edu/index.cfm?fa=viewArticle&id=1339&specialId=42>).

⁸⁵² See Michael P. Ryan, *Brazil's Quiet Bio-Medical Innovation Revolution: Drugs, Patents and the 10/90 Health Research Gap*,

Creative and Innovative Economic Center (Feb. 2006), at pp. 7-8, *supra*).

⁸⁵³ Lacking internal R & D capabilities, they established a program of human trials through university and hospital partnership, paid for by shifting some profits from company sales and from a government R&D grant. The trials showed the compound to be both effective and safe and the Brazilian drug regulatory body approved it for sale in summer 2005... *The expensive R&D process that demonstrated the efficacy and safety of the active ingredient took place only after the Brazilian patent reform act that offered patentability to pharmaceutical products... This innovative product also owes to the existence of a university research base that had long been ignored by the private sector but that provided Ache with capabilities its own organization did not have... Finally, the product owes to the husbandry of Sao Paulo state funders that willingly subsidized a research effort for which there was no guarantee of success or of pay-back (emphasis added). Ibid., at pp. 8-9.*

⁸⁵⁴ Achefflan's progress has been strongly supported by The State of São Paulo Research Foundation (FAPESP), which provides financial assistance for the commercialization of new, locally based technologies in that state, Brazil's economic powerhouse. FAPESP funding programs help to correct critical capital market failures in Brazil where macroeconomic problems have long made capital expensive in the marketplace, and where risk-tolerant venture capital has been in short supply', Ryan says. *See Brazil's New Beat: Social Challenges, Economic Progress: The Two Faces of Intellectual Property in Brazil*, *supra*.

⁸⁵⁵ The successful Ache project with its new innovative product Achefflan was carried out in just the way articulated by the 2004 law [See L. 10,973, discussed *supra*.]... Achefflan gives confidence to Ache that it can be a successful innovator and provides a valuable new revenue stream that justifies its commitment to an R&D strategy and makes possible new research investments. *See Michael P. Ryan, Brazil's Quiet Bio-Medical Innovation Revolution: Drugs, Patents and the 10/90 Health Research Gap*, at p. 9.

⁸⁵⁶ Brazilian drug companies *BioLab and Biosintetica* have formed an R & D strategic alliance partnership because innovation is fundamental to survival, in the words of one of the managers. It is a first of kind initiative in Brazil that was five years in the making. *The partners, whose independent R&D efforts have resulted in some three dozen international patents between them, found in themselves complementary business capabilities. They needed university research collaborators to achieve their objective of developing new innovative*

drugs from snake and insect resources. Model agreements were articulated that have permitted collaborative agreements that have produced R&D activities that have so far yielded *11 international patents, though as yet no marketed innovative products*. The public-private collaborative R&D projects being carried out by BioLab, Biosintetica, and Ache begin a new chapter in the Brazilian innovation system story. *Ibid.*, at pp. 9-10.

⁸⁵⁷ In Brazil, the already dismal projections for the products of biotechnology innovators have deteriorated significantly in the last year. Brazil maintains its technology-discriminatory system for dual review of the patentability of medicinal agents. Patents for such agents are reviewed first by the Brazilian Patent Office and then by ANVISA, the pharmaceuticals regulatory agency. *Contrary to Brazil's own patent statute, and its obligations under the TRIPS Agreement, ANVISA has recently propagated guidelines that declare secondary medical use inventions (i.e., new uses for old products) are not patentable*. In several well-publicized instances, *the [G]overnment of Brazil has also threatened to revoke legitimately granted patent rights to compel the owners of certain patents to conduct business on favorable commercial terms*. BIO members are deeply concerned about developments in Brazil that systematically deprive biotechnology innovators of adequate and effective protection for their products, and we urge USTR to act aggressively to promote needed reforms in that country (emphasis added). See Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment Letter from BIO Director of Intellectual Property Lila Feisee to Sybia Harrison, USTR Special Assistant to the Section 301 Committee (3/31/06), at p. 2, at: (<http://www.bio.org/ip/international/20060331.pdf>).

⁸⁵⁸ See: Vania Resende, *The Biotechnology Market in Brazil*, *supra*.

⁸⁵⁹ The first generation of GMOs were smuggled into Brazil from the Argentina border areas (farmers share or cross-own land and share seeds) and the U.S. The 2nd generation of GMOs is now emerging. Brazil and Monsanto are working together. The 3rd generation is being researched. There are 14 RR cultivars registered in Brazil soybean. Three Brazilian seed producers have adopted these cultivars for the central part of the country. Public-private collaborations are in force between Brazilian and international companies and the Brazilian public and private labs to develop GM soybean varieties. Three Brazilian seed producers are Coodetec, Embrapa, & Monsoy (Monsanto subsidiary). This has enabled the introduction of top RR technology into Brazil's agribusiness, and the reduction of soybean production

costs. International companies include Monsanto, BASF, Jircas. On the negative side, the use of new technology grains from GM soy RR varieties damaged the Brazilian seed industry, competitively speaking. *Brazil is skeptical of the Chinese importing market, given China's growing biotech R&D efforts and development of commercial GMO crops that could compete with those in Brazil.* Japanese institutions have helped considerably with the transfer of this technology to Brazil. See Jose Geraldo Eugenio de Franca, Executive Director, EMBRAPA, 'Presentation Notes' at Brazil at a Crossroads – Repercussions of Embracing Genetically Modified Agriculture, Woodrow Wilson International Center for Scholars (11/17/05).

⁸⁶⁰ See Vania Resende, The Biotechnology Market in Brazil, STAT-USA Market Research Report (3/12/03), at: (<http://strategis.ic.gc.ca/epic/internet/inimr-ri.nsf/en/gr114487e.html>).

⁸⁶¹ In 2000, Brazil established itself as a leader in gene sequencing when the Brazilian consortium the Organization for Nucleotide Sequencing and Analysis (ONSA) surprised the international scientific community by making Brazil the first country to decode the genome of a plant pathogen, *Xylella fastidiosa*, a bacterium that attacks citrus fruits... Using the research model for the *Xylella* project... [scientists then] complete[d] the genome sequence of *Chromobacterium violaceum*, which is of potential interest in developing [medical biotechnology] therapies against certain cancers, tuberculosis and Chagas disease... [National collaborations] ha[ve] encouraged health-related genomics projects, including the jointly funded FAPESP and the Ludwig Institute cancer genome project and the Brazilian National Genome Project (NGP)... [T]he NGP consists of 100 scientists from 25 laboratories in Brazil (emphasis added). See Marcela Ferrer, Halla Thorsteinsdóttir, Uyen Quach, Peter A Singer & Abdallah S Daar, The Scientific Muscle of Brazil's Health Biotechnology, Commentary, Nature Biotechnology, *supra*, at p. DC10.

⁸⁶² A Brazilian inventor, Fernando Damasceno, chief engineer at the Brazilian unit of Italian car parts company Magneti Marelli... created... a flex-fuel device... [that was] cheaper... [than]... Ford Motor Co.[s] flex-fuel device... by programming a standard car computer to constantly calculate the mixture of ethanol versus gasoline in the tank and adjust the engine accordingly. In 2002, the team sold the device to Volkswagen, which introduced its flex-fuel Golf the next year [2003]. Mr. Damasceno's black box is now sold by five major car makers in Brazil. Even Ford's Brazil unit uses the Damasceno device. ⁸⁶² See David Luhn and Geraldo Samor, As Brazil Fills Up on Ethanol, It Weans Off Energy

Imports, *Wall Street Journal* (1/9/06), at p. A-1, accessible at: (http://static.twoday.net/mahalanobis/files/ethanol_brazil.pdf) and (<http://yaleglobal.yale.edu/display.article?id=6817>).

⁸⁶³ About half of Brazil's sugar cane crop is used for domestic ethanol production... In the past twelve months sugar has come to be seen as an energy crop because of the growth in demand for ethanol. Brazil's thirst for ethanol, derived from sugar cane, to power flexfuel cars that also run on petrol... has pushed sugar to a 25-year high. Brazil, which produces 20 percent of the world's annual output against 14 percent seven years ago, has lowered its crop forecasts following drought in the north-east. See Kevin Morrison, Sugar's Success: Prices Soar as Brazil's FlexFuel Cars Set the Pace, *Financial Times* (3/30/06), at p. 7.

⁸⁶⁴ See Vania Resende, The Biotechnology Market in Brazil, *STAT-USA Market Research Report*, *supra*.

⁸⁶⁵ While other countries were busy mapping the human genome, Brazilian scientists at the Centro de Tecnologia Canavieira, a research lab funded by sugar growers, were decoding the DNA of sugar cane. That helped them [to] select varieties that were more resistant to drought and pests and yielded more sugar content... Over the past 20 years, the center has developed some 140 varieties of sugar, which has helped lower growing costs by more than 1% a year... Other improvements include *using remains of processed cane to power sugar and ethanol plants, and using industrial waste from ethanol production to fertilize sugar fields*... Electricity cogeneration in sugar/alcohol plants is from sugar-cane bagasse... Bagasse is a by-product from sugar cane crushing. For 300 million tons of cane, bagasse availability is around 42 million tons (dry weight)... Because bagasse production is quite high... 30% of harvested sugar cane, 50% wet... any surplus is sold to other industries. (emphasis added). See Proalcool: The Brazilian Alcohol Program, *Green Times*, Vol. 7, No. 2 (June 2000), at p. 1, at: (<http://www.crest.org/discussion/bioenergia-espanol/200007/pdf00025.pdf>). As a result, the productivity of Brazil's ethanol producers has steadily increased. In 1975, Brazil squeezed 2,000 liters, or about 520 gallons of ethanol from a hectare, or nearly 2.5 acres, of sugar cane. Today, it's nearly 6,000 liters. See David Luhnrow and Geraldo Samor, As Brazil Fills Up on Ethanol, *It Means Off Energy Imports*, *supra*.

⁸⁶⁶ ... [T]he technological development [is in]... the new varieties of sugarcane... [and]... also [in the]... production and industrialization of sugarcane in the process of sugar and ethanol production... The technology has [also] reached the Brazilian automotive industry as well. In 2003... Brazilian industry... equipped... vehicles with FFV

(Flex Fuel Vehicle) technology in their motors, allowing the use of any mixture of hydrated alcohol and gasoline, from 0 to 100%, as well as pure hydrated alcohol. Six multinational manufacturers with plants in Brazil – Volkswagen, General Motors, Fiat, Peugeot, Renault, Ford – now offer 20 different models of vehicles with the Flex Fuel technology and 607,731 units had been sold by April 2005. In April, this... represented 52% of the total of light vehicles sold [in] the internal market... *The Brazilian Alcohol Program [ProaCool] that [was] begun in the 70's is the most successful program of fossil fuel substitution in the automotive world market. The sugarcane agro-industry complex is today the [best] equipped in the world, with strong investments in biotechnology and industrial technology.* There is also the Brazilian Government's new Biodiesel initiative. [While] the share of alcohol in [the] fuel matrix amounts to 15.4%, biodiesel can reach 2.8% in the next [few] years... The law 11.097/2005 establishes the minimum percentages to the mix of biodiesel to mineral diesel fuel... Biodiesel [involves] the substitution of mineral oil for green fuel that can be produced in non-arable lands... [Two] private companies already have initiated the commercial production of biodiesel in the country: [the] first one... using soy, sunflower and turnip oils, and the [other... [using]... palm oil... Brazil has ideal conditions for becoming a major world producer of biodiesel. It has a vast amount of arable land, part of which is not suitable for food crops, but has the right soil and climate for growing a range of oilseeds. *The establishment of the National Biodiesel Program is made easier by the fact that Brazil already has a large number of raw materials for the production of biodiesel, including castor, soy, palm-nut, sunflower and cotton-seed oils* (emphasis added). See ProaCool Interview.

⁸⁶⁷ See Alan Beattie, Ethanol Puts Power in Brazil's Tank, *Financial Times* (5/16/06), at p. 4. Brazil's campaign of investment and technology transfer combines the 'teach a man to fish' adage with tactical motives. First, it enlarges the global ethanol business, and hence, it lobbying power. Second, it may disarm some developing countries' resentment of Brazil's dominant role in world trade. *Ibid.*

⁸⁶⁸ ... Brazilian Com to Produce Growth Hormone – Developed by the Molecular Biology and Genetic Engineering Center of the State University of Campinas (Unicamp) and the Chemistry Institute of the University of São Paulo (USP), these plants are ready to produce 250 grams of the hormone per ton of seeds – enough to treat hundreds of patients for months. The hormone is identical to the human form, and therefore better than the bacterial source that has one extra amino acid. It proved to be cheaper to produce and extract. Papaya Resistant to

Brazilian Strain of Ring Spot Virus... See Claudia Inês Chamas, Andreia Azevedo, Sergio Salles-Filho, Sérgio Paulino de Carvalho, The Dynamics of Intellectual Protection for Biotechnology in Brazil (April 2005) *supra*, at p. 4.

⁸⁶⁹ Comm on Beans Resistant to Golden Mosaic Virus – Developed by Embrapa - Rice and Beans Center –these plants are undergoing greenhouse tests after a long research period, due to the difficulty of adapting existing technology to the specific virus strain. Researchers expect to complete the cross-breeding of the characteristic into commercial lines in two to three years. See Maria José Amstalden Sampaio, Brazil: Biotechnology and Agriculture to Meet the Challenges of Increased Food Production, in Persley, G.J. and Lantin, M.M. (eds.), Presented at Agricultural Biotechnology and the Poor, An International Conference on Biotechnology, Consultative Group on International Agricultural Research - The World Bank (2000) at pp. 76-77, at: (<http://www.cgiar.org/biotech/rep0100/Sampaio.pdf>).

⁸⁷⁰ See Vania Resende, The Biotechnology Market in Brazil, STAT-USA Market Research Report, *supra*.

⁸⁷¹ Embrapa is the economic player of greatest relevance in the production of protected soy seeds. Individually, it holds 23% of the registered protected plant varieties of the species; however, if its partnerships are included, this participation goes up to 36%. Embrapa holds individually the registry of 27% of the protected plant varieties employed in the production of seeds and, considering its partnerships, this participation becomes 41%. The individual participation of Embrapa in the owned seed production is of 16% and in conjunction with the partner institutions, 28%. Another relevant economic player is the Central Cooperative for Agricultural Research – Coodetec, linked to the Cooperative Organization of Paraná – OCEPAR. It participates with 10% of the registered protection for soy plant varieties. See Claudia Inês Chamas, Andreia Azevedo, Sergio Salles-Filho, Sérgio Paulino de Carvalho, The Dynamics of Intellectual Protection for Biotechnology in Brazil (April 2005) *supra*, at p. 4.

⁸⁷² See Vania Resende, The Biotechnology Market in Brazil, STAT-USA, *supra*.

⁸⁷³ According to Classificação Nacional de Atividades Econômicas (National Classification of Economic Activities), prepared by IBGE, the chemical industry comprises the following: inorganic products (chlorine and alkali, fertilizers, industrial gases, among others); organic products (basic petrochemical products, resins and fibers, among others); resins and elastomers; fibers, artificial and synthetic continuous strands; pharmaceutical products; pesticides; soaps, detergents,

cleaning and perfumery products; paints, varnishes, enamels, lacquer and related products; and other several prepared chemical products... See Portal do Governo do Estado de Sao Paulo – Economic Sectors – Chemical Industry (2003), at: (<http://www.investimentos.sp.gov.br/idiomas/english/setores/quimica.htm>).

⁸⁷⁴ According to IBGE, the participation of the chemical sector in the country's total GDP was 3.3% in 2002; it is also the second largest manufacturing industry, with approximately 13% of the GDP, behind only the food and beverages sector, which accounts for 15% of the total. *Ibid.*

⁸⁷⁵ See U.S. Country Commercial Guide 2006 – Brazil (January 2006), at p. 16.

⁸⁷⁶ *Ibid.*, at p. 17.

⁸⁷⁷ See Antonio Bothelo, Giancarlo Stefanuto, and Francisco Veloso, The Brazilian Software Industry, (9/30/03) at pp. 34-35, at: (http://www.globelicsacademy.net/pdf/FranciscoVeloso_2.pdf).

⁸⁷⁸ See Francisco Veloso, Antonio J Junqueira Botelho, Ted Tschang, and Alice Amnden, Slicing The Knowledge-based Economy in Brazil, China and India: A Tale of 3 Software Industries, (Sept. 2003) at p. 21, at: (http://www.softex.br/media/MIT_final_ing.pdf).

⁸⁷⁹ See Chapter 4: Best Prospects for U.S. Businesses – Computer Software, U.S. Country Commercial Guide 2006 – Brazil (Jan. 2006), at p.16, *supra*.

⁸⁸⁰ Certification is another concern. The Brazilian subsidiary of US-based EDS is the only company that has earned the CMM Level 4 certification in Brazil. Three other companies have earned Level 3 certification, but they are all US subsidiaries (Motorola, IBM, and Xerox). Twelve Brazilian companies have earned Level 2 certification. *Brazil's performance stands in stark contrast to India's, where two thirds of the world's Level 5 companies are based (emphasis added).* See U.S. Country Commercial Guide 2005 – Brazil (January 2005), at p. 52.

⁸⁸¹ *Brazil's information technology business should have gone global years ago... Its world-class skills aren't known in most of the world. Despite boasting state-of-the-art systems and software providers, the country has not been able to export its know-how or products to many markets beyond its vast borders...* Brazilian companies by necessity have developed some of the most advanced software in the world in recent decades. An unstable economy and runaway inflation meant Brazilian banks needed sophisticated software merely to keep up with the value of their assets. Local developers arose to supply them and in

the process have garnered enough skills to create complex systems ranging from security and encryption applications to telecommunications and e-government platforms. The country, for instance, boasts one of the most widely used online income-tax programs on the planet. *But what has traditionally been a plus for Brazil's info-tech sector--the size and potential of its home market--has also hindered its ability to expand on a global scale. Sales growth fueled by domestic demand has kept Brazilian technology groups from learning how to sell their wares in the United States, Europe, and elsewhere. Instead, it's playing catch-up as the bulk of the world's information technology outsourcing goes to rivals in India and other developing nations...* A recent [2003] study by the Massachusetts Institute of Technology and four other universities compared the information technology industries of China, India and Brazil. Brazil has an internal market that is at least half a decade ahead of India,' the report's authors wrote. But in terms of its export sector, it is now where India was probably about a decade ago' (emphasis added).

... Over the past year, for example, various industry groups have come together to begin promoting Brazil as an alternative to India and other countries that have thus far attracted the most outsourcing business. With many of the same attributes as those competitors--specialized labor at a price much cheaper than that available in the United States or Europe--Brazilian software companies are rushing to get on the outsourcing bandwagon. See Paulo Prada, Selling Smarts, LATIN TRADE, (Oct. 2004), at: (http://www.websoftware.com.br/news_200410_latintrade.asp).

⁸⁸² Brazilian players have to prove that competencies acquired in domestic sectors can be successfully applied abroad, while defending their turf from increasing competition at home... The software industry is important because of its potential direct economic impact, but its value for an economy can go much beyond that. Software is a critical leverage for innovation across virtually every area of activity, and plays a major role at the level of intra and inter organizational learning... *Having a sophisticated group of software firms that work with the local industry to leverage national and foreign software tools can have important productivity inducement effects throughout the entire industrial base of a country. In fact, most developing nations that are actively fostering the development of the software industry are aiming at using the industry to 'leapfrog' the economy into more knowledge-based firms and industrial capabilities, hopefully generating high value added exports* (emphasis added). See Francisco Veloso, Antonio J Junqueira Botelho, Ted Tschang, and Alice Amsden,

Slicing The Knowledge-based Economy in Brazil, China and India: A Tale of 3 Software Industries, *supra* at pp. 2, and 4-5.

⁸⁸³ IT services will account for the largest share in technological investments, as acquisitions of infrastructure, software, and hardware have to a great extent already been made in the 2000-2003 period ... In Telecoms, the first set of interesting pockets of competence relevant to the software industry is associated with embedded software... Siemens... is one of the leading examples among foreign players... [T]he company is now the largest... in the electronics and electrical engineering sector... in Brazil... , employing nearly 8900 people in 12 production facilities and 13 sales offices nationwide. The presence of Siemens in Brazil includes also a Telecommunications Technology and Research and Development Center with over a hundred full time researchers and an additional several hundred other affiliated through university grants and contracts. The research laboratory is a world competence Center for four product lines... This means that the unit has global full cycle product responsibilities, including research, development, and manufacturing for these lines. Like Siemens, Ericsson has close to 500 people in its Brazilian research unit, ALL devoted to research and development in software. Among other [things], the Brazilian Unit is responsible worldwide for full cycle development of software for several systems in its fixed and mobile telephony. See Antonio Bothelo, Giancarlo Stefanuto, and Francisco Veloso, *The Brazilian Software Industry* *supra*, at p. 37.

⁸⁸⁴ The high-technology group Itautec Philco is one of Brazil's largest companies. Through a number of subsidiaries it is involved in a wide range of activities including the manufacture of PCs, computer components and consumer audio-visual equipment, as well as Internet security and telecoms services. Itautec [recently] won a five-year outsourcing contract to handle computer operations for Carrefour (France). Itautec is an information technology subsidiary of Itaú, a leading Brazilian banking group. Carrefour is the second-largest retail chain in the country, with 86 hypermarkets, 98 supermarkets, 13 distribution centres and one information centre. See *Brazil Technology: Itautec Wins Five-Year Outsourcing Contract*, Global News Analysis, Global Technology Forum - The Economist Intelligence Unit Limited (7/12/05), at: (http://www.ebusinessforum.com/index.asp?layout=rich_story&doc_id=7451&title=Brazil+technology%3A+Itautec+wins+five%2Dyear+outsourcing+contract&channelid=4&categoryid=28). Another major local group is Splice, which was started in 1962 as a private telecoms operator and is now involved in technology manufacturing activities

that range from communications infrastructure and traffic monitoring systems to smart cards and public telephones. Splice also holds two mobile telephone licenses. Abinee is an industry association that represents about 600 companies in the electrical and electronics industries. Its members include many overseas businesses with operations in Brazil. Camara-e.net is an association that was formed in 2001 to promote e-commerce in Brazil. See Brazil: Telecoms and Technology Background, Doing E-Business in Brazil, Global Technology Forum – Economist Intelligence Unit (2004), at: (http://www.ebusinessforum.com/index.asp?layout=newdebi&country_id=BR&channelid=6&country=Brazil&title=Doing+e-business+in+Brazil).

⁸⁸⁵ Another industry where local industry is extremely sophisticated is telecommunications. See Antonio Bothelo, Giancarlo Stefanuto, and Francisco Veloso, The Brazilian Software Industry *supra*, at p. 33.

Brazil is by far the largest information technology (IT) market in Latin America, and has an industry producing a total value of computer and telecommunications equipment worth over US\$30bn. The telecoms market has been transformed not only by the development of new technologies but also by the privatisation of the state telecoms operator, Telebrás, in 1998, as well as by continuing liberalisation and state encouragement of the development of new technologies... [T]he Brazilian telecoms market returned to growth in 2004... Brazil: Telecoms and Technology Background, Economist Intelligence Unit, *supra*.

⁸⁸⁶ See 2005 U.S. Commercial Service Guide to Brazil Investment Climate, at p. 20. See also, The FDI – Employment Link in a Globalizing World: The Case of Argentina, Brazil and Mexico Employment Strategy Paper 2005/17, International Labor Organization (2005), at:

(<http://www.ilo.org/public/english/employment/strat/download/esp2005-17.pdf>). The new outward oriented development strategy of the 1990s led to a FDI boom in Latin America... Most investment, in particular in Argentina and Brazil went into already existing companies as a result of privatisation, deregulation and increased M&A, especially in the service sector. FDI in the service and manufacturing sector was often combined with modernization and rationalization measures leading to labour shedding. Nevertheless, FDI contributed, to a certain extent, to the modernization of the economy, a rise in competitiveness and to a better integration into the world economy... Brazil, compared with the two other countries, was a late starter with regard to economic reforms, which is also reflected in the timing of FDI inflows. Such

inflows only began to take off after the introduction of the *Real in 1994* and the resulting macroeconomic stabilization... peaking in 2000 at US\$ 32.8 billion. However, in 2003 they fell sharply to US\$ 10.1 billion. The main reasons for this decline were the world recessions in 2000 and 2001, which also affected Argentina and Mexico, Brazil's poor economic performance, an unstable political and economic environment, the crisis in Argentina and the impending national elections. *Ibid.*, at pp. 1 and 3.

⁸⁸⁷ See 2005 U.S. Commercial Service Guide to Brazil, Executive Summary at p. 3. A recent United Nations report confirmed that the FDI increase enjoyed by Brazil in 2004 was experienced globally. On account of a strong increase in foreign direct investment (FDI) flows to developing countries, 2004 saw a slight rebound in global FDI after three years of declining flows. At \$648 billion, world FDI *inflows* were 2% higher in 2004 than in 2003. See Transnational Corporations and the Internationalization of R & D, United Nations Conference on Trade and Development (UNCTAD) World Investment Report, UNCTAD/WIR/2005

(Sept. 2005), at p. 1, at: (http://www.unctad.org/en/docs/wir2005_en.pdf). Following four years of continuous decline, FDI flows to Latin America and the Caribbean registered a significant upsurge in 2004, reaching \$68 billion – 44% above the level attained in 2003. Economic recovery in the region, stronger growth in the world economy and higher commodity prices were contributing factors. Brazil and Mexico were the largest recipients... *Ibid.*, at p. 12.

⁸⁸⁸ According to a recent media article, the actual 2004 amount may have been \$18.17 billion. The [Brazilian] central bank also reported that foreign direct investment in 2005 fell to \$15.19 billion from \$18.17 billion in 2004. See UPDATE 2-Brazil '05 Current Account Surplus a Record \$14 Bln, Reuters (1/19/06), at: (http://yahoo.reuters.com/financeQuoteCompanyNewsArticle.jhtml?duid=mtfh79053_2006-01-19_13-31-32_n19284727_newsml).

⁸⁸⁹ *Ibid.*

⁸⁹⁰ *Ibid.* For example, Japanese investment into China in 2005 hit a record \$6.5 billion... The Beijing office of the Japan External Trade Organization said... that Japanese foreign direct investment into China rose 19.8 percent to \$6.5 billion last year, driven by car manufacturers and electronics companies. Total FDI into China during the year was around \$60 billion. See David Ivison, Japanese FDI In China A Record \$6.5 Bn, Financial Times (4/4/06), at p. 4.

⁸⁹¹ See Prospects for Foreign Direct Investment and the Strategies of Transnational Corporations, 2005-2008, UNCTAD/ITE/IIT/2005/7 (2005), at: (http://www.unctad.org/en/docs/iteiit20057_en.pdf). According to a recent report produced by the United Nations Conference on Trade and Development (UNCTAD), Brazil ranked among transnational corporations (TNCs) the fifth most attractive FDI location in the world after China, India, the U.S. and the Russian Federation. Brazil was also ranked by TNCs as the MOST attractive FDI location in Latin America. *Ibid.*, at pp. iv-v, Table 1 Summary of Survey Results Regional Prospects – Latin America and the Caribbean at p. vi, p.13. More than 80% of TNCs and 90% of FDI experts believe that the country [Brazil] will be one of the region's five most attractive investment locations in the short term. This may be due to a recent upturn in the economy, led by the dynamically expanding export sector... FDI growth in Latin America and the Caribbean is expected to be the highest in service industries... The industries with the most positive prospects are hotels and restaurants, construction/infrastructure related and real estate, tourism and computing and ICT services. In the manufacturing sector, the majority of Latin American IPAs expect no significant change in FDI flows. The only exception to this is the food and beverage sector, for which the outlook is more promising. This suggests that the region's manufacturing industries are still in the process of restructuring. *Ibid.*, at pp. 41-43.

⁸⁹² Heavier dollar inflows from exports have allowed Brazil's central bank to triple its hard currency reserves over the last few years to \$53.8 billion, in part by buying dollars on the spot foreign exchange market. That has paved the way for Brazil to recently repay all debts owed to multilateral lenders like the International Monetary Fund. See UPDATE 2-Brazil '05 Current Account Surplus a Record \$14 Bln, *supra*.

⁸⁹³ On December 23, 2005, the Brazilian government announced that it would pay off in advance (anticipate) the \$2.6 billion debt it has owed to the Paris Club since 1983. This followed a \$15.5 billion payoff to the International Monetary Fund during the previous month. For Brazilian President Luiz Inácio Lula da Silva, the decision to anticipate paying off the IMF debt shows that Brazil can control its own destiny. "We are making this payment because we want to show the world and the market that we are in charge. See Lourenço Melo, Brazil Repays Early US\$ 2.6 Billion Debt With Paris Club and Saves US\$ 100 Million *Brazzil Magazine* (12/23/05), at: (http://www.brazzilmag.com/index.php?option=com_content&task=view&id=4899&Itemid=49). The Paris Club is an informal group of

official creditors whose role is to find coordinated and sustainable solutions to the payment difficulties experienced by debtor nations... Although the Paris Club has no legal basis nor status, agreements are reached following a number of rules and principles agreed by creditor countries, which help a coordinated agreement to be reached efficiently... The 19 Paris Club permanent members are governments with large claims on various other governments throughout the world (the claims may be held directly by the government or through its appropriate institutions). See Description of the Paris Club, at: <http://www.clubdeparis.org/en/presentation/presentation.php?BATCH=B01WP01>); See also Permanent Members and Other Official Creditors at: <http://www.clubdeparis.org/en/presentation/presentation.php?BATCH=B01WP03>).

⁸⁹⁴ [T]he figures for [Brazill's] industrial production in December [2005] apparently show[ed] that last year ended not with the whimper that many expected but with what may be the beginnings of a recovery. Add in falling unemployment and interest rates, a hefty increase in the national minimum wage, tax cuts for the construction industry, [and] a bumper harvest on the way... The better-than-expected industry figures for December suggest the economy may have grown by about 2.5 last year instead of the expected 2.2 percent... It is true that unemployment has fallen and that lower interest rates should help recovery in domestic consumption; recent growth has been driven mostly by exports. Mr. Lula can count on growing popular support not only because of the higher minimum wage but also from a broad recovery in spending power among the poor and from the expansion of poverty-relief programs. *But even if growth picks up it is destined to fall short of Brazil's needs and of its potential. No amount of poverty relief can solve the country's fundamental problem: that the government spends in excess of its means, and spends badly... Non-discretionary spending on debt, pensions and payroll, and a steady increase in other current expenditure, leaves the government with just 2.5 percent of its income to spend on infrastructure and other drivers of growth...* As Raul Velloso, a specialist in public finances says, the steady increase in non-discretionary spending as a percentage of GDP in recent years has been possible only because it has been outstripped each year by an increase in the tax hike... With the tax burden at about 37 percent... Marcelo Salomon, chief economist at Unibanco, a big local bank, says this is driving more and more businesses into the enormous informal sector (emphasis added). See Jonathan Wheatley, *Lula Defies Doubters With*

Popular Revival As Polling Time Nears , *Financial Times* (2/9/06), at p. 4.

⁸⁹⁵ Plenty of evidence exists to suggest... that *leftwing governments* – whether radical populists such as Mr. Chavez [of Venezuela] or more moderate reformers such as Mr. Lula da Silva – are being lulled into a false sense of security about the strength of their economies and are failing to undertake structural reforms to boost efficiency in the long term. One problem is that Latin American governments are failing to diversify, remaining heavily dependent on raw materials exports and extremely vulnerable to adverse external events. In addition, the drive to reform notorious black spots – such as... Brazil's burdensome public pension systems – has lost momentum. More generally, too, little of the surplus money is being invested. Chile is an exception... *In Brazil, only a tiny fraction of last year's 9 percent increase in real public spending was invested in infrastructure such as roads, bridges and railways.* All of this is undermining growth and means the gap between Latin America and its emerging-market rivals in Asia and eastern Europe is widening (emphasis added). See Richard Lapper, *Why Investors Are Deaf to the Latin American March of the Populists*, *supra*.

⁸⁹⁶ It is completely fallacious to assume that the [trade policy] activism one sees in the Lula international trick-or-treats of the moment has much to do with the blossoming trade surplus. Devaluation in 1999 is the real marker and consistency in policy ever since takes the credit – thus spanning two governments, and not just two years... See Mário Marconini, *Brazil's Trade Policy 2004: The Good, The Bad, and the Uppity*, *View Point Brazil*, Council of the Americas, Americas Society Vol. I, Issue 3 (1/17/05), at: <http://www.counciloftheamericas.org/coa/publications/ViewPointBrazil/ViewPoint%20Brazil%20Marconini%20Jan%20'05%20final.htm>).

⁸⁹⁷ In 2004, it accounted for more than half of all resource flows to developing countries and was considerably larger than ODA. However, FDI is concentrated in a handful of developing countries, *not* including Brazil. See *Transnational Corporations and the Internationalization of R & D*, (UNCTAD), *supra* at p. 8.

⁸⁹⁸ Brazil's decision to pre-pay its outstanding debt to the International Monetary Fund and the governments of the Group of Seven industrial nations says a lot about the country's improving circumstances. But it also points to the more confident fashion in which the emerging countries are evolving in the world economy... Less than a year before a presidential election, Brazil has chosen to use part of its foreign exchange holdings to repay all its liabilities to the IMF and members of

the Paris club' of country creditors. The decision reflects the rapid improvement in Brazil's international reserve position, driven by a large trade surplus, growing influx of foreign direct investment and high portfolio flows. See Mohamed El-Erian, *Why Brazil and Friends Want the World to Listen*, *Financial Times* Op-ed (1/5/06), at p. 11.

⁸⁹⁹ See *Transnational Corporations and the Internationalization of R & D*, (UNCTAD), *supra* at p. 20.

⁹⁰⁰ See *The FDI – Employment Link in a Globalizing World: The Case of Argentina, Brazil and Mexico*, *supra*, at p. 6.

⁹⁰¹ See *Transnational Corporations and the Internationalization of R & D*, (UNCTAD), *supra* at p. 20.

⁹⁰² *Ibid.*, at p. 18. In theory, the internationalization of R&D into developing countries is both expected and unexpected. It is expected for two reasons. First, as TNCs increase their production in developing countries, some R&D (of the adaptive kind) can be expected to follow. Second, R&D is a form of service activity and like other services, it is fragmenting, with certain segments being located where they can be performed most efficiently... It is unexpected in that R & D is a service activity with very demanding skill, knowledge and support needs, traditionally met only in developed countries with strong national innovation systems. Moreover, R&D is taken to be the least fragmentable of economic activities because *it involves knowledge that is strategic to firms, and because it often requires dense knowledge exchange (much of it tacit) between users and producers within localized clusters* (emphasis added). *Ibid.*, at pp. 17-18.

⁹⁰³ *Ibid.*, at p. 30.

⁹⁰⁴ "Contrary to the experience of recent years and to widespread expectations about continued strong FDI growth in emerging markets, the bulk of the increase in global FDI in 2006-10 is expected to take place in the developed countries." See "World Investment Prospects to 2010: Boom or Backlash?" Special Edition, Economist Intelligence Unit and Columbia Program on International Investment, Eds. (2006), at Executive Summary, p. 6, at:

(http://www.cpii.columbia.edu/pubs/documents/WIP_to_2010_SPECIAL_EDITION.pdf).

⁹⁰⁵ See *Transnational Corporations and the Internationalization of R & D*, (UNCTAD), *supra*, at pp. 19-20.

⁹⁰⁶ The reader is directed to the discussion within this white paper concerning open source methods'. In that section's footnotes, Brazilian Culture Minister Gilberto Gil discusses Brazil's tropicalism of music culture and what he considers Brazil's tropicalized intellectual property system.

⁹⁰⁷ *Ibid.*, at p. 27.

⁹⁰⁸ *Ibid.*, at p. 29.

⁹⁰⁹ *Ibid.*, at p. 31. The attractiveness of a location for conducting R&D may increase if the IPR regime is more effective, but a strong IPR regime is not necessarily a prerequisite for TNCs to invest in R&D. The policy challenge is to implement a system that encourages innovation and helps to secure greater benefits from such activity, notably when it involves TNCs. At the same time, in order to balance the interests of producers and consumers, IPR protection needs to be complemented by appropriate competition policies. *Ibid.*

⁹¹⁰ *Ibid.*, at p. 20.

⁹¹¹ Brazilian economic growth – at an average of just 2.2 percent a year over the past decade – has fallen far short of [Brazilian auto] manufacturers' expectations. As [manufacturing] capacity grew, production fell to 1.3m vehicles in 1999. Rocked by the Asian and Russian crises and the knock-on crisis of confidence across emerging markets, Brazil's government raised interest rates sharply and sales of credit-sensitive items, led by cars, slumped. In spite of a gradual recovery since then, production remains well below capacity... *The industry has turned to export markets to take up the slack, but the currency has appreciated sharply against the US dollar over the past three years. The government is preparing tax breaks for exporters, a move aimed primarily at the auto industry. But what the industry needs is steady growth – something that continues to elude Brazil* (emphasis added). See Jonathan Wheatley, Brazil Looks to Recapture Good Old Days, *Financial Times* (8/29/06) at p. 14.

⁹¹² See Thorsten Beck and Asli Demirgüç-Kunt, Strengthen Access to Finance for Small & Medium-size Enterprises While Improving Business Environment For All Firms, *World Bank Finance Research*, The World Bank (Aug. 2006), at: <http://econ.worldbank.org/WBSITE/EXTERNAL/EXTDEC/EXTRESEARCH/0,,contentMDK:21031659~pagePK:64165401~piPK:64165026~theSitePK:469382,00.html>). The Bank's latest research emphasizes the importance of strengthening the overall business environment for all firms, instead of focusing on and subsidizing SMEs. In fact, there is no robust evidence that SMEs by themselves matter for growth or poverty alleviation... More fundamental reforms must first be instituted to tackle the underlying reasons why firms do not fulfill their growth potential.' *These reforms should lead to a better business environment that promotes competition, protection of private property rights, and a sound contract environment. All of these are*

proven to boost economic growth, says [Senior Financial Economist] Thorsten Beck (emphasis added). *Ibid.*

⁹¹³ See Jonathan Wheatley, Economy Takes Back Seat in Brazilian Poll, *Financial Times* (9/5/06) at p. 8.

⁹¹⁴ See Jonathan Wheatley, Two Brazilian Candidates With Much in Common, *Financial Times* (7/5/06) at p. 4.

⁹¹⁵ See Jonathan Wheatley, Brazilian Belt-Tightening a Presidential Aspiration, *Financial Times* (7/12/06), at p. 4.

⁹¹⁶ With violence in São Paulo dominating the headlines last week, few in Brazil were paying much attention to the vertiginous swings taking place on the country's financial markets. Many will see this as just another buying opportunity and Brazilian exporters can be expected to sell dollars en masse this week, perhaps boosting the Real's value again. But it is getting harder for the complacent to support their positions. One reason is *the announcement by the Brazilian government... that it is changing the way it calculates its fiscal balance. This allows it to claim it is still set to meet its 4.25 per cent primary surplus target (the difference between revenues and spending, excluding debt interest payments) while actually, under the standard methodology, aiming at just 4.10 per cent. Even this target is unlikely to be met as it assumes growth in the economy of 4.5 per cent, widely regarded as overly optimistic.* This is alarming news. *Only by consistently exceeding its 4.25 per cent target in recent years has the government been able to prevent the ratio of debt to gross domestic product from spiralling out of control.* Brazil's failure to address its fiscal imbalances has been a concern in some quarters for a long time. Look at what has happened to the profile of Brazil's domestic debt. The first-rate team at the Treasury has worked hard over recent years to reduce the government's exposure to dollar-linked debt, cutting it almost to zero. *Reassured by Brazil's comfortable trade and current account surpluses, investors have been happy to go along. But similar efforts to reduce the amount of interest rate-linked debt have met a wall of resistance. The reason is that Brazil's fiscal performance does not warrant such a vote of confidence - far from it.* The benign international environment that has buoyed Brazilian assets along for the past four years is not about to unravel overnight. But after a week that brought home the failure of policy on public security and delivered a cowardly cop-out on fiscal policy, there are now more grounds than ever to question the government's ability to deliver the conditions needed for growth. Even the best possible security policy would do little to tackle the root causes of last week's events. *President Luiz Inácio Lula da Silva identified one such cause in a lack of spending on*

education. That being so, it is even harder to understand why he has overseen what Norman Gall, of the Instituto Braudel in São Paulo, calls the 'gutting' of Brazil's education ministry while diverting money away from essential primary and secondary education and into bloated and inefficient federal universities that provide free places for the children of the rich (the only ones that can afford the tutoring needed to pass the entrance exams) and jobs for the intellectual elite (emphasis added). See Richard Lapper, Brazil's Vulnerability, Financial Times (5/21/06), at: (<http://www.ft.com/cms/s/59ccb922-e8de-11da-b110-0000779e2340.html>).

⁹¹⁷ Economic growth [in Brazil] averaged a mere 2.4% in 1995-2004. In recent years, economic fundamentals have been improving and some observers have started talking about how economic growth could reach 6% a year... If this does not quite sound like fifty years in five, it is still a very optimistic assessment relative to Brazil's more recent performance... Brazil is a relatively closed economy with considerable potential to increase its openness especially as regards trade. Merchandise trade amounted to less than 27% of GDP in 2004 (and this is following a major surge in exports during the preceding years). *This compares poorly to the far more open economies of emerging Asia and even other major Latin American economies...* Trade openness is important for several reasons. First, it creates a greater capacity to generate foreign-currency revenues necessary to service foreign debt (and thus reduce potential future macroeconomic instability). ***Second, greater openness should help attract more FDI inflows, leading to the transfer of technology and skills necessary to increase overall productivity and economic growth.*** Third, greater openness forces the export-oriented and import-substituting sectors to become more competitive... *[T]he recent surge in exports in Brazil is due to a confluence of potentially temporary factors (competitive exchange rate, positive terms of trade shock, strong economic growth in Argentina, China and the US)...* (emphasis added). See Markus Jaeger, Brazil: O país do futuro? Economic scenarios for the next 15 years, Deutsche Bank Research, *supra*, at pp. 2-3. Brazil's public debt will remain at relatively elevated levels. The Lula administration has made some progress on the fiscal front by raising the primary surplus target and partially reforming the social security system. This has led to lower fiscal deficits and a lower public debt burden. Helped by the real currency appreciation since 2002, the gross general government (net public sector) debt-to-GDP ratio declined to around 75% (52%) of GDP at end-2005 from 78% (58%) of GDP at end-2002. Public-sector interest payments (slightly different from the general government

concept) have fluctuated between 7-15% of GDP over the past few years. In 2005, nominal public-sector interest payments amounted to 8% of GDP. This is high, but if measured relative to public-sector revenues (which amount to 35-40% of GDP), it is manageable. *Our debt sustainability analysis shows that, provided the government continues to run 4% of GDP-plus primary surpluses and domestic real interest rates stabilise near or slightly below historical levels, net public-sector debt will decline, albeit only gradually (see chart 13). The still elevated level of public debt represents Brazil's greatest macroeconomic vulnerability* (emphasis added). See Markus Jaeger, *Brazil: O país do futuro? Economic scenarios for the next 15 years*, Deutsche Bank Research, *supra*, at p. 5.

⁹¹⁸ Three months from elections in which the leftwing Mr Lula da Silva will seek a second mandate, concerns are widespread that the country appears unable to grow much more quickly than the average over the past decade of a little above 2 per cent a year... [G]overnment investment has fallen... from about 0.9 per cent of gross domestic product under the previous administration to about 0.7 per cent... [M]any critics say Brazil needs more positive action to deal with the challenges it faces. At the heart of their concerns is the size of the state: it absorbs nearly 39 per cent of GDP in taxes but fails to invest in infrastructure and other drivers of growth and delivers services that are inefficient and of poor quality. They say a lack of imagination about how to reorganise the public sector is putting too much of the burden of maintaining stability on monetary policy. These criticisms cut no ice with the president. He insists Brazil has done what it needs to do in those areas. He accepts the need to restrain spending but has little to say about improving the quality of services. Lots of people say the government spends too much on running costs, he says. But the machinery of government has to work. You can't have the machinery breaking down, with poorly paid public servants working in a climate of ill-will. Similarly, Mr Lula da Silva sees little need for action on the legal and judicial system. Many foreign investors are dismayed by the inconsistency with which Brazilian courts interpret the law – not to mention a climate of scant respect for the law engendered by a series of scandals over alleged misuse of public funds. The president insists that the system is functioning well. Courts are flexible all around the world, he says. I think there are few countries where these things are respected as much as they are in Brazil'. See Richard Lapper and Jonathan Wheatley, *Why Lula Will Shun the Populist Path*, *Financial Times*, *supra*. See also Richard Lapper and Jonathan Wheatley,

Interview Transcript: Luiz Inácio Lula da Silva , Financial Times, *supra*.

⁹¹⁹ On August 31, 2006, the [Brazilian] government's statistics agency released data showing that Brazil's growth slowed sharply in the second quarter as companies cut investment and exports fell for the first time in three years, hurt by a strong currency. Gross domestic product grew 0.5 percent from the first quarter, slowing from a revised 1.3 percent expansion in the first three months of the year... Actual growth came in at the low end of [economists'] forecasts, which ranged from 0.5 to 1.4 percent. Year-on-expansion had been seen at 2.1 percent, according to the [Reuters] survey [of]... 19 economists. Nevertheless, President Luiz Inacio Lula da Silva said... he was convinced that the economy would still grow 4 percent this year in spite of a weak performance in the second quarter... See *Lula Brushes Off Weak Growth Data*, Financial Times (9/2-9/3/06), citing Reuters reports from Brasilia, at p. 3.

⁹²⁰ President Luiz Inacio Lula da Silva unveiled his platform for re-election... promising to stimulate growth by increasing investment in the economy and introducing a higher national minimum wage. Aside from the pledges to lift investment in the economy to more than 25 percent, from 21 percent, and to increase the minimum wage by more than the rate of inflation, the programme for government in 2007-2010 was short on concrete targets and proposals. See Jonathan Wheatley, *Lula's Election Pledges Fall Short on Details*, Financial Times (8/30/06), at p. 5.

⁹²¹ See Jonathan Wheatley, *Economy Takes Back Seat in Brazilian Poll*, *supra*.

⁹²² See Derek H.C. Chen and Carl Dahlman, *Knowledge and Development: A Cross-Section Approach*, World Bank Policy Research Working Paper No. 3366, (Aug. 2004), at p. 44, at: (http://info.worldbank.org/etools/docs/library/117333/37702_wps3366.pdf). We postulate that there exist four preconditions that lead to knowledge becoming an effective engine of growth. These four preconditions, or four pillars of the knowledge economy, are: [1] An economic and institutional regime to provide incentives for the efficient use of existing and new knowledge and the flourishing of entrepreneurship; [2] An educated and skilled population to create, share, and use knowledge well; [3] A dynamic information infrastructure to facilitate the effective communication dissemination, and processing of information; [4] An efficient innovation system of firms, research centers, universities, consultants, and other organizations to tap into the growing stock of global knowledge,

assimilate and adapt it to local needs, and create new technology. In essence, we postulate that the amount of knowledge and how it is used are key determinants of total factor productivity. Strengthening the above four pillars of the knowledge economy will lead to an increase in the quantity and quality of the pool of knowledge available for economic production. This will consequently increase productivity and thus economic growth. *Ibid.*, at p. 4.

⁹²³ See Rod Falvey, Neil Foster, and David Greenway, Intellectual Property Rights and Economic Growth, Research Paper 2004/12, University of Nottingham, (2004), at p. 1. ... [Prior studies have shown] a positive and significant relationship between IPR protection and growth only when countries reach a certain level of development as measured by initial GDP. For countries below this level no significant relationship between IPR protection and growth exists... Our results suggest that the relationship between IPR protection and growth depends upon the level of development, as proxied by initial GDP per capita. For low- and high-income countries we find that stronger IPR protection significantly improves growth, but for middle-income countries no such relationship is found... The results for high-income countries are largely as expected; these countries undertake the vast majority of innovation and where strong IPR protection should encourage further innovation by allowing innovators to profit from their inventions. For low-income countries the positive relationship between IPR protection and growth clearly doesn't reflect a relationship between IPR protection and innovation, but more likely that strong IPR protection in these countries encourages imports and inward FDI that encourage growth without adversely affecting domestic imitative activities. *Ibid.*

⁹²⁴ *Ibid.*

⁹²⁵ See Lee Branstetter, Ray Fisman, Fritz Foley, and Kamal Saggi, Intellectual Property Rights, Imitation, and Foreign Direct Investment: Theory and Evidence, National Bureau of Economic Research (NBER) (Aug. 2005), at pp. 1 and 32-33, at: (<http://faculty.smu.edu/ksaggi/IPR-LEE.pdf>).

⁹²⁶ It takes various forms: basic research, applied research and product and process development. While basic research is mainly undertaken by the public sector, the other two forms are central to the competitiveness of many firms. In the early stages of technological activity enterprises do not need formal R&D departments. As they mature, however, they find it increasingly important to monitor, import and implement new technologies. The role of formal R&D grows as a firm attempts significant technological improvements and tackles

product or process innovation. For complex and fast-moving technologies it is an essential part of the technological learning process. See Transnational Corporations and the Internationalization of R & D , (U N C T A D) , *supra* at Executive Summary, pp. xxiv-xxv.

⁹²⁷ *Ibid.*, at p. xxiv.

⁹²⁸ *Ibid.*, at p. 209.

⁹²⁹ See Kamal Saggi, Trade, Foreign Direct Investment, and International Technology Transfer: A Survey , The World Bank Development Research Group (May 2000), at p. 17.

⁹³⁰ *Ibid.* at p. 18.

⁹³¹ *Ibid.*, at fn 28.

⁹³² *Ibid.*, at p. 18. Actually, one may even argue that a broader definition of FDI spillover may include indirect benefits such as greater access to institutional capital markets, bilateral governmental science and technology exchanges, industrial and scientific tourism, international treaty waivers, extension of preferential trade status, export bank financing and insurance underwriting of critical developing country firm import purchases, etc.

⁹³³ *Ibid.*, at p. 12.

⁹³⁴ In general, we refer to clusters as the geographic concentration of business activities (OECD, 2004).

However, we further discuss more sophisticated versions, such as places where inter-firm communication, common social and cultural patterns and the institutional environment stimulate socially- and territorially embedded collective learning and continuous innovation . *Ibid.*, at p. 7, fn #2.

⁹³⁵ See Lucas Ferrero and Alessandro Maffioli, The Interaction between Foreign Direct Investment and Small and Medium-sized Enterprises in Latin America and the Caribbean: A Look at Regional Innovation Systems , Inter-American Development Bank, Working Paper, Series No. 6A (Nov. 2004), at: (http://www.iadb.org/europe/Working_Papers/SOE_WP_6A_Interaction_FDI-SMEs.pdf). ... [T]his paper... focus[es] on the interaction between FDI-clusters of SMEs and regional innovation systems (RIS)... [W]e uphold the notion that clusters and RIS can provide a better environment to exploit linkages and spillovers between firms... From a policy standpoint, we address a particular dimension of FDI-related policies: embeddedness policies. *Thus the concern is with improving the capacity of local firms to absorb spillovers and develop linkages with MNEs... [O]bstacles fac[e] Latin American clusters in view of the complete lack of government responsiveness. Similarly... even when there is an upgrading in Latin American clusters,*

despite government inaction and the virtual absences of business support systems, there is substantial evidence that the development of external economies and cooperation mechanisms is still minimal... FDI-oriented policies are meaningful only if seen as a complement to a broader and coherent set of strategies geared to stimulating and improving regional performance. In other words, attracting and embedding MNEs should be matched to address the particular weaknesses of a cluster ([e.g.], in the value chain), with local institutions and associations playing a crucial role in the process of FDI selection, information transmission and so on (emphasis added). *Ibid.*, at pp. 5-6.

⁹³⁶ FDI can provide SMEs with access to information, know-how and technologies, increasing their innovative capabilities and improving their positioning on international markets. *In many Latin American and Caribbean countries, weak institutions and an inadequate business environment impede the development of innovative SMEs and of clusters...* *Ibid.*, at p. 5.

⁹³⁷ More than larger firms, SMEs need access to external sources of information, knowledge, know-how and technologies in order to build their own innovative capability and reach their markets. Multinational enterprises (MNEs) usually have the potential to generate the external stimuli necessary to enhance learning and innovation locally. The overall impact on welfare depends on several factors subsumed to the degree to which the MNE is embedded in and linked to the local economy... *Latin American countries... need... to develop a broader set of policies, institutions and organizations so that they can screen, select and attract FDI while trying to absorb and maximize its potential benefits...* [T]he ability of most SMEs to survive, achieve efficient scale levels and create new jobs depends on a number of factors, including their capacity to innovate and engage in collective activities. In order to build their innovative capabilities, *SMEs need to engage in innovative activities, which are fostered by the mass of (explicit/implicit) information, knowledge, and technology exchanges.* Clustering and interconnections among SMEs can be considered major facilitating factors (emphasis added). *Ibid.* at p. 1.

⁹³⁸ [C]ommon indicators of knowledge intensity (research and development [R&D] as a share of GDP, *patent rates*, relative employment or valued added in knowledge intensive sectors, educational attainment), as well as, joint actions and interconnectivity among firms, suggest that *Latin American and Caribbean (LAC) countries are far behind their... OECD... counterparts...* These features are not... the single most important obstacle to SMEs' development.

Rather, *a highly volatile environment* (both economically and politically), limited access to factor services (credit, skilled labor...) and overall governance (including the quality of regulation, dispute settlement, **property rights**...) are often cited as the main barriers to firms' development in the region (emphasis added). *Ibid.*, at p. 2.

⁹³⁹ Traditionally, there are three main broad areas related to the definition of governance. The first one refers to the process by which authorities are selected, monitored and replaced. The second tries to address governments' capacities to effectively formulate and implement sound policies. And, finally, the general respect for the institutions that govern economic and social interactions among members in the society... *Regulatory quality* stresses the features of policies and legal frameworks, usually measured as perceptions of the burden imposed by excessive regulation in areas such as business development, **patenting**, foreign trade and the like. The *Rule of law* dimension focuses on the level of confidence in and compliance with the rules of society (the incidence of crime, the effectiveness and predictability of the judiciary, and the enforceability of contracts). *These indicators try to measure the extent to which the socioeconomic environment is predictable and fair and, importantly, the extent to which property rights are protected (by patents laws, for example)* (emphasis added). *Ibid.*, at pp. 41-42.

⁹⁴⁰ *Ibid.*, at p. 3.

⁹⁴¹ *Ibid.*, at p. 4.

⁹⁴² The relative economic strength of firms within clusters of sectors and industries is important in shaping bargaining positions, and thus the way in which interactions are governed – including information and knowledge flows. For example, in *hub-and-spoke clusters* a number of non-locally embedded key firms act as anchors (hubs) with suppliers and related activities spread around them. The dynamism of the region is dependent on the position of hub organizations in national and international markets. Suppliers and hub firms engage in substantial trading. Intra-district cooperation, however, is driven by the willingness of hub firms, which is generally low and of a vertical nature. Internal scale and scope economies are relatively high, whereas labor market flexibility is low. Fear of specific knowledge leakage is a clear constraint on interactions. *Ibid.*, at p. 13.

⁹⁴³ *Ibid.*, at p. 20.

⁹⁴⁴ A prior World Bank study observed that, because multinationals can take actions to limit technology diffusion and maximize profits when deciding where to establish subsidiaries, developing countries should not expect the spillover effects of FDI to be uniform. According to the

study, spillovers to local firms that directly compete with the multinational would indeed be the most elusive of benefits that host countries may expect to enjoy from FDI. [T]he very act of curtailment of spillovers, may sometimes imply that local agents other than domestic competitors of multinationals (for example local workers) may enjoy positive externalities from FDI. If so, the total welfare effect of FDI on local welfare may be positive despite the lack of technology spillovers. See Kamal Saggi, Trade, Foreign Direct Investment, and International Technology Transfer: A Survey, *supra*, at p. 27.

⁹⁴⁵ See Lucas Ferrero and Alessandro Maffioli, The Interaction between Foreign Direct Investment and Small and Medium-sized Enterprises in Latin America and the Caribbean: A Look at Regional Innovation Systems, Inter-American Development Bank, *supra*, at p. 20-21.

⁹⁴⁶ *Ibid.*, at p. 27. MNEs tend to demand relatively skilled labor in the host country and to invest in training. The movement of labor from MNEs to existing firms or the start-up of new firms can generate outflows of specific knowledge, and the localization of MNEs in a particular area generates new training opportunities for local workers. *Ibid.*, at p. 25.

⁹⁴⁷ *Ibid.*, at p. 26.

⁹⁴⁸ *Ibid.*, at p. 25.

⁹⁴⁹ *Knowledge spillovers* may be related to... technology, management skills, business practice, know-how, information, and enhanced social and environmental standards. MNEs can generate spillovers by transferring technology directly or indirectly. The transfer of *product technology* may occur through: the provision of proprietary product know-how; the transfer of product designs and technical specifications; technical consultations with suppliers (to help them master new technologies); feedback on product performance (to help suppliers improve performance); collaboration on R&D by involving local universities or research institutes. The transfer of *process technology* may occur through: the provision of machinery and equipment to suppliers; technical support on production planning, quality management, inspection and testing; visits to supplier facilities to advise on layout, operations and quality; the formation of cooperation clubs⁴ for interacting with or among suppliers on technical issues (quality control presentations, value analysis and cost reduction activities); assistance to employees to set up their own firms; organizational and managerial know-how (assistance with inventory management and the use of just-in-time and other systems, assistance in implementing quality assurance systems, including ISO certification);

the introduction of new practices (management, financial, marketing) [etc.] (emphasis added). *Ibid.*, at p. 24.

⁹⁵⁰ *Ibid.*, at p. 28. More specifically, clusters can be distinguished across the scale of international embeddedness, not simply by the presence and strength of MNEs but also by the extent and nature of linkages between them and local actors. This depends both on the willingness of the multinational firms to participate in mutual learning-adaptation processes – that is, the degree to which a multinational is responsive and interacts with local actors – and on local conditions in terms of capabilities, governance and the overall business environment. *Ibid.*, at p. 13.

⁹⁵¹ *Ibid.*, at p. 24.

⁹⁵² *Ibid.*, at p. 28. ... [I]t seems that foreign affiliates making standardized products with mature, non-proprietary technologies tend to prefer externalized, arms-length procurement. Where products are specialized and technologically advanced, affiliates tend to prefer in-house production or to retain relationships with a few selected suppliers... [e.g., Electronics, pharmaceuticals, biotechnology, precision instruments, aerospace [p.13]]... MNEs evaluating the potential technological gap between foreign firms and local providers make reference to the development gap between the home and the host countries in terms of technology, structure, reliability, regulation, trust relationships and the flexibility of local suppliers relative to suppliers abroad. *Ibid.*, at pp. 22-23.

⁹⁵³ *Ibid.*, at p. 28.

⁹⁵⁴ See Kamal Saggi, Trade, Foreign Direct Investment, and International Technology Transfer: A Survey, *supra*, at p. 39.

⁹⁵⁵ See Lucas Ferrero and Alessandro Maffioli, The Interaction between Foreign Direct Investment and Small and Medium-sized Enterprises in Latin America and the Caribbean: A Look at Regional Innovation Systems, Inter-American Development Bank, *supra*, at p. 19.

⁹⁵⁶ Naturally, RIS, as clusters, can be quite different from each other along several dimensions – for instance, in their specialization of production, governance, and the like. *More specific dimensions of heterogeneity can be grouped into two categories: regional and business innovation structures.* The first includes *the amount of resources spent on R&D and its origin (public, corporate, MNE-led), initiation and concentration of innovative activities, role of support systems, governance of R&D and the science and technology infrastructure (funding, responsiveness to firm s' demands) and so on.* The business-innovation category refers to *firm s' attitudes towards*

innovation and its governance structure, addressing the characteristics of interactions between firms, with customers, R&D and development agencies. Other aspects must be taken into account, such as the characteristics of the labor force, labor mobility, financial assistance, hard infrastructure, knowledge leakages, institutions regulating dispute-settlement and property rights protection, and so on (emphasis added). *Ibid.*, at p. 16.

⁹⁵⁷ Innovation policy comprises strategies to build basic and applied research capabilities; and raise the rate of technology adoption and product innovation among home country firms. [They] generally increase the number of higher wage, knowledge- and technology-intensive industries in a country or region. *Ibid.*, at p. 32.

⁹⁵⁸ *Ibid.*, at p. 29. [T]he nature of public support... merit[s] attention... First, overall and sectoral regulations [must] provide[] a stable and appropriate framework that [does] not hamper[] the development of activities in the sector. Second... public promotion institutes and funds [must] help[] to stimulate innovation, cooperation among firms and between firms and universities, and the development of appropriate infrastructure. Finally, tax credits for worker training [must] provide[] additional flexibility and capacities to the existing pool of specialized labor. *Ibid.*, at pp. 28-29.

⁹⁵⁹ *Ibid.*, at p. 15.

⁹⁶⁰ *Ibid.*, at pp. 32-33.

⁹⁶¹ See *Inventing a Better Future - A Strategy for Building Worldwide Capacities in Science and Technology*, InterAcademy Council (Jan. 2004), at p. 79, at: (<http://www.interacademycouncil.net/Object.File/Master/6/720/0.pdf>).

... [A] percentage of [national] corporate tax [revenues] are targeted to funding specific research and development objectives... No new taxes are involved, just the redirection of already-established government levies... The sectoral-funds program serves four major government objectives - to promote: [1] Stability of financial resources for medium- and long-term research and development; [2] Transparency in funding decisions, merit review, and evaluation; [3] Reduction of regional inequalities; [4] Interaction between universities, research institutes, and companies. *Ibid.* The ... income tax... incentives [promoting]... private sector... R & D activities that result in patents were created... [pursuant to] (Laws 10.332/01 and 10.637/02)... See *2004 World Technology Awards Winners & Finalists*, Carlos Pacheco, Deputy Minister of Science and Technology of Brazil from 1999-2002, The World Technology Network, (<http://www.wtn.net/2004/bio224.html>).

⁹⁶² See 2004 World Technology Awards Winners & Finalists , *supra*.

⁹⁶³ The purpose of FINEP (study and project financing institution), a government-owned agency under the Ministry of Science and Technology, is to promote technological development and innovation in Brazil. Its role is to foster support to companies and institutions investing in new products and processes, continuously striving for technological innovation and leadership. See Developing an Institutional Structure to Create and Develop Technology-based Companies in Brazil , Capital de Risco Brasil, Ministério da Ciência e Tecnologia, at: (http://www.capitalderisco.gov.br/VCN_ING/EN_oque_PL.asp)

⁹⁶⁴ *Ibid.*

⁹⁶⁵ *Ibid.*

⁹⁶⁶ *Ibid.*

⁹⁶⁷ See Inventing a Better Future - A Strategy for Building Worldwide Capacities in Science and Technology , InterAcademy Council, *supra*, at p. 68.

⁹⁶⁸ *Ibid.*

⁹⁶⁹ See Projects for Biotechnology and Pharmaceuticals , U.S. Commercial Service Brazil Market Research (Aug. 2005).

⁹⁷⁰ See Inventing a Better Future - A Strategy for Building Worldwide Capacities in Science and Technology , InterAcademy Council, *supra*, at pp. 23 and 32. By comparison, Brazil devoted 1.24% of GDP to science and technology R&D in 1997. See Key Facts , Embassy of Brazil in Washington, at: (http://www.brasilemb.org/science_tech/tech2.shtml).

⁹⁷¹ See Jules Duga and Tim Studt 2005 Global R & D Changes in the R & D Community Report R & D Magazine (Sept. 2005), at p. G 3, at: (<http://www.battelle.org/globalrd.pdf>).

⁹⁷² *Ibid.*, at p. 12.

⁹⁷³ *Ibid.*

⁹⁷⁴ *Ibid.*, at p. G4.

⁹⁷⁵ European Union R & D represented 1.93 percent of EU gross domestic product in 2003, compared to... 3.15 percent in Japan. See George Parker and Clive Cookson, EU Urged to Put More Into Research Spending , Financial Times (1/20/06), at p. 2. EU R&D dropped to approximately 1.75 percent of EU GDP in 2004. See 2005 Global R & D Changes in the R & D Community Report at p. G 1.

⁹⁷⁶ See 2005 Global R & D Changes in the R & D Community Report , *supra*, at p. G1.

⁹⁷⁷ *Ibid.*, at p. G12.

⁹⁷⁸ *Ibid.*, at p. G13.

⁹⁷⁹ *Ibid.*, at p. G1.

⁹⁸⁰ It is no secret that the U S is the world's undisputed leader in science and technology. US industry funds roughly two-thirds, and the federal government, one-third, of an approximately US\$ 300 billion/year R & D enterprise... [I]n FY 2001, R & D spending in the US was estimated to be approximately US\$270 billion, comprising US\$ 180 billion spent by industry and US\$ 90 billion by the federal government. In FY2002, the federal government's contribution had increased to US\$ 103 billion, and it continues to rise. The US dominates the world in total R&D spending, contributing approximately 44 % of OECD R&D, and 39% of world R&D. R&D is carried out by four main sectors: industry, government, universities and colleges, and non-profit institutions. Industry: continues to dominate the field, funding two thirds of all R&D in the US, amounting to approximately US\$ 180 billion in FY2001. It performs most of its R&D in-house and also carries out R&D for the government. The federal government funds one third of the total R&D enterprise, amounting to approximately US\$ 90 billion in FY2001 (and US\$ 103 billion in FY2002). Significantly, it funds most basic research, particularly high-risk ventures. Nearly three-quarters of industrial patents cite publicly funded research as the basis for their invention. Most of publicly-funded R&D is carried out by industry, universities, non-profits and federally-funded research and development centers (FFRDCs). Universities and non-profit institutions fund less than 5 percent of research, but they perform almost 15% of the total R&D in the U S . See L isette Ram charan, Science and Technology Overview 2003: United States of America , Canadian Embassy in Washington DC (9/17/04), at: http://www.infoexport.gc.ca/science/UnitedStates_2003-en.htm).

⁹⁸¹ These countries happen all to be in developed countries: Canada, Finland, France, Germany, Italy, Japan, Netherlands, Sweden, Switzerland, United Kingdom, United States, South Korea. See Andrew Dunn, Global R & D Spending Survey 2002-2004 , Cientifica (Oct. 2005), at p. 3 at: <http://www.cientifica.com/www/summarys/Global%20R&%20D%20survey.pdf>).

⁹⁸² Including pharmaceuticals and healthcare, the fifteen sectors surveyed include: aero-defense, automotive, chemicals, computer hardware, conglomerate, consumer products, electronics, food, IT, office equipment, photography, semiconductors, computer software, and telecom. *Ibid.*, at p. 5.

⁹⁸³ *Ibid.*, at p. 7.

⁹⁸⁴ See Jules Duga and Tim Studt 2005 Global R & D Changes in the R & D Community Report R & D Magazine, *supra* at pp. G14-G15.

⁹⁸⁵ See International Agreements, National Institute of Standards and Technology (NIST) at: (<http://www.nist.gov/oiaa/intragre.htm>).

⁹⁸⁶ See Background Note – Brazil, U.S. Department of State, Bureau of Western Hemisphere Affairs (July 2005), at: (<http://www.state.gov/r/pa/ei/bgn/35640.htm>).

⁹⁸⁷ As the result of growing mutual trust grew out of the Brazilian accession to the various multilateral control regimes such as the MTCR (Missile Technology Control Regime), NSG (Nuclear Suppliers Group), the Conventions on Chemical and Biological Weapons, the NPT (Nuclear Non-proliferation Treaty), the CTBT (Comprehensive Test Ban Treaty), and the Safeguards Agreement between Brazil, Argentina, IAEA (International Atomic Energy Agency) and the ABACC (Brazilian-Argentine Agency for the Control and Accounting of Fissile Materials). These major accomplishments, combined with the approval of modern legislation on intellectual property, facilitated the establishment of a new and highly productive agenda of cooperation in several scientific and technological areas, among governmental, commercial and academic entities. See Brazil-US Cooperation, Brazilian Embassy in Washington, at: (http://www.brasilemb.org/science_tech/tech4.shtml).

⁹⁸⁸ The Agreement between the Government of the United States of America and the Federative Republic of Brazil Relating to Cooperation in Science and Technology. (Signed 2/6/84; EIF 5/15/86; extended by written agreement of the two contracting parties; amended and extended 3/21/94; EIF 1/30/96; automatically renewed for 5-year periods). U.S. Department of State Fact Sheet – List of Umbrella Science and Technology Agreements, Bureau of Oceans and International Environmental and Scientific Affairs (Updated 8/9/05), at: (<http://www.state.gov/g/oes/rls/fs/46482.htm>).

⁹⁸⁹ See U.S.-Brazilian ESTH Cooperation, Embassy of the United States Brasilia, Brazil, at: (<http://www.embaixada-americana.org.br/index.php?action=materia&id=2470&submenu=esth.php&itemmenu=174>)

⁹⁹⁰ During June 2003, the United States and Brazil formalized cooperative energy efforts today with the signing of two agreements. The U.S. Secretary of Energy signed a Memorandum Of Understanding with Brazilian Mines and Energy Minister to formally initiate energy cooperation with Brazil. In addition, the U.S. Secretary of Energy and the Brazilian Minister of Science and Technology *signed the U.S. - Brazil International Nuclear Energy Research Initiative (I-NERI)*. The

U.S. - Brazil I-NERI agreement will foster collaborative research and development on advanced nuclear technology that will improve cost performance, enhance safety and increase proliferation resistance of future nuclear energy systems. Additionally, both countries will cooperate on advanced technologies for nuclear power. ... This partnership will strengthen bilateral cooperation on energy modernization and new technologies for both countries, promoting economic growth and energy security, as called for in President Bush's National Energy Policy,' Secretary Abraham said. This dialogue will advance areas of mutual cooperation and help expand trade and investment between the U.S. and Brazil, enhance regional energy security and promote the use of clean energy technologies.' See Secretary Abraham Announces Energy Partnership with Brazil - Supports President Bush's Call for International Energy Cooperation , U.S. Department of Energy Press Release PR-03-132 (6/20/03), at: (http://energy.gov/engine/content.do?BT_CODE=PR_PRESSRELEASES&TT_CODE=PRESSRELEASE&PUBLIC_ID=13532); (http://fossil.energy.gov/international/International_Partners/Brazil.html).

⁹⁹¹ The charter sets the framework for international cooperation in research and development for the separation, capture, transportation and storage of carbon as a means of reducing greenhouse gas emissions. See Brazil: Environmental Issues , Country Analysis Briefs, Energy Information Administration, U.S. Department of Energy (Aug. 2003), at: (<http://www.eia.doe.gov/emeu/cabs/brazenv.html>).

⁹⁹² The U.S. and Brazil are two of the founding members of the International Partnership for the Hydrogen Economy (IPHE). On November 20, 2003, Secretary Abraham and representatives from Australia, Brazil, Canada, China, the European Commission, France, Germany, Iceland, India, Italy, Japan, Korea, Norway, Russia and the United Kingdom signed an agreement formally establishing the IPHE as an international mechanism to coordinate hydrogen research and technology development. The IPHE will allow participating countries to leverage limited resources, bring together the world's best intellectual skills and talents to solve difficult problems, and develop interoperable technology standards. President Bush has committed the U.S. to invest \$1.7 billion for the first five years of a long-term research and development program for hydrogen, hydrogen infrastructure, fuel cells, and hybrid vehicle technologies. See "Secretary Abraham Announces Agreement with Brazil on Hydrogen Energy Research - Supports President Bush's Hydrogen Initiative, International Partnerships , U.S. Department of Energy Press Release (4/19/04), at:

(http://energy.gov/engine/content.do?BT_CODE=PR_PRESSRELEASES&TT_CODE=PRESSRELEASE&PUBLIC_ID=15621).

⁹⁹³ See Energy Secretary Looks Forward to Brazil Meetings Aimed at Expanding Energy Cooperation - Visit Follows Energy Partnership Launched By President Lula and President Bush Last June, U.S. Department of Energy Press Release (4/15/04), at: (http://energy.gov/engine/content.do?BT_CODE=PR_PRESSRELEASES&TT_CODE=PRESSRELEASE&PUBLIC_ID=15598). On October 18, 2005, the Office of Nuclear Energy, Science and Technology's (NE) and the National Nuclear Energy Commission (CNEN) agreed under the NERI to collaborate on one new joint project on October 18, 2005. This collaboration will begin in January 2006, be jointly worth about \$1.8 million over three years, and will be in the area of International Near Term Deployment (INTD). See United States and Brazil Agree on Joint Nuclear Energy Research Projects, International Nuclear Energy Research Initiative (I-NERI) Bilateral Collaborations, U.S. Department of Energy, at: (<http://www.ne.doe.gov/ineri/ineriagreementsbrazil2.html>).

⁹⁹⁴ For example, the Large Scale Biosphere-Atmosphere Experiment in Amazonia (LBA), an international research initiative led by Brazil and NASA that is designed to create the new knowledge needed to understand the climatological, ecological, biogeochemical, and hydrological functioning of Amazonia, the impact of land use change on these functions, and the interactions between Amazonia and the Earth system. *Ibid.* It is possible that this program includes or is related to an initiative known as the National Renewable Energy Laboratory (NREL), an effort in Brazil to develop integrated climate change and air pollution strategies for São Paulo led by the São Paulo State Environmental Sanitary Company and including the participation of the U.S. DOE. *Ibid.*

⁹⁹⁵ *Ibid.*

⁹⁹⁶ See Memorandum of Understanding Between NIST and INMETRO... executed on April 10, 2002, at: (<http://www.nist.gov/oiaa/nistinmetro.pdf>). This Memorandum is being implemented within the framework provided by the Agreement Relating to Cooperation in Science and Technology between the United States of America and the Federative Republic of Brazil (hereinafter referred to as the "Agreement") signed February 6, 1984, as amended and extended. The MOU is scheduled to terminate unless otherwise renewed on April 9, 2007. *Ibid.* See also Technical Cooperation – Inmetro X NIST (United States of America), INMETRO Technical Barriers to Trade website at:

(<http://www.inmetro.gov.br/english/international/cooperation.asp>);

Brazil-U S Technology Open House , NIST Technicalendar (6/30/04), at:

(<http://ois.nist.gov/techcal/search/display.cfm?uniqueID=085633Magda0.00949143>); Brazil-U S Technology Open House , NIST Office of

International and Academic Affairs (6/30/04), at:

(<http://www.nist.gov/oiaa/btdsumm.htm>); Brazil Technology Day ,

Speech by Arden Bement (2/25/03), at:

(http://www.nist.gov/speeches/bement_022503.htm).

⁹⁹⁷ See U.S. Department of State Fact Sheet – List of Umbrella Science and Technology Agreements , Bureau of Oceans and International Environmental and Scientific Affairs, *supra*.

⁹⁹⁸ The areas of LABEX research will be: (i) bioinsecticides and other pest management techniques; (ii) new uses of commodities and value-added; (iii) global climate change; (iv) genetic improvement; (v) biotechnology; (vi) agrifood and agribusiness technologies; (vii) natural resource management; and (viii) agricultural economies. See Brazil - Technological Innovation and New Management Approaches in Agricultural Research – AGROFUTURO , BR-L1001 Loan Proposal, Inter-American Development Bank at p. 18, at: (<http://www.iadb.org/exr/doc98/apr/br1595e.pdf>).

⁹⁹⁹ See U.S.-Brazilian ESTH Cooperation , Embassy of the United States Brasilia, Brazil, *supra*.

¹⁰⁰⁰ See Michael A. Fletcher, In Brazil, Bush Continues Trade Push - Competing Vision for Americas Would 'Roll Back' Democracy, President Says , Washington Post (11/7/05) at p. A15, reprinted at Resource Center of the Americas.org at: (http://www.americas.org/item_22935).

¹⁰⁰¹ See About the IADB – Board of Governors , Inter-American Development Bank website, at: (http://www.iadb.org/aboutus/IV/go_governors.cfm?language=English).

¹⁰⁰² Since 1961, the Bank has made 315 loans totaling \$28.9 billion and disbursements have totaled \$23.2 billion. See Brazil and the IDB , Inter-American Development Bank, at: (<http://www.iadb.org/exr/country/eng/brazil/>). See also Approved Projects – Brazil , Inter-American Development Bank, at: (<http://www.iadb.org/exr/doc98/apr/lcbraz.htm>).

¹⁰⁰³ See Antonio Guiffrida, Learning From the Experience: The Inter-American Development Bank and Pharmaceuticals , Inter-American Development Bank (May 2001), at p.17, at: (<http://www.iadb.org/sds/doc/SOC123.pdf>).

¹⁰⁰⁴ Perhaps, the IADB's earliest effort to transition into this new paradigm was reflected in its 1995 loan facility to the Agency for the Financing of Studies and Projects (FINEP). The purpose of the program [was] to help develop and improve Brazil's scientific and technological capabilities and to increase corporate competitive skills and productivity by modernizing the technology they use... Seventy percent of the program funds [was] to be used to grant reimbursable financing to private companies for technological modernization... Thirty percent of the program resources [were to used] for the financing of research and development projects submitted by universities as well as... nonprofit research institutions. See Science and Technology Program, Loan Proposal BR-0164, Loan # 880/OC-BR, Amt \$160m of \$320m (Approved 9/20/05), at: (<http://www.iadb.org/EXR/doc98/apr/br880e.htm>).

¹⁰⁰⁵ See Alberto Melo, The Innovation Systems of Latin America and the Caribbean Working Paper #460, Inter-American Development Bank (Aug. 2001) at pp. 45-46, at: (<http://www.iadb.org/res/publications/pubfiles/pubWP-460.pdf>).

¹⁰⁰⁶ *Ibid.*, at p. 46. In Brazil, the National Council for Science and Technology (CCT), an advisory body, was created in 1996. *Ibid.* See also, discussion *infra*.

¹⁰⁰⁷ *Ibid.*, at p. 50.

¹⁰⁰⁸ Policies aimed at modifying market incentives... faced by firms... [include]... fiscal policies and *provision of credit, provision of venture capital*, and other financial policies. Fiscal policies include tax incentives; direct funding of research projects; the carrying out of joint cooperation projects between the government and the private sector; and the use of public procurement of goods and services as a tool to induce or guide innovation... Credit incentives to innovation are used in a number of countries. *The most frequent modality is loans for technological innovation and technology acquisition granted by public development banks or similar promotional agencies of the national governments...* Interest rates are preferential, the difference from the market rate being, obviously a subsidy. The loans are granted for extended periods, and sometimes, release from debt obligations is an option in the case of borrower failure... *Given the scarcity of domestic sources of venture capital in Latin America, direct equity investment by the government is a policy issue of prime importance for the Region... [T]he government [can] invest in private venture capital firms which, in turn, provide equity to firms...* Alternatively, the government can create its own venture capital fund or a hybrid fund with private sector participation (emphasis added). *Ibid.*, at pp. 50-53. The MIF

has funded several loan facilities aimed at developing a venture capital fund industry within Brazil that can finance the private sector activities of innovative and technology-based SMEs. *See, e.g.*: Fund for Competitive Technology-Based Companies – Loan# MIF/AT-609 Amt - **\$3.8 m** of \$11.1m, (Approved 9/22/04), at:

(<http://www.iadb.org/mif/v2/projectview.asp?ID=1907&C=8>);

Investment Fund Brazilian Companies – Loan# MIF/AT-620 Amt - **\$4.1m** of \$14.9m, (Approved 11/17/04), at:

(<http://www.iadb.org/mif/v2/projectview.asp?ID=1922&C=8>);

Novorum Seed Investment Fund – Loan# MIF/AT-701 Amt - **\$2.1 m** of \$5.7m, (Approved 11/30/05), at:

(<http://www.iadb.org/mif/v2/projectview.asp?ID=2023&C=8>).

In addition, the IADB itself has also approved the funding of microcredit projects intended to disburse financing among Brazil's SMEs. *See* BNDES: CCLIP Line and Program to Support Micro, Small, and Medium-Sized Enterprises (BR-0358) IDB - **\$1 billion**, intended [t]o support the development and modernization of micro, small, and medium-sized Brazilian enterprises by providing medium- and long-term financing for investment projects designed to make those firms more competitive, at: (<http://www.iadb.org/exr/doc98/apr/br1608e.pdf>).

¹⁰⁰⁹ *See* Brazil – Bank Strategy for Brazil (2004-2007), Inter-American Development Bank (Nov. 2004) at: (<http://enet.iadb.org/idbdocswebservices/idbdocsInternet/IADBPUBLICDOC.aspx?docnum=431614>)

¹⁰¹⁰ *Ibid.*, at p. 40.

¹⁰¹¹ *Ibid.*, at Annex VII at p. 3 of 11 and Annex XII at pp. 1 and 2 of 12

¹⁰¹² However, the IADB recently approved, on January 19, 2006, \$140 million of funding for a long-term Brazilian environmental and social project. The project's purpose is to rehabilitate heavily populated cities along the Amazon basin while preserving their natural ecosystems. It is anticipated that the resettlement portion of the project will entail the registering and titling of land in adjacent areas. *See* Brazil, IDB Sign \$140 Million Loan for Social and Environmental Program for Manaus in the State of Amazonas, Press Release, Inter-American Development Bank (1/19/06), at: (http://www.iadb.org/NEWS/display/PRView.cfm?PR_Num=03_06&Language=English);

See also Brazil – Social and Environmental Program for the Igarapes in Manaus (BR-L1005) Loan Proposal, Inter-American Development Bank (11/8/05), at: (<http://www.iadb.org/projects/projectDocuments/searchDocsADV.cfm?>

[language=English&keywords=&docType=&idboperations=BR-L1005&topics=PA&countries=&subtopics=&dept=&subreg=&fromMonth=&fromYear=&toMonth=&toYear=&doclang=&orderby=docdate&orddir=desc&res=10&imageField.x=38&imageField.y=11](#)).

¹⁰¹³ See Brazil - Technological Innovation and New Management Approaches in Agricultural Research – AGROFUTURO, BR-L1001 Loan Proposal, Inter-American Development Bank (7/20/04), (Loan No. 1595/OC-BR, \$33m of \$60m (Approved 12/1/04) at: (<http://www.iadb.org/exr/doc98/apr/br1595e.pdf>).

¹⁰¹⁴ *Ibid.*, at pp. 1-2.

¹⁰¹⁵ ... [A lthough]... Brazil has made major strides to develop its agricultural R & D capacity... *the country's private sector needs to become more proactive in generating technological innovation. In 1999, just 35% of patent applications filed with the National Industrial Property Institute (INPI) came from Brazilian residents.* Although the private sector provides a significant share of R&D financing (33%), this is well below average of 63% among member... OECD ... countries... Although the Industrial/ Intellectual Property Act of 1996 and the 1997 Plant Variety Protection Act... have made it easier to set up enterprises mainly for the production of maize and soybean, private R&D investment in this sector remains relatively low. This... presents a challenge for the Brazilian Agricultural Research Enterprise (EMBRAPA) to achieve closer ties with the domestic private sector, and for Brazilian enterprises themselves to invest more in R&D... EMBRAPA is the cornerstone of R & D in the agricultural sector, accounting for 60% of financial resources and 41% of the country's researchers (emphasis added). *Ibid.*, at p. 2.

¹⁰¹⁶ *Ibid.*, at p. 6.

¹⁰¹⁷ *Ibid.*, at p. 9.

¹⁰¹⁸ *Ibid.*, at pp. 9-10.

¹⁰¹⁹ *Ibid.*, at p. 11.

¹⁰²⁰ In the past, manufacturers in [Brazil's]... [] public and private [pharmaceutical] sectors [had] not been consistently subject to sufficient monitoring for GMP standards, nor rigorous testing of product quality. The same applie[d] to raw materials... Previous governments [had] made intermittent attempts to improve the quality standards in the pharmaceutical sector in these and other areas. See Jillian Clare Cohen, Public Policies in the Pharmaceutical Sector in Brazil, Department of Human Development LCHD Paper Series No. 54, World Bank (Latin American and Caribbean Office) (Jan. 2000) at p. 19. In addition to the IADB, the World Bank's oversight of such programs had also been lacking. In the discussions leading up to the

third AIDS project, the World Bank has taken the position that although the NAP has a strong record of achievement, both AIDS projects suffered from: (a) the lack of an adequate monitoring and evaluation

system to improve targeting and steer the program to higher impact and more sustainable interventions; and (b) insufficient supervision by the Bank and the government of procurement activities implemented by decentralized entities, including local governments and NGOs. See Chris Beyrer, Varun Gauri and Denise Vaillancourt, Evaluation of the World Bank's Assistance in Responding to the AIDS Epidemic: Brazil Case Study, The World Bank Operations Evaluation Department (2005), at p. 25, at: (http://www.worldbank.org/ieg/aids/docs/case_studies/hiv_brazil_case_study.pdf). It seems that the Brazilian government has recently taken a more proactive approach to ensure such monitoring. The National Agency of Sanitary Surveillance (Anvisa) plans to tighten control of the quality of pharmaceutical raw materials. The agency has created the Active Pharmaceuticals Raw Materials Program to guarantee that the pharmaceutical raw materials used in Brazil are appropriately supervised. A few years ago, the most that was done in Brazil was the inspection of the prepared drug, said Victor Hugo Travesso, Anvisa's Director. The program establishes strict procedures, from the control of the entry of products into Brazil, to industry-wide inspections and the review of pertinent legislation. See Improvement in the Quality Control of Pharmaceutical Raw Materials, U.S. Commercial Service Brazil Market Research (Oct. 2005).

¹⁰²¹ Since 1983, Brazil has had four [World] Bank health projects with direct lending for the pharmaceuticals ... Indirect lending for pharmaceutical activities has been provided to the [Brazilian] government through the Reforsus I project. Total commitments to the [Brazilian pharmaceutical] sector thus far has been about US \$ 93 million. *Ibid.*, at p. 8.

¹⁰²² ... Eighteen of the 32 health sector loans approved by the Bank in the last decade [1991-2001] included a pharmaceutical component. See Antonio Guiffrida, Learning From the Experience: The Inter-American Development Bank and Pharmaceuticals, Inter-American Development Bank (May 2001), at p. 5, at: (<http://www.iadb.org/sds/doc/SOC123.pdf>). Two of these loans were made to Brazil: (BR-0199) 1996, \$9,000,000, with pharma comprising 2.57% of the total loan value, for procurement and distribution purposes; (BR-0308) 1999, \$30,972,000, with pharma comprising 5.85% of loan value, for acquisition and procurement/distribution.

Ibid., at Appendix. ... The total loan amount for BR-0308 was \$2.2 billion. The Project aimed to protect social spending during [a] period[] of economic downturn by financing the provision of basic pharmaceuticals and vaccines. In addition, the Brazil project included, among the conditions for the disbursement of the health component, *the realization of a study to improve public sector procurement and distribution of medicines. This was particularly significant because it recognized explicitly that the acquisition of drugs was only a short-term solution.* Development loans should be better aimed at improving the efficiency of the pharmaceutical system to ensure financial sustainability (emphasis added). See Antonio Guiffrida, Learning From the Experience: The Inter-American Development Bank and Pharmaceuticals, *supra*, at p. 10. The loan was likely structured in this manner because Most local governments in Brazil [did] not [at that time] have the human and institutional capacity to manage the procurement and distribution of pharmaceuticals effectively. See Jillian Clare Cohen, Public Policies in the Pharmaceutical Sector in Brazil, *supra*, at p. 17. According to this report, Brazil [was] one of the Bank's largest recipient's of [Health, Nutrition and Population] HNP financing. During fiscal years 1988-1998, Brazil was the recipient of US \$ 935 million in commitments and had 5 active HNP projects. *Ibid.*, at p. 8.

¹⁰²³ The pharmaceutical sector in Brazil is the sixth largest in the world in terms of value and is the leading market in Latin America... Latin America's 32 countries comprised only 8% of the global pharmaceutical market in 1998. But it is the fastest growing regional pharmaceutical market in the world. From 1989 to 1994, the market grew by 136%. See Jillian Clare Cohen, Public Policies in the Pharmaceutical Sector in Brazil, *supra*, at pp. 10-11.

¹⁰²⁴ In 1998, world sales of pharmaceuticals were estimated at US\$ 302.9 billion... The value of both the public and private pharmaceutical market in Brazil was estimated at US\$ 10.3 billion in 1997, with international and domestic pharmaceutical companies respectively commanding about 70% and 30% of the total market. See Jillian Clare Cohen, Public Policies in the Pharmaceutical Sector in Brazil, *supra*, at p. 11.

¹⁰²⁵ Brazil was so classified by UNIDO [the United Nations Industrial Development Organization]. *Ibid.*, at p. 19.

¹⁰²⁶ In the past... [about 60% -70% of raw materials for pharmaceuticals were imported in Brazil... *Ibid.*

¹⁰²⁷ See Chris Beyrer, Varun Gauri and Denise Vaillancourt, Evaluation of the World Bank's Assistance in Responding to the

AIDS Epidemic: Brazil Case Study, *supra*, at pp. 4-6, 10, 17-21, 30; Brazil – Bank Strategy for Brazil (2004-2007), Inter-American Development Bank (Nov. 2004), *supra* at pp. 23, 58, 70, 79, 100-101.

¹⁰²⁸ The IADB administers the MIF, a technical assistance mechanism of the Bank, in accordance with an agreement with MIF's Donors Committee. Projects in all sovereign developing member countries of the Inter-American Development Bank, and the Caribbean Development Bank are potentially eligible for funding by MIF. MIF is governed by its member countries through the Donors Committee. It should be noted that *the U.S. is a sovereign member of and wields significant influence within the committee*, which is responsible for the approval of all MIF projects, with voting share based on contribution levels. See *Where the MIF Gets Funds*, at: (http://www.iadb.org/mif/v2/where_money.html), and *Members of the Donors Committee*, at: (http://www.iadb.org/mif/v2/mem_part.html). See also MIF Project Database, at: (<http://www.iadb.org/mif/v2/projectsort.asp?Type=Country&Param1=BR&C=8&Status=99>).

¹⁰²⁹ See: *SME Meta-system – Loan# MIF/AT-474, Amt \$352,000 of \$719,000 (Approved 4/22/04)*, at: (<http://www.iadb.org/mif/v2/projectview.asp?ID=1874&C=8>). The project will develop a computing infrastructure that uses PC or special end-user workstations and is geared toward SMEs. Two knowledge-management solutions will be offered: an ERP and a search engine. All software applications will be based on Open Source solutions. Most SMEs cannot afford to invest in advanced ICT systems that would help them improve their competitive position in the market. The project will develop an integrated ICT solution in a highly productive Linux-based configuration with a low TCO (Total Cost of Ownership) (emphasis added). *Ibid*; *Competitiveness Support Program for Software SMEs – Loan# MIF/AT-649, Amt - \$1.3m of \$3m (Approved 4/27/05)*, at: (<http://www.iadb.org/mif/v2/projectview.asp?ID=1925&C=8>). The project seeks to make software SMEs more competitive in Brazil and elsewhere in the region. The purpose is to validate a business model to enhance software SMEs competitiveness through the use of quality tools, internationalization, and localization techniques, and business linkages. *Ibid*.

¹⁰³⁰ The Government of Brazil continues to press for its agencies to favor use of free open source software in order to save money, without reflecting on the resulting challenge to the domestic software industry's needs to sell its software at a profit (emphasis added). See *Intellectual Property Rights, U.S. Country Commercial Service*

Guide – Brazil (Jan. 2005), at p. 32. Recently, city, state and federal government procurement offices have been debating in Brazil a possible preference for "open-source" software (known as Software Livre in Brazil). Several bills have been introduced in the Brazilian Congress requiring federal agencies to acquire and use free, unrestricted open-source systems. Some state and local governments in Brazil have either enacted or are debating laws that call for open-source systems. Brazil's software industry is concerned with this direction, noting with some justification that an official government stance against paying for software might prejudice the domestic industry's basic licensing business model. See Computer Software – Top U.S. Exports, U.S. Country Commercial Service Guide – Brazil (Jan. 2005), at p. 51. See also Brazil Gives Nod to Open Source, Associated Press, (11/17/03), cited on WiredNews.com at: (<http://www.wired.com/news/infostructure/0,1377,61257,00.html>).

Silva's top technology officer wants to transform the land of samba and Carnival into a tech-savvy nation where everyone from schoolchildren to government bureaucrats uses open-source software instead of costly Windows products... Under his guidance, Silva's administration is encouraging all sectors of government to move toward open-source programs, whose basic code is public and freely available. *Ibid.*

¹⁰³¹ On November 16, 2005, Brazil's Minister of Culture and the Secretary-General of UNCTAD signed a memorandum of understanding today to support the promotion of free and open-source software (FOSS). See UNCTAD and Brazil Support Free and Open-Source Software UNCTAD at W SIS (11/16/05), at: (http://www.unctadxi.org/templates/News_5797.aspx).

¹⁰³² See Brazil and the IDB, Inter-American Development Bank, at: (<http://www.iadb.org/exr/country/eng/brazil/>).

¹⁰³³ See Project Priorities in the Southern Cone, Inter-American Development Bank (9/15/05), at pp. 12-13, at: (<http://www.iadb.org/biz/ppt/0915roidan.pdf>).

¹⁰³⁴ As a result of the corruption that led to the fall of Jean Bertrand Aristide's Haitian government during 2003 and the social chaos that later ensued when the Haitian military intervened in the absence of an elected ruler, the Bush Administration ordered several international financial institutions, including the IADB, to withhold disbursement of approximately \$146 million of development funds previously approved for Haiti. The administration's Homeland Security Department apparently believed that terrorists had infiltrated Haiti amid the chaos with the purpose of threatening U.S. national security. It decided that

disbursement of the funds to nongovernmental organizations prior to the resumption of political calm was not prudent. Although the Congressional Black Caucus was outraged and insisted that the administration order the loans disbursed, it recognized the power of the U.S. government to act as it did. *See* CBC Special Order on Helping the People of Haiti – U.S. House of Representatives, Office of Congressman Elijah E. Cummings (4/30/03), at pp. H3558 – H3564.

¹⁰³⁵ This was actually discussed recently between the U.S. Congress and the U.S. Department of Treasury concerning China's currency policies. If the Treasury were to find that the renminbi was 'misaligned' and that this was damaging the U.S. economy, then China would have 180 days to move towards a resolution before a host of sanctions kicked in. These would include using the US vote to block any increase in voting rights at the International Monetary Fund, disapproval of international financing, preventing the issue of trade insurance and guarantees for trade under the Overseas Private Investment Corporation, and less favorable status under US anti-dumping laws. *See* Christopher Swann and Richard McGregor, Renminbi Weakness Tests US Patience, *Financial Times* (3/29/06), at p. 4.

¹⁰³⁶ *See* Eduardo Aguirre, Jr. Export-Import Bank Financing for U.S. Exports to Latin America *Seton Hall Journal of Diplomacy and International Relations* Vol. IV, No. 1 (Winter/Spring 2003), pp. 135-138, at 135, at: (http://www.ciaonet.org/olj/shjdir/v4n1/shjdir_v4n1i.pdf).

¹⁰³⁷ *Ibid.*, at pp. 136. The trade policy of the Eximbank and its sister organization, the Overseas Private Investment Corporation (OPIC) is largely shaped by the U.S. Trade Representative's Office. USTR is part of the Executive Office of the President. Through an interagency structure, USTR coordinates trade policy, resolves disagreements, and frames issues for presidential decision. USTR also serves as vice chairman of the Overseas Private Investment Corporation (OPIC), is a non-voting member of the Export-Import Bank, and a member of the National Advisory Council on International Monetary and Financial Policies. *See* Mission of the USTR – Trade Policy, Office of the United States Trade Representative, at: (http://www.ustr.gov/Who_We_Are/Mission_of_the_USTR.html).

The Export-Import Bank of the United States is an independent federal agency which helps exporters become more competitive in the global marketplace through export finance programs. [It] provides guarantees of working capital loans for U.S. exporters, guarantees the repayment of loans or makes loans to foreign purchasers of U.S. goods

and services and provides credit insurance against non-payment by foreign buyers for political or commercial risk. The Bank focuses on exports to developing countries, aggressively countering trade subsidies of other governments, stimulating small business transactions, promoting the export of environmentally beneficial goods and services, and expanding project finance capabilities. Ex-Im Bank is encouraged to supplement, but not compete with private capital. See USTR's Relationship With Other Government Agencies, Office of the United States Trade Representative, at: (http://www.ustr.gov/Who_We_Are/USTR's_Relationship_with_Other_Government_Agencies.html).

¹⁰³⁸ See Brazilian Economy and Resources at: (<http://www.brazilbrazil.com/economy.html>); Historical Perspective, Embassy of Brazil - London, United Kingdom, at: (<http://www.brazil.org.uk/page.php?n=82>).

¹⁰³⁹ FYE 2004: Loans - \$76.9 million, Guarantees - \$81.2m, Insurance - \$213.1m for total authorizations of \$213.1m. See Exim Bank Annual Report FY 2004, Authorizations by Market at p. 2, at: (<http://www.exim.gov/about/reports/ar/ar2004/pdf/authorizations.pdf>); FYE 2003: Loans - \$52.7m, Guarantees - \$120m, Insurance - \$55.1m, for total authorizations of \$227.8m. See Exim Bank Annual Report FY 2003, Authorizations by Market, at p. 2, at: (<http://www.exim.gov/about/reports/ar/ar2003/pdf/Financial%20Section/Authorizations.pdf>); FYE 2002: Loans - \$24m, Guarantees - \$20.5m, Insurance - \$29.4m, for total authorizations of \$73.9m. See Exim Bank Annual Report FY 2002, Authorizations by Market, at p. 2, at: (<http://www.exim.gov/about/reports/ar/ar2002/authoriz.pdf>); FYE 2001: Loans - \$623.7 m, Guarantees - \$69m, Insurance - \$36.1m, for total authorizations of \$728.8m. See Exim Bank Annual Report FY 2001, Authorizations by Market, at p. 2, at: (<http://www.exim.gov/about/reports/ar/ar2001/AuthList.pdf>); FYE 2000: Loans - \$0, Guarantees - \$404m, Insurance - \$83.1m, for total authorizations of \$487.1m. See Exim Bank Annual Report FY 2000, Authorizations by Market, at p. 2, at: (http://www.exim.gov/about/reports/ar/ar2000/8_auth_sum_market_loans.pdf); FYE 1999: Loans - \$152.8m, Guarantees - \$50.7m, Insurance - \$310.2m, for total authorizations of \$513.7m. See Exim Bank Annual Report FY 1999, Authorizations by Market, at p. 2, at: (<http://www.exim.gov/about/reports/ar/ar1999/PDF/03.pdf>); FYE 1998: Loans - \$68.7m, Guarantees - \$171.4m, Insurance - \$112.9m, for total authorizations of \$353m. See Exim Bank Annual Report FY 1998, Authorizations by Market, at p. 2, at:

(<http://www.exim.gov/about/reports/ar/ar1998/financia.pdf>); FYE 1997: Loans - \$177.2m, Guarantees - \$198.2m, Insurance - \$116.2m, for total authorizations of \$491.7m. See Exim Bank Annual Report FY 1997, Authorizations by Market, at p. 2, at: (<http://www.exim.gov/about/reports/ar/ar1997/financi.pdf>).

¹⁰⁴⁰ The Ex-Im Bank authorized a \$178 million long-term direct loan to support the \$136.5 million export by Bechtel International Inc., Gaithersburg, MD, of gas turbines and other equipment to build a 469-megawatt combined cycle power plant in Araucaria, Parana, Brazil. It is Ex-Im Bank's first power project in Brazil to use limited recourse project financing, in which repayment comes from project revenues. Suppliers on the project include Siemens Westinghouse Power Corp., Orlando, FL, which is supplying the turbines; Sulzer Bingham Pumps Inc., Portland, OR; and ABB Automation Inc., Wickiffe, OH. The project company, UEG Araucaria Ltda., is owned by project sponsors El Paso Energy, Inc., COPEL (Companhia Paranaense de Energia), and Petrobras (Petroleo Brasileiro S.A.). The Ex-Im Bank loan will cover both the construction and operating phases of the project. The sole source of repayment is the tariff revenue from the 20-year power purchase agreement with COPEL. The U.S. Overseas Private Investment Corporation (OPIC) also is participating in the financing of the \$360 million project. This power plant will be fueled by gas from the Bolivia-Brazil pipeline. El Paso plans to expand this facility into one of the largest power plants in Latin America. See Ex-Im Bank Supports \$136.5 Million in U.S. Exports for Brazil's Araucaria Power Project, Press Release (10/5/01), at: (<http://www.exim.gov/pressrelease.cfm/B0BA8E6C-1032-5B0F-B5E2289C420F4A26>).

¹⁰⁴¹ Rio Polimeros (RioPol), a Brazilian joint venture company, is building grass roots gas-based petrochemical complex. The facility is set to produce 520,000tpa of ethylene, which will feed a 540,000tpa polyethylene (PE) production unit. The complex requires a total investment of \$1.08 billion. The project is strategic for Brazil and for the development of the Rio de Janeiro region. The project will allow the country to reduce its dependence on polyethylene imports. See Rio Polimeros (RioPol) Gas-Based Petrochemical Complex, Brazil, Chemicals-technology.com, at: (<http://www.chemicals-technology.com/projects/rio>). See also Rio Polímeros, which will be inaugurated tomorrow, receives a R\$ 680 million financing from BNDES, BNDES - The Development Bank (6/22/05), at: (http://www.bndes.gov.br/english/news/not154_05.asp).

¹⁰⁴² See Eduardo Aguirre, Jr. Export-Import Bank Financing for U.S. Exports to Latin America, *supra* at p. 137.

¹⁰⁴³ *Ibid.*, at p. 138. See also Ex-Im Bank Announces New Program to Accept the Credit of Emerging Market Cities, States, Press Release (8/11/00), at p. at: (<http://www.exim.gov/pressrelease.cfm/B0D6D97E-1032-5B0F-B1730FE01F1AB40C/>). Municipalities and other sub-sovereign governments whose foreign currency debts are currently rated B/B2 or stronger are eligible... *Ibid.* Ex-Im Bank has provided short-, medium- and long-term financing in the public as well as private sectors... [since 1998, when it first]... approved an increase of up to \$1 billion in the credit limit for six Brazilian banks financing Brazilian purchases of U.S. goods and services. Public sector financing facilitates exports to government entities or private sector projects guaranteed by the Brazilian government. Private sector financing supports exports to Brazilian corporations and banks. Ex-Im Bank has received nearly two dozen inquiries from Brazilian companies interested in Ex-Im Bank financing. See Ex-Im Bank Opens Financing in the Public Sector of Brazil, Increases Credit Limit for Brazilian Banks by \$1 Billion Press Release (12/3/98) at: (<http://www.exim.gov/pressrelease.cfm/B0F7C410-1032-5B0F-B28119316702519A>).

¹⁰⁴⁴ The Export-Import Bank of the United States (Ex-Im Bank) approved nearly \$60 million in financing to support the export of 10 model S-76C+ helicopters and spare parts by Sikorsky Aircraft Corporation of Stratford, Conn., to Lider Taxi Aereo of Belo Horizonte, Brazil. Ex-Im Bank is providing a direct loan to the Lider Group to support the transaction. Lider Taxi, a leading provider of offshore helicopter services in Brazil, will use the helicopters to fulfill five-year service contracts with Petrobras and other customers to support offshore oil and gas exploration and operations. The helicopters will also be used for passenger and cargo transportation within Brazil. See Ex-Im Bank Supports Export of Sikorsky Commercial Helicopters to Brazil, Press Release (12/28/04), at: (<http://www.exim.gov/pressrelease.cfm/DED49A9E-912C-A04C-F2EF25C35CCE07C0>).

¹⁰⁴⁵ Ex-Im Bank has approved a \$39 million loan guarantee to support the sale of U.S. equipment to a wholly-owned subsidiary of Petroleo Brasileiro, S.A. (Petrobras), to be installed on one of the world's largest oil production platforms off the coast of Brazil. Using equipment provided by Petreco International Inc. and National Tank Co., both of Houston, Tex., and numerous other U.S. suppliers, Petrobras will build the P-52 semi-submersible floating platform to be stationed in the

Roncador Oil Field, located 80 miles off Brazil's coast in the Campos Basin. It will produce 180,000 barrels of oil and 330 million cubic feet of gas per day. See Ex-Im Bank Finances U.S. Export Sale to Build High-Technology Deep Water Oil and Gas Production Platform Off Brazil, Press Release (5/25/05), at: (<http://www.exim.gov/pressrelease.cfm/19B9CB5A-9A39-AE82-FB57A98A9E856658>).

¹⁰⁴⁶ In 1994, Ex-Im backed two projects for a total of \$23.7 million in financing through which Stewart & Stevenson Services provided Petroleo Brasileiro (Petrobras) with TG 2500 gas turbine sets ([Project#s] AP067246 and AP067247)... [And]... [i]n 1995, Ex-Im financing backed a \$44.4 million contract in which various (unnamed) suppliers sold oil and gas equipment to Petrobras ([Project#] AP069258)... In a continuation of the 1995 package, "various"... U.S. suppliers sold \$327.7 million of equipment to Petrobras for oil and gas production. See Project Profile: Petrobras Oil and Gas Developments Sustainable Energy and Economy Network, at: (<http://www.seen.org/db/Dispatch?action-ProjectWidget:637-detail=1>). After initially approving \$44.25 million in financing, on Jan. 25, 2001, for GE equipment sales... [steam turbines and generators]... to a project at Petrobras' Canoas ... [Ibrite 250MW gas-fired]... power plant, adjacent to Petrobras refinery, the Ex-Im increased this amount to \$97.6 million on May 10, 2001. See Project Profile: Canoas 250MW Gas-fired Power Plant, Sustainable Energy and Economy Network, at: (<http://www.seen.org/db/Dispatch?action-ProjectWidget:422-detail=1>); (<http://www.seen.org/db/Dispatch?action-ProjectWidget:425-detail=1>).

¹⁰⁴⁷ Ex-Im Bank is helping U.S. hospital equipment manufacturers to break into the southern Brazilian market by providing a long-term guarantee to assist in financing the nearly \$35 million sale of U.S. equipment and related services by Magna Medical Systems Inc. in Miami, Fla., to Comunidade Evangélica Luterana São Paulo (CELSP), a private, non-profit organization in Canoas, Rio Grande do Sul, Brazil. CELSP will use the equipment in a new 600-bed, teaching hospital currently under construction in Canoas. Magna Medical Systems, an integrator and exporter of hospital equipment and technology, will export equipment from 93 U.S. sub-suppliers... See Ex-Im Bank Supports U.S. Exports to Equip New Hospital in Brazil, Press Release (8/3/00), at: (<http://www.exim.gov/pressrelease.cfm/B0D80DB5-1032-5B0F-B1E713D7D1BC6AAE>).

¹⁰⁴⁸ Ex-Im Bank approved a \$2.1 million medium-term guarantee to assist Engenharia Brasileira de Construções SA of Pinhais, Brazil, in buying 11 heavy construction Terex cranes from M.D. Moody & Sons Inc. of Pompano Beach, FL. The U.S. supplier is Terex Corporation of Westport, CT. Amtrade International Bank of Atlanta, GA, is the guaranteed lender. See Ex-Im Bank's Medium-Term Financing to Assist Brazilian Buyers in Purchase of U.S. Construction, Manufacturing Equipment, Press Release (2/16/00), at: (<http://www.exim.gov/pressrelease.cfm/2B7FAF42-A9F6-9B9C-87CFD35A1B50A204>).

¹⁰⁴⁹ In a separate transaction, the Bank authorized a \$383,000 medium-term guarantee to help Itabuna Textil, SA, of Bahia, Brazil, purchase a Braun dye extractor from Jim Martin Industries, Inc., a small business exporter in Charlotte, NC. The U.S. supplier, Braun G.A. Inc., is a small business in Syracuse, NY. Banco Itau SA, New York, NY, is the guaranteed lender. *Ibid.*

¹⁰⁵⁰ H.R. 1690, 'The Export-Import Bank HIV/AIDS Medicine Access Promotion Act', was sponsored by California Representative Maxine Waters. It would prohibit [which] EXIM from assisting in the export of any good or service to or by any country that is challenging an intellectual property law or government policy of a developing country, which regulates and promotes access to HIV/AIDS pharmaceutical or medical technology. See James K. Jackson, 'Export-Import Bank: Background and Legislative Issues', CRS Report for Congress (Order Code 98-568 E) (10/2/02), at: (<http://www.fas.org/asmp/resources/govern/crs-98-568E.pdf>); See also 'The Export-Import Bank Should Not Oppose AIDS Drug Access!', Letter, dated May 4, 2001, from Representative Maxine Waters, at: (<http://www.cptech.org/ip/health/country/waters05042001.html>).

¹⁰⁵¹ The following summarized proposed amendments to H.R. 2871, 'The Export-Import Bank Reauthorization Act of 2001', were submitted to the House Rules Committee by former California Congressman Doug Loe: Ose #1 Bans Ex-Im Bank assistance to companies involved in an *intellectual property rights* case relating to the entertainment industry. Ose #2 Bans Ex-Im Bank assistance to companies involved in an *intellectual property rights* case relating to computers and software. Ose #3 Bans Ex-Im Bank assistance to companies involved in an *intellectual property rights* case relating to the aircraft industry. Ose #4 Bans Ex-Im Bank assistance to companies involved in an *intellectual property rights* case relating to the telecommunications industry. Ose #5 Bans Ex-Im Bank assistance to companies involved in an *intellectual property rights* case relating to

the agricultural industry (emphasis added). See Summary of Amendments Submitted to the Rules Committee on H.R. 2871 – Export-Import Bank Reauthorization Act of 2001, U.S. House of Representatives Committee on Rules (4/3/02) at: (http://www.rules.house.gov/archives/sum_exim_107.htm). They ultimately were not adopted. See Summary of Amendments Made in Order - H.R. 2871 - Export-Import Bank Reauthorization Act of 2001, Committee Action (4/30/02) / Floor Action (5/1/02), at: (<http://www.rules.house.gov/Archives/107rule2871.htm>).

¹⁰⁵² See Grassley Wins Initial Approval of Funding Ban for Project Benefiting Brazilian Ethanol Producers, Press Release, Offices of U.S. Senator Charles Grassley (7/20/05), at: (<http://finance.senate.gov/press/Gpress/2005/prg071905.pdf>). Sen. Chuck Grassley, chairman of the Committee on Finance, has won initial Senate approval of his amendment to bar the continued use of Export-Import Bank funds to administer credit insurance for the construction of an ethanol dehydration plant in Trinidad using Brazilian ethanol. It doesn't make sense that U.S. taxpayer money is being used to help build facilities to dehydrate Brazilian ethanol for export to the U.S. market, Grassley said. And from what I can see, the Export-Import Bank's approval of credit insurance for this ethanol plant violated the Export-Import Bank's authorizing statute by causing substantial injury to U.S. producers of the same commodity. It's only right that no further taxpayer funds should be provided for this facility.' Senator Grassley's floor speech explaining the rationale underlying his Amendment No. 1250 can be found at: Department of State, Foreign Operations and Relation Programs Appropriations Act of 2006 (7/18/05), at: (http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?dbname=2005_record&page=S8408&position=all)

¹⁰⁵³ OPIC insurance coverage indemnifies for asset impairment or loss due to asset expropriation or nationalization by governments, and for asset damage or loss arising from politically motivated violence such as civil or international wars. See Insurance Department – Overseas Private Investment Corporation, at: (<http://www.opic.gov/Insurance>).

¹⁰⁵⁴ See OPIC's Development Mission, at: (http://www.opic.gov/Mission/DM_Intro.asp).

¹⁰⁵⁵ The project is expected to drastically increase the feasibility of using clean-burning compressed natural gas (CNG) in rural areas that are not currently served by natural gas pipelines, as well as its use in natural gas-powered vehicles. Although Brazil has a growing network of gas pipelines, much of the country still lacks access to branch pipelines, thereby denying direct availability of natural gas to

consumers and industries. NEOgas transports gas that is available through the state gas distribution companies and delivers it to industrial and natural gas vehicle sites i.e., retail stations and industrial parks. See U.S. Small Business Uses OPIC Loan to Expand Clean Energy Technology in Brazil, OPIC Press (1/11/06), at: (<http://www.opic.gov/pressreleases/2006/6-05.htm>).

¹⁰⁵⁶ The mission's purpose was to help U.S. firms find business partners and sell renewable energy equipment and services in Rio de Janeiro, São Paulo, and Salvador da Bahia. It [t]argeted all of the sectors... [falling within Brazil's]... Program for Alternative Electric Energy Sources (PROFINA)... include[ing] hydro, wind, solar, biodiesel and biomass... [The PROFINA] program is expected to attract more than US\$ 2 billion in investments from 2005 to 2008. See Trade Mission Statement - Renewable Energy Trade Mission to Brazil October 17-19, 2005, at: (http://www.trade.gov/doctm/energy_brazil_1005.html).

¹⁰⁵⁷ FYE 2004: Finance - \$13.5m, Insurance - \$127, for total investments of \$140.5 million. See Overseas Private Investment Corporation Annual Report 2004 - 2004 Investment Activities, at p. 22, at: (http://www.opic.gov/pdf/publications/04_AnnualReport.pdf); FYE 2003: Finance - \$210.8m, Insurance - \$56.2m, for total investments of \$267m. See Overseas Private Investment Corporation Annual Report 2003 - 2003 Investment Activities, at p. 20, at: (http://www.opic.gov/pdf/publications/03_AnnualReport.pdf); FYE 2002: \$0; FYE 2001: Finance - \$341.1m, Insurance - \$265.4m, for total investments of \$606.5m. See Overseas Private Investment Corporation Annual Report 2001 - 2001 Investment Activities at pp. 24-25, at: (http://www.opic.gov/pdf/publications/01_AnnualReport.pdf); FYE 2000: Finance - \$61m, Insurance - \$450m, for total investments of \$511m. See Overseas Private Investment Corporation Annual Report 2000 - 2000 Investment Projects at p. 18, at: (http://www.opic.gov/pdf/publications/00_AnnualReport.pdf).

¹⁰⁵⁸ *Ibid.*

¹⁰⁵⁹ See David Ivanovich, Enron Pipeline in Bolivia Gets U.S. Loan Guarantee, Houston Chronicle (6/15/99), at: (<http://www.amazonia.net/Articles/353.htm#Enron>).

¹⁰⁶⁰ See OPIC's Deep Pockets, The New American (8/4/97), at: (http://www.stopthefaa.org/artman/publish/article_45.shtml).

¹⁰⁶¹ See National Export Strategy Update - New Initiatives, U.S. Department of State Newsletter, Office of the Coordinator for Business Affairs (6/1/95), at:

(http://dosfan.lib.uic.edu/ERC/economics/Trade_Policy_Newsletter/9506.html).

¹⁰⁶² See Executive Summary, U.S. Country Commercial Guide – Brazil 2005, at p. 1.

¹⁰⁶³ See Breaking Patents Is Not the Way to Go, Says US to Brazil, *Brazzil Magazine* (5/18/05), at: (<http://www.brazzilmag.com/content/view/2470/49/>).

¹⁰⁶⁴ See: Duncan Hooper and Kevin Costelloe, U.S., EU threaten zero tolerance for copyright violations *Bloomberg* (12/1/05), at: (<http://www.businessday.co.za/articles/world.aspx?ID=BD4A121407>).

¹⁰⁶⁵ See Sec. 410 of the Trade Act of 2002 (P.L. 107-210).

¹⁰⁶⁶ On October 6, 2005, the Office of the United States Trade Representative (USTR) requested public comments to determine whether the Administration's operation of the [General System of Preferences (GSP)] program should be changed so that benefits are not focused on trade from a few countries and developing countries that traditionally have not been major traders under the program receive benefits. The type of information requested in such comments is unrelated to the information relevant to its annual review of product coverage and competitive need limits under the GSP program. (70 FR 58502) (FR Doc. 05-20089 Filed 10-5-05). The USTR's Trade Policy Staff Committee (TPSC) conducted a hearing on November 3, 2005 and invited the public to submit comments by November 14, 2005. *Ibid.*

¹⁰⁶⁷ In 2004, the top ten GSP beneficiary developing countries by trade volume (not including trade in petroleum products) were India, *Brazil*, Thailand, Indonesia, Turkey, Philippines, South Africa, Venezuela, Argentina, and Russia (emphasis added). *Ibid.*

¹⁰⁶⁸ Reaching agreement on trade-related regulations is more difficult than reaching agreements on tariff reductions... One option is for the United States to tighten the linkage between access to American markets and compliance with American regulatory standards by ensuring that imported goods are manufactured in a manner congruent with American values... The chances that WTO members will agree to incorporate... American... preference[s]... are slim... A *second-best option would be to propose a tighter link between rigorous regulatory standards and the Generalized System of Preferences (GSP) that the United States grants to developing- country members of the WTO.* The GSP program waives all duties and tariffs for 4,000 products from 140 developing countries. Since 1984, the United States has linked GSP considerations to whether eligible countries adhere to internationally recognized worker rights- and some evidence suggests that the

linkage has helped improve labor rights in the developing world. Yet GSP considerations have not been linked to environmental standards, and even on labor rights, private-sector groups complain of lax enforcement (emphasis added). See Daniel W. Drezner, U.S. Trade Strategy Free Versus Fair: Critical Policy Choices, Council on Foreign Relations, *supra*, at pp. 69-70.

¹⁰⁶⁹ See Testimony of James E. Mendenhall Testimony, Acting General Counsel, Office of the United States Trade Representative, to the United States Senate Committee on the Judiciary Piracy of Intellectual Property held May 25, 2005, at: (http://judiciary.senate.gov/print_testimony.cfm?id=1514&wit_id=4302).

¹⁰⁷⁰ See (<http://www.cptech.org/ip/health/c/brazil/brown-waite05242005.pdf>); (<http://lists.essential.org/pipermail/ip-health/2005-May/007950.html>).

¹⁰⁷¹ See (<http://www.cptech.org/ip/health/c/brazil/wilson05242005.pdf>).

¹⁰⁷² See Breaking Patents Is Not the Way to Go, Says U.S. to Brazil, *supra*.

¹⁰⁷³ The investigation was triggered by a petition filed in 2000 by the International Intellectual Property Alliance (IIPA) on behalf of several U.S. copyright-based industries, including computer software. The petition had sought to withhold more than US\$3 billion in annual preferential GSP trade benefits to compensate for annual trade losses due to copyright piracy since 2000. In 2004 alone, losses had been estimated at US\$960 million. See U.S. Copyright-based Industries Welcome Progress on Combating Piracy and Commitments by Brazil to Pursue Sustained Actions to Deter Piracy and Improve Enforcement and Public Awareness Measures, International Intellectual Property Alliance Press Release (1/13/06), at: (<http://www.iipa.com/pdf/IIPA%20BRAZIL%20GSP%20case%20terminated%20Press%20Release%2001132006.pdf>).

¹⁰⁷⁴ See Breaking Patents Is Not the Way to Go, Says U.S. to Brazil, *supra*. Given the vitriol of the debate over drug patents, one must question whether this article was planted for propaganda purposes by the Brazilian government and/or the NGO community.

¹⁰⁷⁵ See Generalized System of Preferences (GSP): Notice of Closure of Case 013-CP-05, Protection of Intellectual Property in Brazil, in the 2005 Annual Country Practice Review (1/13/06), 71 FR 2292 (FR Doc. 06-368 Filed 1-12-06), at: (<http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/06-368.htm>).

¹⁰⁷⁶ See Second Annual BSA [Business Software Alliance] and IDC Global Software Piracy Study (May 2005), at pp. 6 and 9, at: (<http://www.bsa.org/globalstudy/upload/2005-Global-Study-English.pdf>). The Business Software Alliance is a member of the International Intellectual Property Alliance. See Member Associations, International Intellectual Property Alliance, at: (<http://www.iipa.com/memberassociations.html>); About BSA - BSA Members, at: (<http://www.bsa.org/usa/about/BSA-Members.cfm>).

¹⁰⁷⁷ Generally speaking, The primary benefit of protecting computer software through the patent system is the strength of protection provided by the patent laws. *An owner of a patent may prevent all others from making, using, or selling the patented invention in connection with software, an issued patent may prevent others from utilizing a certain algorithm (such as the GIF image compression algorithm) without permission, or may prevent others from creating software programs that perform a function in a certain way.* In contrast, *copyright law can only prevent the copying of a particular expression of an idea.* In connection with computer software, *copyright law can be used to prevent the total duplication of a software program, as well as the copying of a portion of software code* (both of which are examples of literal infringement). In addition, copyright does provide some protection against non-literal infringement, such as the creation of 'cloned' software. However, courts have recently been reluctant to interpret copyright protection of computer software in a broad manner. In addition, the basic tenet of copyright law is that copyright will protect only the expression of an idea, and not the idea itself. Consequently, *copyright law will not prevent the creation of a competing program that utilizes the same ideas as an existing program.* As a result, *software patents can provide much greater protection to software developers than copyright law* (emphasis added). See Why Protect Software Through Patents, Bitlaw, A Resource on Technology Law, at: (<http://www.bitlaw.com/software-patent/why-patent.html>).

¹⁰⁷⁸ See U.S. Generalized System of Preferences Guidebook, Office of the United States Trade Representative (Nov. 2005), at: (http://www.ustr.gov/assets/Trade_Development/Preference_Programs/GSP/asset_upload_file267_8359.pdf). See also Criteria For Eligibility Under GSP, *Ibid.*, at pp. 18-19.

¹⁰⁷⁹ See Martyn Williams, IIPA Piracy Petition Criticizes Russia: U.S. Trade Associations Call For Possible Sanctions Against Russia For Serious Copyright Violations, IDG News Service (2/13/06), at: (http://www.infoworld.com/article/06/02/13/75302_HNpiracypetition1.html).

¹⁰⁸⁰ U.S. business leaders have appealed to President George W. Bush to delay Russia's accession to the World Trade Organization until it has demonstrated that it will be a reliable partner in the global trading community... [A] letter signed by groups such as the Chamber of Commerce and the Emergency Committee for American Trade... called on Mr. Bush to resist pressure at the summit of Group of Eight leaders in St. Petersburg [in July] to smooth the way for Russia's accession to the world body... [It] details specific concerns, including the need for Russia to improve its protection of intellectual property and to remove technical barriers to U.S. agricultural exports. See Edward Alden, "Calls for Delay in Russia's WTO Accession", *Financial Times* (7/8-7/9/06), at p. 5.

¹⁰⁸¹ In his January 24, 2006 remarks to the Brazil-U.S. Business Council in Washington, U.S. Commerce Deputy Secretary David Sampson... outlined areas for closer U.S.-Brazilian cooperation, including streamlining customs clearance, combating pirated goods and advancing the Doha round of World Trade Organization (WTO) negotiations... In the Americas, we are pursuing comprehensive trade agreements. The U.S. wants to create the conditions for global competitiveness by negotiating trade agreements that eliminate barriers to innovation, investment and trade. Beyond market access, we seek agreements containing broad commitments that provide a predictable climate for all businesses -- manufacturers, service-providers and investors. This policy is working. For example, U.S. exports to Chile have nearly doubled since our free-trade agreement was implemented. We expect a similar increase in trade to occur when CAFTA goes into effect. And, of course, NAFTA has been very successful over the years. On related fronts, the U.S. Congress will consider the Peru Trade Promotion Agreement later this year. And we're negotiating with Colombia, Ecuador and Panama. When all is said and done, more than 90 percent of U.S. trade in the Americas will be covered by free-trade agreements in the years ahead. Still, as we look at a map of the Americas, Brazil and the rest of Mercosur stand out as the exception. But it would be a mistake to assume a lack of progress with Brazil on the FTAA means there is no cooperation on trade and other economic issues. Nothing could be further from the truth. We look forward to making progress in other areas as our new trade dialogue unfolds. Both the U.S. and Brazil see this dialogue as an opportunity to make our economies more competitive by looking at concrete steps we can take to facilitate trade and investment. See Remarks By U.S. Commerce Deputy Secretary David A. Sampson, cited in U.S.-Brazil Cooperation on Trade Is Crucial, Says U.S. Official - Commerce

Department outlines Areas for Closer Cooperation , U.S. Department of State International Information Programs (1/27/06), at: (<http://usinfo.state.gov/wh/Archive/2006/Jan/27-588350.html>).

¹⁰⁸² Pascal Lamy, WTO director-general, has said that of the big four economies at the centre of negotiations, the US must agree to more cuts in farm subsidies, the EU to sharp reductions in agricultural tariffs and Brazil and India to lowering tariffs on industrial goods. But disagreement remains over tariff cuts and exemptions. Brazil wants to cut industrial goods tariffs to a maximum of 30 per cent. The EU and US say they cannot accept more than 15 per cent.

It would help the negotiations a lot if the big emerging market countries such as Brazil were prepared to offer bigger cuts in industrial goods tariffs,' said Peter Allgeier, the US ambassador to the WTO... Celso Amorim, Brazilian foreign minister, said although the basic trade-offs that would underpin a deal were well known, political will to make concessions was lacking. See Alan Beattie, Doha Talks Likely to Miss Next Deadline , Financial Times (4/17/06), at: (<http://news.ft.com/cms/s/6ce1f500-ce52-11da-a032-0000779e2340.html>).

¹⁰⁸³ "U.S. Trade Representative Susan C. Schwab will attend a meeting of G-20 trade ministers, hosted by Brazil, on September 10, 2006, in Rio de Janeiro, Brazil. Ambassador Schwab will use this opportunity to continue work toward reviving the multilateral negotiations under the World Trade Organization's Doha Development Agenda. Ambassador Schwab will continue to focus on market access and increasing trade to generate economic development." See USTR Susan C. Schwab to Travel to Brazil for G-20 Ministerial Meeting , Press Release, Office of the United States Trade Representative (9/7/06), at: (http://www.ustr.gov/Document_Library/Press_Releases/2006/September/USTR_Susan_C_Schwab_to_Travel_to_Brazil_for_G-20_Ministerial_Meeting.html?ht).

¹⁰⁸⁴ See Report Notes Continued Progress on Intellectual Property Rights, Identifies Significant Improvements Still Needed in China and Russia: USTR To Initiate Review of China's Province Level IPR Enforcement Efforts , Office of the United States Trade Representative (4/28/06), at: (http://www.ustr.gov/Document_Library/Press_Releases/2006/April/Report_Notes_Continued_Progress_on_Intellectual_Property_Rights,_Identifies_Significant_Improvements_Still_Needed_in_China_R.html).

Addressing weak IPR protection and enforcement, particularly in China and Russia, continues to be one of the Administration's top priorities. Although this year's Special 301 Report shows positive

progress in many countries, rampant counterfeiting and piracy problems continue to plague both China and Russia, indicating a critical need for stronger intellectual property protection in China and Russia... In addition to China and Russia, the Special 301 Report sets out significant concerns with respect to such trading partners as Argentina, Belize, **Brazil**, Egypt, India, Indonesia, Israel, Lebanon, Paraguay, Turkey, Ukraine, and Venezuela. In addition, the report notes that the United States will consider all options, including, but not limited to, initiation of dispute settlement consultations in cases where countries do not appear to have implemented fully their obligations under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (emphasis added). See 2006 Special 301 Report, Executive Summary, Office of the United States Trade Representative (4/28/06), at: <http://hongkong.usconsulate.gov/uscn/trade/ipr/2006/042802.htm>.

¹⁰⁸⁵ The Congressional International Anti-Piracy Caucus, which includes 73 members of Congress, said at a Wednesday [April 5th] Capitol Hill press conference that the "scope and depth" of copyright theft in China and Russia make the two stand out in the international piracy world. See Roy Mark, China, Russia Top International Piracy List, Business - Internetnews.com (4/6/06), at: <http://www.internetnews.com/bus-news/article.php/3597216>.

¹⁰⁸⁶ Russian President Vladimir Putin... [has] accus[ed] the United States of intentionally trying to stall Russia's WTO bid by renewing demands on Russia that had already been worked out. The United States has rejected this, saying that Russia is being held to the same standard as all WTO candidates. In particular, the United States is demanding from Russia: [1] Access to the Russian market for subsidiaries of foreign banks and insurance companies[;] [2] The reduction of import duties on aircraft and aircraft engines[;] [3] **Tougher legislation on the protection of intellectual property**[;][4] The lifting of quotas on the importation into Russia of poultry and meat products[;] [5] **The reduction of the number of agricultural goods requiring sanitary-inspection certificates**[.] In addition, the U.S. Department of Commerce upped the ante by including the liberalization of Russia's telecommunications and forestry sectors on its list of requirements issued on March 31... Maksim Medvedkov, the chief Russian WTO negotiator, during an appearance on the NTV talk show 'National Interest'... said **Russia should do more in terms of protecting intellectual property rights, as demanded by the United States**. Speaking on the same show, Mosfilm General Director and noted filmmaker Karen Shakhnazarov shared his own experiences with

pirated versions of his own work. He revealed that he was recently given a counterfeit DVD containing seven of his films that was purchased for a mere 148 rubles (\$5.30). *Shakhnazarov suggested that the stricter protection of intellectual property in Russia could also help prevent the piracy of Russian multimedia products abroad.* In the West the cost of multimedia products is higher and, therefore, the losses incurred [by Russia] due to piracy are bigger,' he explained (emphasis added). See Victor Yasmann, Analysis: Moscow And Washington Spar Over WTO Membership, Radio Free Europe, Radio Liberty (4/25/06), at: (<http://www.rferl.org/featuresarticle/2006/4/43C57B11-C600-40DF-8276-183C47CB0828.html>).

¹⁰⁸⁷ In a letter to the President, U.S. Senators Charles Grassley (R-Iowa) and Max Baucus (D-Mont.) and Reps. Bill Thomas (R-Calif.) and Charles Rangel (D-N.Y.) expressed strong concerns about Russia's commitment *to intellectual property rights (IPR) and science-based standards for agricultural trade policies.* The committee leaders urged the administration to require definitive action from Russia on these issues before concluding current WTO negotiations (emphasis added). See Ways and Means and Senate Finance Leadership Urge White House to Address Russian Trade Practices In WTO Accession Talks - Thomas, Rangel, Grassley, Baucus Will Not Support PNTR Unless Russia Takes Definitive Action to Improve, House Ways and Means Committee Press Release (5/11/06), at: (<http://waysandmeans.house.gov/News.asp?FormMode=print&ID=394>).

¹⁰⁸⁸ Apparently, U.S. congressional concerns about how Russia has continued to permit the rampant counterfeiting of U.S. copyrighted products and to use disguised EU-style regulatory trade barriers to block market access of U.S. agricultural exports were not adequately addressed during recent bilateral U.S.-Russia trade negotiations. As a result, the U.S. administration was unable to execute a bilateral trade deal with Russia, thus blocking, at least temporarily, Russia's accession to the World Trade Organization. U.S. Trade Representative Susan Schwab said 'significant progress' had been made in narrowing differences over the protection of U.S. copyrights and patents and boosting the sale of American manufactured goods. She said negotiators were unable to resolve a dispute over Russian barriers to the sale of American beef and pork. She said the hope was that the agreement could be completed in the next couple of months.' See U.S., Russia Fail to Agree on WTO membership: U.S. Remains Only Member Not Backing Russia's Entry into Economic Group,

Associated Press (7/15/06), at: <http://www.msnbc.msn.com/id/13855682>).

¹⁰⁸⁹ For example, it is possible that the closure of the case was motivated by concerns of the White House and State Department that go beyond the realm of the USTR, i.e., security and geo-strategic concerns may drive the newfound effort to strengthen bilateral relations with Brazil. Better relations would serve as a counterweight to growing Latin American populism and political instability that might otherwise provide opportunities for foreign criminals and terrorists.

There are new opportunities for us to cooperate. For example, it is in our mutual best interest to disrupt the international supply chain of pirated goods. Global illicit trade is a huge problem. It's getting worse every day. And the potential for undermining civil society is alarming. I just finished a book, *Illicit Trade*, by the foreign policy expert Moises Naim. He stated in no uncertain terms that *the very fabric of society is at stake. He believes that global illicit trade is sinking entire industries -- and destabilizing some governments and propping up others.*' *Ibid.*

See also Larry Rohter, *Dwindling Debt Boosts Argentine Leader*, *New York Times* (1/3/06), at: <http://www.nytimes.com/2006/01/03/international/americas/03argentina.html>); Marcela Sanchez, *Fear of Evo*, *Washingtonpost.com* (12/22/05), at: <http://www.washingtonpost.com/wp-dyn/content/article/2005/12/22/AR2005122201147.html>); Juan Forero,

Latin America Looks Leftward Again, *New York Times Week in Review* (12/18/05), at:

<http://www.nytimes.com/2005/12/18/weekinreview/18forero.html?ei=5088&en=559c4c44714a08c7&ex=1292562000&adxnnl=1&partner=rssnyt&emc=rss&adxnnlx=1140023337-7Vb855D7/IOTkSEg2YhiOg>).

¹⁰⁹⁰ See Letter from Lila Feisee to Sylvia Harrison, *Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment*, *supra*.

¹⁰⁹¹ The USTR, either in response to a petition, or of its own volition, can initiate an investigation into a foreign unfair trade practice, including failure to protect intellectual property, pursuant to Section 301 of the Trade Act of 1974. The most likely basis for an IP-related section 301 petition is a World Trade Organization member's noncompliance with the agreement on Trade Related Aspects of Intellectual Property. A section 301 investigation generally begins with consultations between the trade representative and the investigated country, which sometimes resolves the controversy. If consultations fail, the trade representative can file a complaint with the World Trade Organization, which forms a dispute settlement panel to decide the

merits of the complaint. Section 306 monitoring¹⁰⁹² indicates that a country is taking action to address concerns raised in connection with a Section 301 investigation and are monitoring whether that country is satisfactorily implementing those actions. Each year, USTR issued the 2005 Special 301 Report on April 29, which catalogues the IPR problems in dozens of countries around the world and places them in a hierarchy – ranging from the lowest ranking of Watch List (WL) to the mid-level Priority Watch List (PWL) to the ranking reserved for the worst offenders, Priority Foreign Country. Priority Foreign Country is the most serious designation; USTR is obligated to decide whether to initiate an investigation under section 301 against any country designated a PFC. Priority Watch List indicates that the United States has a high level of significant concerns. Watch List indicates that there are serious IPR issues in that country that warrant attention. A country's ranking in the report sends a message to the world including potential investors about a country's commitment to IPR protection. The trade representative prepares the list after receiving comments from American companies. See John H. Jackson, William J. Davey and Alan O. Sykes, Jr., *Legal Problems of International Economic Relations – Cases, Materials and Text*, 4th ed. (© 2002 West Pub.), at pp. 319-335. Pursuant to Section 332 of the Trade Act of 1974, American companies can [also] draw attention to a country's failure to protect IP rights by encouraging the institution of a [S]ection 332 fact-finding investigation at the U.S. International Trade Commission. There are no enforcement provisions under section 332[, however. Yet], the report can be a valuable reference for the administration and Congress in their efforts to oppose a country's failure to protect IP rights. See Greg Mastel, James B. Altman, and Daniel P. Wendt, *Protecting IP Rights Overseas* *IP Law & Business* (Sept. 2004), at: <http://www.ipww.com/texts/0904/smartpills0904.html>.

¹⁰⁹² Explosive rates of innovation have taken place in countries, such as South Korea, Mexico, Jordan and Singapore, which have understood that growth and prosperity can only occur once the institutional framework is in place. If intellectual property rights are responsible for restricted access to medicines in poor countries, then drugs should be plentiful in countries where the patents are expired or were never present. On the contrary, many of the most critical drugs that Africa still lacks have been off-patent for 30 or 40 years. These include most anti-diarrhoea drugs, antibiotics, derivatives of penicillin and cephalosporin, many antihypertensive drugs and almost all antipyretic drugs. The human genome project hardly serves as a basis for

completely altering the current model of intellectual property rights. While it has provided information with potential use, the benefits of its initial research must not be overstated. Removing property rights and making companies conduct open-source research and development could lead to disaster. Without the chance of recovering investments, why would research-based pharmaceutical companies invest large sums in drug development? Open-source models might work in some businesses that are not so capital-intensive, but it is a pipe-dream to rely on the philanthropy of chemists, physicians, researchers and financiers to contribute voluntarily to such schemes. *See* John Kilama, *Protecting Patents Protects Patients*, Bangladeshweb.com (7/22/05), at: (<http://bangladesh-web.com/view.php?hidDate=2005-08-03&hidType=FEA&hidRecord=0000000000000000053492>); John Kilama, *Drug Patents Are Part of The Cure*, Business Day (7/28/05), at: (<http://www.businessday.co.za/articles/topstories.aspx?ID=BD4A73957>).

¹⁰⁹³ Contracting States... constitute a Union for cooperation in the filing, searching, and examination, of applications for the protection of inventions, and for rendering special technical services. *See* Article I, Establishment of a Union, Patent Cooperation Treaty, Done at Washington on June 19, 1970, amended on September 28, 1979, modified on February 3, 1984, and October 3, 2001 (as in force from April 1, 2002), at: (<http://www.wipo.int/pct/en/texts/articles/atoc.htm>).

¹⁰⁹⁴ *See* Hepeng Jia, *China Joins Top Ten for International Patents*, Science Development Network (2/7/06), at: (<http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=2642&language=1>).

¹⁰⁹⁵ Most Chinese film executives believe movie piracy, which accounts for more than 90 percent of the market in China, will expand in the short term and is unlikely to shrink in the future, according to a [recent June 2006] survey [conducted and] released... by the Centre for American Studies of the Chinese Academy of Social Sciences on behalf of the [US-based] Motion Picture Association... Pirated movies have fundamentally undermined the production capabilities of China's movie industry, with the private sector hit most severely,' the report says. *See* Richard McGregor, *Piracy Destroying China's Own Movie Industry*, Financial Times (6/20/06), at p. 3.

¹⁰⁹⁶ *See* Improvement of Intellectual Property System Stimulates Innovation: Official Xinhua News Service (12/29/05), at People's Daily Online at: (http://english.people.com.cn/200512/29/eng20051229_231515.html).

¹⁰⁹⁷ See US Presses China on Global Trade, Rights Obligations , Agence France Presse (1/27/06), at: (http://www.channelnewsasia.com/stories/afp_asiapacific/view/190289/1/.html); Piracy Fight Strains Ties With the U.S. The Wall Street Journal Briefing: China Manufacturing Vol. 2 Issue 3 (1/27/06), at: (<http://www.briefing.wsj.com/article.html?id=0100270000>); See also Christopher Swann and Edward Aiden, US demands Chinese Reply over Intellectual Property , Financial Times (1/25/06) at: (<http://www.msnbc.msn.com/id/11012821>).

¹⁰⁹⁸ See Christopher Swann, US to Monitor China's Trade Practices , Financial Times at p. 1 (2/15/06).

¹⁰⁹⁹ Brazil has become the first country to take a stand against the abstinence dominated agenda of US funding for HIV and Aids. Brazil's Aids Commission last month told the US Agency for International Development (USAID) it didn't want the \$40 million remaining from a 2003-2004 grant and refused to sign a pledge condemning prostitution. It said the US requirement that recipient groups condemn prostitution would hamper their work in a country where prostitution is not a crime and sex workers are active in HIV prevention work... Pedro Chequer, director of Brazil's Aids programme, said: 'We can't control the disease with principles that are Manichean, theological, fundamentalist or Shiite. US demands are an interference that harm the Brazilian policy regarding diversity, ethical principles and human rights,' Chequer continued. See Brazil Rejects US Funds and Fundamentalism , Positive Nation World News Issue 113 (June/July 2005), at: (<http://www.positivenation.co.uk/issue113/regulars/worldnews/news113.htm>).

¹¹⁰⁰ Brazil says it plans to distribute a billion free condoms *next year* as part of its fight against HIV and Aids (emphasis added). See Brazil Plans Massive Condom Drive BBC News (12/1/05), at: (<http://news.bbc.co.uk/1/hi/world/americas/4487100.stm>).

¹¹⁰¹ During July 2005, it was reported that The Chinese government has begun to promote condoms to prevent the spread of HIV. In Beijing, HIV prevention advertisements were posted publicly around World AIDS Day in December, including some that promoted condom use. Ordinarily ads for family planning products are banned, but condom ads are considered acceptable if they focus on prevention of HIV/AIDS. See News Briefs , Treat Asia Report AMFAR AIDS Research (July 2005), at: (<http://www.amfar.org/cgi-bin/iowa/asia/news/?record=66>).

¹¹⁰² We have a few solutions but they have relatively strong side-effects'... Vice Health Minister Wang Longde... said. The government has cast its eyes on several alternatives. *Among the most controversial is compulsory licensing*... Having sat on a decision for three years, the government has decided that conditions are not mature' for such an action. China is not yet in an emergency situation,' Mr Mao Qunan, deputy director-general for the Health Ministry's department of general administration, told The Straits Times. See Access to Drugs Key to Controlling AIDS, China Daily (6/28/04), at: (<http://www.china.org.cn/english/China/99598.htm>).

¹¹⁰³ See Jason Leow, China Seeks Low-Cost Drugs for AIDS Patients The Straits Times (6/30/04), cited on Yale Global Online at: (<http://yaleglobal.yale.edu/display.article?id=4158>).

¹¹⁰⁴ On 29 November 2005, the State Intellectual Property Office ("SIPO") of China issued the Measures for Compulsory Licensing of Patents Concerning Public Health ("Measures")... Article 49 of the current Patent Law provides that when an emergency or an extraordinary situation occurs in China, *or for the purpose of the public interest*, SIPO may grant a compulsory license for the exploitation of an invention patent or utility model patent. The Measures now define public interest' to include the prevention and control of the breakout and spread of infectious diseases, as well as the treatment thereof. National emergency' means a public health crisis caused by the breakout and spread of infectious diseases. Infectious diseases' include AIDS, Tuberculosis, Malaria and many others prescribed in the PRC Infectious Diseases Prevention and Treatment Law. Such interpretation has its origin in the Doha Declaration passed at the WTO Ministerial Conference in 2001... Compulsory licensing may be granted for any patented products or products *produced [in China]* using patented methods for treating infectious diseases... *for domestic use*... For a patented medicine for infectious diseases which China has no or insufficient capacity to produce... *foreign production for domestic use*... [and] where a WTO member or a least developed non-member notifies China of its desire to import medicines for infectious diseases from China... *[for] domestic production for foreign use* (emphasis added). See Horace Lam and Vivian Lui, China's New Rules on Compulsory Licensing of Patents for Public Health Lovells Intellectual Property, Mondaq (5/30/06) at: (http://www.mondaq.com/article.asp?articleid=38056&email_access=on). The new Chinese law, which has been in effect since January 1, 2006, could present problems for U.S. pharmaceutical and biotech companies, no matter where they produce their products. While

just/reasonable compensation' is required in the case of foreign production for domestic use and in the case of domestic production for foreign use, it is *not* required in the case of domestic production for domestic use. Hence, China could decide to invoke, or threaten to invoke, this new law under the guise of national public interest' concerns, in much the same way that Brazil has done under its compulsory licensing law, to improve its domestic scientific and technological capabilities, i.e., to engage in IP opportunism.

¹¹⁰⁵ China has bold plans to [control technical standards]... in fields from third-generation mobile telephony and optical discs to nanotechnology and bio-engineering. It is backing its ambitions with heavy state spending on research and showcase projects aimed at promoting indigenous innovation'. Though aggressive in intent, the strategy's inspiration is defensive. China is caught in what a [recent] study by the National Bureau of Asian Research (NBR)... calls a technology trap. Lacking advanced technology of its own, its exporters have to license much of it from abroad, often at high cost. Giving them a head start, by creating home-grown standards and know-how and using domestic demand as a springboard, offers a way out... [It] is [not]... clear... whether China's standards push is the best way to realize its ambition to develop from a basic manufacturing economy into an advanced industrial power, with the science, base, creative skills and technological strength in depth needed to equip its producers to become global leaders. See Guy de Jonquieres, *To Innovate, China Needs More Than Standards*, *supra*, citing Richard P. Suttmeier, Xiangkui Yao, and Alex Zixiang Tan, *Standards of Power? Technology, Institutions, and Politics in the Development of China's National Standards Strategy*, The National Bureau of Asian Research (2006), at: (<http://www.nbr.org/publications/specialreport/pdf/SR10.pdf>).

¹¹⁰⁶ Hu Jintao, China's president, said on Tuesday the protection of intellectual property rights was essential' for China's development and its ability to build an economy based on innovation rather than low-cost manufacturing... [U.S. technology companies such as] Microsoft ha[ve] been unable to build a substantial business in China, or at least one to match the market's potential, because of rampant software piracy. An estimated nine out of ten users of its operating systems in China are using illegal copies... China has long had laws compatible with global IPR rules but their enforcement has been patchy and at times non-existent. Under heavy pressure from the US government, China has announced a series of measures in recent weeks in an attempt to ensure that computers in China are sold pre-loaded with licensed software... In impromptu remarks to reporters after the Microsoft tour, with Mr Gates

standing by his side, Mr Hu said IPR protection was indispensable if China was to continue to open to the wider world. [IPR protection] is necessary to create a favourable investment environment, good and fast development, and for China's own innovative capability,' he said. 'We take very seriously our promises to enforce our laws on this issue.' It is unusual for the Chinese president, who operates in a highly-controlled environment, to respond to questions from reporters (emphasis added). See Richard McGregor, Hu Makes IPR Pledge During Microsoft Visit, FT.com (4/19/06), at: (<http://news.ft.com/cms/s/593f213c-cf54-11da-925d-0000779e2340.html>). See also, Richard McGregor, Hu Starts US Trip With Microsoft Visit, FT.com (4/19/06), at: (<http://news.ft.com/cms/s/005f0fc0-cecb-11da-925d-0000779e2340.html>).

¹¹⁰⁷ It is indeed possible that political considerations influenced the outcome of a recent patent decision rendered in favor of Pfizer, Inc. by a Chinese court. A Chinese court backed patent protection for Pfizer's... block-buster drug Viagra, a potential[] landmark case for foreign companies seeking greater protection of intellectual property against the flood of fakes and knock-offs in one of the world's fastest-growing markets. The verdict announced by a Beijing court Friday [6/2/06] afternoon, overturns a ruling by the country's patent review board. In July 2004, the board sided with a group of about a dozen Chinese generic-drug makers that had banded together to challenge New York-based Pfizer's patent on sildenafil citrate, the main ingredient in the popular impotence drug... sales of which totaled about \$1.6 billion world-wide last year. The verdict sends a positive signal to other foreign pharmaceutical companies that feared the government's decision to challenge Pfizer's patent would open up other drugs to attack on similar grounds. At the same time, a court ruling that defends a foreign company's intellectual property could prove politically useful for China at a time when runaway piracy of products from Gucci handbags to Microsoft software has provoked exasperation among the country's trading partners. See Nicholas Zamiska, Beijing Court Backs Patent Protection for Viagra: Pfizer's Win May Mark Turn In International Struggle Over Intellectual Property, Wall Street Journal (6/3/06), at p. A3. These political considerations may have taken into account the United States-China Economic and Security Review Commission hearings that took place on June 7-8, 2006, entitled, China's Enforcement of Intellectual Property Rights and the Dangers of the Movement of Counterfeited and Pirated Goods into the United States, at: (http://www.uscc.gov/pressreleases/2006/06_05_18pr.php) and

(http://www.uscc.gov/pressreleases/2006/agenda/06_06_7_8agenda.php).

¹¹⁰⁸ See Wu Wei and Li Yongmei, An Introduction to the Draft Property Right Law, King and Wood China Bulletin (Oct. 2005), at: (http://www.kingandwood.com/Bulletin/China%20Bulletin/Issue%20Oct%202005/bulletin_2005_10_en_wuwei.htm).

¹¹⁰⁹ This debate continues today, despite the Indian government's passage of TRIPS-compliant patent laws. See HIV/AIDS Victims in India Protest Over Drug Patent, Financial Times (5/11/06), at p. 4.

The Indian Network for People Living With HIV/AIDS and the Delhi Network of Positive People this week registered a pre-grant opposition to the patenting of tenofovir disoproxil fumarate (Viread), an important second-generation treatment made by US pharmaceutical group Gilead Sciences. The challenge will test the Indian patent regime put in place last year, and comes after Roche announced in March that it had become the first drugs company since 1972 to receive a product patent in India. In January, the Indian patent office rejected a patent application filed by Novartis for its anti-cancer drug Gleevec in response to a pre-grant opposition filed by the Cancer Patient Aid Association. *Ibid.*

¹¹¹⁰ Dr. Mashelkar is Director General of the Indian Council of Scientific and Industrial Research, President of the Indian National Science Academy, and Vice-chairman of the World Health Organization's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH).

¹¹¹¹ See Raghunath A. Mashelkar, India's R&D: Reaching for the Top, Science Magazine Vol. 307, no. 5714, (3/4/05), at pp. 1415-1417, at: (<http://www.sciencemag.org/cgi/content/full/307/5714/1415>).

¹¹¹² See No Spiralling of Drug Prices, Says Kamal Nath The Hindu Business Line, Vol. 11, No. 359 (12/28/04), at: ([Link to article at http://www.thehindubusinessline.com](http://www.thehindubusinessline.com)).

¹¹¹³ ... Rafiq Dossani, a senior research scholar for the Stanford University Institute for International Studies, says R&D is simply following the movement of information technology work to India... [Companies are]... attracted primarily by the country's large talent pool of engineers, designers and scientists... Saikat Chaudhuri, [also] a management professor at Wharton, believes India faces three crucial challenges as it strives to become a global R&D player. *The first impediment, which is steadily improving, is the intellectual property regime, or perhaps its perception,' he says. If this is perceived as solid, then more mass-scale investments by global multinational firms in India will blossom (for instance, pharmaceutical majors*

simultaneously developing future blockbuster drugs in India along with the U.S.), producing cutting-edge technologies and products, and thereby creating strong agglomeration effects'... Chaudhuri notes that India can accelerate this positive development, as well as the growth in indigenous R&D by aiming to remove the third obstacle -- lower levels of basic research. This can be achieved by investing in R & D facilities and improving the research atmosphere at Indian universities,' he says... Funding and policy changes would be required to effect a change here. High standards and levels of basic research will feed directly into top-notch applied research and product development, both in content and mindset. See R & D in India: The Curtain Rises, The Play Has Begun... , Law and Public Policy, *Knowledge@Wharton* (11/21/05), at: (<http://knowledge.wharton.upenn.edu/index.cfm?fa=printArticle&ID=1278>). See also India A II Set to Become R & D Hub , Sify Business (8/25/05), at: (<http://sify.com/finance/fullstory.php?id=13924944>).

¹¹¹⁴ (1) ... India's rapid growth rate and its large and rapidly expanding middle class is likely to create a preference among some consumers for branded as opposed to generic drugs that simply wasn't present in 1970. Moreover, *as the Indian market grows, the previously negligible effect of an Indian patent system on the incentives of foreign innovators becomes measurable. This incentive effect could be especially important in inducing foreign investment on drugs aimed at treating previously neglected diseases prevalent in India and similarly situated developing countries* (emphasis added). See Presentation by Richard C. Levin, Patents in Global Perspective , Sir Purshotamdas Thakurdas Memorial Lecture at the Indian Institute of Banking and Finance (Jan. 2005), at: (http://www.domain-b.com/economy/general/2005/20050112_perspective.html).

¹¹¹⁵ (2)... *[E]ven more significant than India's growing market is its increased capacity for indigenous innovation. India's largest pharmaceutical firms and some of its research institutes now have the scale, the trained personnel, and the technical capacity to develop new drugs, either alone or in partnership with foreign firms... The availability of domestic patents, combined with the low cost of performing research and development in India, could help to make India's largest pharmaceutical companies very successful globally. Moreover, a number of government institutes and private enterprises have developed the capacity to do large scale, highly cost-effective clinical trials. With product patents in place, India is likely to become a major centre for outsourced ' clinical trials undertaken by the US and European pharmaceutical giants. Without domestic patent protection,*

neither India's potential for neither indigenous discovery nor its potential to become a leading centre for clinical trials will be fully realized (em phasis added). Ibid.

¹¹¹⁶ (3)... [T]he flexibility inherent in the TRIPS agreement that will allow India to avoid most of the adverse consequences envisioned by the opponents of reform ... some of the adverse impacts feared by opponents of reform are likely to be less severe than imagined, and others can be mitigated by effective use of the flexibility permitted under the recent Doha declaration. The notion that drug prices and the overall cost of health care will skyrocket as a consequence of the government ordinance is exaggerated, because 90 per cent of the drugs currently classified by India as essential medicines are either unpatented or the patent has expired. The prices of drugs patented before 1995 (including some of the most important anti retroviral treatments for HIV/AIDS) will not be affected, because these drugs will not be eligible for Indian patents and generic substitutes produced domestically are likely to continue to dominate the market. It is true that those domestic producers that have been successful in copying foreign drugs without developing a capability for independent research are likely to be hurt, but, as I mentioned, the largest firms are likely to benefit from the opportunity that domestic patent protection will provide (em phasis added). *Ibid.* .

¹¹¹⁷ See Mickey Kantor, US Free Trade Agreements and Public Health , World Health Organization Submission, at p. 10, at: (<http://www.who.int/intellectualproperty/submissions/US%20FTAs%20and%20the%20Public%20Health.pdf>).

¹¹¹⁸ Apparently, Jordan's growing medical tourism industry stands in stark contrast to what some Brazilian journalists refer to as Brazil's 'sex tourism industry'. In Jordan, schooling is obligatory until completion of high school. No child stays out of school. Seventy-eight percent of the young people finish high school, as opposed to 35% of Brazilian youths. In Brazil, we have a per capita income two times greater than Jordan's and two times fewer young people finishing high school. All Jordanian schools are open from 8 A.M. to 2 P.M. but when there is need of reinforcement, the students remain there up to eight hours per day. The illiteracy rate is 3.5% for the entire population, both men and women. For men less than 40 years of age, it is practically zero. *It has been two decades since King Hussein declared that the name of development is education, and the consequences of this priority can now be seen. Today Jordan is an exporter of science and technology.* It is the principal center of medicine in the Middle East. Besides drawing tourists to its archeological ruins, the country has a

strong medical tourism ' industry of people traveling there from other countries in search of medical treatment. When I saw the network of hospitals that attract tourists' seeking healthcare, *I remembered the show on the O Globo TV network two weeks earlier about the sexual tourism targeting children in Brazil. If Jordan was capable of doing this, why did Brazil not do it as well? Because it never decided to do so. Because education and children are relegated to a secondary place in Brazil.* See Cristovam Buarque, *While Jordan Brings Medical Tourists Brazil Does Sex Tourism*, *Brazzil Magazine* (4/6/06) at: (<http://www.brazzil.com/content/view/9569/78>).

¹¹¹⁹ Jordan's economy ha[d] expanded significantly since Jordan implemented better intellectual property laws between 1998 and 2001... *Much of this success can be attributed to the improved protections for intellectual property rights (e.g., patents and trademarks)...* The improved IP regime paved the way for a broad range of benefits in the Jordanian health care sector and has fueled the growth of Jordan's knowledge economy. This has been reflected in the growth of health-service contributions to the Jordanian GDP, which increased from 2.8 percent in 1997 to 3.5 percent in 2001. Health-services employment has grown 52 percent since 1997. *The increase in employment opportunities reflects, in part, the contribution of clinical research and trials. Health care-sector growth has included the development of new sub-sectors, like contract clinical research organizations, and the integration of Jordan's scientific community into international clinical research... Clinical trials are enhancing physician and hospital know-how and, in the process, vastly enhancing economic growth in the medical-tourism industry.* Jordan's generic pharmaceutical companies have benefited from the stronger IP-protection laws both by gaining new export markets and by starting to engage in innovative research. The pharmaceutical industry represents Jordan's second leading sector, and from 1999 to 2002, drug exports from local firms grew by 30 percent.. [At least one company,] Triumpharma has created innovative drug-delivery systems by developing improved formulations of off-patent molecules, resulting in patentable inventions that bring new benefits to patients... Since 2000 the international research-based pharmaceutical industry has also greatly increased its presence in the Jordan market. These companies have established offices and/or significantly expanded their local operations, and have hired more Jordanian employees... Companies have greatly expanded their educational programs in the country through programs that are aimed at improving the standards of medical care. Strengthened IP protections have also led to improved

transparency and clarity in Jordan's regulations and policies. For example, Jordan has streamlined its registration process for products from several years to 180 days. *This provides better access to new medicines for Jordanian patients* (emphasis added). See Michael P. Ryan and Jillian Shanebrook, *Establishing Globally Competitive Pharmaceutical and Bio-Medical Technology Industries in Jordan: A Assessment of Business Strategies and the Enabling Environment*, International Intellectual Property Institute (Aug. 2004), Executive Summary at pp. 1-2, at: (http://www.iipi.org/reports/Jordan_Report.pdf).

¹¹²⁰ Local law enforcement agencies say they work closely with content providers to shut down any sites advertising infringing articles for sale. Law enforcement efforts have contributed to a sharp reduction in the production of pirated material and blatant storefront piracy. In 2004, the Singapore Police seized nearly US\$8 million worth of counterfeit and pirated goods. The Singapore Police also cooperated with the FBI to crack down two Internet piracy operations, one with links to an international crime syndicate. See 2005 Investment Climate Statement – Singapore – Protection of Property Rights, U.S. Department of State, at: (<http://www.state.gov/e/eb/afd/2005/42111.htm>).

¹¹²¹ There is also the possibility of working with local research institutions through collaborative agreements, as companies such as Phillips, HP, Motorola and Rolls Royce have done. As a result of these factors converging, R&D spending in the city-state has increased and is now 2.2% of GDP. This offers an indication that more and more companies are finding it attractive to conduct R&D here,' says Manohar Khatani, director for the logistics and transport cluster and for European business at the Singapore Economic Development Board (EDB). See *Made in Singapore*, Foreign Direct Investment Magazine (4/12/05), at: (http://www.fdimagazine.com/news/fullstory.php/aid/1205/Made_in_Singapore.html).

¹¹²² See *Motorola Stays the Course in Singapore*, Foreign Direct Investment Magazine (4/5/04), at: (http://www.fdimagazine.com/news/fullstory.php/aid/641/Motorola_stays_the_course_in_Singapore.html).

¹¹²³ Wharton management professor Harbir Singh and two colleagues studied how companies learn from the experience of managing strategic alliances and analysed the steps these companies took to ensure successful alliances. They found that companies that have experience and dedicated alliance function achieve greater success with

alliances... Another Wharton professor, Gerald McDermott, believed that it can be helpful to have a third party act as a mediator between the partners so that trust can be established and the alliance can benefit from a sound beginning. A local government can play this role by providing infrastructure development, training facilities, or tax incentives. Partners should keep an eye on how the institutional environment is developing and how it can provide an adequate framework for the alliance to operate. *McDermott emphasised that patents, contract law, and property rights are important because they allow alliance partners to feel more secure as they transfer proprietary knowledge to one another.* In Singapore, for example, the Info-Comm Development Authority initiated its Calls for Collaboration (CFC) programme to encourage collaborative efforts between industry members in specific areas that will have an impact on Singapore's information-communication sector such as mobile commerce, location-based services, and wireless multimedia. IDA will provide the necessary funding and institutional infrastructure support to help such collaborations (emphasis added). See Ian E.C. Chan, Collaborate to Innovate, Singapore Institute of Management (Aug.-Sept. 2003), at: (http://www1.sim.edu.sg/sim/pub/mag/sim_pub_mag_list.cfm?ID=1305).

¹¹²⁴ Mexico strengthened pharmaceutical patent protection in 1991 in anticipation of entering into the NAFTA Agreement. As a result, investments in research and development and pharmaceutical facilities increased markedly... Chile signed a free trade agreement with the United States which came into effect in January 2004. As early as September 2003, multinational pharmaceutical companies were already increasing their investments in Chile, as two Dutch research based companies relocated their regional headquarters to Chile in anticipation of strengthened patent laws... Morocco, another trading partner which entered into a free trade agreement with the United States in June 2004, expressed in a letter sent to a U.S. Congressman that the Government of Morocco is strongly committed to and has agreed to the highest-standard intellectual property rights provisions in the free trade agreement. The Government of Morocco believes that effective intellectual property rights protection will play a vital role in the continued economic development of our country. See Mickey Kantor, U.S. Free Trade Agreements and Public Health, *supra*, at p. 11.

¹¹²⁵ ... [D]eveloping countries should not rely on international goodwill alone. Instead, they need to adopt a more proactive stance. One can but applaud, therefore, that there is a growing realization among these countries of the nature and extent of their own individual

potential and assets, and of the fact that these can, and must, be developed from within. No country in the world is entirely without resources. Yet, while in the days before globalization-on-steroids such resources were not even considered as wealth, nowadays the valuation mechanism has changed. These assets are now understood to have a worth, they have value added. The more exclusive they are, the more unique they are, the greater their worth... Protecting this ownership, and the modalities of this protection, are of absolutely crucial importance to all developing countries, including Indonesia, if they are to thrive economically in the modern trading environment (emphasis added). See Makarim Wibisono, *The Role of IPR in Developing the Economy*, Opinion and Editorial, Jakarta Post.com (11/28/05), at: (<http://www.thejakartapost.com/yesterdaydetail.asp?fileid=20051128.F04>).

¹¹²⁶ Korea was elevated from the Special 301 Watch List to the Priority Watch List in January 2004... [T]he U.S. Government [was] seriously concerned that modern copyright protection continues to be lacking in important areas. Key among these is Korea's failure to adequately update its laws to protect sound recordings against digital piracy... Other important flaws in Korea's legal regime for the protection of IPRs relate to temporary copies, technological protection measures, Internet Service Providers liability, reciprocity provisions regarding database protection, ex parte relief, the lack of full retroactive protection for pre-existing copyrighted works, and copyright term extension. In addition, serious concerns have arisen over continuing book piracy in universities, street vendor sales of illegally copied DVDs, counterfeiting of consumer products, protection of pharmaceutical patents, and lack of coordination between Korean health and IPR authorities on pharmaceutical marketing approvals. See *Special 301 Priority Watch List*, Office of the United States Trade Representative (5/3/04), at: (http://www.ustr.gov/Document_Library/Reports_Publications/2004/2004_Special_301/Special_301_Priority_Watch_List.html).

¹¹²⁷ We are lowering Korea from the Priority Watch List in 2004 to the Watch List this year to recognize Korea's efforts. Meaningful improvements made by Korea include: introducing legislation that will create protection for sound recordings transmitted over the Internet (using both peer-to-peer and web casting services); implementing regulations that restore the ability of the Korea Media Rating Board to take necessary steps to stop film piracy; and increasing enforcement activities by the Standing Inspection Team against institutions using illegal software. Notwithstanding these improvements, more needs to

be done... In addition, we call on Korea to further strengthen the relevant provisions of its Copyright Act and Computer Programs Protection Act related to technological protection measures and ISP liability, to clarify the scope of the private copy exception, and to join the global trend to extend the term of copyright protection for works and sound recordings. The United States has urged Korea to continue accelerating efforts to combat piracy of DVDs, computer software, and university textbooks, as well as to decrease street vendor sales of pirated and counterfeit goods. The United States also has emphasized the importance of Korea continuing to fulfill its WTO TRIPS obligations in the near term to provide adequate protection of pharmaceutical test data from unfair commercial use. We encourage Korea to improve coordination between the Korean health and patent authorities to prevent marketing authorizations of patent-infringing products. See 2005 Special 301 Report, United States Trade Representative, *supra*, at pp 42-43.

¹¹²⁸ According to Assistant USTR Wendy Cutler, U.S. negotiators recognized that Korea faces an aging population and rising health care costs – the United States and other countries around the world faces similar challenges... [and sought to ensure that] any reform [contemplated Korea] should be transparent and fair, and not disproportionately target foreign pharmaceutical products. Going into these negotiations, we had agreed to establish a dedicated working group to discuss pharmaceutical trade issues. To our surprise, upon our arrival in Seoul, we were informed that Korea was going to switch to a positive list system for the reimbursement of pharmaceutical products before we had the opportunity to have meaningful negotiations on these issues. See Statement of Assistant USTR Wendy Cutler on the Conclusion of the Second Round of Negotiations of the KORUS FTA, Office of the United States Trade Representative (7/14/06), at: http://www.ustr.gov/Document_Library/Press_Releases/2006/July/Statement_of_Assistant_USTR_Wendy_Culter_on_the_Conclusion_of_the_Second_Round_of_Negotiations_of_the_KORUS_FTA.html).

¹¹²⁹ Generally speaking, when a drug or medicinal product is approved by government authorities to be included in a positive list, it is usually covered by the national health insurance system. When it is excluded from such list, on the other hand, it usually results in non-reimbursement. In the case of EU Member States subject to the rules of EC Directive 89/105/EEC, positive list prices are negotiated between the governmental pricing and reimbursement agency and the pharmaceutical manufacturers. For drugs excluded from the reimbursement system, prices are based on an unregulated

manufacturer's price with limited mark-ups for wholesalers and pharmacies. See Pharmaceuticals – Latvia, World Health Organization Regional Office for Europe, at: (http://www.euro.who.int/pharmaceuticals/Topics/Overview/20020416_3). [S]ince 1989, the pricing of medicinal products in EU countries has been loosely governed at the supranational level by the transparency directive (89/105/EEC). This directive establishes that authorities must make a price decision within 90 days of receipt of adequate information and the manner in which any negative decisions are to be communicated. It also specifies that in the event of price freeze, an annual review must be conducted to determine whether the macroeconomic conditions justify continuing of the freeze. The directive also indicates that any direct or indirect mechanisms for controlling profits of those placing a medicine on the market need to be explicit, as must the decisions of including products on a positive list or excluding them from reimbursement through a negative list. See Monique F. Mrazek, Comparative Approaches to Pharmaceutical Price Regulation in the European Union, Croatian Medical Journal 43(4):453-461, at p. 456, (2002), at: (<http://www.cmj.hr/2002/43/4/12187524.pdf>).

¹¹³⁰ Recent problems regarding Korean pricing and reimbursement policies for pharmaceuticals will also likely be given priority in the FTA negotiations since they allegedly pose significant access barriers for, or undercut the profitability of, US products in the \$4 billion Korean pharmaceutical market— among the top 15 markets worldwide (CRS 2006)... Korea has a nationalized healthcare system, which, like the US system, poses large fiscal challenges. *The Korean government has responded to the mounting deficits in its healthcare programs by enacting cost containment measures that reportedly discriminate against imports by systematically undervaluing pharmaceuticals and skewing demand toward domestically produced generic drugs. As a result, per capita spending on pharmaceuticals in Korea averages \$115 annually, less than half the OECD average* (AMCHAM Korea 2004) (emphasis added). See Jeffrey J. Schott, Scott C. Bradford, and Thomas Moll, Negotiating the Korea–United States Free Trade Agreement Policy Briefs in International Economics, Institute for International Economics Report No. PB06-44 (June 2006), at p. 10, at: (<http://www.iie.com/publications/pb/pb06-4.pdf>).

¹¹³¹ See Anna Fifield, Seoul Hopes Bilateral Trade Deal With US Will Be Catalyst For Change, Financial Times (4/11/06), at p. 4. After three decades of export-led growth, South Korea's business sector

underwent radical restructuring and market opening in the wake [of] the 1997 Asian financial crisis. But economists say still more change is needed, particularly in the services sector, to lessen the economy's reliance on global demand for the products of manufacturers such as Samsung and Hyundai. Exports make up 70 percent of the country's gross domestic product volume. *Ibid.*

¹¹³² *Ibid.*

¹¹³³ See Yoo Soh-jung, Opponents Say Trade Deal With the U.S. Will Lead to Poverty, Loss of Competitiveness, *The Korea Herald* (7/12/06), at: (http://www.koreaherald.co.kr/SITE/data/html_dir/2006/07/11/200607110018.asp).

¹¹³⁴ See Inkyo Cheong, Exploring the Possibility for a U.S.-Korea FTA, *Inha University* (5/30/05), at pp. 10 and 17, at: (http://jri.inha.ac.kr/upload/_event/0530/Session2_Cheong.pdf).

¹¹³⁵ See Steve Suranovic, Argument for U.S.-Korea FTA, *Korea Times Forum* (6/7/06), at: (<http://times.hankooki.com/lpage/opinion/200606/kt2006060718355054300.htm>).

¹¹³⁶ In Australia, the Therapeutic Goods Amendment Act 1998 established a 5 year data exclusivity period for new products containing pharmaceutical actives approved after 17 April 1998. The data exclusivity period begins on the date of marketing approval. Data exclusivity is provided in relation to therapeutic goods which contain a 'new active component'. This is defined as a substance having a therapeutic effect. The Explanatory Memorandum to the Act states that substance 'may include a biological product or compound'. This suggests that the data exclusivity period applies to biotechnology products requiring TGA approval. Data exclusivity is only provided in relation to new active components which have never been included in the Australian Register of Therapeutic Goods. *Therefore, data exclusivity is not provided for new uses or new formulations of existing compounds* (emphasis added). See Alfred Adebare, *Data Exclusivity: The Implications for India*, *supra*. Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). If data is used to gain approval in another territory that provides up to five years of data exclusivity for drugs, the data exclusivity in that territory must be honored in each party. See Article 17.10(1). If a drug's patent expires before the period of data exclusivity, the data exclusivity remains in tact. See Article 17.10(3). (<http://www.cptech.org/ip/health/trade/st/1-data-protection.doc>).

¹¹³⁷ In Chile, Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). See Article 17.10(1). (<http://www.cptech.org/ip/health/trade/st/1-data-protection.doc>).

¹¹³⁸ In Colombia, data exclusivity is provided for new molecules for a period of 5 years.

¹¹³⁹ In the European Union, the period [from marketing approval during which test or other data must be protected] has now become up to 10 years[.] [During [this time] generic companies are allowed to develop the product, and may submit an application for authority to market it after eight [8] years. See Public Health, Innovation and Intellectual Property Rights, Report on the Commission on Intellectual Property Rights, Innovation and Public Health World Health Organization, *supra*, at p. 143.

¹¹⁴⁰ In Japan, the data exclusivity period varies from 4 years (for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions) to 6 years (for drugs containing a new chemical entity or medicinal composition, or requiring a new route of administration) to 10 years (for orphan drugs or new drugs requiring pharmaco-epidemiological study). See Alfred Adebare, Data Exclusivity: The Implications for India, *supra*.

¹¹⁴¹ In Jordan, TRIPS Article 39.3 applies. Furthermore, in cases where a generic firm seeks regulatory approval *based on originator data submitted to regulatory authorities in another country*, the Government must provide exclusivity of the data for the same period as granted by the country where the data was originally filed. (This is typically 5-10 years in industrialized countries.) See Article 4(22). (<http://www.cptech.org/ip/health/trade/st/1-data-protection.doc>).

¹¹⁴² In Korea, data exclusivity is afforded for a period of 4 or 6 years. See Article 26-2 of the PAL; Article 30.1 of PAL; Article 5 Paragraph 10 of the KFPA Regulations Regarding Safety and Efficacy Examination of Drug Products. See Data Exclusivity – A Competitive Advantage in Biosciences Environment, Pharmaceutical Association of Malaysia (PHAMA) (2005), at p. 6, *supra*.

¹¹⁴³ As does Colombia, Mexico provides a 5 year period of data exclusivity for new molecules. See The Financial Express Op-Ed (8/22/05), at: (http://www.financialexpress.com/fe_full_story.php?content_id=99950).

¹¹⁴⁴ In Morocco, Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). If a drug's patent expires before the period

of data exclusivity, the data exclusivity remains in tact. *See* Article 15.10(1). (<http://www.cptech.org/ip/health/trade/st/1-data-protection.doc>).

¹¹⁴⁵ New Zealand implemented Article 39.3 of TRIPS via the Medicines Amendment Act 1994 (NZ), effective as from 1 January 1995. Generally, the protection period is 5 years. There is no data exclusivity period for data relating to new uses or formulations of old active ingredients. *See* Alfred Adebare, *Data Exclusivity: The Implications for India*, *supra*.

¹¹⁴⁶ In Singapore, Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). In cases where a generic supplier seeks regulatory approval based on data submitted in another country, the period begins on the date of approval in whichever country is later. If the patent expires before the term of data exclusivity, the data will still be kept confidential for the rest of the period. *See* Article 16.8(1-3). (<http://www.cptech.org/ip/health/trade/st/1-data-protection.doc>).

¹¹⁴⁷ In Taiwan, 5 years of data exclusivity has been provided. *See* Pharmaceutical Affairs Law Article 40-1 and Article 40-2. *See* *Data Exclusivity – A Competitive Advantage in Biosciences Environment*, Pharmaceutical Association of Malaysia (PHAMA), *supra*.

¹¹⁴⁸ Under Article 35 of the Implementing Regulations of the Drug Administration Law of 4 August 2002, China provides 6 years of data exclusivity as from the date of marketing approval. *Ibid*.

¹¹⁴⁹ In these countries, Five years of data exclusivity from the date of the originator's approval mandated for pharmaceutical products (10 years for agricultural products). If data is used to gain marketing approval in one CAFTA country, the data exclusivity must be honored in all of the CAFTA countries, regardless of whether the data is submitted in the other countries or not. *See* Article 15.10(1)(a & b). (<http://www.cptech.org/ip/health/trade/st/1-data-protection.doc>).

¹¹⁵⁰ The U.S.-Peru Trade Promotion Agreement Provides for the restoration of patent terms to compensate for delays in granting the original patent, consistent with U.S. practice[;] Limits the grounds for revoking a patent, thus protecting against arbitrary revocation[;] Clarifies that test data and trade secrets submitted to a government for the purpose of product approval will be protected against unfair commercial use for a period of 5 years for pharmaceuticals and 10 years for agricultural chemicals[; and] Requires a system to prevent the marketing of pharmaceutical products that infringe patents. *See* *Free Trade with Peru: Summary of the U.S.-Peru Trade Promotion Agreement*, Office of the United States Trade Representative U.S.

Peru Trade Promotion Agreement, Policy Brief – (Dec. 2005), at p. 5, at:

(http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2005/asset_upload_file490_8547.pdf). The trade promotion agreement was signed by the executives of each country on April 12, 2006. See United States and Peru Sign Trade Promotion Agreement, Office of the United States Trade Representative (4/12/06), at: (http://www.ustr.gov/Document_Library/Press_Releases/2006/April/United_States_Peru_Sign_Trade_Promotion_Agreement.html).

¹¹⁵¹ The relevant text of the US-Colombia Trade Promotion Agreement is identical to that contained within the U.S.-Peru Trade Promotion Agreement. See Free Trade with Colombia Summary of the Agreement, Office of the United States Trade Representative (2/27/06), at pp. 4-5, at: (http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2006/asset_upload_file485_9023.pdf); See also United States and Colombia Conclude Free Trade Agreement, Office of the United States Trade Representative (2/27/06), at: (http://www.ustr.gov/Document_Library/Press_Releases/2006/February/United_States_Colombia_Conclude_Free_Trade_Agreement.html).

¹¹⁵² *Ibid.*

¹¹⁵³ See Robert J. Shapiro and Kevin A. Hassett, The Economic Value of Intellectual Property, at p. 10, *supra*.

¹¹⁵⁴ FDI is likely to be particularly important for LDCs. The weak investment climates that prevail in many of these countries may justify a temporary case for encouragement of FDI inflows to these countries, although such incentives should avoid discrimination across sectors. We argue also for improving the infrastructure and reducing entry barriers for local firms that could be effective input suppliers for vertical MNEs. While licensing is an important source of technical transformation, successful transfer generally requires capacity to learn and adaptive investments by local firms to apply technologies. Poor countries are most likely to achieve these gains by taking advantage of mature technologies that are in the public domain or available cheaply. Thus, policy could aim at improving information flows for domestic enterprises about such technologies. A secondary priority in low-income nations could be programs to build skills and R&D capacity. Middle-income countries in which firms have engineering skills and active R&D programs are more likely to be the recipients of (and benefit from) significant licensing flows. However, moving up the technology ladder requires expanding inward flows of voluntary licensing and encouraging local R&D and adaptation. To do this, policy

efforts could focus on reducing the costs of absorbing technology and enhancing the direct flow of ITT [international technology transfer]. The upper-middle-income economies presumably require no active intervention in licensing, where technology markets may be expected to operate effectively. *Note that our analysis in no case supports extensive government involvement in selecting technologies or placing restrictions on the use of technical information. For local economies to gain productivity from ITT, broader policy initiatives are important. This is a complex task that involves building human capital, expanding national innovation systems, and effectively protecting IPRs, which may be critical for fostering innovation and supporting trade in knowledge.* Economic reasoning and history strongly indicate that IPR regimes should vary depending on levels of development and technological capacities (emphasis added). See Bernard M. Hoekman, Keith E. Maskus and Kamal Saggi, *Transfer of Technology to Developing Countries – Unilateral and Multilateral Policy Options*, World Bank Policy Research Working Paper 3332, June 2004, at pp. 28-29, at: (http://www-wds.worldbank.org/servlet/WDSContentServer/WDSP/IB/2004/07/29/000160016_20040729155005/Rendered/PDF/wps3332.pdf).

¹¹⁵⁵ All countries benefit from foreign technology spillovers... foreign patents generate significant technology spillovers in middle- and low-income countries... [T]he technology spillover effect of trade openness from attracting foreign patents is larger than that from enhancing capital goods imports in both the middle- and low-income samples, and is particularly significant in the low-income sample. An improvement in IPR protection has a large productivity effect as well. In our experiment with the middle income sample, a 40 per cent increase in IPR protection would increase TFP [total factor productivity] growth rate by 0.15 percentage points, and a 40 per cent increase in foreign trade would increase TFP growth by 0.13 percentage points... Our results suggest that countries at different development stages benefit from different sources and different forms of international technology spillovers, and that economic policies play a significant role in determining both the amount and form of foreign technology spillovers. See Bin Xu and Eric P. Chiang, *Trade, Patents and International Technology Diffusion*, 14 *J. Int. Trade & Economic Development* No. 1, 115 – 135 (March 2005), at p. 131, at: (<http://www.iprsonline.org/resources/docs/XuChiangTechDiffus.pdf>).

¹¹⁵⁶ Robert Stein, Ph.D., is a Clinical Psychologist licensed in the State of New York. He is a certified Bilingual School Psychologist and teaches Psychology part-time at SUNY Rockland Community College,

where he specializes in developmental psychology. Dr. Stein also received an M.A. in Diplomacy & International Relations from the John C. Whitehead School of Diplomacy and International Relations at Seton Hall University, South Orange, NJ. He has extensive experience in psychological assessment and therapy, working with adolescents and adults, and has testified as an expert witness and currently serves on a misconduct review board for the Carmelite Order.

¹¹⁵⁷ The Inter-American Development Bank has also used this analogy to describe the stage of development of Brazil's largest cities in a recently released report that documents how Brazil has converted urban slums into more affluent suburbs. Progress... continues to be slow and uneven. One problem – highlighted by the IADB in a recent report – is governance. Latin America, with its strong traditions of centralized authoritarian government, has embraced the idea of elected local government only within the last 20 years or so. Local government tends to be poorly resourced: while 35 percent of public spending is directed through local government structures in Europe or the US, the figure is only about 20 percent in Latin America. More importantly, urban growth has been so rapid that it has often rendered irrelevant many administrative decisions. Latin America's penchant for bureaucracy has made matters worse. Mr. Rojas at the IADB says that more effective and properly resourced local government will be an essential ingredient in tackling the region's housing problems. He compares cities such as Sao Paulo and Rio to fast growing teenagers.

Their brain – or governance – is just not able to cope with the speed of fast-growing limbs'. See Richard Lapper, *From Slums Into Suburbs: How Sao Paulo is Showing the Way to Civilise the Megacity*, *Financial Times Comment and Analysis* (8/25/06), at: p. 7.

¹¹⁵⁸ Nation-states, being composed of people, are subject to the same broad types of developmental and behavioral disorders as their citizens. Group process however, consists of more than a simple summation of the constituent parts. Rather, group dynamics, in this case, national group dynamics, has both a summative and interactive effect. Often, despite advancing to the next developmental level, both nations and individuals continue to maintain immature and regressed identities and continue to utilize immature coping strategies, which are no longer consistent with their advanced development. Viewed from a developmental perspective, Brazil can be seen to have graduated to this next level, which roughly corresponds to early adulthood. It is self-sufficient both economically and agriculturally. It has become an acknowledged major player in the hemisphere and internationally. It commands the respect and solicitude of states around the world. And

yet, it still clings to outmoded and self-defeating behaviors... that relate to an inadequate self image... Brazil still views itself as the psychological equivalent of a weak adolescent, who must constantly project a false bravado, despite its obvious well endowed adult status. See Comments from Dr. Robert Stein, provided during a series of written and telephone interviews conducted during February 15-20, 2006.

¹¹⁵⁹ When an adult believes it is still an adolescent all kinds of problems are created. When adults act like adolescents and engage in vandalism and non-conformist behaviors, it creates two problems. The first, true adolescents, in this case less developed nations, feel more emboldened to engage in similar acts which show contempt for the basic world order. Second, it causes responsible adults, in this case the developed nations, to take retaliatory actions and to insist on punishment. Adolescents are typically excused for all sorts of unseemly behavior. In most western cultures they are viewed with annoyance or bemused indifference. As a not-so-young adult which engages in such behaviors, Brazil currently runs the risk of incurring these kinds of responses, despite its obvious capacity to compete with the big boys'. *Ibid.*

¹¹⁶⁰ Further, as with various adult compulsive behaviors which begin as voluntary, nations with a major stake in the present world order that indulge in the economic equivalent of *shoplifting* eventually degenerate into kleptomania. The self-reinforcing nature of getting something for nothing makes it increasingly difficult to cease such behaviors, once begun. The further an individual, or nation, becomes consumed with such behavior, the more difficult it becomes to distinguish reality from its own rationalizations, resulting in more overt insults to the other adult members of the community and eventually provoking retaliation. Not only that, it encourages disrespect for its own inventions and innovations from newly emerging states, which seek to replicate the developed state's progress.

Ibid.

¹¹⁶¹ [T] there will be even more pressures on U.S. drug companies to give up their intellectual property rights and patent protections, under the rationale of improving access to healthcare. But where will the innovations of tomorrow come from, if not from profits on the drugs of today? Already U.S. consumers complain that they are cross-subsidizing sales of drugs elsewhere in the world in markets that adopt price controls. And what incentive do drug companies have to invest in products for the developing world if they cannot reap the benefits of

that investment? See John Gardner, Healthcare in the Developing World: Obstacles and Opportunities, TCSDaily.com, *supra*.

¹¹⁶² By imposing greater restrictions on the use of their products and services, OECD life sciences and information technology companies would, in effect, necessitate additional purchases of them.

¹¹⁶³ For interesting discussion about how governments might use advanced market commitments plans to create 'markets in drugs needed to treat life-threatening developing country diseases, See Making Markets for Vaccines: Ideas to Action, The Report of the Center for Global Development Advanced Market Commitment Working Group (April 2005), at: (<http://www.cgdev.org/doc/books/vaccine/MakingMarkets-complete.pdf>).

¹¹⁶⁴ See Christopher Earl and Harvey Bale, A Market Remedy that Can Bring Vaccines to the Poor, op-ed, Financial Times (7/3/06) at p. 13.

¹¹⁶⁵ ... [A] novel, business-friendly plan to persuade drug companies to develop vaccines for deadly diseases in the developing world... The proposal appeared to be on the fast track in February [2006] when G-8 finance ministers, including then-Treasury Secretary John Snow, endorsed the idea... G-8 officials say that drug companies, although initially skeptical, have rallied behind the idea... The plan aims to address a problem in global drug markets: The countries that most need new treatments for diseases such as AIDS and tuberculosis are those that can least afford to pay for them ... [Pursuant to the plan,]... *the G-8 would guarantee a market for pharmaceuticals companies that develop successful vaccines... Under the advance market commitment plan, the G-8 would guarantee a subsidy -- valued at \$800 million to \$6 billion depending on the disease -- for any company or companies that produce vaccines that meet agreed-upon safety-and-efficacy standards. Once the donors spend that initial subsidy, the pharmaceuticals companies would discount the vaccine sharply for developing-world customers... Germany and Japan are reluctant to contribute much money for the vaccine plan... because of concern about the cost. A number of other governments in the G-8 don't want to pony up more money for something right now,* said a senior U.S. Treasury official. (emphasis added). See Michael M. Phillips, Global Vaccine Initiative Hits Snag, Wall Street Journal (7/7/06), at p. A5, at: (<http://lists.essential.org/pipermail/ip-health/2006-July/009809.html>).

¹¹⁶⁶ The... advance market commitment plan... proposal is one of three major drug-finance plans floating around the G-8... **France** has lobbied hard for an *airline-ticket tax* to fund drug purchases. A week ago, Paris took the lead by imposing *a tax* of =801, or about \$1.25, on

domestically purchased tickets for economy-class flights within Europe, as well as a =8010 levy on business- and first-class tickets. For flights outside Europe, *the tax rises* as high as =8040. The revenue will go for drugs to treat AIDS and other illnesses in poor countries, according to a French official, who says 13 other countries have agreed to the tax plan. At the summit-preparatory meeting last month, France argued that the G-8 should endorse its approach, provoking opposition from the U.S. and reluctance from Japan on anti-tax grounds. The U.K. gave only tempered support for its European Union partner. A U.K. Treasury spokesman said London would only go so far as to divert some of its current ticket-tax revenue to the French effort; it won't impose a new tax. *Failing to win support for the ticket tax, the French negotiator blocked the advance-market-vaccine proposal* from the G-8 leaders' statement being drafted for the coming summit, according to the senior official (emphasis added). *Ibid.*

¹¹⁶⁷ See Making Markets for Vaccines: Ideas to Action, The Report of the Center for Global Development, at pp. 30-32. For a contrary view towards these arrangements, See David Dobbs, Run-AMC: The Latest Idea in Vaccine Funding Won't Cure AIDS and Malaria, Slate Magazine (12/29/05), at: (<http://www.bioethics.net/News/?id=1012>), citing, Andrew W. K. Farlow, Donald W. Light, Richard T. Mahoney, Roy Riddus, Concerns Regarding the Global Center for Development Report Making Markets for Vaccines', Submission to: Commission on Intellectual Property Rights, Innovation and Public Health, WHO (4/29/05), at: (<http://www.economics.ox.ac.uk/members/andrew.farlow/CIPRH1May2005.pdf>).

¹¹⁶⁸ One of the most recent proposals comes from liberal academia. It argues in favor of national government and intergovernmental organization-imposed generic drug price-level mandates, consistent with a newly established supranational governance framework. The proposal aims at capitalizing on the pharmaceutical sector's flexible domestic differential and tiered national pricing models, and calls for national governments and/or intergovernmental bodies such as, the WHO, UN, WTO, and the Global Fund, and even for the Bill Gates foundations, to offer "a *non-exclusive, no royalty license* to all legitimate pharmaceutical manufacturers. *Negotiations will not be required* and transaction costs will remain very minimal. Pharmaceutical companies have demonstrated remarkable skill in segmenting markets with tiered differential pricing within particular countries. The persistence of domestic differential pricing within the US, even in the face of extensive donor programs, is a testament to the

effectiveness of market segmentation by PhRMA companies and the apparent weakness of actual pharmaceutical arbitrage pressure... Governments can exercise compulsory licensure powers within their territories, **but this proposal cannot rely solely on the current scope of compulsory licensure**. The transaction costs and political opposition to negotiating compulsory licenses for each market country have proven to be almost insurmountable... **By offering compensation in exchange for non-OECD licensure, it is hoped that pharmaceutical companies will embrace this proposal rather than force governments to pursue parallel compulsory licensure processes**... The buy-out price must be set high enough to optimize global pharmaceutical innovation and **low enough to be affordable for all global diseases**. Lanjouw and Jack effectively **set the price at zero by requiring drug companies to choose between patents in rich countries or poor countries**... If the goal of the buy-out is to mimic what would have happened under best-case competitive market conditions, then the price should be based on expected profits rather than sales or costs... The purpose of the buy-out price should be to restore the expected profits, and more particularly, the lost R&D cost recovery. *Expected future profits will of course be difficult to estimate and subject to gaming*... For a remarkably modest price, the battles over TRIPS and essential medicines could be largely resolved” (emphasis added). See Kevin Outterson, “Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries”, *American Journal of Law and Medicine*, Vol. 32 No. 2 and 3(2006) at: pp. 13-16, at:

(http://papers.ssrn.com/sol3/papers.cfm?abstract_id=873402) .

¹¹⁶⁹ Interestingly, Mr. Outterson will be holding a CPTEch-sponsored seminar in Washington on or around October 10, 2006, to explain the theory underlying patent buy-outs’. According to CPTEch, The mismatch between global pharmaceutical markets and global disease burdens leads to an interesting opportunity. **Patented pharmaceuticals could be offered to more than 84% of the world's population at generic prices. (Only high-income country patients would bear pharmaceutical patent rents)**. The gain in health from increasingly affordable pharmaceuticals would be considerable. **The primary disadvantage of this plan would be a quite small reduction in global R&D cost recovery; but even this small deficit could be restored to the companies through a carefully designed patent buy-out mechanism** (emphasis added). See CPTEch Brown Bag Lunch in D.C. with Kevin Outterson (9/15/06), at: (<http://lists.essential.org/pipermail/ip-health/2006-September/009995.html>).

¹¹⁷⁰ What human motivation leads to the most wonderful things getting done? How about the charity and selflessness we've seen from people like Mother Teresa? What about the ceaseless and laudable work of organizations like the Red Cross, Habitat for Humanity and Salvation Army? What about the charitable donations of rich Americans, to use the silly phrase, who've given something back? While the actions of these people and their organizations are laudable, results motivated by charity and selflessness pale in comparison to other motives behind getting good things done... A wonderful thing about free markets is that the path to greater wealth comes not from looting, plundering and enslaving one's fellow man, as it has throughout most of human history, but by serving and pleasing him. Many of the wonderful achievements of the 20th century resulted from pursuit of profits. Unfortunately, demagoguery has led to profits becoming a dirty word. Nonprofit is seen as more righteous, particularly when people pompously stand before us and declare, 'We're a nonprofit organization.' Profit is cast in a poor light because people don't understand the role of profits. Profit is a payment to entrepreneurs just as wages are payments to labor, interest to capital and rent to land. To earn profits in free markets, entrepreneurs must identify and satisfy human wants in a way that economizes on society's scarce resources. Here's a little test. Which entities produce greater consumer satisfaction: for-profit enterprises such as supermarkets, computer makers and clothing stores, or nonprofit entities such as public schools, post offices and motor vehicle departments? I'm guessing you'll answer the former. Their survival depends on pleasing ordinary people, as opposed to the latter, whose survival is not so strictly tied to pleasing people. See Walter E. Williams, *Caring vs. Uncaring*, *The Washington Times* (5/22/06), at: (<http://washingtontimes.com/commentary/wwilliams.htm>).

¹¹⁷¹ If the Government of Brazil chooses the path of individual-centric property-rights-based innovation, OECD nations, including the United States, will gladly work to help her to develop and prosper. If, however, Brazil chooses the path of opportunism and opposes the protection of individual-based private property rights, including IPRs, which is necessary to foster free trade, foreign direct investment, open markets, and indigenous economic growth, then this will make positive international, hemispheric and bilateral relations infinitely more difficult.