

## ARTICLES

### **Brazil’s IP Opportunism Threatens U.S. Private Property Rights**

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## I. INTRODUCTION

A. *Brazil's Knowledge Deficit*

Brazil is a country rich in entrepreneurial spirit,<sup>1</sup> economic growth opportunities,<sup>2</sup> and natural resources.<sup>3</sup> Yet, according to experts, Brazil lacks the core human capital,<sup>4</sup> namely, education,<sup>5</sup> and a market-friendly enabling environment<sup>6</sup> that incorporates

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1. "Brazilian entrepreneurs have the unique characteristic among such large and relatively wealthy countries of being 'necessity entrepreneurs' . . . [T]hese types of entrepreneurs are most prevalent in countries with poor economic stability and low job availability. Though Brazil is certainly not considered a 'poor' country with a gross domestic product (GDP) of almost \$1.4 trillion, it certainly suffers some of the other characteristics of countries with a large group of necessity entrepreneurs, such as unemployment and infrastructure problems." See JONATHAN ORTMANS, PUBLIC FORUM INST., GOVERNMENT AND EDUCATION EFFORTS TO FURTHER ENTREPRENEURSHIP IN BRAZIL, NATIONAL DIALOGUE ON ENTREPRENEURSHIP 2 (2005), available at <http://www.publicforuminstitute.org/nde/sources/reports/Brazil-2005.pdf>.

2. "Although Brazil holds the potential to become an economic powerhouse, social conditions stemming from Brazil's early years as a plantation society have continued to cause inequalities in the distribution of wealth and power." See Brazil, MSN ENCARTA (2006), <http://encarta.msn.com/encnet/refpages/RefArticle.aspx?refid=761554342> (last visited Dec. 19, 2006) [hereinafter Brazil, ENCARTA]. "Despite its status as South America's leading economic power, Brazil remains an unrealized potential. It has a large population that seeks entrepreneurial opportunities and an innovative telecommunications sect that can provide a strong arena for these individuals." ORTMANS, *supra* note 1, at 2.

3. Although "all Latin American countries may be classified as resource-rich in absolute terms[, Brazil is] both resource-rich (relative to the world market) and industrialising (relative to the regional market) . . ." Michel Fouquin et al., *Natural Resource Abundance and its Impact on Regional Integration: Curse or Blessing?*, ELSNIT/FUNDACAO GETULIO VARGAS CONFERENCE, April 7, 2006, 8 n.1, available at <http://www.cepii.fr/anglaisgraph/communications/pdf/2006/070406/fouquin.pdf>. "The economic development of Brazil has been strongly influenced by a series of economic cycles in which different [natural] resources were exploited in different parts of the country . . . Brazil contains a wealth of mineral and plant resources that have not yet been fully explored. It possesses some of the world's largest deposits of iron ore and contains rich deposits of many other minerals, including gold and copper." See Brazil, ENCARTA, *supra* note 2.

4. See Norman Gall, *Democracy 4: Brazil Needs a New Strategy - Lula and Mephistopheles*, 37 BRAUDEL PAPERS 1, 11 (2005), available at [http://www.braudel.org.br/novo/publicacoes/bp/bp38\\_en.pdf](http://www.braudel.org.br/novo/publicacoes/bp/bp38_en.pdf).

5. See Cristovam Buarque, *Brazil Agrees It Needs More Education But Nobody Wants to Foot the Bill*, BRAZZIL MAG., Apr. 20, 2006, available at [http://www.brazzil.com/index2.php?option=com\\_content&do\\_pdf=1&id=9581](http://www.brazzil.com/index2.php?option=com_content&do_pdf=1&id=9581).

6. "[R]igid government regulations, difficulties in transferring foreign technology to the domestic arena, and an underdeveloped infrastructure stifle the burgeoning business opportunities. The country's failure to completely utilize the economic potential of its citizens has left the economy vulnerable to continued damage from unequal income distribution, high government debt, and dangerous inflation that contributed to the 2003 recession and continues to suffocate potential entrepreneurial development." ORTMANS, *supra* at 1. The World Bank's recently released Doing Business 2007 report found that the registering of property in many Brazilian states

strong recognition and protection of exclusive intellectual property rights (IPRs).<sup>7</sup> These deficiencies have substantially impaired the Brazilian Government's ability to facilitate development of indigenous know-how (inventions) and the conversion of it into commercially relevant products and processes (innovations).<sup>8</sup> The Government of Brazil recognizes that it must remedy these shortcomings if it is to maintain and improve Brazil's international competitiveness during the twenty-first century.<sup>9</sup>

The Government of Brazil, furthermore, has unsustainable domestic priorities<sup>10</sup> and is plagued by endless systemic corruption.<sup>11</sup> This has only further compromised its ability to deliver

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is more difficult than in the rest of Latin America. See SIMEON DJANKOV ET AL., INT'L BANK FOR RECONSTRUCTION & DEV., WORLD BANK GROUP, DOING BUSINESS 2007: HOW TO REFORM 3 (2006), available at [http://www.doingbusiness.org/documents/DoingBusiness2007\\_Overview.pdf](http://www.doingbusiness.org/documents/DoingBusiness2007_Overview.pdf). According to the Bank's accompanying report, these and other statistical indicators led the World Bank to rank Brazil "17[th] out of 22 countries in Latin America" and 121st out of 175 countries globally. ZENAI DA HERNANDEZ ET AL., THE INT'L BANK FOR RECONSTRUCTION & DEV., WORLD BANK GROUP, DOING BUSINESS IN BRAZIL 6-7 (2006), available at [http://www.doingbusiness.org/documents/doing\\_business\\_in\\_brazil\\_07.pdf](http://www.doingbusiness.org/documents/doing_business_in_brazil_07.pdf).

7. The Brazilian Government is ideologically reluctant to recognize private IPRs in the field of life science technologies, despite the existence of national patent and data exclusivity legislation. See U.S. COM. SERV. BRAZ., CS BRAZ. MKT. RES., STATISTICS AND DEVELOPMENTS IN INTELLECTUAL PROPERTY RIGHTS (2005), [http://www.buyusainfo.net/docs/x\\_5064324.pdf](http://www.buyusainfo.net/docs/x_5064324.pdf) [hereinafter BRAZIL MARKET RESEARCH]. In addition, leading Brazilian scientists 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. See Claudia Inês Chamas et al., The Dynamics of Intellectual Protection for Biotechnology in Brazil, Address at the Triple Helix 5 Conference on the Capitalization of Knowledge: Cognitive, Economic, Social & Cultural Aspects (May 19, 2005), available at [http://www.triplehelix5.com/pdf/A196\\_THC5.pdf](http://www.triplehelix5.com/pdf/A196_THC5.pdf).

8. See ORTMANS, *supra* note 1, at 2; see also Markus Jaeger, *Brazil: O País do Futuro? Economic Scenarios for the Next 15 Years*, DEUTSCHE BANK RES., May 30, 2006, at 3 ("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.").

9. Gall, *supra* note 4, at 9-10.

10. See Mark F. Schultz & David B. Walker, *How Intellectual Property Became Controversial: NGOs and the New International IP Agenda*, 6 ENGAGE: THE J. OF THE FEDERALIST SOC'Y PRAC. GROUPS 82, 89 (2005) (citing Daniel Dutra, *Brazil Space Program to Get Greater Funding*, BRAZZIL MAG., Jan. 28, 2005) ("In addition to increasing costs, some governments display questionable priorities. . . . [For example], Brazil [is] aggressively funding space programs. . . . [S]overeign nations . . . 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.").

11. 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. See Gall, *supra* note 4, at 12-14;

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affordable national healthcare, digital knowledge, and economic opportunities to the majority of Brazil's poorest citizens.<sup>12</sup> The Brazilian Government has been unable to resolve these domestic issues and is acting out on the world stage to divert attention away from them. This would explain why Brazil has endeavored, during the past decade, to establish a new anti-private property international economic order that exploits the private property rights of Organisation for Economic Co-operation and Development (OECD) member nation citizens and appeals to developing and emerging economies.<sup>13</sup>

The Brazilian Government has focused on two key policy areas, global information technology and global health, in an effort, assisted by certain United Nations (UN) agencies, to help promote the 'public international good' of global knowledge.<sup>14</sup> It has articulated national and international positions concerning each of these areas.<sup>15</sup> Although these positions appeared initially

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Jonathan Wheatley, *New Corruption Charges Target Brazil Deputies*, FIN. TIMES, May 11, 2006, at 3; Jonathan Wheatley, *Lula Accused of Knowing About Bribery*, FIN. TIMES, May 8, 2006, at 4; Raymond Collitt, *Brazil Corruption Scandal Dogs Lula, Not Congress*, REUTERS, April 5, 2006; see also Fouquin, *supra* note 3, at 14.

12. 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, and lack of available and affordable private health insurance. See INT'L POLICY NETWORK, CIVIL SOCIETY REPORT ON INTELLECTUAL PROPERTY, INNOVATION AND HEALTH (2006), [http://www.policynetwork.net/uploaded/pdf/Civil\\_Society\\_text\\_web.pdf](http://www.policynetwork.net/uploaded/pdf/Civil_Society_text_web.pdf).

13. In some ways, this new anti-IP economic order resembles the prior 'New International Economic Order' that developing countries, including Brazil, endeavored to establish for the purpose of restructuring the global economy during the 1970's. See, e.g., THOMAS G. WEISS ET AL., THE UNITED NATIONS AND CHANGING WORLD POLITICS 239-240 (Westview Press 3d ed. 2001) (1989); THOMAS WALDE & ABBA KOLO, CTR. FOR PETROLEUM, MINERAL LAW AND POL'Y, UNIV. OF DUNDEE, MULTILATERAL INVESTMENT TREATIES AND ENVIRONMENTAL EXPROPRIATION OF FOREIGN INVESTMENT (1998), available at <http://www.gasandoil.com/goc/speeches/waelde2.htm>.

14. See, e.g., Univ. of Oxford Ctr. for Brazilian Studies, Workshop: Global Intellectual Property From a Brazilian Perspective (Nov. 4, 2005), <http://www.brazil.ox.ac.uk/confreports/IP%20report%20final3.pdf> [hereinafter Brazilian Studies]; MINISTRY OF SCIENCE & TECH., INFORMATION SOCIETY IN BRAZIL - GREEN BOOK 31-32 (2000) [hereinafter GREEN BOOK]; Bernardo Sorj, U.N. Educ. Sci. and Cultural Org. [UNESCO], *Brazil@digitaldivide.com: Confronting Inequality in the Information Society* 29-48 (2003), available at <http://unesdoc.unesco.org/images/0013/001318/131870e.pdf> (discussing how a "large majority of consumption products are pre-conditions of access to health, education, work, and sociability").

15. See discussion *infra* Part III.

to be inconsistent with one another, they have, over time, become more closely aligned.<sup>16</sup> In fact, each now emphasizes the benefits to Brazilian society of creating basic scientific and technological know-how and of making that know-how universal and accessible to all, minimizing the cost.

*B. Brazil Promotes a New Anti-IP Framework  
Premised on Negative Sustainable Development*

Brazil is an emerging economy and an aspiring regional and global power possessing great potential.<sup>17</sup> The Government of Brazil, however, has assumed a leadership role in international fora by promoting a new but highly controversial global framework 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.<sup>18</sup> Brazil, along with a growing chorus of developing nations, activists, and self-proclaimed new social and environmental thinkers, has alleged that this new paradigm is predicated upon an expanded notion of sustainable development (SD)<sup>19</sup> that eschews strong IPRs.<sup>20</sup> Furthermore, Brazil has opportunistically defined itself, for these and other purposes, as a developing country.<sup>21</sup>

The Brazilian Government's allies in this effort include other

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16. *Id.*

17. See, e.g., Richard Lapper & Jonathan Wheatley, *Why Lula Will Shun the Populist Path*, FIN. TIMES (London), July 11, 2006, at 13, available at <http://www.ft.com/cms/s/1b048dd4-1109-11db-9a72-0000779e2340>; Humberto Marquez, *New Member Venezuela Politicizes Mercosur*, INSIDE COSTA RICA, July 6, 2006, [http://insidecostarica.com/special\\_reports/2006\\_07/south\\_america\\_venezuela\\_mercosur.htm](http://insidecostarica.com/special_reports/2006_07/south_america_venezuela_mercosur.htm); Richard Lapper & Jonathan Wheatley, *Interview Transcript: Luiz Inácio Lula da Silva*, FIN. TIMES, July 11, 2006, available at <http://www.ft.com/cms/s/6d42ae3a-110b-11db-9a72-0000779e2340.html>; Richard Lapper & Jonathan Wheatley, *Brazil's Lula to Promote Doha Trade Talks During G8 Summit*, FIN. TIMES, July 12, 2006.

18. See discussion *infra* Part III.B.

19. See Yasmin Crowther, *Stories for Our Times?*, in SUSTAINABILITY: RADAR CREATIVITY, Apr. 10, 2006, at 20, available at [http://www.sustainability.com/downloads\\_public/insight\\_radar/creativity.pdf](http://www.sustainability.com/downloads_public/insight_radar/creativity.pdf).

20. See GREEN BOOK, *supra* note 14, at 31-32.

21. In 2005, the U.S. House of Representatives adopted Resolution 3141 "directing the President to terminate Brazil's designation as a developing country" when Brazil was believed to be exploiting to maintain its qualification for preferred trade status under the U.S. Generalized System of Preferences. Newsroom, *US Congress Moves to Strip Brazil of Developing Country Status*, BRAZZIL MAG. July 26, 2005, available at <http://www.brazzilmag.com/content/view/3341>. According to the E.U., Brazil is an "advanced" developing country. See Eur. Comm'n Trade and Dev., *Different Needs, Different Responsibilities: What is the EU Asking from Developing Countries?*, EU AND GLOBAL TRADE, Dec. 14, 2005, [http://ec.europa.eu/trade/issues/global/development/pr141205\\_en.htm](http://ec.europa.eu/trade/issues/global/development/pr141205_en.htm).

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socialist Governments, neo-Marxist politicians, activist non-governmental organizations (NGOs), anti-private property and anti-free market academics,<sup>22</sup> as well as some conservative libertarians.<sup>23</sup> Many of these advocates are well skilled in manipulating public opinion and the organs of the UN to promote an alternative global framework.<sup>24</sup> Their desired international framework, in large part, employs a definition of sustainable development that potentially minimizes *all* private property ownership rights in favor of public (shared) communal rights,<sup>25</sup> along with the role of

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22. 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. See Aleksander Boyd, *São Paulo Forum: The Backbone of Communism & Terrorism Spread in Latin America – Interview with Olavo de Carvalho*, VCRISIS, Nov. 21, 2005, <http://www.vcrisis.com/index.php?content=letters/200511210932>; Antony P. Mueller, *The Ghost That Haunts Brazil*, LUDWIG VON MISES INST., Aug. 5, 2002, <http://www.mises.org/story/1020>; Augusto Zimmermann, *In Brazil the Law is Never For You When You Have Friends*, BRAZZIL MAG., January 23, 2006, available at <http://www.brazzil.com/content/view/9509/78>; Augusto Zimmermann, *In Brazil Work is a Dirty Word Unless You Hold Public Office*, BRAZZIL MAG., Feb. 3, 2006, available at <http://www.brazzil.com/content/view/9517/78>.

23. There are some extreme libertarian ideologues who argue that IPRs are government-granted monopolies which are anathema to pure laissez faire, 'state of nature' capitalism. See Michele Boldrin & David K. Levine, *IER Lawrence Klein Lecture: The Case Against Intellectual Monopoly*, in FEDERAL RESERVE BANK OF MINNEAPOLIS RESEARCH DEPARTMENT STAFF REPORT 339 (June 2004), available at <http://minneapolisfed.org/research/sr/sr339.pdf>; MICHELE BOLDRIN & DAVID K. LEVINE, *AGAINST INTELLECTUAL MONOPOLY 1* (2005), <http://levine.sscnet.ucla.edu/general/intellectual/against.htm>.

24. For example, during 2000, the United Nations Conference on Trade and Development (UNCTAD) launched a joint project with the INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT (ICTSD), an NGO, on Intellectual Property Rights and Sustainable Development. This project recently released a report the purpose of which is "to contribute to a better understanding of the use of patent *exceptions* for the pursuit of various national policy objectives," and to thus, contribute to the debate over whether IPRs "adversely affect the pursuit of sustainable development strategies . . ." Christopher Garrison, Indep. Consultant to Int'l Intell. Prop. Law & Pol'y, ICTSD & UNCTAD, *Exceptions to Patent Rights in Developing Countries: Issue Paper No. 17*, Aug. 2006, at vii-viii, available at [http://www.unctad.org/en/docs/iteipc200612\\_en.pdf](http://www.unctad.org/en/docs/iteipc200612_en.pdf).

25. "Exclusive patent rights may constitute important tools for the promotion of a country's technological capacities, depending on that country's level of development in a particular sector. On the other hand, a government may prefer to keep certain activities outside the scope of exclusive rights, considering it more beneficial for society to have unlimited access to the products or services related to such activities." *Id.* at vii. "One of the main issues of the globalized world is to control the colonization of global public goods by private interests. The challenge to national governments – which continues to be the most important institution for organizing social cohesion and citizen rights – is to regulate the public interest and actively participate in the construction of a new international order." Sorj, *supra* note 14, at 19. "Agenda 21 also recommends property law changes in a variety of specific contexts." John C. Derbach,





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the emergence of extreme economic, scientific, technological and social disparities and popular backlashes against globalization that will serve to threaten international peace and security.<sup>32</sup> These advocates also claim that the Millennium Development Agenda requires such actions to enable developing countries to liberate themselves from endemic poverty and disease, so that they may ultimately achieve economic and social parity with the developed world.<sup>33</sup> In other words, the ‘enlightened’ notion of sustainable development, originally articulated almost twenty years ago, has since been effectively hijacked, distorted and propagandized into a *negative* anti-market, anti-private property and anti-WTO doctrine that focuses only on the flaws, rather than the strengths, of the established international order.<sup>34</sup>

Recent research, however, has shown that the pursuit of such

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19, 2006), available at <http://www.cptech.org/ip/health/who/59wha/congress05192006.pdf> [hereinafter Leavitt] (proposing adoption of WHO Executive Board’s recommendation for a new international agreement on medial research and development (R&D) by arguing that “the U.S. Government’s practice of including extensive intellectual property provisions in bilateral trade agreements [will not necessarily] . . . lead to more R&D investment”).

32. See, e.g., Tim Radford, *Two-Thirds of World’s Resources Used Up*, GUARDIAN UNLIMITED, Mar. 30, 2005, <http://www.guardian.co.uk/international/story/0,3604,1447863,00.html>; The Secretary-General, *Report of the Secretary-General’s High-Level Panel on Threats, Challenges and Change, A More Secure World: Our Shared Responsibility*, ¶ 52-59, U.N. Doc. A/59/565 (Dec. 2, 2004), available at <http://www.un.org/secureworld/report2.pdf>.

33. See, e.g., The Secretary-General, *The Millennium Development Goals Report-2006*, U.N. Econ. & Soc. Aff., U.N. Doc. DESA (June 2006), available at <http://unstats.un.org/unsd/mdg/Resources/Static/Products/Progress2006/MDGReport2006.pdf>; Brazilian Studies, *supra* note 14, at 4 (“[I]n 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.”) (emphasis added).

34. The doctrine of sustainable development is arguably a social welfare state doctrine that describes free market capitalism, neo-liberal economics, and strong legal protection of private contract and intellectual property rights in negative fashion. See e.g., Lawrence A. Kogan, *Precautionary Preference: How Europe’s New Regulatory Protectionism Imperils American Free Enterprise*, ITSSD, July 2005, at 93, available at <http://www.itssd.org/White%20Papers/PrecautionaryPreference-EURegProtectionism-FULLVERSION.pdf> [hereinafter Kogan, *Precautionary Preference*]; Lawrence A. Kogan, *Exporting Precaution: How Europe’s Risk-Free Regulatory Agenda Threatens American Free Enterprise*, WASH. LEGAL FOUND., Nov. 2005, at 99, available at <http://www.wlf.org/upload/110405MONOKogan.pdf>; see also Derbach, *supra* note 25, at 94-95 (“Here, perhaps more than in any other area of international law, substantial concern exists that the activities fostered and encouraged by treaties themselves will prevent or undermine national efforts to achieve sustainable development.”). “Trade treaties also trump soft law instruments such as Agenda 21, including its recommendations on production and consumption. Unlike Agenda 21, trade liberalization agreements have created and strengthened a substantial constituency of economic beneficiaries who support continued efforts to open up trade.

a negative paradigm of sustainable development actually harms, rather than helps developing country prospects for scientific, technological, economic and social advancement.<sup>35</sup> 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.<sup>36</sup>

Given this reality, it has become ever clearer that the Government of Brazilian President Luiz Inacio Lula da Silva has portrayed itself as something other than what it really is. In other words, while pretending to work diligently on the world stage as a political moderate and dependable market-friendly force<sup>37</sup> within a highly volatile and populist region of the world,<sup>38</sup> the country has actually operated behind the scenes to help craft a new version of the 1970's New International Economic Order (NIEO)<sup>39</sup> that endeavors to undermine exclusive private property rights and the rule of law.<sup>40</sup>

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Put starkly, the central achievement of Rio was an attempt to superimpose a nonbinding framework on long-existing legal norms." *Id.*

35. See Lawrence A. Kogan, *'Enlightened' Environmentalism or Disguised Protectionism: Assessing the Impact of EU Precaution-Based Standards on Developing Countries*, NAT'L FOREIGN TRADE COUNCIL, Apr. 2004, available at [http://www.wto.org/english/forums\\_e/ngo\\_e/posp47\\_nftc\\_enlightened\\_e.pdf](http://www.wto.org/english/forums_e/ngo_e/posp47_nftc_enlightened_e.pdf); Lawrence A. Kogan, *Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science*, NAT'L FOREIGN TRADE COUNCIL, May 2003, at 46-62, available at [http://www.wto.org/english/forums\\_e/ngo\\_e/posp47\\_nftc\\_looking\\_behind\\_e.pdf](http://www.wto.org/english/forums_e/ngo_e/posp47_nftc_looking_behind_e.pdf).

36. "There is no country in the world where the sentiment for property shows itself more active and more restive than in the United States, and where the majority evinces less inclination to doctrines that threaten to alter the constitution of goods in any manner whatsoever." ALEXIS DE TOCQUEVILLE, *DEMOCRACY IN AMERICA* 610-11 (Harvey C. Mansfield & Delba Winthrop eds., Univ. of Chi. Press 2000) (1840).

37. See Mary Anastasia O'Grady, *There's No Such Thing As a Free HIV Cocktail*, WALL ST. J., Apr. 30, 2004, at A15, available at <http://www.aegis.com/news/wsj/2004/WJ040405.html>.

38. See Jonathan Wheatley & Daniel Dombey, *Bolivian Nationalisation Leaves Lula's Foreign Policy in Disarray*, FIN. TIMES (London), May 15, 2006, at 10.

39. Declaration on the Establishment of a New International Economic Order [NEIO], G.A. Res. 3201 (S-VI), U.N. Doc. A/9559 (May 1, 1974).

40. "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 . . . . The NIEO movement ran out of steam [during the 1980's, and] . . . [d]eveloping countries had the votes inside the United Nations, but they lacked

*C. Brazil Works to Undermine the Established International Order*

The Government of Brazil and its allies have undertaken numerous provocative activities within various intergovernmental fora, such as the WTO, WHO, WIPO, UNCHR, UNDP, UNEP and UNESCO.<sup>41</sup> These remain the enduring foundations of the established international order, which was first conceived by the United States and its allies following World War II, in the absence of a world government. That order is comprised of longstanding and time-proven international principles of law, economics and politics formalized collectively by the UN and the Bretton Woods institutions—the International Monetary Fund (IMF), the World Bank, the General Agreement on Tariffs and Trade (GATT) (1948 and 1994) and the WTO.<sup>42</sup>

The goal of the established international order was and still is the facilitation of international trade and investment as well as economic growth and development for the sake of ensuring international peace and security.<sup>43</sup> The established international order is strongly rooted in the recognition and protection of strong private property rights, adherence to the rule of law, benchmarked

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economic and military power outside the world organization that could be converted to bargaining success.” WEISS, *supra* note 13, at 184.

41. In addition to its efforts to help reform the WTO’s Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), Brazil has endeavored to expand its ‘open source,’ ‘universal access’ paradigm to biotechnology, chemistry, music, art, and science through various UN agencies. Those agencies are the UN Education, Science and Cultural Organization (UNESCO); the UN World Intellectual Property Organization (WIPO); the UN International Telecommunications Union (ITU); the World Summit on the Information Society (WSIS); the UN World Health Organization (WHO); the UN Convention on Biological Diversity (CBD); the UN Environment Program (UNEP); the UN Development Program (UNDP); and the UN Human Rights Commission (UNHRC).

42. *See generally* Global Policy Forum, NGOs and the Bretton Woods Institutions, <http://www.globalpolicy.org/ngos/wbank/index.htm> (last visited Oct. 29, 2006).

43. “During and after World War II, governments developed and enforced a set of rules, institutions, and procedures to regulate important aspects of international economic interaction. . . . [T]his order, known as the Bretton Woods Regime, was effective in controlling conflict and in achieving the common goals of the states that had created it. . . . Some [] believed that a liberal international economic system would enhance the possibilities of peace, that a liberal international economic system would lead not only to economic prosperity and economic harmony, but also to international peace. One of those who saw such a security link was Cordell Hull, the U.S. Secretary of State from 1933-1944.” *See* JOAN E. SPERO & JEFFREY A. HART, *THE POLITICS OF INTERNATIONAL ECONOMIC RELATIONS* 1-2 (S. Martin’s Press 5th ed. 1997) (1981); *see also* LAWRENCE ZIRING ET AL., *THE UNITED NATIONS: INTERNATIONAL ORGANIZATION AND WORLD POLITICS*, 1-2, 386-389, 407-410, 421-422 (Wadsworth Publ’g 3d ed. 1999) (1988).

objective science and economic cost-benefit analysis, continuous incentive-based technological innovation, and an aversion to trade protectionism.<sup>44</sup>

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.<sup>45</sup> “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.”<sup>46</sup> This result is not only desirable, but also essential, because these mechanisms also serve as perhaps the only remedy to the poverty, ill health and environmental degradation that pervade developing nations.<sup>47</sup> The United States has long championed exclusive ownership of private property, especially intellectual property (IP),<sup>48</sup> as have the members of OECD.

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44. “Psychological factors have often been more decisive than economic considerations in state decisions to increase barriers to trade. It was the need to change popular attitudes about ‘protectionism’ that presented the most difficult obstacle to proponents of freer trade in the postwar era. . . . Probably the most useful function performed by GATT was helping to resolve disputes over alleged infractions of its trading rules. The lesson of the 1930’s, burned indelibly into the pages of economic history, is that the greatest danger to a liberal trading system is retaliation that touches off a spiral of increasing protectionism.” ZIRING, *supra* note 43, at 389, 392-394; *see also* SPERO, *supra* note 43, at 52.

45. *See* Interview with Ronald Bailey, Economist, Professor of Economics at Stanford University’s Graduate School of Business, Post-Scarcity Prophet: Economist Paul Romer on Growth, Technological Change, and an Unlimited Human Future, REASON MAG., Dec. 2001, *available at* <http://www.reason.com/0112/fe.rb.post.shtml>; *see also* DANIEL W. DREZNER, COUNCIL ON FOREIGN RELATIONS, U.S. TRADE STRATEGY FREE VERSUS FAIR: CRITICAL POLICY CHOICES 22 (2006), <http://www.cfr.org/content/publications/attachments/CPCTrade.pdf>.

46. *See* Armen A. Alchian, *Property Rights*, THE CONCISE ENCYCLOPEDIA OF ECONOMICS, in LIBR. ECON. & LIBERTY (David R. Henderson ed., 2002), *available at* <http://www.econlib.org/LIBRARY/Enc/PropertyRights.html>.

47. *See* President’s Remarks at the Initiative for Global Development’s 2006 National Summit on June 15, 2006, 42 WEEKLY COMP. PRES. DOC. 1139, 1142 (June 19, 2006), *available at* <http://www.whitehouse.gov/news/releases/2006/06/20060615.html> (“Free nations produce the vast majority of the world’s economic output. . . . Nations that build institutions that secure the rule of law and respect human dignity also are more likely to create an economic climate that fosters investment and growth.”).

48. *But see* SYLVIA KRAEMER, SCIENCE & TECHNOLOGY POLICY IN THE UNITED STATES: OPEN SYSTEMS IN ACTION 1, 8 (2006) (“[T]he principle of ‘open systems’ has been in use in human society for over two millennia [and should be] understood as an essential characteristic of a large variety of historical and contemporary ideological and institutional proclivities [and] can help explain a broad array of institutional variations. . . . [T]he history of science, technology, and politics in the United States

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Although the established international order may have had some objectionable features, as has been pointed out by the nations of Europe and increasingly, by Brazil and Argentina who, on behalf of the developing world, have called for major reforms amounting to a new world order,<sup>49</sup> the established order has nevertheless been, and continues to be, an overwhelming success.<sup>50</sup> Indeed, even though the prevailing global system has required periodic revisions, 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.<sup>51</sup> As complex and elaborate as it has become, the established order has, nonetheless, remained flexible enough to permit provisional exceptions or derogations upon demonstration of genuine national needs and exigencies.<sup>52</sup>

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[reflects] an interplay of institutions, ideas, and issues in the ongoing tension between open and closed systems [in which] effective policymaking . . . [is] something that occurs within the dynamic 'range of play' [involving] three essential sets of variables . . . *politics . . . ideology . . . and law.*" (emphasis in original)).

49. See, e.g., DIRK MESSNER ET AL, FRIEDRICH-EBERT-STIFTUNG, GOVERNANCE REFORM OF THE BRETTON WOODS INSTITUTIONS AND THE UN DEVELOPMENT SYSTEM, DIALOGUE ON GLOBALIZATION (2005), <http://www.globalpolicy.org/soecon/bwi-wto/wbank/2005/05governance.pdf>.

50. See e.g., Ngaire Woods, *Bretton Woods Institutions*, in OXFORD HANDBOOK ON THE UNITED NATIONS WEISS 15-16 (Thomas G. Weiss & Sam Daws eds., 2006); Michael P. Dooley et al., Nat'l Bureau of Econ. Res., *The Revived Bretton Woods System*, 9 INT. J. FIN. ECON. 307-313 (2004), available at <http://web.ku.edu/~intecon/Read/Dooley04.pdf>; KLAUS LIEBSCHER, GOVERNOR, The Importance of the Bretton Woods Institutions for Small Countries, PRESENTED AT THE OESTERREICHISCHE NATIONALBANK Conference: 60 Years of Bretton Woods – Governance of the International Financial System – Looking Ahead (June 21, 2004) (transcript available at [http://www.oenb.at/en/service\\_events/fruehere\\_va/va2004/bretton\\_woods/the\\_importance\\_of\\_the\\_bretton\\_woods\\_institutions\\_for\\_small\\_countries\\_opening\\_address.jsp](http://www.oenb.at/en/service_events/fruehere_va/va2004/bretton_woods/the_importance_of_the_bretton_woods_institutions_for_small_countries_opening_address.jsp)); Derbach, *supra* note 25, at 102 ("Governments should strive not just for peace and security, social development and economic development but also for protection of the environment and natural resources on which the rest depend. Moreover, they should seek to foster those goals for both present and future generations. Apart from environmental protection, the framework is directed toward a more equitable society.").

51. See DEAN T. JAMISON, DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES 3-4, 6 (Dean T. Jamison, et al. eds., Oxford Univ. Press 2d ed. 2006) (1993) (expressing that technologic improvements have increased the life expectancies in developing countries throughout the world, specifically doubling such expectancies in Chile).

52. For example, Article 30 of the TRIPS agreement contains a number of exceptions to patent enforcement. However, the availability of these exceptions to WTO member governments is conditioned upon satisfaction of certain requirements. Generally speaking, the invocation of any such exception must "not unreasonably conflict with a normal exploitation" of the patent and must "not unreasonably prejudice the legitimate interests of the [patent] owner . . . , taking account of the legitimate interests of third parties." Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the

## II. BRAZIL THREATENS U.S. AND OECD NATION PRIVATE PROPERTY RIGHTS

Both the TRIPS and the WIPO Agreement clearly recognize and protect exclusive individual private property rights.<sup>53</sup> In addition, so do the Universal Declaration of Human Rights, the American Declaration on the Rights and Duties of Man,<sup>54</sup> the International Covenant on Economic, Social and Cultural Rights,<sup>55</sup> the Universal Declaration on the Human Genome and Human Rights,<sup>56</sup> and the Vienna Declaration and Programme of Action.<sup>57</sup>

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World Trade Organization, Annex 1c, Legal Instruments-Results of The Uruguay Round, 33 I.L.M. 1125, 1197 (1994) [hereinafter TRIPS], *available at* [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf). It has been claimed that the exceptions recognized as existing at the time that the TRIPS agreement was negotiated consist of the following: 1) de minimis use; 2) experimental use; 3) medical prescriptions; 4) freedom of international movement of foreign vessels; 5) Bolar regulatory review exception to Hatch-Waxman Act; and 6) patent exhaustion. *See* Garrison, *supra* note 24, at x. Interestingly, the thesis of this author's paper is that "the approach of a new [WTO] Panel to the issue of exceptions under Art. 30 TRIPS must likely be expected to be different from that which the Panel took back in 2000." *Id.* Other exceptions to the international trade rules exist within Article XX to the GATT 1947, but they, too, are circumscribed by general conditions for eligibility. In order to invoke any one of ten enumerated exceptions (Art. XX (a)-(j)) as a justification to adopt and/or apply regulatory or standards-based measures, a GATT/WTO member government must demonstrate that "such measures [are] not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail" and that it is not "a disguised restriction on international trade." *See* General Agreement on Tariffs and Trade, Oct. 30 1947, 61 Stat. A-11, 55 U.N.T.S. 194, *available at* [http://www.wto.org/english/docs\\_e/legal\\_e/gatt47\\_e.pdf](http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf).

53. *See* TRIPS, *supra* note 52; *see also* Convention Establishing the World Intellectual Property Organization, art. 3, July 14, 1967, 6 I.L.M. 782, 784.

54. American Declaration of the Rights and Duties of Man, AG/RES. 1591 (XXVIII-O/98) (May 2, 1948), *available at* <http://www.oas.org/juridico/English/ga-Res98/Eres1591.htm>.

55. *See* International Covenant on Economic, Social and Cultural Rights [ICESCR], G.A. Res. 2200A, art. 15((1)(a)-(c)(3), U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316 (Dec. 16, 1966) (recognizing the importance of the International Covenant on Economic, Social and Cultural Rights, of which property rights are recognized as a fundamental principle).

56. *See* G.A. Res. 152, U.N. GAOR, 53d Sess., U.N. Doc. A/53/625/Add.2 (1998) (adopting Universal Declaration on the Human Genome and Human Rights, UN Educ., Scientific and Cultural Org. [UNESCO], 29th Sess., 29 C/Resolution 19, *reprinted in* Records of the General Conference, UNESCO, 29th Sess., 29 C/Resolution 19, at 41 (1997)), *available at* <http://unesdoc.unesco.org/images/0010/001096/109687eb.pdf>.

57. *See* World Conference on Human Rights, June 14-25, 1993, *Vienna Declaration and Programme of Action*, U.N. Doc. A/CONF.157/23 (July 12, 1993), *available at* [http://www.unhchr.ch/huridocda/huridoca.nsf/\(Symbol\)/A.CONF.157.23.En](http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/A.CONF.157.23.En).

*A. Property Rights Broadly Defined*

## 1. Property Consists of Both Things and Ideas

The following discussion sets forth a basic definition of property that describes the relationship between persons and things, including ideas. Broadly speaking, the notion of private property

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.<sup>58</sup>

As so defined, property includes tangible natural assets and resources, especially raw land and converted real estate, as well as man-made structures and personal assets, which may be efficiently and cost-effectively managed with the proper incentives for both private and public benefit.<sup>59</sup>

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

[One policy] 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. [Another] policy underlying intellectual property law is to regulate and manage competition. Innovators should be entitled to monetary gain from their ideas. . . . The granting of property status to ideas is consistent with the basic definition of property. . . .<sup>60</sup>

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58. Andrew Beckerman-Rodau, *Are Ideas Within The Traditional Definition of Property? A Jurisprudential Analysis*, 47 ARK. L. REV. 603, 648-49 (1994).

59. *Id.*

60. *Id.* at 649.



## 2. Exclusive Private Property Rights Have Historical Significance

One of the key features of private property is its exclusive nature. “[T]he 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.”<sup>61</sup>

*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.*<sup>62</sup>

The right to own and enjoy real and personal property, including IP, and the inventions and innovations derived from it, has historical significance beyond 18th century English statutory and common law.<sup>63</sup> *The Federalist Papers* also clearly reflect that private property rights have long been among the most fundamental, inalienable, and liberating of all *natural* rights guaranteed to U.S. citizens by the U.S. Constitution and its accompanying Bill of Rights.<sup>64</sup> Founding Father James Madison wrote in *Federalist Paper No. 10* that “[t]he protection of . . . the faculties of men, from which the rights of property originate . . . is the first object of government.”<sup>65</sup>

In addition, in *Federalist Paper No. 54*, Madison wrote that “[g]overnment 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

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61. Alchian, *supra* note 46 (emphasis added).

62. Beckerman-Rodau, *supra* note 58, at 649 (emphasis added).

63. See PAT CHOATE, HOT PROPERTY: THE STEALING OF IDEAS IN AN AGE OF GLOBALIZATION 26-27 (2005) (stating that U.S. IP law concepts have derived substantially from England’s Statute of Monopolies, its Statute of Anne, and from English common law).

64. See U.S. CONST. amend. V. The U.S. Constitution and accompanying Bill of Rights provide that federal, state and local governments shall not “take private property. . . for public use[] without just compensation.” *Id.*

65. THE FEDERALIST NO. 10, at 40, 41 (James Madison) (Terence Ball ed., 2003).

charged with the government.”<sup>66</sup> Several years later, in an article published in the *National Gazette*, Madison wrote what is arguably his most articulate expose on private property rights:

[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.<sup>67</sup>

Furthermore, French author and historian Alexis de Tocqueville wrote about the liberating power of private property, as envisioned by the U.S. Constitution, to promote democracy, scientific and creative discovery, and innovation.<sup>68</sup>

As soon as citizens began to own land other than by feudal tenure, and transferable wealth was recognized, and could in its turn create influence and give power, discoveries in the arts could not be made, nor improvements in commerce and industry be introduced, without creating almost as many new elements of equality among men. Once works of the intellect had become sources of force and wealth, each development of science, each new piece of knowledge, each new idea had to be considered as a seed of power put within reach of the people.<sup>69</sup>

Moreover, since 1948, the world community has deemed the right to private property a fundamental and inalienable *human right*.<sup>70</sup> Since 1992, the Constitution of the Independent and Sovereign

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66. THE FEDERALIST NO. 54, at 264-67 (James Madison) (Terence Ball ed., 2003).

67. JAMES MADISON, *Property*, THE NAT’L GAZETTE, Mar. 29, 1792, reprinted in 14 THE PAPERS OF JAMES MADISON 266-67 (Robert A. Rutland et al. eds., 1983) (emphasis in original).

68. ALEXIS DE TOCQUEVILLE, 1 DEMOCRACY IN AMERICA 3, 5 (Francis Bowen & Phillips Bradley eds., Henry Reeve trans., Random House 1945) (1840).

69. *Id.*

70. See Universal Declaration of Human Rights, G.A. Res. 217A, art. 17, U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc A/810 (Dec.12, 1948), available at <http://www.udhr.org/UDHR/default.htm>.

Republic of Mongolia has been consistent with this vision with Chapter 2 entitled *Human Rights and Freedoms* and Article 16 entitled *Citizens' Rights*. These provisions have expressly provided for the protection of exclusive private property rights, including patents and copyrights.<sup>71</sup>

### *B. Brazil Monitors OECD Nations' Property Rights Debates*

Brazilian politicians are likely influenced, to some extent, by the current political debates concerning the scope of European and U.S. patent system reform, and the effectiveness of the current European and U.S. regulatory frameworks that finance university-based R&D and facilitate commercial innovations by private industry.<sup>72</sup> These crosscurrents have generated more policy conflict than consensus among the various expert groups within the Government of Brazil. It may even have emboldened Brazil's ruling party to promote a culture of IP opportunism that has now transcended national boundaries and debates, proof of the essential link between private IPRs and innovation.<sup>73</sup>

#### 1. The Age-old Debate Concerning Private vs. Public Property Rights

Clearly, the Brazilian Government's strategy, in part, is to exploit the age-old societal debate over what is and should be 'private' versus 'public' property<sup>74</sup> and the extent to which govern-

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71. See MONG. CONSTITUTION arts.16, §§ 3, 8, available at <http://www.concourt.am/wvconst/const/mongolia/mongol-e.htm> (last visited Nov. 1, 2006).

72. See generally F. SCOTT KIEFF, COORDINATION, PROPERTY & INTELLECTUAL PROPERTY: AN UNCONVENTIONAL APPROACH TO ANTICOMPETITIVE EFFECTS & DOWNSTREAM ACCESS, WASH. UNIV. SCHOOL OF LAW & STAN. UNIV. - HOOVER INST., June 2006, [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=910656](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=910656) ("Stronger . . . property rule[] enforcement facilitates the good type of coordination that increases competition and access.").

73. Guilherme Patriota of the Permanent Mission of Brazil in Geneva is a member of a new WHO panel on IPRs and public health, which is an outgrowth of the controversial WHO Report of the Commission on Intellectual Property Rights, Innovation and Public Health [CIPRH] released this past November. Mr. Patriota has theorized that "there is an inconsistency between intellectual property rights, which grant a monopoly to the right holder, and trade principles, which are based on competition. Developing countries are in a 'very difficult environment.'" WILLIAM NEW, VIEWS MIXED ON WTO DOHA DECLARATION ON PUBLIC HEALTH AFTER FIVE YEARS, INTELL. PROP. WATCH, Nov. 16, 2006, <http://www.ip-watch.org/weblog/index.php?p=460&res=1024&print=0> (summarizing Guilherme Patriota's statements from a panel on policy related IPRs and public health on November 14, 2006).

74. See Alchian, *supra* note 46. "The definition, allocation, and protection of property rights is one of the most complex and difficult set of issues that any society

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ment should protect and regulate each. No doubt, the Government of Brazil is aware that this debate continues today in various countries throughout the world,<sup>75</sup> including China,<sup>76</sup> Vietnam,<sup>77</sup> France,<sup>78</sup> the EU,<sup>79</sup> Finland, Norway and Sweden,<sup>80</sup> and even within the United States.<sup>81</sup> It also likely realizes that civil society activists and socialist political parties have largely precipitated this debate, at both the national and international levels, in order to promote greater public welfare benefits at the expense of private interests, and to establish an express public policy of societal parity over societal progress.<sup>82</sup> Within Europe, Brazil, and certain less developed countries, influential NGOs have exacerbated the division between these two forms of property ownership, and have secured the imposition of more regulation, both nationally and internationally, to redefine and limit how science, technology and

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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." *Id.*

75. *See id.* ("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.").

76. *See, e.g.,* Howard W. French, *China Media Battle Hints at Shift on Intellectual Property*, N.Y. TIMES, Jan. 6, 2007, § International, at A03; Joseph Kahn, *A Sharp Debate Erupts in China Over Ideologies*, N.Y. TIMES, Mar. 12, 2006, § 1, at 1.

77. *See, e.g.,* Amy Kazmin, *State Control Stops Vietnam Realising its IT Potential Progress Towards an Economy Centred on High-Technology Industry is Being Hampered by Vested Interests*, FIN. TIMES (London), Apr. 24, 2006, § Asia-Pacific, at 7.

78. *See* John Thornhill, *Lone Voice Calls on France to Tame the State*, FIN. TIMES (London), Apr. 26, 2006, § Europe, at 5; Tom Braithwaite, *Threat to Apple iTunes Business from French law*, FIN. TIMES (London), Mar. 22, 2006, at 19.

79. *See* Stephanie Bodoni, *Half of EU Countries Set to Miss Enforcement Directive Deadline*, MANAGING INTELL. PROP. (London), Mar. 15, 2006, <http://www.managingip.com/default.asp?page=9&PubID=198&SID=619370&ISS=21503&LS=EMS67693>; *Interoperability and the Software Patents Directive: What Degree of Exemption is Needed?*, FOUND. FOR A FREE INFO. INFRASTRUCTURE, <http://swpat.ffii.org/papers/eubsa-swpat0202/itop/index.en.html> (last visited Jan. 2, 2007).

80. *See* Tom Braithwaite & David Ibson, *Apple Faces New Threat to iTunes Music*, FIN. TIMES (London), June 10, 2006, § Int'l News, at 6.

81. *See* discussion *infra* Part III.C.6.

82. *See* Foundation for a Free Information Infrastructure, <http://www.ffii.org/Statutes> (last visited Aug 30, 2006) (supporting the development of public information goods); Arvind Panagariya, *The Pursuit of Equity Threatens Poverty Alleviation*, FIN. TIMES (London), Jun. 1, 2006, § Comment, at 11.

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industrial IP know-how should be generated, accessed and utilized.<sup>83</sup>

## 2. Brazil Observes the European Debates Concerning IPRs and Innovation

The Brazilian Government has likely observed how the EU Commission and several EU Member States have embraced NGO demands for a more public property than private property-centric regulatory approach to health, environment and intellectual property/innovation issues<sup>84</sup> than that called for by United States<sup>85</sup> and international law,<sup>86</sup> and it has arguably tried to exploit this difference.<sup>87</sup> Unfortunately, Europe's more social welfare state and,

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83. See Lawrence A. Kogan, *Exporting Europe's Precaution: How Europe's Risk-Free Agenda Threatens American Free Enterprise*, WASH. LEGAL FOUND., Nov. 2005, at 37-42, available at <http://www.wlf.org/upload/110405MONOKogan.pdf>; see also D. BETTCHER & K LEE, *Globalisation and Public Health*, 56 J. EPIDEMIOLOGICAL COMMUNITY HEALTH 8-17 (2002), available at <http://jech.bmj.com/cgi/reprint/56/1/8> ("NGO influence has been greatest when it has captured the imagination of mass publics in powerful states."); Roger Bate & Richard Tren, *Do NGOs Improve Wealth and Health in Africa?*, AM. ENTERPRISE INST., June 2003, at 7, available at [http://www.aei.org/docLib/20030612\\_batepub.pdf](http://www.aei.org/docLib/20030612_batepub.pdf).

84. See, e.g., R.C. Longworth, *Activist Groups Gain Influence in Global Body*, CHI. TRIBUNE, Dec. 1, 1999, available at <http://www.globalpolicy.org/ngos/issues/ngos99.htm>; BRIJESH NALINAKUMARI & RICHARD MACLEAN, *THE SHIFTING ROLES OF NGOS - MOVING TOWARD A 'SUPERPOWER,' PERC REPORTS (2005)*, available at <http://www.perc.org/perc.php?id=757>; Lee Jong-Wook, *Addressing Global Health: WHO Confronts AIDS, Drugs, and the Future of Health*, 26 INT'L TRADE 2 (2004), available at <http://hir.harvard.edu/articles/1274>; Rene Loewenson, *Civ. Soc'y Initiative, Annotated Bibliography on Civil Society and Health: Civil Society Influence on Global Health Policy*, WHO, CSI/2003/BI4, April 2003, available at <http://www.tarsc.org/WHOCSI/pdf/WHOTARSC4.pdf>.

85. This has also occurred within the United States. See Scott McLarty, *AIDS Drugs for Africa*, ZMAG, July 2000, available at <http://www.zmag.org/ZMag/articles/july00mclarty.htm> (referencing President Clinton's EO titled Access to HIV/AIDS Pharmaceuticals and Medical Technologies).

86. See Tobias Buck & George Parker, *Washington Bridles at EU's Urge to Regulate*, FIN. TIMES (London), May 12, 2006, § Europe, at 6.

87. It is arguable that the Brazilian Government is trying to create a division between the U.S. and Europe concerning the scope of private intellectual property rights under international law, while at the same time staking out a position for itself that is closer to the European approach. See U.N. Dep't of Pub. Rel., *Brazil, Chile, France, Norway, United Kingdom Launch New International Drug Purchase Facility to Improve Access to Treatment for HIV/AIDS, Malaria, TB*, DEPT. OF PUB. INFO. MEETINGS COVERAGE AIDS/127, Sept. 19, 2006, <http://www.un.org/News/Press/docs/2006/aids127.doc.htm>. This may reflect its growing ties with the EU, particularly with the French Government. See Marcos Chagas, *Chirac Wants More Brazil-France Cooperation on Biotechnology and Space*, BRAZZIL MAG., May 26, 2006, available at <http://www.brazzilmag.com/content/view/6499/53>. It may also indicate the Brazilian Government's willingness to support the idea of European-style regional economic and legal integration for purposes of forming a "continent-wide" trading bloc to

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thus, communal treatment of knowledge and property ownership has had an increasingly negative impact on the innovation potential of European, and particularly, German pharmaceuticals, biotechnology, computer software, and information and communication technology sectors.<sup>88</sup>

For example, the EU's relatively weaker<sup>89</sup> but more expensive<sup>90</sup> IP protections circumscribed by *civil law* notions of *ordre public*,<sup>91</sup> equity and morality,<sup>92</sup> public welfare interests,<sup>93</sup> and free-

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compete against the United States and its current and future Latin American trading partners. According to recent media reports, "[t]he leaders agreed to form a study group in Rio de Janeiro to look at the possibility of creating a continent-wide union, and even a South American parliament. Brazilian President Luiz Inacio Lula da Silva, a former metalworker who was re-elected in October, assured his fellow leaders that the group could rise above its historical divisions to unite the continent - though the process would not be easy." *Latin Leaders Look To European Union As Model*, ASSOCIATED PRESS, Dec. 10, 2006; Dan Keane, *Unity Plan Develops at South American Summit*, ASSOCIATED PRESS, Dec. 9, 2006; Eduardo Garcia, *Morales Calls For EU-style Unity in South America*, REUTERS, Dec. 10, 2006.

88. See Andrew Jack & Patrick Jenkins, *The Birthplace of Aspirin Finds Its Drug Innovation Numbed*, FIN. TIMES, Mar. 31, 2006, at 13 ("[F]or 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.").

89. See Ingrid Marson, *EU Prefers 'Computer-Aided' Patents*, ZDNET UK, Jun. 14, 2005, <http://news.zdnet.co.uk/business/legal/0,39020651,39203722,00.htm> ("[T]he 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 . . . innovations in the field of data processing . . . cannot be patented."); Munir Kotadia, *EU Votes Through Software Patent Changes*, ZDNET (UK), June 18, 2005, available at <http://news.zdnet.co.uk/business/legal/0,39020651,39155028,00.htm>.

90. See Tobias Buck, *'One Final Effort' to Create a Low-Cost EU Patent*, FIN. TIMES (London), Jan. 16, 2006, at 1; EUR. SOFTWARE ASS'N, RESPONSE TO THE EUROPEAN COMMISSION'S CONSULTATION ON THE PATENT SYSTEM IN EUROPE 1, available at [http://www.europeansoftware.org/pdf/EuSftwAssn\\_Response\\_to\\_patent\\_questionnaire.pdf](http://www.europeansoftware.org/pdf/EuSftwAssn_Response_to_patent_questionnaire.pdf).

91. "[O]rdre public originated in French law . . . [and] 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.'" Timothy G. Ackerman, *Dis'ordre'ly Loopholes: TRIPS Patent Protection, GATT, and the ECJ*, 32 TEX. INT'L L.J. 489, 495-496, 510 (1997) (quoting DENNIS LLOYD, PUBLIC POLICY 6 (1953)). "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.'" *Id.* (quoting M. Forde, *The 'Ordre Public' Exception and Adjudicative Jurisdiction Conventions*, 29 INT'L & COMP. L.Q. 259, 259 (1980)); see also Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 9 (2001).

dom of expression and human rights,<sup>94</sup> 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 universally accessible information technology and health care).<sup>95</sup>

As the result of such regulations and policies,<sup>96</sup> a growing number of European-based multinational companies have shifted their research and development facilities to the United States, which better recognizes the essential link between private property rights and innovation, and thus, has laws more favorable to and protective of private IP ownership. This has prompted the European Commission to urgently reformulate its regional and

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92. Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2004).

93. See F.M. Scherer, *The Pharmaceutical Industry and World Intellectual Property Standards*, 53 VAND. L. REV. 2245, 2245-54 (2000). "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." *Id.* at 2247-48.

94. See e.g., Marco Pistis, *The European Convention on Human Rights: Copyright Implications*, MONDAQ, June 4, 2006, <http://www.mondaq.com/article.asp?articleid=40204>.

95. See e.g., WALT SCACCHI, INST. FOR SOFTWARE RESEARCH UNIV. OF CAL IRVINE UNDERSTANDING OPEN SOURCE SOFTWARE EVOLUTION: APPLYING, BREAKING, AND RETHINKING THE LAWS OF SOFTWARE EVOLUTION (2003), available at <http://opensource.mit.edu/papers/scacchi3.pdf>; Jill Coffin, *Analysis of Open Source Principles in Diverse Collaborative Communities*, FIRST MONDAY, Sept. 18, 2006, [http://www.firstmonday.org/issues/issue11\\_6/coffin/index.html](http://www.firstmonday.org/issues/issue11_6/coffin/index.html); 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*, TECH. REVIEW, Sept. 2004, at 46; Wade Roush, *The Linux Revolution – Part II: Linux is Finally Offering Windows Users a Real Choice*, TECH. REVIEW, Sept. 2004, at 50.

96. See Press Release, Council of the E.U., Adoption of A Regulation On Compulsory Licensing of Patents Relating To The Manufacture of Pharmaceutical Products For Export To Countries With Public Health Problems (Apr. 28, 2006), available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=PRES/06/120>; Commission Regulation 816/2006, Compulsory Licensing Of Patents Relating To The Manufacture of Pharmaceutical Products for Export to Countries With Public Health Problems, 2006 O.J. (L 157) 1, available at [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_157/l\\_15720060609en00010007.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609en00010007.pdf); Council for TRIPS, *Implementation of Paragraph 11 of The General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of The Doha Declaration on The TRIPS Agreement and Public Health*, IP/C/41 (Dec. 6, 2005), available at [http://www.wto.org/english/news\\_e/news05\\_e/trips\\_decision\\_e.doc](http://www.wto.org/english/news_e/news05_e/trips_decision_e.doc).

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global policies concerning R&D investment and innovation in order to maintain international competitiveness and stem industry flight and the accompanying brain drain.<sup>97</sup> It has also drawn the socialist governments of Brazil and Europe closer together on IP issues,<sup>98</sup> given that, they both evidently lag behind the United States in patented inventions<sup>99</sup> and commercialized innovations.<sup>100</sup>

### 3. Brazil Observes the American Debates Concerning IPRs & Innovation

Although the United States has arguably struck the most successful balance between private and public intangible property rights the world has ever known, considering that it remains both the world's largest economy and the world leader in innovation,<sup>101</sup>

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97. See Comm'n Staff Working Paper, *European Competitiveness Report 2004*, SEC(2004) 1397 (Aug. 11, 2004), available at [http://ec.europa.eu/enterprise/enterprise\\_policy/competitiveness/doc/compreg\\_2004\\_en.pdf](http://ec.europa.eu/enterprise/enterprise_policy/competitiveness/doc/compreg_2004_en.pdf); *Innovation and Entrepreneurship in the Information Society: Final Report of the 5-Year Assessment of ESPRIT*, ESPRIT, June 25, 1997, <http://cordis.europa.eu/esprit/src/carneiro.htm>; Jean-Michel Chassériaux, *Long Term Research in ESPRIT in the Perspective of the 5th Framework Programme*, ERCIM NEWS ONLINE, April 1997, [http://www.ercim.org/publication/Ercim\\_News/enw29/chasseriaux2.html](http://www.ercim.org/publication/Ercim_News/enw29/chasseriaux2.html); Tobias Buck, *EU Is 50 Years Behind the US for Innovation*, FIN. TIMES (London), Jan. 13, 2006, § Europe, at 8; Pierre Simon, President, Eurochambres, *EU is Failing to Close US Innovation Gap*, FIN. TIMES (London), Jan. 20, 2005, § Letters to the Editor, at 12.

98. See Inter-American Dev. Bank [IADB], *Brazil: Technological Innovation and New Management Approaches in Agricultural Research - AGROFUTURO* (BR -L1001 Loan Proposal), July 20, 2004, <http://www.iadb.org/exr/doc98/apr/br1595e.pdf> (Loan No. 1595/OC-BR approved \$33 million of \$60 million on Dec. 1, 2004).

99. "The use of the patent system internationally has increased markedly in recent years . . . [despite] the growth rate of patent filings by non-residents (7.4% average annual increase since 1995) and in the increase in patent filings in countries such as Brazil, China, India, the Republic of Korea and Mexico. . . . The use of the patent system remains highly concentrated with only five patent offices (United States of America, Japan, Republic of Korea, China and the European Patent Office) accounting for 75% of all patent applications and 74% of all patents granted." WIPO, WIPO PATENT REPORT: STATISTICS ON WORLDWIDE PATENT ACTIVITY (2006), available at [http://www.wipo.int/ipstats/en/statistics/patents/pdf/patent\\_report\\_2006.pdf](http://www.wipo.int/ipstats/en/statistics/patents/pdf/patent_report_2006.pdf) (presenting an overview of worldwide patenting activity based on statistics up to the end of 2004).

100. See Michael Luger et al., *European Trend Chart on Innovation: Annual Innovation Policy Trends Report for United States, Canada, Mexico and Brazil 2005*, EUR. COMM'N ENT. DIRECTORATE-GENERAL i-iii, 4-5 (2005).

101. See *id.* at i; see also ORG. OF ECON. COOPERATION & DEV. [OECD], SCIENCE, TECHNOLOGY AND INDUSTRY SCOREBOARD 7-9 (2003), available at <http://www.oecd.org/dataoecd/41/0/17130709.pdf> ("In the United States, investment in knowledge – the sum of investment in R&D, software and higher education – amounted to almost seven percent of GDP in 2000, well above the share for the European Union or Japan. . . . R&D expenditure has risen faster in the United States (5.4% a year) than in the European Union (3.7%) and Japan (2.8%). . . . OECD data on patent families (a set of patents filed in various countries to protect a single invention) show the existence



the United States' IPR framework covering patents and trade secrets has increasingly become the subject of heated national debate.<sup>102</sup> Brazilian politicians have likely monitored the recent congressional hearings on U.S. patent reform.<sup>103</sup> Many articles have also likely influenced their commentaries and panel presentations disputing the utility of the current regulatory framework by which U.S. federally funded university-based R&D is commercialized by hi-tech industries.<sup>104</sup>

Some of these debates have become politically and ideologically charged, as they have led to legislative proposals that would, if enacted, likely undermine U.S. exclusive private property rights, both here *and* abroad.<sup>105</sup> If foreign governments<sup>106</sup> with weak IPR regimes believe that American society is uncertain about the scope of protection to accord IPRs, they will opportunist-

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of more than 40,000 patent families in 1998 in the OECD area, a 32% increase from 1991. The United States accounted for around 36%, followed by the European Union (33%) and Japan (25%).” (emphasis added)).

102. See, e.g., F.M. Scherer, *The Political Economy of Patent Policy Reform in the United States*, Aug. 2006, available at <http://www.ksg.harvard.edu/m-rcbg/papers/scherer/PATPOLIC.pdf> (unpublished comment, on file with Harvard University).

103. *Perspectives on Patents: Post-Grant Review Procedures and Other Litigation Reform*, Notice of Subcomm. Hearing before The S. Comm. on the Judiciary Subcomm. on Intellectual Property (May 23, 2006); Anne Broache, *Senators Offer Sweeping Patent System Changes*, CNET NEWS.COM, Aug. 4, 2006, [http://news.com.com/2100-1028\\_3-6102493.html](http://news.com.com/2100-1028_3-6102493.html); H.R. 5096, 109th Cong. (2d Sess. 2006), available at <http://www.govtrack.us/data/us/bills.text/109/h/h5096.pdf>; Rick Boucher, *Overview of Patents Depend on Quality Act of 2006*, [http://www.boucher.house.gov/index2.php?option=com\\_content&do\\_pdf=1&id=678](http://www.boucher.house.gov/index2.php?option=com_content&do_pdf=1&id=678) (commenting on H.R. 5096); *Patents Depend on Quality Act of 2006: Hearing on H.R. 5096 Before the H. Comm. on the Judiciary*, 109th Cong. (2d Sess. 2006) (statement of congressman Howard Berman representing the 28th District of California).

104. See e.g., Dianne N. Irving, *Revisiting the Bayh-Dole Act (1980): Spawned Big Biotech Now Has Opposite Debilitating Effects*, LIFEISSUES.NET, Sept. 22, 2005, [http://www.lifeissues.net/writers/irv/irv\\_104bayh\\_dole.html](http://www.lifeissues.net/writers/irv/irv_104bayh_dole.html) (citing Clifton Leaf, *The Law of Unintended Consequences*, FORTUNE MAG., Sept. 19, 2005, at 250); *Bayh-ing for Blood or Doling Out Cash*, ECONOMIST.COM, Dec. 24, 2005, [http://www.economist.com/science/PrinterFriendly.cfm?story\\_id=5327661](http://www.economist.com/science/PrinterFriendly.cfm?story_id=5327661); David Mowery, U.N. Indus. Dev. Org. [UNIDO] Meeting in Venice, Oct. 3, 2002, *Developing Countries and TRIPS* (Oct. 27, 2002), available at <http://www.unido.org/en/doc/7983>; David C. Mowery & Bhaven N. Sampat, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?*, 30 J. TECH. TRANSFER 115 (2005); David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99 (2001).

105. See e.g., 152 CONG. REC. S5135, S5245-52 (May 25, 2006) (statement of Sen. Lugar & Sen. Leahy), available at [http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?dbname=2006\\_record&page=S5245&position=all](http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?dbname=2006_record&page=S5245&position=all); Press Release, Senator Patrick Leahy, *Bill to Foster Low-Cost Drugs for World's Poorest* (May 21, 2006), available at <http://leahy.senate.gov/press/200605/051906.html>.

106. BRIC is used to refer to a combination of the economies of Brazil, Russia, India, and China.

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tically seek to exploit our uncertainty to the detriment of U.S. private property owners abroad. How can we demand that such nations protect our IPRs (i.e., patents, data exclusivity, trade secrets, etc.) *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 in the United States, concerning IP rights, will reverberate throughout the world and have an impact on both the international IP framework and other countries' national IP laws and policies. In other words, we must ensure that the type of IP message we convey both at home and abroad is positive *and* consistent.<sup>107</sup>

#### 4. Brazil's 'Gaming' of OECD Nation IPRs Violates Constitutional and Human Rights

During the past seven years, the Brazilian Government, prodded by activists and supported by the WHO, has repeatedly threatened to 'take' the private IPRs of OECD life science companies operating in Brazil (via issuance of compulsory licenses) for an ostensible 'public use' without paying 'just compensation.'<sup>108</sup> In addition, the Brazilian Government has threatened to abrogate U.S. pharmaceutical patents and/or to otherwise disclose confidential U.S. and European company pre-clinical testing data, much of which qualifies as proprietary trade secrets, if such companies fail to sell their HIV/AIDS and other drugs at-or-below *cost*. It is believed, however, that Brazilian generic drug makers and corrupt Brazilian politicians, rather than the poor and HIV-

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107. See PREPARED TESTIMONY OF EDWARD JUNG FOUNDER, INTELLECTUAL VENTURES, Before The US - China Economic & Security Review Commission Hearing on Intellectual Property Rights Issues and Dangers of Counterfeited Goods Imported Into the United States, 109th Cong. (2006), available at [http://www.uscc.gov/hearings/2006hearings/written\\_testimonies/06\\_06\\_07wrts/06\\_06\\_7\\_8\\_jung\\_edward.php](http://www.uscc.gov/hearings/2006hearings/written_testimonies/06_06_07wrts/06_06_7_8_jung_edward.php).

108. See Ministry of Health of Braz., *The Government Declares Anti-retroviral Kaletra to be of Public Interest and Will Produce it in Brazil*, PR NEWSWIRE, June 24, 2005, available at <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/06-25-2005/0003950348&EDATE>; WHO *Congratulates Brazil for the Breaking of the Patent of the Aids Medicine*, EUROPEAN AIDS TREATMENT GROUP, July 1, 2005, available at <http://www.eatg.org/modules.php?op=modload&name=News&file=article&sid=467&mode=thread&order=0&thold=0>; *Merck to Allow Brazil to Copy AIDS Drug Stocrin, Valor Says*, BLOOMBERG.COM, Dec. 2, 2004, [http://www.bloomberg.com/apps/news?pid=10000086&sid=anv51yXhZdtk&refer=latin\\_america](http://www.bloomberg.com/apps/news?pid=10000086&sid=anv51yXhZdtk&refer=latin_america); *Brazil to Break AIDS Drug Patents*, BBC NEWS, Dec. 1, 2004, available at <http://news.bbc.co.uk/2/hi/health/4059147.stm>; Keith Alcorn, *Brazil wins 75% Discount on New HIV Drug*, AIDSMap News, Nov. 11, 2003, available at <http://www.aidsmap.com/en/news/5719B079-1568-4614-89D7-C51F8A3DC6A1.asp>; Alex Bellos, *Roche Bows to Brazil on AIDS Drug*, GUARDIAN, Sept. 9, 2001, available at <http://www.guardian.co.uk/international/story/0,3604,545328,00.html>.



U.S. companies' constitutional rights. The President and the Congress have sworn to protect these rights no matter where such property is located.<sup>111</sup> As previously acknowledged, the right to own and enjoy exclusive private property has been recognized as a fundamental and inalienable *human right*.<sup>112</sup>

##### 5. Brazil's 'Gaming' of U.S. IPRs Threatens U.S. Economic Competitiveness

The Government of Brazil's international conduct also threatens to dampen foreign and Brazilian industry confidence in and enthusiasm for investment in basic research and development, and to discourage international and Brazilian commercialization of those inventions.<sup>113</sup> It may even substantially impair the ability of Brazil and its industries to secure real economic and social advancement in the future.

Of even greater concern, however, is the influence that Brazil's continued anti-IP activities has had on the thinking of other emerging and developing countries,<sup>114</sup> and the impact that it will have on future U.S. international competitiveness. Indeed, a substantial portion of the U.S. economy is now based on the performance of IP-based assets and the research and development of those assets is increasingly being exported abroad for 'competitiveness' reasons.<sup>115</sup> Indeed, one recent economic study estimates that

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111. See discussion *infra* Part III.C.6.

112. See Universal Declaration of Human Rights, *supra* note 70, at art. 17 ("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.").

113. Apparently, as the international investment community has discovered, the Brazilian Government's words (i.e., Brazil's IPR legislation) do not match its actions (i.e., the government's implementation of the national law) – Brazil does not 'walk the talk.' See ROBERT M. SHERWOOD, INTELLECTUAL PROPERTY AND ECONOMIC DEVELOPMENT (1990), [http://www.kreative.net/ipbenefits/iped/body\\_9\\_chapter.htm](http://www.kreative.net/ipbenefits/iped/body_9_chapter.htm) ("[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. . . . The test of whether protection is weak or not . . . 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)).

114. *Id.* ("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.").

115. See Steven Lohr, *Outsourcing is Climbing Skills Ladder*, N.Y. TIMES, Feb. 16, 2006, available at <http://www.mindfully.org/WTO/2006/Outsourcing-Ladder-Lohr16feb06.htm> (including the companies of Dow Chemicals, IBM and Hewlett-Packard)

[t]he current value of the intellectual property which 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 United States GDP and greater than the GDP of any other nation in the world.<sup>116</sup>

Consequently, Brazil's attempts to weaken intellectual property rights internationally will certainly jeopardize America's continued ability to function as the engine of global scientific and technological innovation and economic growth.<sup>117</sup> And, if Brazil is successful, America's long-held advantages in international trade and innovation and its higher GDP and living standards will likely be significantly reduced.<sup>118</sup>

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("A new study [prepared by] the nation's leading advisory groups on science and technology suggests that more and more research work at corporations will be sent to fast-growing economies with strong education systems like China and India. In a survey of more than 200 multinational corporations [from the United States and Western Europe] on their research center decisions, 38% said they planned to 'change substantially' the worldwide distribution of their research and development work over the next three years - with the booming markets of China and India, and their world-class scientists, attracting the greatest increase in projects."). Europe is also experiencing its own wave of R&D outsourcing. See Annie Kahn, *The New Frontiers of French Research*, LE MONDE, Sept. 15, 2005, available at [http://www.truthout.org/issues\\_06/091605LA.shtml](http://www.truthout.org/issues_06/091605LA.shtml).

116. See Robert J. Shapiro & Kevin A. Hassett, *The Economic Value of Intellectual Property*, USA FOR INNOVATION, Oct. 2005, at 3, available at [http://www.usaforinnovation.org/news/ip\\_master.pdf](http://www.usaforinnovation.org/news/ip_master.pdf).

117. "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." U.S. TRADE REP., SPECIAL 301 REPORT 9-10 (2005), available at [http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2005/2005\\_Special\\_301/asset\\_upload\\_file195\\_7636.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_Special_301/asset_upload_file195_7636.pdf); see also Bruce P. Mehlman, Assistant Sec'y for Tech. Policy U.S. Dep't of Com., Offshore Outsourcing and the Future of American Competitiveness, Address Before the ITA ISAC-13 Advisory Committee (Oct. 14, 2003), available at [http://www.technology.gov/Speeches/BPM\\_2003-Outsourcing.pdf](http://www.technology.gov/Speeches/BPM_2003-Outsourcing.pdf); S. Joseph L. Lieberman, *Offshore Outsourcing and America's Competitive Edge: Losing Out in the High Technology R&D and Services Sectors*, May 11, 2004, at 3, 14-15, 23, <http://lieberman.senate.gov/documents/whitepapers/Offshoring.pdf> ("Higher skilled professional jobs ranging from engineering, computer chip design, to nanotechnology research are also starting to move overseas. . . . U.S. corporations are moving sophisticated design and R&D overseas to their own subsidiaries abroad or contracting the work to third parties to assist product development in existing manufacturing facilities abroad. . . . The continued shift of corporate R&D to overseas is a threat to our economic prosperity and national security.").

118. The International Intellectual Property Alliance (IIPA) has alleged that

### III. BRAZIL CHALLENGES THE ESTABLISHED GLOBAL IPR FRAMEWORK

#### A. *Brazil Actively Engages in 'Regime Shifting' to Reform International IP Law*

Brazil and other developing countries that have become dissatisfied with the TRIPS and WIPO agreements<sup>119</sup> and the American capitalist economic model of 'risk and reward,' which serves as the basis for the current international IP framework, are now employing, with the assistance of well-funded global civil society

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Brazil's continued theft of intellectual property rights cost American businesses an estimated 900 million U.S. dollars 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 MAG., May 18, 2005, available at <http://www.brazzilmag.com/content/view/2470/49>.

119. "[M]any developing countries and civil society groups [had] bec[ome] increasingly critical [during the 1990's] of the legal and policy constraints that the nesting of trade and IP rules [in the TRIPS agreement and a second generation WIPO treaties] had imposed. NGOs in particular were frustrated at being shut out of negotiations by the limited participation rights provided to non-state actors in WTO, WIPO, and bilateral trade talks. The dramatic expansion of intellectual property that nesting and bilateralism had engendered provided these groups with an alternative strategy. By the late 1990s, new coalitions of state and non-state actors were shifting their energies to multilateral venues within *other* international regimes whose principles, norms, and rules were being undermined by TRIPs and TRIPs plus treaties. These coalitions were highly strategic in their selection of issue areas, venues, and arguments. *They emphasized subjects—such as public health, human rights, and biodiversity—with high visibility and the potential to generate strong public support. They selected forums that were open to participation by non-state actors or venues in which the United States was not a participant (having refused to ratify the relevant treaties).* And they attempted to influence international bureaucrats and legal and technical experts whose support would give their claims the imprimatur of neutrality and legitimacy. Having selected these venues, these coalitions adopted a twofold strategy. First, they challenged TRIPs and TRIPs-plus bilateral treaties on moral, legal, political, and economic grounds. And second, they established new and often conflicting legal rules in an effort to rollback or block further expansion of intellectual property rights. . . . *The result of these initiatives is that IP is now nested within many distinct international regimes, which together form a multi-modal, multi-venue 'conglomerate regime' or a 'regime complex,' made up of multilateral, regional, and bilateral treaties, soft law resolutions and declarations, and competing networks of state and non-state actors.*" Laurence R. Helfer, *Nesting and Complexity in the International Intellectual Property Regime*, Presented at the Interdisciplinary Nested and Overlapping Institutions Conference at Princeton University's Woodrow Wilson School of Government (Feb. 2006), at 1-3, available at <http://www.princeton.edu/~smeunier/Helfer%20memo.pdf> (footnotes omitted) (emphasis added) [hereinafter Helfer, *Nesting*].

(activist NGOs),<sup>120</sup> a strategy known as ‘regime shifting.’<sup>121</sup> Supporters of the socialist welfare state model of sustainable development have also employed this strategy with relative success in the fields of international environmental and human rights law.<sup>122</sup> NGOs, for one, “have proposed to curtail [IPRs] in one international forum after another, even where 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 World Health Organization, and others.”<sup>123</sup> Brazil and other developing countries have engaged in regime shifting despite the overall mutual and balanced concessions to which 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.<sup>124</sup>

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120. “For NGOs, particularly those shut out of a forum by state-only access rules, regime shifting also offers the obvious advantage of greater access to lawmaking processes. By attending meetings, submitting documents to expert and working groups, and interacting with government officials inside and outside of negotiating halls, NGOs can shape debates over principles, norms, and rules in ways that are foreclosed to them within more state-centric regimes.” Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 2, 50 (2004) (footnotes omitted) [hereinafter Helfer, *Regime Shifting*].

121. “A regime refers to the principles, norms, and rules governing a particular issue area of international relations, and to the formal institutional structures and decision making procedures through which those principles, norms, and rules are developed. Regimes form when the interests of states converge around certain shared objectives that can best be achieved through interstate cooperation. . . . [An] international ‘regime’ describes a concept that is broader than simply a single intergovernmental organization or a particular international agreement.” *Id.* at 5 n.16.

122. See Lawrence A. Kogan, *Looking Behind the Curtain: The Growth of Trade Barriers That Ignore Sound Science*, NAT’L FOREIGN TRADE COUNCIL, May 2003, <http://www.nftc.org/default/white%20paper/TR2%20final.pdf>; see also Kogan, ‘Enlightened’ Environmentalism, *supra* note 35.

123. Schultz & Walker, *supra* note 10, at 82; see also Helfer, *Regime Shifting*, *supra* note 120, at 54 (“One important consequence of post-TRIPs regime shifting has been a sharp increase in intellectual property lawmaking in four international regimes, including two regimes (public health and human rights) not previously concerned with the products of human creativity or innovation.”).

124. Indeed, as the result of the “negotiation of a 1995 agreement between the WTO and WIPO [intergovernmental organizations]” and the enactment of both the TRIPs agreement and a second generation of technical WIPO treaties, U.S. and EU IPRs were collectively promoted at the international level. It was hoped that these international treaties would establish a stable “bimodal’ [IP] regime in which the two intergovernmental organizations would cooperate and share policy space . . . [This was followed by the introduction of] . . . a new form of bilateral treaty [that was used] to induce developing countries to ratify these new WIPO agreements (or standards equivalent to them) in exchange for favorable [U.S. and EU] trade and investment treatment.” Helfer, *Nesting*, *supra* note 119, at 1.

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Their goal is to reform WTO and WIPO law from the inside *and* to develop new customary international law norms beyond those legal regimes from the outside that can eventually swallow up the general principles, norms, and rules that comprise the corpus of IP law.<sup>125</sup> In other words, if regime shifting is achieved in the name of promoting international regulatory harmonization,<sup>126</sup> the temporary and provisional exceptions and derogations (e.g., compulsory licensing) to the general rule of strong IPR protection made expressly available in the TRIPS and WIPO Copyright and Patent agreements will ultimately overtake and subsume the general rule.<sup>127</sup> 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 be allowed] only when it is clearly necessary . . . and where the benefits outweigh the costs of protection.”<sup>128</sup>

The ostensible public health and knowledge goals that Brazil and other developing nations, such as Argentina, assert as the primary motivation behind such regime shifting are likely overshadowed by their more ambitious but less transparent economic and

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125. See, e.g., Kogan, *Precautionary Principle*, *supra* note 34, at 57-61; Lawrence A. Kogan, *Exporting Europe's Protectionism*, 77 NAT. INT. 91, 96-97 (2004); Kogan, *Precautionary Preference*, *supra* note 34, at 11.

126. See *Trans-Atlantic Trade Vision*, WALL ST. J., Jan. 10, 2007 (criticizing the often hidden goals behind regulatory harmonization); Pascal Lamy, Address Before the Eur. Soc'y of Int'l Law (May 19, 2006) (transcript available at [http://www.wto.org/english/news\\_e/sppl\\_e/sppl26\\_e.htm](http://www.wto.org/english/news_e/sppl_e/sppl26_e.htm)); see also Matthew Ocheltree, *Conversation with Rufus Yerxa, WTO Deputy Director-General, on the Doha Round*, CARNEGIE ENDOWMENT FOR INT'L PEACE, May 24, 2006, <http://www.carnegieendowment.org/events/index.cfm?fa=eventDetail&id=888&&prog=zgp&proj=zted> (summarizing remarks of Rufus Yerxa, which emphasized that despite the many criticisms lodged against it, the multilateral trade system is the foundation of all of the most important trade relationships in the world, including US-European Union, US-Japan, and US-China).

127. WTO, Gen. Council Trade Negotiations Committee, *Doha Work Programme: The Outstanding Implementation Issue on the Relationship Between the Trips Agreement and the Convention on Biological Diversity*, U.N. Doc. WT/GC/W/564 (May 31, 2006), available at [http://docsonline.wto.org/GEN\\_highLightParent.asp?qu=&doc=D%3A%2FDDDOCUMENTS%2FT%2FTN%2FC%2FW41%2EDOC%2EHTM](http://docsonline.wto.org/GEN_highLightParent.asp?qu=&doc=D%3A%2FDDDOCUMENTS%2FT%2FTN%2FC%2FW41%2EDOC%2EHTM) [hereinafter *Doha Work Programme*].

128. WIPO, *Proposal to Establish a Development Agenda for WIPO: An Elaboration Of Issues Raised in Document*, ¶ 16, U.N. Doc. WO/GA/31/11 (Apr. 6, 2005), available at [http://www.wipo.int/edocs/mdocs/mdocs/en/iim\\_1/iim\\_1\\_4.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/iim_1/iim_1_4.pdf). “WIPO . . . must be open to, and actively consider, alternative non-intellectual property-type systems for fostering creativity, innovation and the transfer of technology, while recognizing the benefits and costs of each system.” *Id.*





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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.<sup>134</sup>

International regimes also have an institutional component. They “consist[ ] of the cooperative arrangements states use to create principles, norms and rules,”<sup>135</sup> 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.<sup>136</sup>

Regime rules are often shaped by power politics and tailored to favor the national interests of stronger and more influential states, though power alone does not determine how international regimes subsequently evolve.<sup>137</sup> Intergovernmental organizations and international institutions have played an increasing role in limiting the actions of stronger and more influential states (i.e., the United States).<sup>138</sup> This has afforded weaker states and non-state actors greater latitude to influence the development of principles, norms and rules.<sup>139</sup> 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.<sup>140</sup>

Indeed, relatively weaker states, such as Brazil, may lead other less developed countries, together with non-state actors (i.e., 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.<sup>141</sup> Alternatively, or in addition thereto, weaker states and non-state actors may endeavor to alter the substantive principles, norms and rules of a particular

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134. *Id.* at 11.

135. *Id.*

136. *Id.*

137. *Id.* at 10.

138. *Id.*

139. *Id.* at 13

140. *Id.* at 13-14.

141. *Id.* at 11.

regime by generating “‘counter-regime norms’ – binding treaty rules and nonbinding soft law standards that seek to alter the prevailing legal landscape.”<sup>142</sup>

[C]ounter-regime norms may be revolutionary rather than evolutionary, posing more fundamental challenges to underlying principles. [States and non-state actors] who 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.<sup>143</sup>

State 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.<sup>144</sup>

This decision usually entails a comparative analysis of the participating states and their level of influence, the law-making methods, the monitoring and dispute settlement procedures, and the relative roles of intergovernmental institutions and nongovernmental organizations.<sup>145</sup> Given that many of the same state and non-state actors may be participating in multiple regimes simultaneously, that once distinct regimes have become more interdependent over time, and that individual regimes no longer focus singularly on isolated well-defined issues, this has become a complex and other than orderly process. This is especially the case with respect to IPRs,<sup>146</sup> where it has become more difficult to ascertain a given regime's boundaries, and thus, to decide

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142. *Id.* at 14.

143. *Id.* at 14-15.

144. *Id.* at 12. For example, “[a] state that expands the negotiation of new free trade obligations from a multilateral setting to a regional trade pact or to a web of bilateral trade agreements is engaging in intra-regime shifting. A state that introduces rules to protect the global environment into an intergovernmental organization previously devoted to lowering trade barriers is attempting an inter-regime shift.” *Id.* at 13.

145. *Id.* at 15.

146. “In the case of intellectual property rights, developing countries and their allies are shifting negotiations and hard and soft lawmaking initiatives to international regimes whose institutions, actors, and subject matter mandates are more closely aligned with these countries' interests. Within these regimes, developing countries are challenging 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 complex international environment in which seemingly settled treaty bargains are contested and new dynamics of lawmaking and dispute settlement must be considered.” *Id.* at 6.

whether to shift regimes at all.<sup>147</sup>

### 1. Brazil's IPR Regime Shifting from TRIPS to WHO and UNHRC

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. The Organization introduced the concept of 'essential drugs' and urged its member nations to adopt 'national drug policies.' The WHO first became concerned with IPRs in 1996, following the enactment of the TRIPS Agreement that imposed expanded obligations on states to protect pharmaceutical patents.<sup>148</sup> 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, the 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, South Africa, and Zimbabwe, together with public health NGOs . . . were the principal catalysts for the WHO's critical review of TRIPs. . . . The [WHO's] 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.<sup>149</sup>

Although the United States 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 issue 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

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147. *Id.* at 15-16.

148. *Id.* at 42.

149. *Id.* at 43 (internal citations omitted).

policies.”<sup>150</sup>

However, they could not prevent Brazil and other developing nations from later shepherding such language into a controversial 2000 UN human rights resolution (2000/7)<sup>151</sup> for strategic regime shifting purposes.<sup>152</sup> That resolution declared that “there are apparent conflicts between the IPR regime embodied in the TRIPS Agreement and international human rights law,”<sup>153</sup> and sought to establish “the primacy of human rights obligations over economic policies and agreements” (i.e., property rights).<sup>154</sup> First, it encouraged NGOs to persuade their governments to integrate their economic and human rights into their laws and policies.<sup>155</sup> Second, it requested that national governments and intergovernmental bodies integrate into their laws and policies and protect the social function of IP.<sup>156</sup> Third, it recommended that intergovernmental organizations such as the WHO, WIPO, UNDP, UNEP and UNCTAD undertake a critical examination of TRIPS “including a consideration of its human rights implications.”<sup>157</sup> This highly debated resolution was later recycled and adopted again, without a vote, in August 2001.<sup>158</sup>

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150. *Id.* (quoting Chakravarthi Raghavan, *Health: Assembly Adopts New Revised Drug Strategy, South-North Development Monitor*, May 24, 1999, <http://www.twinside.org.sg/title/assembly-cn.htm> (noting the deletion of these statements from proposed resolutions)).

151. See UNHCHR, Sub-Comm. on the Promotion and Protection of Human Rights, Res. 2000/7, U.N. Doc. E/CN.4/Sub/2/2000/L.20 (Aug. 17, 2000) [hereinafter 2000 Sub-commission Intellectual Property Resolution], *available at* <http://www.unhchr.ch/Huridocda/Huridoca.nsf/0/c462b62cf8a07b13c12569700046704e?Opendocument>.

152. See, e.g., Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5 MINN. INTELL. PROP. REV. 47, 56 (2003).

153. “Declar[ing] . . . that . . . there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other. . . .” 2000 Sub-commission Intellectual Property Resolution ¶ 2; *see also id.* at pmbl. (“[A]ctual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights . . . .” (emphasis in original)).

154. *Id.* ¶ 3. (“Remind[ing] all Governments of the primacy of human rights obligations under international law over economic policies and agreements.”). For example, the UN 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.’” Helfer, *Regime Shifting*, *supra*, note 120, at 49-50 (quoting 2000 Sub-commission Intellectual Property Resolution, *supra* note 151).

155. 2000 Sub-commission Intellectual Property Resolution, *supra* note 151, ¶ 14.

156. *Id.* ¶¶ 5-6.

157. *See id.* ¶ 12.

158. *See* U.N. High Comm’r for Hum. Rts. [UNHCHR], Sub-Comm. on the Promotion and Protection of Human Rights, Res. 2001/21, U.N. Doc. E/CN.4/Sub/2/

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Developed countries, particularly those in the EU, opposed ceding to the WHO competence to review health-related IP issues.<sup>159</sup> But they later softened their position as the HIV/AIDS crisis worsened.<sup>160</sup> This position reversal later proved very costly, as the WHO adopted an approach that has since been skeptical of IPRs, though somewhat less critical than the more aggressive approach adopted by those UN human rights bodies in which Brazil actively participated.<sup>161</sup> The WHO approach has also set forth suggestions on how states may reconcile competing WTO/WHO regime objectives.<sup>162</sup> A March 2001 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 mechanisms' to lower drug prices and increase their availability. . . . [T]he bulletin [also] 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.<sup>163</sup>

In May 2003, the WHO World Health Assembly (WHA) adopted a resolution (WHA 56.27) recommending the creation of a time-limited body whose purpose was to evaluate the impact of IP protections on the development of new drugs and to issue a report analyzing its findings.<sup>164</sup> This well-recognized body is otherwise

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2001/L.21 (Aug. 16, 2001) [hereinafter 2001 Sub-commission Intellectual Property Resolution], available at [http://www.unhchr.ch/Huridocda/Huridoca.nsf/\(Symbol\)/E.CN.4.SUB.2.RES.2001.21.En](http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.SUB.2.RES.2001.21.En).

159. See Helfer, *Regime Shifting*, *supra* at 120, at 47 n.187.

160. *See id.* at 39.

161. *See id.*

162. *See id.*

163. *See id.* at 39-40 (quoting WHO, *Globalization, TRIPS and Access to Pharmaceuticals, WHO Policy Perspectives on Medicines*, No. 3, U.N. Doc. WHO/EDM 2001.2 (Mar. 2001)).

164. *See id.* at 40; *see also* CIPIH, Background on the Commission, <http://www.who.int/intellectualproperty/background/en/index.html> (last visited Nov. 1, 2006). The resolution was accompanied by a report that essentially concludes that the scope of intellectual property rights must be narrowed to stimulate healthcare innovation, reduce drug prices and to prevent market monopolies, all of which contributes to ensuring access to essential healthcare. *See* The Secretariat, WHO, *Intellectual*

known as the Committee on Intellectual Property Rights, Innovation and Public Health (CIPIH).<sup>165</sup> The analysis was to have focused on IPRs, innovation, public health, and the appropriate funding and incentive mechanisms that were needed 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 pharmaceutical and health policies’ and ‘to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in [TRIPS].”<sup>166</sup> Brazil was the lead developing country in this effort, arguing that “access to new medicines ‘must not be impeded by patent protection.’”<sup>167</sup>

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* IP issues do *not* reflect an attempt to roll back IPR protections.<sup>168</sup> He contends, rather, that they were intended to heighten member governments' recognition of the flexibilities already inherent within the TRIPS Agreement.<sup>169</sup>

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*Property Rights, Innovation and Public Health*, ¶¶ 16-19, U.N. Doc. A56/17 (May 12, 2003), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA56/ea5617.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA56/ea5617.pdf).

165. See The Director-General, WHO, *Intellectual Property Rights, Innovation and Public Health: Terms of Reference For Review Group*, U.N. Doc. EB113/INF/DOC.1 (Jan. 15, 2004), available at [http://www.who.int/gb/ebwha/pdf\\_files/EB113/eeb113id1.pdf](http://www.who.int/gb/ebwha/pdf_files/EB113/eeb113id1.pdf).

166. Helfer, *Regime Shifting*, *supra* note 120 (citing WHA, *Intellectual Property Rights, Innovation and Public Health*, WHA 56.27, ¶¶ 1(1), 1(2), 2(2) (May 28, 2003) (emphasis added)).

167. *Id.* (quoting WHO, *Globalization, TRIPs and Access to Pharmaceuticals, WHO Policy Perspectives on Medicines*, No. 3, U.N. Doc. WHO/EDM/2001.2 (Mar. 2001)). “The final draft of the resolution represent[ed] a compromise between developing countries led by Brazil - which argued that access to new medicines ‘must not be impeded by patent protection’ - and the United States, which advanced a competing resolution urging member states to promote innovation by encouraging respect for strong intellectual property rights.” *Id.* at 44 (citing WHA56/NGO News Center, *Intellectual Property Rights, Innovation and Public Health*, (May 28, 2003), at Executive Summary, available at <http://www.wha56.org/1054122412598/view>); see also Daniel Pruzin, *WHO Creates Body to Study Impact of IP on Drug Development*, 20 INT'L TRADE RPTR. 957, 958 (June 5, 2003)). Dissatisfied with the outcome, the U.S. Government subsequently tried to shape the *implementation* of this resolution's recommendations. See Letter from William R. Steiger, Ph. D., Special Assistant to the Secretary for Int'l Aff., U.S. Dep't of Hum. Health & Servs., to the Honorable J.W. Lee, Director-General of the WHO, United States Proposed Terms of Reference and Areas for Substantive Consideration of an Intellectual Property Body (Oct. 30, 2003), <http://www.cptech.org/ip/health/rnd/usawho-ocr.pdf>.

168. Helfer, *Regime Shifting*, *supra* note 120, at 40.

169. *Id.*

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.<sup>170</sup>

This expert's analysis obviously places a 'positive spin' on the controversial activities undertaken by the Brazilian and other developing country governments. However, the reality is that Brazil and its fellow complainants have not stopped there. Contrary to his assertion, it would seem that they are most definitely seeking to rollback IP protection anyway they can!<sup>171</sup>

In May 2004, the WHA adopted another WHO resolution that took account of and expanded upon the prior 2003 resolution noted above.<sup>172</sup> WHA Res. 57.14 urged member states as a matter of priority "to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the [TRIPS Agreement]."<sup>173</sup> It also urged WHO member states to ensure that bilateral trade agreements, an allusion to U.S. TRIPS-plus Free Trade Agreement (FTA) provisions, take into account the flexibilities in the TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement on Public Health.<sup>174</sup>

Furthermore, on January 24, 2006, the Governments of

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170. *Id.* (citing WTO, Declaration on the TRIPs Agreement and Public Health, WTO Doha Ministerial Conference, 4th Sess., U.N. Doc. WT/MIN(01)/DEC/W/2 (Nov. 14, 2001)).

171. See Schultz & Walker, *supra* note 10, at 131.

172. See WHA, *Scaling Up Treatment and Care Within a Coordinated and Comprehensive Response to HIV/AIDS*, U.N. Doc. 57.14 (May 22, 2004), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA57/A57\\_R14-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA57/A57_R14-en.pdf).

173. *Id.* ¶ 2(4).

174. *Id.* ¶ 2(6).



Kenya<sup>175</sup> and Brazil<sup>176</sup> were finally able to secure the ear of the WHO Executive Board. They proposed a new resolution for adoption (EB117/Conf.Paper No. 3),<sup>177</sup> that alluded to “the primacy of human rights obligations over economic policies and agreements” and cast serious doubt about the ability of the current international IPRs paradigm to stimulate innovation, promote technology transfer and enhance public welfare – i.e., to secure at-or-below *cost* price universal access to essential medicines and life sciences know-how.<sup>178</sup> Three days later, on January 27, 2006, the WHO Executive Board voted to adopt this resolution (EB117/R.13) and to submit it to the WHA for consideration.<sup>179</sup> Brazil, in other words, was ultimately successful in shifting regimes—moving the prior 2000 and 2001 resolution language it had advanced within the UN Human Rights Sub-commission on the Promotion and Pro-

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175. Kenya submitted its first draft of this resolution to the WHA in November 2005. See WHO, *Proposed Resolution on a Global Framework on Essential Health Research and Development*, 117th Sess., Nov. 16, 2005, available at <http://www.cptech.org/ip/health/rndtf/kenya11162005.html>. The draft resolution, in its preamble, cites a controversial report that had been issued by the UK Government in 2002 as the basis for moving forward on this initiative. See COMM'N ON INTELL. PROP. RTS., *INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY* (2002), available at [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfullfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf). Due to the international furor created by this UK report, the Kenyan delegation dropped that reference prior to submitting the final version for WHA consideration. See WHO, *Resolution from Kenya on a Global Framework on Essential Health Research and Development* (Jan. 20, 2006), available at <http://www.cptech.org/ip/health/rndtf/kenya01202006.html>.

176. While Brazil and Kenya have primarily been associated with this draft resolution, “[t]he governments of . . . Thailand and South Africa [also] played a particularly important role in moving this initiative forward . . .” James Love, *CPTech Statement on WHO EB Resolution on Global Framework for Essential Health R&D*, CPTech, Jan. 27, 2006, <http://lists.essential.org/pipermail/ip-health/2006-January/009037.html>.

177. See WHO, *Global Framework on Essential Health Research and Development* (Draft Resolution proposed by Brazil and Kenya), U.N. Doc. EB117/Conf.Paper No.3 (Jan. 24, 2006), available at [http://www.medico-international.de/kampagne/gesundheit/downloads/kenya-brazil-eb\\_20060124.pdf](http://www.medico-international.de/kampagne/gesundheit/downloads/kenya-brazil-eb_20060124.pdf) [hereinafter *Essential Health Research*].

178. See WHO, Executive Board Proposal, [*Global Framework On*] *Essential Health Research and Development*, at 2, U.N. Doc. EB117.R13 (Jan. 27, 2006), available at [http://www.who.int/gb/ebwha/pdf\\_files/EB117/B117\\_R13-en.pdf](http://www.who.int/gb/ebwha/pdf_files/EB117/B117_R13-en.pdf).

179. Although the WHO Executive Board had agreed to adopt the resolution during its 117th session, various portions of the text and several of the proposals remained open for discussion. It therefore recommended that a committee be established to review a forthcoming report expected during April 2006 from the WHO Commission on Intellectual Property Rights, Innovation and Public Health. See WHO, Jan. 23-27, 2006, *Report of the Executive Board on its 116th and 117th Sessions*, ¶ 17, U.N. Doc. A59/2 (May 11, 2006), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA59/A59\\_2-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_2-en.pdf).

tection of Human Rights and Intellectual Property Rights into the WHO.<sup>180</sup>

Three assumptions underlie this resolution's many points: 1) IPRs are not necessary to promote innovation since most (70%) "drug approvals are for medicines that do not provide incremental benefits over existing ones";<sup>181</sup> 2) IPRs "are [only] one of several important tools to promote innovation, creativity and the transfer of technology. . . ."; and 3) a "proper balance [must be provided] between [IPRs] and the public domain and IP rules . . . need to be . . . implemented 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."<sup>182</sup>

The draft resolution's authors thus sought to dramatically change the way research and development for new essential medicines is to be financed and conducted globally for the benefit of developing countries, taking into account the limited role that IPRs must ultimately play in such activities. The resolution, for this purpose, references all four of the IPR-related resolutions noted previously, and calls 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.<sup>183</sup> Although both the Governments of the United States and the EU have thus far opposed this resolution,<sup>184</sup> it has become a growing partisan politi-

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180. See 2000 Sub-commission Intellectual Property Resolution, *supra* note 151; 2001 Sub-commission Intellectual Property Resolution, *supra* note 158.

181. Essential Health Research, *supra* note 177, at 1. See Joseph A. DiMasi & Cherie Paquette, *The Economics of Follow-on Drug Research and Development Trends in Entry Rates and the Timing of Development*, 22 PHARMACOECONOMICS 1, 8-10 (Supp. 2 2004), available at <http://biag.org/BIAG/images/articles/art06.pdf> ("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."). *But see id.* at 10 (stating that other findings contradict the previous statement in that during recent studies, "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").

182. Essential Health Research, *supra* note 177, at 2.

183. *Id.* at 1 ("Recalling Resolutions WHA 52.19. . .WHA 54.10, WHA 56.27 and WHA 57.14. . ."). 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). *Id.*

184. See, e.g., Posting of Tove Iren S. Gerhardsen to Intellectual Property Watch, *US Declares Opposition to WHO R&D Resolution As Proponents Raise Questions*, May 22, 2006, <http://ip-watch.org/weblog/wp-trackback.php?p=311> (last visited Nov. 1, 2006); Posting of Ellen T. Hoen, [ellen.t.hoen@paris.msf](mailto:ellen.t.hoen@paris.msf), to Ip-health Archives, *NEWS*

cal issue on both sides of the Atlantic.<sup>185</sup>

The “alternative simplified IP systems referred to within draft resolution EB117/R.13 are likely ‘borrowed’ from the utopian archetypes provided by anti-free market, anti-IP HIV/AIDS activists,”<sup>186</sup> who, as a matter of ideology,<sup>187</sup> advocate the abandonment of drug patents in favor of a more government-centralized and state socialized system of R&D and healthcare.<sup>188</sup> That system, which would sanction the royalty-free copying of drug patents for public health policy reasons, would require 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 and are a fixed percentage of a nation’s Gross Domestic Product (GDP).<sup>189</sup>

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on *European Commission position at the WHA* (May 24, 2006, 11:07:01), <http://lists.essential.org/pipermail/ip-health/2006-May/009596.html> (last visited Nov. 1, 2006).

185. See Leavitt *supra* note 31; Sixty-four Members of the European Parliament, *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*, May 18, 2006, <http://www.cptech.org/ip/health/who/59wha/meps05182006.pdf>.

186. Susan K. Sell & Aseem Prakash, *Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights*, 48 INT’L STUD. Q. 143, 145, 154-55, 170 (2002) (“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.”).

187. Andrés Mejía-Vergnaud, *Drug Delusions at the WHO*, MANILA TIMES, May 02, 2005, available at <http://www.manilatimes.net/national/2006/may/20/yehey/opinion/20060520opi6.html> (“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.”).

188. Schultz & Walker, *supra* note 10, at 90.

189. Joseph A. DiMasi & Henry G. Grabowski, *Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D*, June 25, 2004, at 4, 16, available at <http://www.who.int/intellectualproperty/news/en/Submission3.pdf> (emphasis added); see also Tim Hubbard, Reply to the Comments Requested by CIPIH and WHO to the CPTech Proposal for a Med. Research and Dev. Treaty (MRDT) (Aug. 15, 2005), at 1-2, available at <http://www.who.int/intellectualproperty/submissions/SubmissionsHubbard.pdf>; Schultz & Walker, *supra* note 10, at 87 (citing Letter from James Love, Dir., CPTech, to CIPIH

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.<sup>190</sup>

In addition, there are apparently, still, other alternatives that have been submitted and evaluated. They include:

- 1) A proposal . . . for a mandatory employer-based research fee to be distributed through intermediaries to researchers (Love 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); and
- 4) A proposal . . . to finance pharmaceutical research through a set of competing publicly supported research centers (Kucinich 2004).<sup>191</sup>

One other proposal was to reward the development of new drugs using an evidence-based system regarding health outcomes.<sup>192</sup>

The objectivity of the academics that have promoted these alternatives to the current U.S. and international private property rights-based patent and R&D systems appears strained at best.<sup>193</sup>

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(Feb. 24, 2005), available at <http://www.cptech.org/workingdrafts/rndsignonletter.html>.

190. Kevin Outterson, *Nonrival Access to Pharmaceutical Knowledge*, Submitted to the CIPIH (Jan. 3, 2005), at 1, available at <http://www.who.int/intellectualproperty/submissions/KevinOutterson3january.pdf>.

191. See Dean Baker, *Financing Drug Research: What Are the Issues?*, CTR. FOR ECON. & POLY RES. (Sept. 21, 2004), at 3, available at [http://www.cepr.net/publications/intellectual\\_property\\_2004\\_09.htm](http://www.cepr.net/publications/intellectual_property_2004_09.htm).

192. See James Packard Love, *Drug Development Incentives to Improve Access to Essential Medicines*, 84 BULL. WORLD HEALTH ORG. 408 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/405.pdf> (discussing how H.R. 417, the Medical Innovation Prize Fund, was proposed by Representative Sanders [I-VT] during 2005 as “a working model for a new paradigm of drug development”).

193. “The immediate cause of high drug prices is government granted patent monopolies, which allow drug companies to charge prices that are often 400 percent,

In fact, at least one such academic has proposed that the U.S. Bayh-Dole Act be amended to legislatively impose a 'public interest limitation' on IPRs created as the result of federally funded basic research and development.<sup>194</sup> In addition, he has suggested that the U.S. Government surrender national sovereignty to the WHO by delegating power to the 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. . . ."<sup>195</sup>

Within this menu of multiple, murky, mystifying, and myopic options, lay two discernible certainties. First, no matter which

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or more, above competitive market prices." Baker, *supra* note 191, at Executive Summary. Indeed, Professor Baker's anti-patent and pro-government intervention views are not dissimilar to those held by other individuals whom he has credited in his report as giving "helpful comments on an earlier draft." *Id.* They include James Love, a healthcare and anti-intellectual property and anti-business activist (his controversial work is referenced throughout this article) and Simone Baribeau, researcher-activist-author and contributor to Marxist publication *Political Affairs*. See Politicalaffairs.net: Marxist Thought Online, <http://www.politicalaffairs.net/article/author/view/1118> (last visited Nov. 1, 2006). *Political Affairs* is a monthly magazine of partisan Marxist ideology, politics, and culture, and a publication of the Communist Party, USA. See About Us, Political Affairs - A Marxist Monthly, available at <http://www.politicalaffairs.net/article/static/17/1/3> (last visited Nov. 1, 2006); Dr. Aidan Hollis would seem to be in favor of greater governmental intervention in the healthcare markets. He is an assistant professor of economics at the University of Calgary in Alberta, who is credited with "devis[ing] a different approach [for stimulating drug innovation]: the government would set up a fund to compensate drug companies based on how much their new drugs improve the quality of life and how often they were used." Eduardo Porter, *Do New Drugs Always Have to Cost So Much?*, N.Y. TIMES, Nov. 14, 2004. Professor Hollis also authored an article that appears to have resonated with the WHO CIPIH. He also credits James Love for providing him with "helpful comments, questions and critiques which forced me to clarify my thinking." See Aidan Hollis, *An Optional Reward System for Neglected Disease Drugs* (Univ. of Calgary, Inst. of Health Econ., Working Paper Last Updated May 18, 2005), available at <http://econ.ucalgary.ca/fac-files/ah/optionalrewards.pdf> ("The essence of the proposal is to offer rewards to drug innovators who relinquish the exclusivity rights of their patents, with the rewards to be based on the incremental health effects of the innovation in developing countries."). Prof. Hay, a pharmaceutical economist and associate professor at the University of Southern California School of Pharmacy, also seems to be an advocate for more governmental intervention in the healthcare markets – i.e., in the pricing of medicines and medical treatments. See Joel W. Hay & Minnie M. Yu, *Drug Patents and Prices: Can We Achieve Better Outcomes*, in MEASURING THE PRICES OF MEDICAL TREATMENTS 152, 154 (Jack E. Triplett ed., 1999) ("[D]oes current policy for patent protection and monopoly pricing of innovative medications achieve the best possible outcomes for society? We will argue that the answer is emphatically negative . . ."); see generally *id.* at 152-94.

194. Jonathan Kahn, *Rights and Practical Access to Medicine*, 84 BULL. WORLD HEALTH ORG. 409 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/405.pdf>.

195. *Id.*

one of these idyllic alternatives is ultimately chosen, the individual private property rights of citizen-owners within OECD nations, especially the United States, are likely to be sacrificed without their consent for the ostensible (illusory) benefit of serving the global public interest, and perhaps even simultaneously rehabilitating 'Brand America.'<sup>196</sup> This is the end-result sought by anti-private property and anti-free market activists, academics, bureaucrats and politicians, who have painstakingly erected the opaque multilateral process that is now unfolding.

Television and written media focusing on the issue of HIV/AIDS have conveyed this message in a less than candid and transparent manner.<sup>197</sup> Beginning with a discussion of this devastating disease, recent television programming then implored individuals and corporations, as a matter of morality and human decency, to take all necessary actions in addition to underwriting taxpayer-funded government aid to eradicate HIV/AIDS internationally no matter the cost.<sup>198</sup> Through use of such an approach, this programming had, in effect, bypassed private property and economic concerns. As a result, an unsuspecting public is unaware that it has been denied an open and informed debate that sheds light on the many other debilitating global diseases for which additional funding, subsidization, and private property right sacrifices will also be required.<sup>199</sup>

Anti-private property and anti-free market activists, bureaucrats, academics and politicians are reluctant to publicize this kind of information, especially within the United States, because of the serious negative political ramifications it would have during election time. Tragically, developed nation citizens do not realize

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196. See e.g., Keith E. Maskus, *Reforming U.S. Patent Policy: Getting the Incentives Right*, COUNCIL ON FOREIGN RELATIONS CSR NO. 19, Nov. 2006, at 12, 15, 47, available at <http://www.cfr.org/content/publications/attachments/PatentCSR.pdf> (reasoning that because "patents and copyrights have become one of the most contentious issues in U.S. trade negotiations" with developing countries, the U.S. government's insistence that developing countries adopt U.S. IP protections for all privately owned U.S. patented pharmaceuticals and copyrighted recordings and movies, would only "generat[e] . . . [further] trading partner. . . citizen. . . resentment" against the United States) (emphasis added).

197. See CNN Presents: The End of AIDS: A Global Summit with Bill Clinton, (CNN television broadcast Apr. 29, 2006), available at <http://transcripts.cnn.com/TRANSCRIPTS/0604/29/cp.02.html>.

198. *Id.*

199. See WHA, *Declaration on the TRIPS Agreement and Public Health*, U.N. Doc. 57.14, ¶¶ 1, 4 (Nov. 20, 2001) (including broad language that covers almost any disease, now and in the future, that is characterized as having reached epidemic proportions).

that, although this appeal is now focused on and limited to HIV/AIDS drugs, it will eventually expand to include many other diseases and be used to curtail their private property rights in other economic areas beyond healthcare. In addition, the written media have more recently based their appeals for all corporations, including small and medium-sized enterprises, no matter where they are located, to contribute more than philanthropic aid, in order to eradicate HIV/AIDS based on the notion of corporate social responsibility.<sup>200</sup>

Any one of these choices will likely be prohibitively expensive from both an individual and societal perspective, as the OECD nations, including the United States, 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 being imposed in countries such as Australia, Canada, Japan, and the Member States of the EU, some of which are extremely proud of their social welfare systems, it is arguable that Americans are likely to bear most of these costs, especially in the near term. In fact, this concern was duly noted within a recent 2004 United States Commerce Department study evaluating pharmaceutical pricing in high income countries. It called for higher patented drug prices in Canada, Europe, Japan, Australia and other OECD countries in order to reduce the degree to which American consumers subsidize global drug development costs.<sup>201</sup>

*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. Implicit in this estimate is the assumption that about a third of incremental revenues would be spent on R&D. . . .*<sup>202</sup>

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200. See Richard Holbrooke & Mark Moody-Stuart, *Business Has Vital Role to Play in Fighting Aids*, FIN. TIMES (London) May 21, 2006, at 21, available at <http://news.ft.com/cms/s/e9c83790-e8f2-11da-b110-0000779e2340.html>; see also Carlo Stagnaro & Lawrence A. Kogan, *Corporate Social Restriction*, TCSDaily.com, Apr. 4, 2006, <http://www.tcsdaily.com/article.aspx?id=040406F>.

201. Outterson, *supra* note 190, ¶ 7.2.

202. *Id.* (citations omitted) (emphasis added).

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Despite the fact that U.S. taxpayers have continued individually<sup>203</sup> and collectively<sup>204</sup> to fund the world's largest HIV/AIDS relief programs<sup>205</sup> 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, and higher United States pharmaceutical prices.<sup>206</sup>

These certainties notwithstanding, the CIPIH continued its relentless assault on the WTO and WIPO-anchored international IP framework, primarily patents and trade secrets, with the release of its April 2006 report.<sup>207</sup> 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*

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203. See, e.g., Bill & Melinda Gates Foundation, Global Health, <http://www.gatesfoundation.org/GlobalHealth> (last visited Nov. 1, 2006).

204. See *Bush Touts Foreign HIV/AIDS Funding as 'Great Compassion' and 'In Our National Interest'*, MedicalNewsToday.com, <http://www.medicalnewstoday.com/medicalnews.php?newsid=37072> (last visited Nov. 1, 2006) ("[T]he 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 fifteen focus countries and provides funding to the Global Fund To Fight AIDS, Tuberculosis and Malaria.") [hereinafter *Bush Touts Foreign HIV/AIDS Funding*]; see also KaiserNetwork.org, *Daily HIV/AIDS Report, Politics and Policy: Bush Touts PEPFAR, Urges Congress to Reauthorize Ryan White CARE Act*, Dec. 2, 2005, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=34092](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=34092); U.S. Dep't of State Bureau of Oceans & Int'l Env'tl. & Sci. Aff., *Helping Those in Greatest Need: Fighting HIV/AIDS is a U.S. Priority*, Sept. 22, 2003, available at <http://www.state.gov/goes/rls/fs/2003/24196.htm>; Press Release, The Global Fund to Fight AIDS, Tuberculosis & Malaria (Dec. 1, 2006), available at [http://www.theglobalfund.org/en/media\\_center/press/pr\\_061201.asp](http://www.theglobalfund.org/en/media_center/press/pr_061201.asp)

205. See U.S. DEPT. OF STATE, INT'L INFO. PROGRAMS, FACT SHEET: IMPLEMENTING THE PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF, July 2, 2003, available at <http://usinfo.state.gov/gi/Archive/2003/Jul/03-85849.html>.

206. 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*, L.A. TIMES, June 3, 2006, at A14, available at <http://www.aegis.com/news/lt/2006/LT060602.html>.

207. See WHO, CIPIH, *Public Health, Innovation and Intellectual Property Rights*, U.N. Doc. 02/H434 (Apr. 2006), available at <http://www.who.int/intellectualproperty/documents/thereport/CIPIH23032006.pdf> [hereinafter WHO, *Public Health*]. The CIPIH had apparently deferred submission of its report to the WHO Executive Board for consideration at the prior January 2006 Executive Board meeting. See The Secretariat, WHO, *Intellectual Property Rights, Innovation and Public Health*, ¶ 1.4, U.N. Doc. EB 117/9 (Dec. 22, 2005), available at [http://www.who.int/gb/ebwha/pdf\\_files/EB117/B117\\_9-en.pdf](http://www.who.int/gb/ebwha/pdf_files/EB117/B117_9-en.pdf).



*to stimulate innovation* in the absence of a profitable market . . . which can apply in . . . developing country markets.<sup>208</sup>

It then premises its conclusions on several assumptions that seemingly reflect a preconceived anti-patent/private property ideology shared by several of the Commission's developing country members.<sup>209</sup> It seems "[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 IPRs may be limited or nonexistent."<sup>210</sup> Further,

[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.<sup>211</sup>

Consistent therewith, left-leaning academics have argued that, "misuse or waste of IP slows the development of new health technologies for developing countries."<sup>212</sup> A comprehensive review of the WHO report's assumptions and conclusions, however, reveals a broader anti-private property and anti-market agenda similar to that advanced by Brazil and Argentina in other international

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208. *Id.* at 10 (emphasis added).

209. *See id.* at 168, 171.

210. *See* Tomris Turmen & Charles Clift, *Public Health, Innovation and Intellectual Property Rights: Unfinished Business*, 84 BULL. OF THE WHO 338 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/338.pdf>.

211. WHO, *Public Health*, *supra* note 207, at 224 (emphasis added) (referencing the comments of Dr. Carlos and Dr. Pakdee Pothisiri in the report annex).

212. *See* Anatole Krattiger & Richard T. Mahoney, *Intellectual Property and Public Health*, 84 BULL. WORLD HEALTH ORG. 340 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/340.pdf> (citing E. van Zimmerman et al., *A Clearing-house For Diagnostic Testing: The Solution To Ensure Access To and Use Of Patented Genetic Inventions?*, 84 BULL. WORLD HEALTH ORG. 352 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/352.pdf>); David J. Winters, *Expanding Global Research and Development for Neglected Diseases*, 84 BULL. WORLD HEALTH ORG. 414 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/414.pdf>; S.F. Musungu, *Benchmarking Progress In Tackling The Challenges Of Intellectual Property And Access To Medicines In Developing Countries*, 84 BULL. WORLD HEALTH ORG. 366 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/366.pdf>.

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[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.<sup>214</sup>

At least two of the Commission's ten members criticized the report's assumptions and conclusions as lacking substantiation,<sup>215</sup> while a third disputed the main conclusion, that patent reform was necessary at all.<sup>216</sup>

Furthermore, the report recommends that an alternative open source/universal access cycle of innovation be developed in lieu of the linear innovation model employed in the United States.<sup>217</sup> It justifies this in terms of morality,<sup>218</sup> fairness (i.e., edu-

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213. See WHO, *WHO Bulletin Interview: Do Patents Work For Public Health? - Interview with Carlos Correa*, 84 BULL. WORLD HEALTH ORG. 349 (May 2006), available at [http://www.who.int/bulletin/volumes/84/5/who\\_news.pdf](http://www.who.int/bulletin/volumes/84/5/who_news.pdf).

214. WHO, *Public Health*, *supra* note 207, at 31.

215. See *id.* at 226-27. "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 market. . . . The report did not analyze the effects of patents on competition in developing countries . . .*" *Id.* at Comments of Dr. Hiroko Yamane (emphasis added).

216. See *id.* at 225; see also *id.* at Comments of Dr. Trevor Jones ("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."; *id.* at Comments of Dr. Favio Pammolli ("As for [IPRs], an undifferentiated recommendation . . . 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." (emphasis added)).

217. WHO, *Public Health*, *supra* note 207, at 35-39.

218. *Id.* at 21 ("Although much of this report is couched in the language of science,

educational reciprocity),<sup>219</sup> and by reference to the human right to health<sup>220</sup> (e.g., the ICESCR).<sup>221</sup> Civil society groups<sup>222</sup> and academics<sup>223</sup> have portrayed the right to health, for political purposes, as being distinguishable from, in conflict with, and having primacy over, economic rights such as private property rights-IPRs.<sup>224</sup> Although the report's conclusions<sup>225</sup> have failed to make this case successfully, they have since, nevertheless, been elevated within a recent draft CIPIH resolution to the level of a proposed global strategy and plan of action (i.e., the development of a proposed set of international guidelines/standards).<sup>226</sup> The long-term goal is for a newly established WHO intergovernmental working group to formalize the resolution into an international R&D and innova-

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medicine, economics, or law, it should not be forgotten that there is an underlying moral issue.”).

219. *Id.* at 166 (discussing the emigration of scientists from countries such as China and India to developed countries and their return to their home countries, bringing talent both to and from the nations).

220. Xavier Seuba, *A Human Rights Approach to the WHO Model List of Essential Medicines*, 84 BULL. WORLD HEALTH ORG. 405 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/405.pdf>.

221. See ICESCR, *supra* note 55.

222. WHO, *Public Health*, *supra* note 207, at 22 (referring to CESCR Article 12.1 and General Comment No. 14 to Article 12).

223. See Davinia Ovet, *Policy Brief on Intellectual Property, Development and Human Rights: How Human Rights Can Support Proposals for a World Intellectual Property Organization Development Agenda*, 3D → TRADE – HUMAN RIGHTS – EQUITABLE ECONOMY [3D] (Feb. 2006), available at [http://www.3dthree.org/pdf\\_3D/3DPolBrief-WIPO-eng.pdf](http://www.3dthree.org/pdf_3D/3DPolBrief-WIPO-eng.pdf) (“Strict IP rules have had an adverse impact on the ability of many governments to fulfill their human rights obligations, of which obligations to ensure access to affordable medicines, educational goods and adequate food.”); see also 3D, HUMAN RIGHTS AND THE ESTABLISHMENT OF A WIPO DEVELOPMENT AGENDA, INFORMATION NOTE 5 (June 2006), available at [http://www.3dthree.org/pdf\\_3D/3Dnote5\\_WIPO\\_June06.pdf](http://www.3dthree.org/pdf_3D/3Dnote5_WIPO_June06.pdf) (“[H]uman rights law requires impact assessments and evaluations of WIPO norm-setting and technical assistance in order to ensure that such activities do not impede the realization of human rights, nor constitute a move away from the realization of development objectives.”); *id.* ¶ D; 3D, TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS, ACCESS TO MEDICINES AND HUMAN RIGHTS – MOROCCO, ¶ 3 (April 2006), available at [http://www.3dthree.org/pdf\\_3D/3DCESCR\\_Morocco\\_April06Eng.pdf](http://www.3dthree.org/pdf_3D/3DCESCR_Morocco_April06Eng.pdf) (“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.”).

224. Seuba, *supra* note 220, at 406; see also Helena Nygren-Krug & Hans V. Hogerzeil, *Human Rights: A Potentially Powerful Force for Essential Medicines*, 84 BULL. WORLD HEALTH ORG. 410 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/405.pdf>.

225. See Elisabeth Rosenthal, *A WHO Report Finds System Fails the Poor*, INT’L HERALD TRIB. (May 21, 2006), available at <http://www.ihrt.com/articles/2006/05/21/news/who.php>.

226. See WHA, *CIP: Report*, ¶ 8, U.N. Doc. A59/16 Add.1 (May 18, 2006), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA59/A59\\_16Add1-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_16Add1-en.pdf).

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tion treaty.<sup>227</sup>

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 is intended: 1) To confirm for all time that WTO Members must, consistent with a broad reading of the Doha Declaration, 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 at the expense of private IP rights,<sup>228</sup> and 2) "[t]o initiate consultations on the possibility of elaborating a *framework convention* on research, development and innovation in public health in order define priorities and determine financing options."<sup>229</sup> The Swiss chair of a drafting group at the WHA has even proposed to merge the CIPIH resolution with the prior Brazil-Kenya resolution (that called for alternatives to the current international IP-patent framework) to accelerate commencement of this initiative.<sup>230</sup> A somewhat modified form of the CIPIH resolution was ultimately acceded to by the United States and adopted by the WHO at the recent WHA meeting (Resolution WHA 59.24).<sup>231</sup> Notwithstanding the resolution's 'softer' language, with the establishment of an intergovernmental working group to

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227. *Id.* ¶ 8.2[3] (stating that the resolution takes direct aim at U.S. bilateral free trade agreements' TRIPS-plus provisions, which urge Member States and, where applicable, regional economic integration organizations "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" (emphasis added)).

228. See WTO, Ministerial Declaration of 14 Nov. 2001, ¶ 17, U.N. Doc. WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002).

229. WHO, CIPIH, *Intellectual Property Rights: Report of the Meeting of the Committee of the Executive Board*, UN Doc. A59/16, Annex 1 (May 18, 2006).

230. See Posting of Tove Iren S. Gerhardsen & William New, *World Health Assembly Debates New Draft Text Merging IP Resolutions*, to INTELL. PROP. WATCH, <http://www.ip-watch.org/weblog/index.php?p=316&res=1280&print=0> (May 25, 2006).

231. See WHA, May 27, 2006, *Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action*, WHA59.24, U.N. Doc. A59VR/9, available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA59/A59\\_R24-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf) [hereinafter Resolution WHA 59.24]; Frances Williams, *WHO To Prompt R&D For Poorer Countries*, FIN. TIMES, May 29, 2006, at 4 ("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 also *WHO Agree "Breakthrough" Deal to Research and Develop Drugs*, M&C NEWS, May 27, 2006, [http://news.monstersandcritics.com/health/article\\_1167569.php](http://news.monstersandcritics.com/health/article_1167569.php).

“draw up a global strategy and plan of action,”<sup>232</sup> it is clear that the activists still intend to press for development and adoption of a binding treaty in the longer term.<sup>233</sup>

The WHO report and the subsequent resolution each fail, nevertheless, to substantiate (or prove) the need for IP reform. First, as a matter of logic, there is *no* such conflict between human rights and private property rights.<sup>234</sup> Second, as a matter of human rights law, Article 17 of the Universal Declaration of Human Rights 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.”<sup>235</sup> In fact, various other provisions within this seminal document, when read together with Article 17, as well as with certain provisions of the ICESCR, support the conclusion that there exists *no* hierarchy at all among the various types of human rights, whether health, education, or economic-related.<sup>236</sup>

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

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232. Resolution WHA 59.24, *supra* note 231, at 3(1); *see id.* at 3(3-4).

233. *See* Posting of James Love to <http://lists.essential.org/pipermail/ip-health/2006-May/009641.html> (May 29, 2006, 11:52:02) (“[T]he 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 . . .”).

234. Alchian, *supra* note 46 (arguing that private property rights do not conflict with human rights and moreover protect individual liberty as private property rights are the rights of humans to use specified goods and to exchange them; “restraint on private property rights shifts the balance of power from impersonal attributes toward personal attributes and toward behavior that political authorities approve.”).

235. *See* Universal Declaration of Human Rights, *supra* note 70, at art. 17.

236. *See id.* pmbl., arts. 2, 3, 8, 12, 17, 25, 27-29, 30; ICESCR, *supra* note 55, at pmbl., arts. 1.2, 2.2, 4, 5.1, 15.1, 15.3, 25; *see, e.g.*, *Abigail Alliance v. Von Eschenbach*, 445 F.3d 470, 486 (D.C. Cir. 2006) (interpreting federal statutory law and U.S. constitutional due process 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 Due Process Clause”). The Appellate Court subsequently denied the FDA’s Motion for Rehearing finding that Alliance had Article III standing to pursue the case on the merits. *See Abigail Alliance v. Von Eschenbach*, 469 F.3d 129 (D.C. Cir. 2006). Although there were no opposed *economic* interests at issue in this case at either the District or Circuit Court levels, some will nevertheless argue that the ruling recognizes the existence of such a hierarchy in the United States.

include: 1) establishing 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”);<sup>237</sup> 2) defining international aid requirements and related UN and member state foreign aid programs and budgets;<sup>238</sup> and 3) providing much-needed empirical evidence that healthy populations are indeed more productive and wealthy<sup>239</sup> to justify the need for international health care aid.

Fourth, a close inspection of the WHO report, itself, plus subsequently prepared CIPIH IGWG documents, will reveal the hidden agenda of these developing country governments and activist groups: to acquire U.S. and OECD nation scientific and technological know-how on the cheap by discrediting the current international and U.S. IP frameworks that protect it. In other words, by successfully convincing WHO member states that the current international and U.S. private IP rights-based scientific and technological discovery process is flawed and that the very successful medicines, vaccines, medical treatments, and biomedical innovations produced<sup>240</sup> as the result of the current international and U.S. private IP rights-based commercialization process are ‘over

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237. Dean T. Jamison et al., *International Collective Action in Health: Objectives, Functions, and Rationale*, 351 LANCET 514, 516 (Feb. 14, 1998).

238. *Id.*; see also WHO, Nov. 2, 2006, Intergovernmental Working Group on Pub. Health, Innovation and Intell. Prop. [IGWG], *Elements of a Global Strategy and Plan of Action*, U.N. Doc. A/PHI/IGWG/1/4 [hereinafter IGWG Nov. 2, 2006]; *id.* ¶ 7 (noting, as an area for action, the “provi[sion] [of] support for development of innovative capacity through investment by developing countries in human resources and the knowledge base, especially in tertiary education”); *id.* ¶ 8 (noting, as an area for action, “[i]mproved delivery, access and appropriate use could be addressed by encouraging governments to invest in the health-delivery infrastructure and in financing the purchase of medicines and vaccines through insurance”); *id.* ¶ 9 (noting, as an area for action, the “establish[ment] [of] a funding mechanism for research and development for neglected diseases”).

239. See JAMISON, *supra* note 51, at 7-9.

240. CIPIH, Public Health Innovation and Intellectual Property Rights, WHO 2006, 20-21, available at <http://www.who.int/intellectualproperty/report/en/index.html> (last visited Jan. 3, 2007) (discussing the UN Millennium project and concluding that “innovation for ‘medicines and other products’ must be situated within a wider picture of efforts across sectors to improve health and development,” defining “other products” to include not only those for improved diagnosis and prevention, but also low technology interventions that can be “brought to bear on complex public health challenges”); see also WHO, Dec. 8, 2006, IGWG, *Elements of a Global Strategy and Plan of Action – Progress to Date in the Intergovernmental Working Group*, annex 2, n.1, U.N. Doc. A/PHI/IGWG/1/5, available at [http://www.who.int/gb/phi/PDF/phi\\_](http://www.who.int/gb/phi/PDF/phi_)

priced,' Brazil and others will better be able to establish a new global anti-IP paradigm. Such a paradigm would establish the primacy of *public* health considerations over private property rights,<sup>241</sup> and thereby provide for the legal appropriation of U.S. IPRs for developing country public use and benefit at less than fair market value.<sup>242</sup> Fortunately, it may be reported that the Brazilian Government delegate to the CIPIH IGWG was somewhat frustrated by the lack of tangible progress in moving many of the work action items forward that Brazil had favored during the working group's most recent meetings<sup>243</sup> which they have criti-

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igwg1\_5-en.pdf [hereinafter IGWG Dec. 8, 2006] ("The term 'products' hereafter should be understood to include vaccines, diagnostics and medicines.").

241. See IGWG, Dec. 8, 2006, *supra* note 240, at annex 2, app. (referencing Comments of Libyan Arab Jamahiriya on behalf of the Eastern Mediterranean Region, "[t]hese statements of principles remain incomplete if we do not also refer to a third principle which completes the circle, and that is that *human public health considerations have precedence over rights to intellectual property protections.*" (emphasis added)).

242. See *id.* ¶ 2-3 ("The text in the annexes has not been the subject of an intergovernmental negotiation process. The basis of Annex 1 ["Elements of a Plan of Action"] was document A/PHI/IGWG/1/4 . . . . The text in Annex 2 ["Elements of a Global Strategy"] was prepared by the Secretariat at the request of the Working Group on the basis of material drawn from the Constitution, Health Assembly resolutions and other relevant sources."). This intergovernmental working group document clearly prefers to 'manage' foreign *private* IP in order to convert it to host country *public* IP, rather than to promote and create indigenous private IP; see also *id.* at annex, ¶ 6 ("Management of intellectual property. The plan of action should address the development of capacities for the management of intellectual property and technologies in developing countries. . . establish or work within national and/or regional institutional frameworks to promote and manage intellectual property . . . explore and implement alternative incentive schemes for research and development . . . strengthen education and training in the management of intellectual property. . . promote interrelation between national regulatory authorities for medicines and health products and intellectual property offices, and define a workplan for harmonization; focus on specific aspects of the intellectual property system, such as test data exclusivity, 'me-too' patents, and patent linkages." (emphasis in original omitted)).

243. See Posting of Tove Iren S. Gerhardsen, tgerhardsen@ip-watch.ch, to INTELL. PROP. WATCH, <http://www.ip-watch.org/weblog/index.php?p=484&res=1280&print=0> (Dec. 11, 2006) [hereinafter Gerhardsen, WHO Group Lays Foundation] ("Some countries had specific suggestions, such as Brazil . . . . Many of the omitted recommendations were brought back in during the week and are now reflected in the final paper, but Brazil still took issue with the process toward the end. Brazil told the meeting that the discussion paper, as of 7 December, was inadequate as it still did not reflect affordability and price of medicines, patent pooling and access to health *as an overriding human right* . . . . 'Everything Brazil found important is not in there' Sabina Voogd . . . told *Intellectual Property Watch* . . . [I]ssues highlighted in Brazil's submission, such as technology transfer to developing countries according to Article 7 of the WTO Agreement on [TRIPS], 'early working' exception and general encouragement of generic market entry upon patent expiry, data exclusivity regulations related to clinical trials data that delays the entry of generic medicines

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cized all along.<sup>244</sup>

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.<sup>245</sup> With respect to Brazil, at least one recent study 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.<sup>246</sup> In addition, there is widespread reporting of the Brazilian Government's failure to adequately address its urgent national public health care, education, pension and physical infrastructure needs,<sup>247</sup> of the Brazilian Government's rampant corruption scandals,<sup>248</sup> and of the Brazilian Government's questionable priority on spending hundreds of millions of dollars per year on an international image-enhancing space program.<sup>249</sup> As noted above, it is well recognized how sustained national spending on public health care improves a middle income or a developing country's long-term economic, technological and social productivity and attracts

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and ensuring strict application of the patentability criteria, were not included in the original draft." (emphasis added)).

244. *Id.* at 173 (formulating an approach to facilitating technology transfers, assuming that technology owners are willing to part with is, based in part on the TRIPS Agreement, which requires developed countries to provide incentives to their enterprises to promote and encourage the transfer of technology to least developed countries, and which involves enhancing the capacity of developing countries to receive and use complex technologies).

245. See CIVIL SOCIETY REPORT ON INTELLECTUAL PROPERTY, *supra* note 12. These failings were recognized by the WHO CIPIH intergovernmental working group; see also IGWG Nov. 2, 2006, *supra* note 238; IGWG Dec. 8, 2006, *supra* note 240, at annex 2, ¶ 5 ("[I]t is important to strengthen capacity of local public institutions and businesses in developing countries in order to contribute to, and participate in, research and development efforts (resolution WHA59.24).") (emphasis in original); *id.* ¶ 6 ("Capacity building is needed in developing countries in science and technology, regulation, clinical trials, the transfer of technology, traditional medicine, and intellectual property.").

246. See Libby Levison & Richard Laing, *The Hidden Costs of Essential Medicines*, ESSENTIAL DRUGS MONITOR 20-21 (2003), available at <http://mednet2.who.int/edmonitor> (follow hyperlink to EDM 33) (noting that 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.).

247. See, e.g., Buarque, *supra* note 5; see also WHO, *Public Health*, *supra* note 207, at Comments of Dr. Trevor Jones.

248. See, e.g., Gall, *supra* note 4, at 12; Jonathan Wheatley, *Fresh Corruption Charges Target Brazil's Deputies*, FIN. TIMES, May 11, 2006, at 6.

249. Schultz & Walker, *supra* note 10, at 89 (citing Dutra, *supra* note 10).



badly needed domestic *as well as* foreign investment.<sup>250</sup>

## 2. 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. Dr. Bernard Fabre-Teste, the WHO adviser for disease in the Western Pacific region, made a bold pronouncement.<sup>251</sup> He said that he supported developing countries' rights 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.<sup>252</sup> He believed that this could be accomplished either through aggressive use of the flexibilities contained within the 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.<sup>253</sup> Although Brazil was not mentioned as one of these countries, Fabre-Teste 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.<sup>254</sup> Apparently, the WHO and Fabre-Teste agree with Brazil that "[t]his kind of decision is really a sign of political commitment [for] public health."<sup>255</sup>

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.<sup>256</sup>

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250. See JAMISON, *supra* note 51, at 7-8 (noting that foreign investors "shun environments in which the labor force suffers a heavy disease burden").

251. See Meraiah Foley, *WHO Urges Nations to Bypass Patent Laws for HIV/AIDS Drugs*, ASSOCIATED PRESS, Sept. 22, 2005, available at <http://mmrs.fema.gov/news/publichealth/2005/sep/nph2005-09-26b.aspx>.

252. See *id.*

253. See *id.*

254. See *id.*

255. See *id.*

256. See Humberto Costa, *foreward to* HUMBERTO COSTA ET AL., *INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH 10* (Jorge A.Z. Bermudez & Maria Auxiliadora Oliveira eds., 2004), available at [http://www.who.int/intellectualproperty/submissions/Trips\\_ingles%20nova%20versao%202005.pdf](http://www.who.int/intellectualproperty/submissions/Trips_ingles%20nova%20versao%202005.pdf) (noting the recent development in the field of public health of

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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 right holder, all in the name of promoting the public interest – i.e., open source/universal access to health. This is perhaps why a regional bloc of nineteen Latin American and Caribbean nations confidently announced their execution of an agreement, in January 2006, to act collectively in an effort to reduce the price of HIV/AIDS drugs by, among other things, increasing their drug manufacturing capabilities.<sup>257</sup>

Judging from the 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.<sup>258</sup> Brazil remains one of two emerging economies with a growing generic drug manufacturing sector (the other is India) that, along with Egypt,<sup>259</sup> has thus far refused to both enact *and* implement WTO/TRIPS-consistent national legislation recognizing the exclusivity of undisclosed *health-related* clinical test data

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examining the implications of intellectual property rights on access to medicines, highlighted by the 49th World Health Assembly, during which the consequences of globalization and trade agreements on access to medicines was brought to the forefront).

257. See *19-Nation Bloc to Negotiate Price of AIDS Drugs*, CNN.COM, Jan 14, 2006, <http://www.procaare.org/archive/procaare/200601/msg00025.php>.

258. See Gerhardsen, WHO Group Lays Foundation, *supra* note 243 (referring specifically to data exclusivity).

259. See *Brazil fights for affordable drugs against HIV/AIDS*, 9 REV PANAM. SALUD PUBLICA [Pan. Am. J. Public Health] 331-337 (May 2001), available at <http://www.scielosp.org/pdf/rpsp/v9n5/5137.pdf> (noting that PhRMA has charged that Brazil is noncompliant with the "data exclusivity" provisions of TRIPS); Latha Jishnu, *Data Exclusivity: The Cost of Protecting Data*, BUS. WORLD, Jan. 26, 2004 (according to Dilip Shah, secretary-general of the Indian Pharmaceutical Alliance, which comprises some of the world's largest pharmaceutical companies, the IPA does not accept the principle of data exclusivity, and that India should not permit data exclusivity); Rehab El-Bakry, *Jagged Little Pills: Drug Makers Struggle with Pricing and Patents*, 21 BUS. MONTHLY, Apr. 2005, available at <http://www.amcham.org/eg/publications/BusinessMonthly/April%2005/coverstory.asp> (according to Magdy Rady, a former adviser to the minister of health, "only in cases where a drug is not already approved in a benchmark country does the Ministry of Health apply the . . . method . . . of drug testing and data gathering. In this case, the ministry requests that the drug company submits [sic] 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 . . . [b]ut this scenario has never actually taken place in Egypt.'").

and trade secrets.<sup>260</sup> Pharmaceutical and biotech companies typically submit this data to safety orientated regulators to secure pre-market authorization to commercialize their products.

Arguably, the CIPIH 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.<sup>261</sup> In fact, although a plain reading of TRIPS Article 39, which falls under Section 7 of the TRIPS agreement, entitled *Protection of Undisclosed Information*, reveals that its objective is to prevent the commission of the tort of *unfair* competition by protecting proprietary intellectual property rights inherent in both undisclosed information generally (trade secrets), and in the particular types of testing data and other information generated, composed, presented and submitted to governments or governmental agencies (which may or may not include trade secrets),<sup>262</sup> the WHO has denied that any such property right exists at all!<sup>263</sup>

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260. See Jon W. Dudas, Sec. of Comm'n for Intell. Prop. and Dir. of the U.S. Patent and Trademark Office, Remarks Prepared for Delivery to the Confederation of Indian Industries at the India International Center, New Dehli, India (Dec. 7, 2006), available at <http://newdelhi.usembassy.gov/pr120706.html> ("The U.S. Government would like to work with India to encourage the establishment of [TRIPS] - a consistent data protection regime for innovative pharmaceutical and agricultural chemical test data. Innovative pharmaceutical companies expend immense resources and capital to collect data for their clinical dossiers. Allowing third parties to rely on this information to obtain marketing approval without authorization of the right holder provides an unfair commercial advantage to third parties, creating a disincentive for innovative products to be developed and registered in India. As a result, the Indian population may have lower access to new medicines. It is my understanding that a growing number of Indian pharmaceutical companies, technology firms and educational and research institutions favor the development of a TRIPS-consistent data exclusivity regime. We will continue to encourage the Indian Government to implement this protection, which is consistent with Article 39 of the TRIPS Agreement." (emphasis added)).

261. See generally WHO, *Public Health*, supra note 207.

262. See CARLOS MARÍA CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENTS 9 (2002), available at <http://www.southcentre.org/publications/protection/protection.pdf> (arguing that the requirement for member countries of TRIPS to establish protections for submitted test data is narrowly drawn, and allows for substantial flexibility of implementation in favor of the public's interest in promoting competition, driving down price, and affording greater accessibility to medicines); *id.* at 55 ("Unfair competition' [is] defined as 'any act of competition contrary to honest commercial practices in industrial or commercial matters.'" (quoting Paris Convention for the Protection of Industrial Property of March 20, 1883, art. 10bis, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305)); *id.* at 44-45 (citing STEPHEN LADAS, 3 PATENTS, TRADEMARKS, AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION (1975)).

263. WHO, *Public Health*, supra note 207, at 143 (arguing that Article 39.3 of the TRIPS agreement creates neither property rights, "nor a right to prevent others from

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Interestingly, at least one of the WHO report's authors has articulated for international consumption a series of arguments to justify this interpretation.<sup>264</sup> Unfortunately, his position, that the meaning to be ascribed to a particular 'unfair' circumstance or practice will vary from country to country as a matter of cultural diversity<sup>265</sup> and national law,<sup>266</sup> is aimed at reframing the legal technical discussion about data exclusivity into a debate about cultural preferences, which is likely to be 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.<sup>267</sup> Lacking the necessary

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relying on the data for the marketing approval of the same product by a third party, or from using the data, except where [dishonest] commercial practices are involved," this is in contrast to some countries, such as the United States, that have adopted *sui generis* regimes prior to TRIPS which grants that 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).

264. See CORREA, *supra* note 262.

265. See *id.* at 39 ("The concept of 'unfair' is relative to the values of a particular society at a given point in time. It varies among Members, and this variation is in fact one of the premises on which the discipline of unfair competition is grounded. There is no absolute universal rule to determine when certain practices should be deemed unfair . . .").

266. This commentator states that the legal doctrine of unfair competition protects fairness in commercial activities, and lists a number of acts that certain WTO members have considered "fair" and "honest" practices in commercial behavior. See *id.* at 55 ("They may include competitor's misrepresentation, fraud threats, defamation, disparagement, enticement of employees, betrayal of confidential information commercial bribery, among others. In many but not all jurisdictions, the misappropriation of trade secrets is regulated under unfair competition law, as is the case with the TRIPS Agreement."). He also states that, given such cultural diversity, it is inevitable that some countries "may consider it an 'unfair practice' for a 'follower' company to commercially benefit from the data produced by the originator, via a marketing approval system based on 'similarity'; or hold that such commercial benefit gives rise to claims of 'unjust enrichment' leading to a compensation for the use of the data. In others, it may be regarded as the legitimate exploitation of an externality created during legitimate competition in the market." *Id.* at 40 (citations omitted) (emphasis added).

267. See ELISABETTA MINELLI, WORLD HEALTH ORGANIZATION: THE MANDATE OF A SPECIALIZED AGENCY OF THE UNITED NATIONS, [http://www.gfmer.ch/TMCAM/WHO\\_Minelli/P1-4.htm](http://www.gfmer.ch/TMCAM/WHO_Minelli/P1-4.htm); see also Posting of Tove Iren S. Gerhardsen, tgerhardsen@ip-watch.ch, *US Advises Developing Country FTA Partners Not to Follow WHO IP Plan*, to INTELL. PROP. WATCH, <http://www.ip-watch.org/weblog/index.php?p=485&res=1280&print=0> (Dec. 11, 2006) (discussing how U.S. developing country trading partners received an e-mail "in the form of a 'démarche' from the US Government before the 4-8 December meeting of the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights. The demarche said that it had become apparent that the WHO was trying to go beyond its competency and address intellectual property rights and trade, which could have impact on the scope and

WHO membership consensus, at the present time, to establish a supranational global governance framework for public healthcare, some organizations have embarked on a global mission to promote a variant of the distinct international relations concept known as 'shared sovereignty.'<sup>268</sup> Shared sovereignty, in the context of international health,<sup>269</sup> has been defined as requiring the creation of public international goods at the expense of nationally sanctioned private property rights.<sup>270</sup> Brazil, a proponent of this version of 'shared sovereignty,' "expressed concern that the ['plan of action' and 'strategy'] documents [developed at the December 2006 meeting of the CIPIH IGWG] did not refer to medicines as being considered a *public good* or that access to health is an overriding human right."<sup>271</sup> Thus, there can be no doubt that the Brazilian

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effect of FTAs, according to a government source. This, the email said, and the proposed global framework described in World Health Assembly resolution WHA59.24 from May this year, could potentially harm the patent system. The United States was therefore proposing a more 'pragmatic' solution, as it appeared the WHO tried to go beyond its technical expertise, the source said.").

268. See Stephen D. Krasner, *Sharing Sovereignty: New Institutions for Collapsed and Failing States*, INT'L SECURITY, Fall 2004, at 85-120 (discussing how pursuant to the concept of 'shared sovereignty,' arrangements are created under which "individuals chosen by international organizations, powerful states, or ad hoc entities would share authority with nationals over some aspects of domestic sovereignty. . . . Ideally, shared sovereignty would be legitimated by a contract between national authorities and an external agent. In other cases, external interveners may conclude that the most attractive option would be the establishment of a de facto trusteeship or protectorate. Under such an arrangement, the Westphalian/Vatellian sovereignty of the target polity would be violated, executive authority would be vested primarily with external actors, and international legal sovereignty would be suspended. There will not, however, be any effort to formalize through an international convention or treaty a general set of principles for such an option." (footnotes omitted)).

269. See Jamison, *supra* note 237, at 515 (arguing that because individual nation states are unlikely to give up sovereignty in favor of supranational governance, the problems of collective action in the area of health could in theory be resolved by the alternative method of "shared sovereignty, whereby individual nation states pool their resources into a multilateral organization or their commitments into an international treaty").

270. *Id.* (arguing that nation states sharing rather than giving up sovereignty must define the special functions for which international collective action is essential, and that 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 . . . two core functions to address these problems are the promotion of international public goods and the surveillance and control of international externalities," which in turn require research and development, information and databases capable of facilitating sharing across countries, harmonized norms and standards for national use, and regulation of the growing number of international transactions).

271. Riaz K. Tayob, *Who's Mandate on IPRs Defended by South Against US Attack*, THIRD WORLD NETWORK, Dec. 14, 2006, <http://www.twinside.org.sg/title2/health.info/twninfohealth060.htm> ("The United States seemed to be challenging the mandate of

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Government has long played a leading role in the international effort to weaken exclusive individual private property rights.<sup>272</sup>

And, if all of this were not yet enough, the Health Ministers of Brazil and other Latin American countries very recently issued their own public anti-private property declaration.<sup>273</sup> 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.<sup>274</sup> It also asserts that it is the sovereign duty and obligation of every government to ensure the fulfillment of such right.<sup>275</sup> In order to satisfy this responsibility, the declaration expressly voices commitment to the utilization of 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.<sup>276</sup> It is therefore arguable that the Latin American Declaration seeks to undermine bilateral free trade agreements reached between the United

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the World Health Organisation to deal with issues relating to intellectual property rights and public health, when the WHO's inter-governmental working group on public health, innovation and intellectual property met here last week . . . . The US position was strongly opposed by several developing countries, including Brazil, Iran, Chile and Cuba.”)

272. *See, e.g.*, MINELLI, *supra* note 267 (noting that participation to the preparatory process in the Framework Convention on Tobacco Control (FCTC) 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’” (quoting Brazilian Ambassador Celso Amorin, Remarks at the Meeting of Interested Parties (2002)).

273. *See generally*, Posting of Thiru Balasubramaniam to IP-Health, Unofficial English Translation of Declaration of Ministers of South America Over Intellectual Property, Access to Medicines and Public Health, <http://www.lists.essential.org/pipermail/ip-health/2006-May/009594.html> (May 24, 2006, 09:05:03). The original Spanish version was signed by the Ministers of Health from Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay and Venezuela on May 23, 2006.

274. *Id.*

275. *See id.*

276. *Id.* *But see* Int'l Fed'n of Pharm. Mfg. & Ass'n, *World Health Assembly Resolution Recognizes IP is Important Incentive for Development of New Health-Care Products*, May 31 2006, <http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=5022> (attempting to put a positive ‘spin’ on the WHA resolution).

States and Chile,<sup>277</sup> Peru<sup>278</sup> and Colombia.<sup>279</sup>

### 3. Brazil's IPR Regime Shifting from WTO to UNEP/CBD

Brazil is also assisting developing nations and global activists to re-characterize otherwise lawful (WTO/TRIPS and WIPO-consistent) recognition and protection of exclusive privately owned life science (genetic resource) patents in compounds extracted and derived from plants and other forms of biodiversity as potential violations of international environmental law, unless sweeping changes are made to the international IPR framework to ensure

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277. Chile has been a U.S. bilateral trading partner since 2003. The US-Chile Free Trade Act was approved by the U.S. House of Representatives on July 23, 2003. President Bush signed domestic legislation implementing the obligations assumed by the United States under the agreement on September 3, 2003. It should be noted that the Lagos administration in office at the time was not associated with the left-wing of that country's socialist party as was the successor Bachelet administration now in power. See Press Release, Office of the U.S. Trade Representative, United States and Chile Sign Historic Free Trade Agreement (June 6, 2003), [http://www.ustr.gov/Document\\_Library/Press\\_Releases/Section\\_Index.html](http://www.ustr.gov/Document_Library/Press_Releases/Section_Index.html) (follow hyperlink for 2003 Press Releases, then follow June 6, 2003 hyperlink); Press Release, Office of the U.S. Trade Representative, Zoellick Statement Following House Approval of Chile and Singapore FTAs (July 23, 2003), [http://www.ustr.gov/Document\\_Library/Press\\_Releases/Section\\_Index.html](http://www.ustr.gov/Document_Library/Press_Releases/Section_Index.html) (follow hyperlink for 2003 Press Releases, then follow July 23, 2003 hyperlink); Press Release, White House, President Bush Signs Chile, Singapore Free Trade Agreements (Sept. 9, 2003), <http://www.whitehouse.gov/news/releases/2003/09/20030903-3.html>; Roberto Espindola, *Chile's New Era*, OPENDEMOCRACY.COM, Jan. 16, 2006, <http://www.opendemocracy.net/debates/article.jsp?id=3&debateId=33&articleId=3181>.

278. The U.S.-Peru Trade Promotion Agreement was signed by both parties on April 12, 2006. See OFFICE OF THE U.S. TRADE REPRESENTATIVE, PERU TPA FACTS, FREE TRADE WITH PERU: SUMMARY OF THE U.S.-PERU TRADE PROMOTION AGREEMENT (Dec. 2005), available at [http://www.ustr.gov/assets/Document\\_Library/Fact\\_Sheets/2005/asset\\_upload\\_file490\\_8547.pdf](http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2005/asset_upload_file490_8547.pdf); Press Release, Office of the U.S. Trade Representative, United States and Peru Sign Trade Promotion Agreement (Apr. 12, 2006), [http://www.ustr.gov/Document\\_Library/Press\\_Release/Section\\_Index.html](http://www.ustr.gov/Document_Library/Press_Release/Section_Index.html) (follow hyperlink for 2006 Press Releases, then follow April 12, 2006 hyperlink).

279. The US-Colombia Trade Promotion Agreement contains IP provisions virtually identical to those contained in the US-Peru agreement. It was concluded during late February 2006 and signed by both parties on November 22, 2006. See OFFICE OF THE U.S. TRADE REPRESENTATIVE, TRADE FACTS: FREE TRADE WITH COLOMBIA: SUMMARY OF THE AGREEMENT 4-5 (Feb. 27, 2006), available at [http://www.ustr.gov/assets/Document\\_Library/Fact\\_Sheets/2006/asset\\_upload\\_file485\\_9023.pdf](http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2006/asset_upload_file485_9023.pdf); Press Release, Office of the U.S. Trade Representative, United States and Colombia Conclude Free Trade Agreement (Feb. 27, 2006), available at [http://www.ustr.gov/Document\\_Library/Press\\_Releases/Section\\_Index.html](http://www.ustr.gov/Document_Library/Press_Releases/Section_Index.html) (follow hyperlink for 2006 Press Releases, then follow Feb. 27, 2006 hyperlink); Press Release, Office of the U.S. Trade Representative, United States and Colombia Sign Trade Promotion Agreement (Nov. 22, 2006), available at [http://www.ustr.gov/Document\\_Library/Press\\_Releases/Section\\_Index.html](http://www.ustr.gov/Document_Library/Press_Releases/Section_Index.html) (follow hyperlink for 2006 Press Releases, then follow Nov. 22, 2006 hyperlink).

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the harmonization of these two regimes.<sup>280</sup> Brazil has opportunistically promoted such changes in recent negotiations among the parties to the UNEP CBD, which entered into force in 1992.<sup>281</sup> The treaty's objective is to conserve biological diversity, to promote the sustainable use of genetic resources, and to ensure that any benefits flowing from their use are fairly and equitably shared.<sup>282</sup> Although the CBD was originally intended to "protect[] intellectual property rights as part of a package of treaty commitments that mediate competing claims of industrialized and developing countries," this "approach to intellectual property protection has evolved in ways that could not have been predicted from a simple reading of the CBD's text."<sup>283</sup>

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280. The Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) has devoted considerable attention to harmonizing intellectual property rights (sanctioned by the WTO/TRIPs Agreement) with the CBD's objectives. See Helfer, *Regime Shifting*, *supra* note 120 (citing Intersessional Meeting on the Operations of the Convention on Biological Diversity, June 1999, U.N. Doc. UNEP/CBD/ISOC/5 (May 11, 1999)); JONATHAN CURCI STAFFLER, TOWARDS A RECONCILIATION BETWEEN THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE TRIPs AGREEMENT 33-34 (Sept. 2002), available at <http://www.iucn.org/themes/pbia/themes/trade/training/Reconciliation%20Between%20CBD%20and%20TRIPs.pdf> ("It is argued that the potential benefits flowing from conservation and exploitation of biological diversity as called for by the CBD are jeopardized under a global regime of private monopoly rights . . . In this situation, governments and communities will have little means of regulating access or demanding a share of benefits because they will be subject to private ownership."); *id.* at 34 ("[A]n IPR regime without derogations, namely inflexible, can first of all seriously hinder the environmentally-sound technology transfer among States, and particularly from industrialized countries to developing ones.").

281. See Secretariat of the Convention on Biological Diversity, *Sustaining Life on Earth: How the Convention on Biological Diversity Promotes Nature and Human Well-Being*, Apr. 2000), at 5, available at <http://www.biodiv.org/doc/publications/cbd-sustain-en.pdf> ("At the 1992 Earth Summit in Rio de Janeiro, world leaders agreed on a comprehensive strategy for 'sustainable development' - meeting our needs while ensuring that we leave a healthy and viable world for future generations. One of the key agreements adopted at Rio was the Convention on Biological Diversity."); Kelly Day-Rubenstein & Paul Heisey, *Plant Genetic Resources: New Rules for International Exchange*, AMBER WAVES, June 2003, at 22 [hereinafter Day-Rubenstein], available at <http://www.ers.usda.gov/Amberwaves/June03/Features/PlantGeneticResources.htm> ("The U.N. Convention on Biological Diversity (CBD) was established, with a focus on the preservation of biodiversity, especially those genetic resources *with pharmaceutical and industrial rather than agricultural uses.*" (emphasis added)).

282. See Helfer, *Regime Shifting* *supra* note 120, at 30.

283. *Id.* at 28 (stating that the CBD provisions were intended to facilitate the *quid pro quo* transfer of proprietary technologies to developing states for access to genetic resources, where "biotechnology-poor developing countries sought financial benefits and technology transfers as incentives to conserve rather than exploit the genetic resources within their borders . . . [and by contrast where] Biodiversity-poor but biotechnology rich industrialized states [] sought to minimize benefits and transfers while maximizing access to those resources.").



The Government of Brazil has worked with other nations to exploit broad language within the treaty text according intellectual property right protection for genetic resources residing in developing countries to promote the nationalization of those resources and the creation of new IP right categories not recognized by the TRIPS and WIPO agreements.<sup>284</sup> IPR-related CBD negotiations have thus 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 applications.”<sup>285</sup> The TRIPS Agreement requires neither.<sup>286</sup> The CBD text focuses considerably on the issue of access.<sup>287</sup> Apparently, these governments have discovered the inherent value of

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284. Commentators have long observed that CBD Article 15(4) and (5) require CBD parties to obtain the prior consent of other CBD parties on mutually agreed upon terms, in order to secure access to genetic resources. They have also cited CBD Article 15(7), which anticipates that legal measures, including IPRs may be used, and therefore “call[ing] on Parties to take legislative, administrative or policy measures to ensure the benefits arising from research, development and commercial use of genetic resources are shared in an equitable way with the provider of the genetic resources.” CATHERINE MONAGLE, CTR. FOR ENVTL. & INT’L L. [CEIL], REVIEWING INTELLECTUAL PROPERTY RIGHTS IN LIGHT OF THE OBJECTIVES OF THE CONVENTION ON BIOLOGICAL DIVERSITY – JOINT DISCUSSION PAPER 4 (Mar. 2001), <http://www.ciel.org/Publications/tripsmay01.PDF> (footnote omitted).

285. See Helfer, *Regime Shifting*, *supra* note 120, at 29 n.119 (“[T]he terms ‘traditional knowledge’ and ‘indigenous knowledge’ refer to knowledge that is ‘held collectively (at the community or national level),’ has been ‘used for generations by local communities and [has] contributed to the development of crop varieties, food security and medicines, as well as the emergence and continuation of artistic work in the form of music, handicrafts and artisanship.” (citation omitted)); STAFFLER, *supra* note 280, at 33 (“The categories of IPRs traditionally recognized in [the] TRIPS Agreement are not completely adequate to guarantee the protection of practices and the knowledge held by local and indigenous communities which have informally crystallized along the centuries and which play an outstanding role in the conservation of biological diversity.”).

286. *Id.* at 29-30 (noting that TRIPS does not require that (1) the traditional knowledge of indigenous communities’ as such be protected, (2) applicants seeking intellectual property protection provide information about the origin of genetic resources, (3) the sharing of financial or technological benefits of biodiversity-related patents and plant innovations with source countries or communities, and (4) members consider unwritten traditional knowledge as a form of ‘prior art,’ thus permitting such knowledge to be patented in its original form).

287. See *id.* at 31 (arguing that the CBD recognizes a state’s “sovereign right to control genetic resources within their borders and to determine conditions of access to them, [where] access may be granted only upon mutually agreed terms and subject to the prior informed consent of the state providing the resources;” such access may be conditioned upon a promise of “compensation, technology transfers, or other benefits should those innovations prove commercially profitable”).

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IPRs, at least, on a national ownership level, and now aim to secure and allocate it to themselves as against the otherwise legitimate claims and interests of private third party developed country companies that rely upon them to innovate.

In early 2005, for example, Brazil and other parties proposed the creation of a new international IPR treaty that sanctions the nationalization of biodiversity and any derivative IP.<sup>288</sup> It calls for tighter patent rules to prevent misappropriation of their 'sovereign' biological resources and to ensure fair sharing of benefits arising from their use.<sup>289</sup> 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."<sup>290</sup> Their "chief concern was 'biopiracy,' 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."<sup>291</sup>

A proposed treaty would, if adopted as a final text, most likely become a Protocol to the UN CBD. Brazil and other like-minded nations have opposed an alternative market-based approach that involves execution of individual private agreements governing access to and use of genetic resources.<sup>292</sup> They argue that such approach would require them to police their own biodiversity, and

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288. See Priya Shetty, *Biodiverse Countries Call For Tighter Patent Rules*, SCI. & DEV. NETWORK, Feb. 28, 2005, <http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=1954&language=1>. Brazil is a member of the Like-Minded group of Mega-diverse Countries (LMMCs) which contain most of the world's biodiversity.

289. See *id.*

290. *Id.*

291. *Id.*; see also Alan Oxley, *The Phantom Menace*, TCSDDAILY, Mar. 21, 2006, <http://www.tcsdaily.com/article.aspx?id=032106F> [hereinafter *Phantom Menace*] (defining 'biopiracy' as "either the misuse intellectual property (when patents or trademarks are erroneously issued) or restricting the access of foreign companies to genetic resources"); see also Alan Oxley, *Green Gold and Cargo Cults*, TCSDDAILY, Mar. 29, 2006, <http://www.tcsdaily.com/article/asp?id=032906A> [hereinafter Oxley, *Green Gold*] (noting that 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.").

292. Alan Oxley, *A Healthy Dose of Property Rights is Good Medicine*, BANGKOK POST, Feb. 18, 2005, at 1, available at <http://www.williams.edu/go/native/moreipr.htm> [hereinafter Oxley, *Healthy Dose*] (noting that while countries like Costa Rica have entered into private agreements granting drug companies access to their genetic resources, countries like Brazil have proposed the creation of an international convention granting the country from which the patented material was sourced the right to determine how products based on a patented invention from it would be used).

that entails significant economic costs.<sup>293</sup> A more important reason is that a (regulatory) convention would permit them to control how products *derived from* their biological resources can be used by others.<sup>294</sup> This would consequently provide them with economic benefits to which they would not otherwise be entitled under the TRIPS and WIPO agreements. In effect, “[e]ven 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.”<sup>295</sup>

Interestingly, a largely parallel framework has arisen in connection with the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which had been recognized several years ago (in 2002) as contributing to the three objectives of the CBD.<sup>296</sup> Although the ITPGRFA falls under the auspices of the UN Food and Agriculture Organization (FAO)<sup>297</sup> and engen-

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293. See Shetty, *supra* note 288.

294. See *id.*

295. See Oxley, *Healthy Dose*, *supra* note 292.

296. See Secretariat of the CBD, Statement by Dr. Ahmed Djoghlaif, Executive Secretary, Convention on Biological Diversity to the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture at it[s] first Session, at 2 (June 12, 2006) [hereinafter Statement by Dr. Djoghlaif], *available at* <http://www.biodiv.org/doc/speech/2006/sp-2006-06-12-itpgrfa-en.doc> (“At its sixth meeting, in 2002, the Conference of the Parties to the Convention on Biological Diversity recognized that the International Treaty on Plant Genetic Resources for Food and Agriculture will have an important role for the conservation and sustainable utilization of agricultural biological diversity, for facilitating access to plant genetic resources for food and agriculture, and for the fair and equitable sharing of the benefits arising out of their utilization. *It thus recognized that your Treaty will make a significant contribution to the achievement of the three objectives of the Convention in the strategic area of agricultural biodiversity.*” (emphasis added)).

297. See Executive Secretary of the CBD, Compilation of Submissions Provided by Parties, Governments, Indigenous and Local Communities, International Organizations and Relevant Stakeholders Regarding an Internationally Recognized Certificate of Origin/Source/Legal Provenance, Addendum, Submission by the International Agriculture Research Centres of the Consultative Group on International Agriculture Research [CGIAR], at 3, U.N. Doc. UNEP/CBD/GTE-ABS/1/3/Add.2 (Dec. 13, 2006) [hereinafter UNEP Compilation of Submissions], *available at* <http://www.biodiv.org/doc/meetings/abs/absgte-01/official/absgte-01-03-add2-en.pdf> (“The Treaty [ITPGRFA] is in harmony with the CBD. The scope of the Treaty is all PGRFA [plant genetic resources for food and agriculture]. The Treaty creates, *inter alia*, a multilateral system of access and benefit-sharing (MLS).”); Day-Rubenstein, *supra* note 281, at 27-28 (“[The ITPGRFA] mandates the conservation and sustainable use of plant genetic resources for food and agriculture. . .seeks fair equitable sharing of benefits arising out of the use of these resources [and]. . .establishes a multilateral system to facilitate access to all crops listed. . .and to share the benefits derived from such facilitated access under the terms of a standard Material Transfer Agreement (MTA) . . . established by the [treaty’s]

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ders contentious intellectual property rights and benefit sharing issues of its own, its evolution may likely inform the IP debate surrounding the CBD.<sup>298</sup> Indeed, the scope of Brazil's proposed international IPR treaty is likely intended to cover the subject matter of both the CBD and the ITPGRFA (chemical and pharmaceutical as well as agricultural food and feed-based genetic resources), given their similar objectives,<sup>299</sup> the ongoing cooperation between their secretariats<sup>300</sup> and Brazil's recent ratification of

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Governing Body."); CLAUDIO CHIAROLLA, U.N. UNIV., FAO INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES AND FARMERS' RIGHTS, [http://www.ias.unu.edu/redirect\\_UNU.aspx?ddlID=191&catID=35](http://www.ias.unu.edu/redirect_UNU.aspx?ddlID=191&catID=35) ("Article 9.2 of the International Treaty provides that 'the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments.' Thus, this provision does not contain an international obligation like that imposed by the . . . TRIPS agreement.").

298. For example, Treaty Article 12.3(d) provides that "recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System." See ITPGRFA, opened for signature Nov. 3, 2001, art. 12.3(d) (entered into force June 29, 2004) [hereinafter ITPGR], available at <ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRRe.pdf>; KALPAVRIKSH (INDIA) & GENETIC RESOURCES ACTION INTERNATIONAL, THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES: A CHALLENGE FOR ASIA 5-6 (Feb. 2002), [http://www.grain.org/briefings\\_files/it-asia-feb2002-en.pdf](http://www.grain.org/briefings_files/it-asia-feb2002-en.pdf) [hereinafter KALPAVRIKSH] ("Thus, *the lack of a clear ban on patents or any other IPRs on crops for food and fodder* is troublesome to farmers' and civil society organisations. The Treaty envisages the commercialisation of plant genetic resources in the context of benefit sharing, *but does not mention IPRs as the basis for benefit sharing*, as the biotech industry would have liked. The industry . . . does not support the treaty as *the IPR provisions are ambiguous* and there is a lack of reference to contractual agreements for access and benefit sharing. . . [It] is a compromise; IPRs on genetic resources have not been excluded, there is no guarantee against the commercialisation of the genetic resources and there is no clarity on benefit sharing from commercial use. Nonetheless. . . [i]ssues relating to farmers' rights, *intellectual property rights* and international agricultural research can all be dealt with at the international level through the space the Treaty provides." (emphasis added)).

299. See ITPGR, *supra* note 298, at 12.3(a); UNEP Compilation of Submissions, *supra* note 297, at 3.

300. See Statement by Dr. Djoghlaif, *supra* note 296, at 2-3 ("Articles 19 and 20 of the Treaty and decision VI/6 of the Conference of the Parties to the Convention on Biological Diversity require cooperation between the secretariats and the governing bodies of the two instruments. I am pleased that we were able quickly to conclude a memorandum of cooperation between the Convention Secretariat and the interim Secretariat of the Treaty. I can assure you that the Convention Secretariat will continue to work closely with the Treaty Secretariat to ensure that the two instruments go forward in continued harmony."); see also Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at Its Eighth Meeting, March 20-31, 2006, Curitiba, Brazil, at 180, 204-212, 216, U.N. Doc. UNEP/CBD/COP/8/31, available at <http://www.biodiv.org/doc/decisions/COP-08-dec-en.pdf> (referring to Decisions regarding cooperation with other conventions and international organizations and initiatives, and agricultural biodiversity).

the latter.<sup>301</sup>

According to at least one commentator, there is also a political reason/message that underlies Brazil's CBD proposal. It is clearly anti-patent, anti-private property, anti-free market, and anti-WTO.<sup>302</sup> For all of these reasons, it may be appropriate to perceive Brazil's continuous efforts to putsch this proposal forward as a neo-Marxist attempt to nationalize ('take' in 'trust' for the public for ostensible 'public use')<sup>303</sup> natural resources that actually provide benefits to the state or to favored private individuals, irrespective of the costs to both foreign *and* domestic private investors.<sup>304</sup> Alternatively, one may interpret Brazil's international proposal as being rooted in the more locally-focused historic Roman and English common law 'public trust doctrine,' pursuant to which all natural resources, including air, are currently susceptible to environmental regulation 'for the benefit of the public.'<sup>305</sup>

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301. See Press Release, Embassy of Brazil in London, Brazil Ratifies International Treaty on Plant Genetic Resources for Food and Agriculture (May 23, 2006), <http://www.brazil.org.uk/newsandmedia/pr20060523.html>.

302. See Oxley, *Healthy Dose*, *supra* note 292 ("Klaus Topfler, the [former] head of the United Nations Environment Programme underlined 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)).

303. It has been claimed that, through national regulation of genetic resources in compliance with the CBD and the ITPGRFA, participating national governments and government-supported and/or private Centres of the Consultative Group on International Agricultural Research (CGIAR) "are bound to hold designated germplasm 'in trust for the benefit of the international community', and 'not to claim ownership, or seek intellectual property rights over the designated germplasm and related information.'" See KALPAVRIKSH, *supra* note 298, at 5 (citations omitted in original). Whether such entities will actually resist 'taking' natural resources for their own benefit or to redistribute national wealth to favored citizens is largely subject to question.

304. See Oxley, *Green Gold*, *supra* note 291 ("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 access' (i.e. stop foreigners) to these genetic resource [sic] 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.*" (emphasis added)).

305. See ED OWENS, CITIZENS FOR RESPONSIBLE WILDLIFE MGMT., FOR THE GOOD OF THE PEOPLE (July 2001), [http://www.nrpa.com/public\\_trust.htm](http://www.nrpa.com/public_trust.htm) (explaining the public trust doctrine); *id.* at n.1 ("While interpretations vary, the premise that Saxon and Norman kings 'owned' all that they ruled is the basis most commonly cited to justify the premise that hunting of game and wildlife management responsibilities

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No doubt, even American environmental extremists and apologetic political multilateralists would prefer this approach.<sup>306</sup> In addition, at least one study has likened an access and benefit sharing (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 fifty percent and twenty percent respectively.<sup>307</sup>

Cynicism aside, the Government of Brazil has taken its participation in the CBD process very seriously, and is 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*, which was then passed on to the CBD Conference of the Parties (COP) for consideration at their subsequent meeting, held in Curitiba, Brazil, in late March 2006.<sup>308</sup>

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are elements of the historical record associated with the public trust doctrine.”); WIS. CONST. art. IX, § 1 (discussing the public trust doctrine and its roots in English common law); see also Patrick S. Ryan, *Application of the Public-Trust Doctrine and Principles of Natural Resource Management to Electromagnetic Spectrum*, 10 MICH. TELECOMM. & TECH. L. REV. 285 nn.1-6 (2004).

306. See David Kaye et al., Op-Ed., *Pacts Americana?*, N.Y. TIMES, Dec. 15, 2006 (“What can the incoming Democratic Congress do to help reverse the steep erosion of America’s standing abroad, particularly the impression that the United States has disengaged from global problem-solving? . . . the Senate can . . . approve a raft of treaties awaiting action. . . . Early approval of key agreements in areas of great international concern, like the environment. . . would show the world that the United States is committed to solving global problems. . . . There is a pressing need to repair America’s image now. . . . Approving treaties from [the following] list would make a good start.”). These include the UN CBD, the UN Stockholm Convention on Persistent Organic Pollutants and the UN Convention on the Law of the Sea. See *id.*; see also John Pomfret, *Schwarzenegger Remakes Himself as an Environmentalist*, WASH. POST, Dec. 23, 2006, at A01.

307. TIMOTHY A. WOLFE & BENJAMIN ZYCHER, PACIFIC RES. INST., BIOTECHNOLOGICAL AND PHARMACEUTICAL RESEARCH AND DEVELOPMENT INVESTMENT UNDER A PATENT-BASED ACCESS AND BENEFIT SHARING REGIME, AUSTRALIA, 1 (2005), [http://www.pacificresearch.org/pub/sab/health/2005/ABS\\_EU\\_LMMC.pdf](http://www.pacificresearch.org/pub/sab/health/2005/ABS_EU_LMMC.pdf) (“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.”).

308. See Chee Yoke Ling, *New CBD Meeting Ends with Draft Elements of ABS Regime*, SOUTH-NORTH DEV. MONITOR (Feb. 7, 2006), [http://www.choike.org/nuevo\\_eng/informes/3946.html](http://www.choike.org/nuevo_eng/informes/3946.html) (“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.”); *CBD COP-8 Highlights: Monday, 27 March 2006*, EARTH NEGOTIATIONS BULL., Mar. 28, 2006, at 1, available at <http://www.iisd.ca/download/pdf/enb09359e.pdf> (“Marina Silva, Brazil’s Minister of the Environment, instilled a sense of responsibility to mainstream

At least until April 2006, sufficient developed country government and industry opposition appeared to exist to the draft ABS convention text introduced in Curitiba to temporarily place it 'on ice' until 2010, and away from the TRIPS Agreement.<sup>309</sup> However, the ground, apparently, had already begun to shift, as the result of civil society's heightened concerns about the negotiation of new bilateral free trade agreements alleged to be in conflict with the CBD.<sup>310</sup> And, the TRIPS Council's February 2006 review of the CBD-TRIPS relationship did not help matters any.<sup>311</sup>

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,<sup>312</sup> to promote harmonization between CBD and TRIPS. On May 29, 2006, Brazil and India proposed an amendment to the TRIPS Agreement, Article 29, that was supported by a number of

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environmental issues into public policy, especially cross-cutting issues such as ABS [and] 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.”)

309. See also Posting of Tove Iren S. Gerhardsen, tgerhardsen@ip-watch.ch, *Decision on International Regime On Genetic Resources Postponed Until 2010*, to INTELL. PROP. WATCH, <http://www.ip-watch.org/weblog/index.php?p=260&res=1024&print=0> (Apr. 4, 2006) (stating that 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”).

310. See Mario Osava & Haider Rizvi, *Biodiversity: Progress at a 'Multilateral Pace'*, INTER PRESS SERV. NEWS AGENCY, Apr. 1, 2006, <http://www.ipsnews.net/news.asp?idnews=32740> (noting the heightened urgency created by the race against free trade agreements, and the attendant antagonism between the CBD and the WTO at the expense of natural resources).

311. See WTO, Council for TRIPS, *Note by the Secretariat: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, U.N. Doc. IP/C/W/368/Rev.1 (Feb. 8, 2006), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/ipcw368\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf).

312. See Pascal Lamy, Director-General, WTO, Videoconference Address to the Opening Session of the European Commission's Green Week 2006 in Brussels, Belgium (May 30, 2006), available at [http://www.wto.org/english/news\\_e/sppl\\_e/sppl28\\_e.htm](http://www.wto.org/english/news_e/sppl_e/sppl28_e.htm) (stating that the “Appellate Body of the WTO has repeatedly confirmed that WTO rules are not to be interpreted in isolation of other bodies of law . . . . 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 . . . . The issues of access to genetic resources, of prior informed consent and of benefit sharing are currently being explored in the WTO. . . . 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 also Ocheltree, *supra* note 126.

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developing countries.<sup>313</sup> 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.”<sup>314</sup> 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, though with certain caveats.<sup>315</sup> Brazil and India warmly welcomed the Norwegian proposal.<sup>316</sup>

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 (or commercial) innovations can be derived. They represent nothing less than patent opportunism

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313. See Posting of Tove Iren S. Gerhardsen, tgerhardsen@ip-watch.ch, *Developing Countries Propose TRIPS Amendment on Disclosure* to INTELL. PROP. WATCH, <http://ip-watch.org/weblog/index.php?p=323&res=1280&print=0> (June 1, 2006) [hereinafter Gerhardsen, *Developing Countries Propose*]; Posting of Tove Iren S. Gerhardsen, tgerhardsen@ip-watch.ch, *Brazil, India, Get Developed Country Support for TRIPS Amendment on Biodiversity*, to INTELL. PROP. WATCH, [http://www.ip-watch.org/weblog/index\\_test.php?p=332](http://www.ip-watch.org/weblog/index_test.php?p=332) (June 15, 2006); *Doha Work Programme*, *supra* note 127.

314. See *Doha Work Programme*, *supra* note 127, ¶¶ 1-2 (establishing “a mutually supportive relationship between this [TRIPS] 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”); see also Ocheltree, *supra* note 126.

315. See General Council, Trade Negotiations Comm., *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*, ¶ 1, U.N. Doc. WT/GC/W/566, TN/C/W/42 (June 14, 2006), available at [http://www.ip-watch.org/files/Norway Proposal.doc](http://www.ip-watch.org/files/Norway%20Proposal.doc) (“The TRIPS Agreement and the Convention on Biological Diversity (CBD) can and should be implemented in a mutually supportive manner. . . . However, 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.” (emphasis added)); Gerhardsen, *Developing Countries Propose*, *supra* note 313 (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.”).

316. See Gerhardsen, *Developing Countries Propose*, *supra* note 313.



cloaked in more diplomatic international regulatory harmonization and free technology transfer development language.

*B. Brazil Actively Promotes a New International Paradigm of 'Open Source' / 'Universal Access' to Knowledge*

1. Open Source Methods

A new paradigm of 'open source' methods is being advanced by Brazil and other developing countries in international fora to further facilitate 'regime shifting.' Although the notion of open source methods was not invented by them, the opportunistic Brazilian Government and a group of similar-minded developing nations<sup>317</sup> immediately recognized its 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.<sup>318</sup> Both he and the organization are known for their socialist leanings.<sup>319</sup> According to these advocates, open source methods are intended to operate as a 'gift' rather than a 'market' economy. And, although such methods were originally applied to computer software,<sup>320</sup> they are now being extended nationally and interna-

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317. 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.' See Int'l Env't Governance Dossier, Friends of Development, <http://www.stakeholderforum.org/fod.html> (last visited Jan. 3, 2007) ("During the 31st Session of the WIPO General Assembly (September 27 to October 5, 2004), the delegations of Argentina, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Egypt, Iran, Kenya, Peru, Sierra Leone, South Africa, Tanzania and Venezuela co-sponsored a proposal to establish a 'Development Agenda' for the World Intellectual Property Organization. The group of countries is commonly referred to as the Group of Friends of Development. The basic concern of the Group of Friends of Development is to ensure that WIPO activities and intellectual property discussions are driven towards development-oriented results.").

318. See The Young Foundation, About, Introduction, <http://www.youngfoundation.org/uk/?p=2> (last visited Nov. 13, 2006).

319. *Id.*; see also The Young Foundation, About, Personal Profiles, Staff, Geoff Mulgan, <http://www.youngfoundation.org.uk/?p=32> (last visited Nov. 13, 2006).

320. See GEOFF MULGAN ET AL., WIDE OPEN: OPEN SOURCE METHODS AND THEIR FUTURE POTENTIAL, DEMOS 9-10 (2005), available at <http://www.demos.co.uk/publications/wideopen> (follow "Full Text as a PDF" hyperlink) (explaining that open source software is any computer software distributed under a license which allows users to change or share the software's source code). Different kinds of open source

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tionally to other industry sectors that have nothing at all to do with software, including biosciences and pharmaceuticals.<sup>321</sup> 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 restricted to the creators and people they choose to sell the knowledge to.”<sup>322</sup> 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.<sup>323</sup>

And some have persuaded their governments to act on it. In May 2005, for example, the Government of France announced its intention to establish and support a legal framework under its bilateral science and technology agreement with China that “ensure[s] the sustainable development of ObjectWeb . . . [an open source software platform] . . . as a major process for Sino-European collaboration.”<sup>324</sup> In light of the French software and telecommunications industries’ diminishing European and international market share,<sup>325</sup> one should question whether France was motivated to consummate this agreement more by competition than innovation needs.

Apparently, certain American business executives, scientists and academics, as well, have taken a fancy to open source methods,<sup>326</sup> but for all of the wrong reasons. Representing open source methods as supportive of the public good of intellectual capital

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software share the core similarity that “they insist that the source code be made available whenever a piece of software is used, distributed, or modified.” *See id.* at 11.

321. *See id.* at 8-9 (adding that the application of open source methods to wider areas of social and economic life is attractive given that promise of huge returns from relatively little investment, as well as a sense that non-professionals outside big corporations now have a chance to beat those corporations at their own games).

322. *Id.* at 10.

323. *See, e.g.,* Brazilian Studies, *supra* note 14, at Summary of Presentation by Dr. Christian Ahlert.

324. Press Release, *ObjectWeb to Expand Intercontinental Collaboration on Industrial Open-Source Software*, OBJECTWEB.ORG, May 13, 2005, <http://www.objectweb.org/phorum/read.php?admview=1&f=25&i=121&t=121>.

325. *See* Martin Arnold, *France Failing to Close Hi-Tech Gap*, FIN. TIMES, Apr. 26, 2006, at 5 (noting that given that the combined revenues of France’s top 100 software companies is still smaller than the three biggest companies in the software sector, Microsoft, Oracle, and SAP, France’s inability to compete against the likes of Microsoft and Apple has likely triggered trade protectionism); *see also* Tom Braithwaite, *France to Take Bite Out of Apple Monopoly on iTunes Digital Downloads*, FIN. TIMES, Mar. 21, 2006, at 6; Braithwaite, *Threat to Apple*, *supra* note 78, at 19; Rob Pegoraro, *France Takes a Shot at iTunes*, WASH. POST, Mar. 26, 2006, at F06.

326. *See* Sam Palmisano, *The Information Puzzle*, NEWSWEEK, Nov. 28, 2005, at 54.

rather than the private good of intellectual property,<sup>327</sup> they have aggressively promoted open source methods as a new global knowledge paradigm for the development of public international goods in the information *and* health sectors.<sup>328</sup> In fact, in 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.<sup>329</sup>

Indeed, the growing open source movement that 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.<sup>330</sup>

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327. See *id.* (arguing that IBM's position on being a leading investor and innovator in open source movement is not contradictory, but driven by underlying patterns shaping innovation towards a balanced approach between open source and open standards, and between intellectual property and intellectual capital).

328. See Kenneth Neil Cukier, *Open Source Biotech: Can a Non-Proprietary Approach to Intellectual Property Work in the Life Sciences?*, ACUMEN J. OF LIFE SCI. (2003), available at <http://cukier.com/writings/opensourcebiotech.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.")

329. See Letter from Members, Consumer Project on Technology, to Dr. Kamil Idris, Dir. Gen. WIPO (July 7, 2003), available at <http://www.cptech.org/ip/wipo/kamil-idris-7july2003.pdf> ("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." (emphasis added)).

330. See James Love & Ralph Nader, *What to Do About Microsoft?*, LE MONDE DIPLOMATIQUE, Nov. 1997, <http://mondediplo.com/1997/11/nader>; Ralph Nader & James Love, *Ralph Nader Tells Feds to Stop Microsoft*, CNN.COM, Nov. 11, 1998, available at <http://www.cnn.com/TECH/computing/9811/11/nader.idg/index.html>; James Love, *Nader Colleague Responds*, INFO. WK., June 13, 2002, available at <http://www.informationweek.com/story/IWK20020613S0004>; James Love, *CPT Urges Gore to Reverse Policy on South African Policies Regarding Access to HIV/AIDS Drugs, Other Medicines*, COMMON DREAMS NEWSWIRE, Apr. 9, 1999, available at <http://www.commondreams.org/pressreleases/april99/040999i.htm>; Ralph Nader, *A Framework for ICANN and DNS Management*, proposal submitted to Governing the Commons: The Future of Global Internet Administration Conference organized by Computer Professionals for Social Responsibility in Alexandria, VA, Sept. 25, 1999, [http://www.eff.org/Infrastructure/DNS\\_control/ICANN\\_IANA\\_IAHC/](http://www.eff.org/Infrastructure/DNS_control/ICANN_IANA_IAHC/)

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They claim, in effect, that traditional intellectual property rules often have the effect of restricting rather than encouraging the competition for new ideas.<sup>331</sup> For this reason, the movement seeks to transplant what they perceive to be the collegial ‘open sharing’ work ethic in academia and the sciences into industry.<sup>332</sup>

While it is easy to see why developing country governments would gravitate towards and seek to exploit any opportunity to acquire free and open source software (FOSS),<sup>333</sup> it should be noted that there is actually more than one licensing model of FOSS to choose from,<sup>334</sup> and the definition of ‘open source’ software itself remains “very much in flux.”<sup>335</sup> This raises several important questions: which of the two primary FOSS licensing models does the Government of Brazil and the Friends of Development (FoD) seek to establish as the new international IP paradigm – the GNU

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19990927\_nader\_icann\_coms.html; Letter from Ralph Nader & James Love to Madeleine Albright, Secretary of State (Feb. 18, 1999), available at <http://www.cptech.org/ip/health/cl/mafeb181999.html>.

331. See Virginia Barbour et al., *The Impact of Open Access Upon Public Health*, 84 BULL. OF THE WORLD HEALTH ORG. 339 (May 2006), available at <http://www.who.int/bulletin/volumes/84/5/339.pdf>.

332. See Cukier, *supra* note 328 (“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 . . . likely to expand well beyond software design.”). Such areas may include biotechnology and bioinformatics, given that there well may be moral imperatives facing the biotechnology industry that propel it in the direction to improve and preserve life.

333. See Sholto MacPherson, *The Penguin Sees Red*, CIO GOVT., Jan. 17, 2005, <http://www.cio.com.au/index.php/id;1491647901;fp;4;fpid;21> (“In June 2003 the financial daily Valor announced plans to migrate 80 percent of all computers in state institutions and state-owned businesses from Windows to Linux over a three-year period. The stated goals were to save money, foster the production of local software and ‘democratize access to knowledge,’ according to Amadeu . . . . In the same month [t]he [Brazilian] House of Representatives announced it would not renew Microsoft Office licenses and was considering free software alternatives. The House also migrated to a free software e-mail system . . . . Since June 2004, Amadeu believes that taking software development in-house does much more than free Brazil from the relatively powerless role of consumer. The bulk of money spent on developing open source software for government is marked for local software developers, keeping Brazilian currency . . . within the country and improving trade debt. In turn this would lead to greater employment in the software sector and a more advanced skill base, which could write and fix source code instead of simply administering the software. These new skills would improve local administration and support services and could be exported to other countries that have been slower to move towards open source.”).

334. See Melise R. Blakeslee & Brian E. Ferguson, *United States: The Truths and Myths of Open Source Software*, MCDERMOTT WILL & EMERY (May 31, 2006), <http://www.mondaq.com/article.asp?articleid=40128>.

335. AM. BAR ASS’N SECTION OF INTELL. PROP. L, AN OVERVIEW OF “OPEN SOURCE” SOFTWARE LICENSES, <http://www.abanet.org/intelprop/opensource.html> (last visited Jan. 3, 2007).

General Public License (GPL) or the Berkeley Software Distribution License (BSD)?<sup>336</sup> How do they intend to apply their preferred open source model to the health care sector?<sup>337</sup> And, is this same model favored by European governments and industry, and by American companies?

Pursuant to the GPL model, software authors who would otherwise possess or be entitled to exclusive private property rights (copyrights) in their expressed creations (i.e., the right to *exclude* others from use, reproduction and derivative works and distribution),<sup>338</sup> affirmatively waive those rights, including the right to profit from them, when contributing their work to the software collective.<sup>339</sup> They do so in exchange for the right to receive attri-

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336. See Blakeslee & Ferguson, *supra* note 334 (stating that a number of alternatives and variations and tensions exist between the two types of licenses); Steve Kingstone, *Brazil Adopts Open-Source Software*, BBC NEWS, June 2, 2005, <http://news.bbc.co.uk/1/hi/business/4602325.stm> (“Increasingly, Brazil’s Government ministries and state-run enterprises are abandoning Windows in favour of ‘open source’ or ‘free’ software, like Linux . . . [Sergio Amadeu of the National Institute for Information Technology explains] ‘If you switch to open source software, you pay less in royalties to foreign companies.’”).

337. For one answer to this question, see KRISHNA RAVI SRINIVAS TRIPS, ACCESS TO MEDICINES AND DEVELOPING NATIONS: TOWARDS AN OPEN SOURCE SOLUTION (Nov. 2006), <http://ssrn.com/abstract=952435> (analyzing the solution of Open Source as a potential model for drug discovery).

338. See EBEN MOGLEN, FREE SOFTWARE MATTERS: ENFORCING THE GPL 1 (Aug. 12, 2001), <http://emoglen.law.columbia.edu/publications/lu-12.pdf> (“The essence of copyright law, like other systems of property rules, is the power to exclude. The copyright holder is legally empowered to exclude all others from copying, distributing, and making derivative works. This right to exclude implies an equally large power to license—that is, to grant permission to do what would otherwise be forbidden.”).

339. See Stephen Fishman, *Open Source Licenses Are Not All the Same*, ONLAMP, Nov. 18, 2004, <http://www.onlamp.com/pub/a/onlamp/2004/11/18/licenses.html> (“The GPL (General Public License) . . . require[s] that all software constituting a single work fall under the GPL if any of the software used in the work is GPL . . . . If a license contains a strong copyleft provision, anyone who modifies the source code and distributes it to the public must license the modifications back to the public under the same terms as the original software. This means that you must give up private ownership of any changes you make to copyleft software, unless you elect not to make the modified software available publicly.”); cf. Letter from Ed Black, Founder, Open Source and Industry Alliance, to Lois Boland, Acting Director of the U.S. Patent & Trademark Office, Office of International Relations (Aug. 22, 2003), [http://www.osaia.org/documents/pto\\_letter\\_032108.pdf](http://www.osaia.org/documents/pto_letter_032108.pdf) (“[T]he GPL and the BSD are not ‘waivers’ of intellectual property rights, but assertions of them. Instead of receiving a royalty fee for the license, the open source licensor is receiving something that might be of even greater value – access to the licensee’s creative output. Significantly, the licensee’s subsequent creative output benefits not only the licensor, but also the entire community of open source developers and users. In turn, the creative outputs of these other open source developers benefit the original licensor and licensee, as well as the open source community as a whole.”).

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bution, as a matter of contract (or license).<sup>340</sup> They then leverage that resulting legal contract right to compel future creators of derivative works to waive also their otherwise *exclusive* private property rights. This ensures that they, too, will *not* profit from their creations.<sup>341</sup> As a result, the software standard remains ‘open’ indefinitely, with the effect of forcing more code into the open community.<sup>342</sup> This type of restriction is referred to as a ‘copyleft,’<sup>343</sup> as opposed to a ‘copyright,’ and it serves to remove the software from the ‘public domain.’<sup>344</sup>

The operating system Linux is “available under the GNU General Public Licence (GPL), which is designed to *eliminate*

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340. See *Open Source Software and the Free Software Movement: The Committee on Information and Technology*, 61 RECORD OF THE ASS'N OF THE BAR OF THE CITY OF N.Y. 325, 330 (2006) [hereinafter RECORD], available at <http://www.nycbar.org/Publications/THERECORD.htm> (follow hyperlink for 2006 Issue 2). Legal experts have debated whether GPL is a license rather than a contract; Mitchell L. Stoltz, *The Penguin Paradox: How the Scope of Derivative Works in Copyright Affects the Effectiveness of the GNU GPL*, 85 B.U. L. REV. 1439, 1446-47 (2005) (footnotes omitted).

341. See Richard Stallman, *Copyleft: Pragmatic Idealism*, <http://www.gnu.org/philosophy/pragmatic.html> (last visited Jan. 3, 2007) (“[F]ree software is motivated by an idealistic goal: spreading freedom and cooperation. I want to encourage free software to spread, replacing proprietary software that forbids cooperation, and thus make our society better. That’s the basic reason why the GNU General Public License is written the way it is - as a copyleft. All code added to a GPL-covered program must be free software, even if it is put in a separate file. I make my code available for use in free software, and not for use in proprietary software, in order to encourage other people who write software to make it free as well. I figure that since proprietary software developers use copyright to stop us from sharing, we cooperators can use copyright to give other cooperators an advantage of their own: they can use our code.”).

342. See Blakeslee & Ferguson, *supra* note 334.

343. See *GNU Project, What is Copyleft?*, <http://www.gnu.org/copyleft/copyleft.html> (last visited Jan. 3, 2007) (“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 . . . . 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 . . . . 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. 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.’” (emphasis in original)).

344. See Blakeslee & Ferguson, *supra* note 334.

*closed source software.*<sup>345</sup> 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,<sup>346</sup> 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 been known to invalidate. Newly formed and existing small and medium-sized hi-tech businesses, in particular, would be adversely affected by such restrictions if they serve as a disincentive for venture capitalists to invest in their companies. The GPL license furthermore is arguably analogous to a 'house of cards' waiting to fall if, for no other reason, its terms remain insufficiently clear and misunderstood by existing and potential parties.<sup>347</sup> As experience has shown, however, if any single member of the GPL collective violates the terms of this communal contract (e.g., as concerns 'derivative works'),<sup>348</sup> it is likely to trigger a dom-

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345. LEMIS, Explaining BSD, <http://www.lemis.com/bsdpaper.html> (last visited Nov. 22, 2006) (emphasis added).

346. See Stoltz, *supra* note 340, at 1442 n.19 ("Professor Margaret Jane Radin has questioned whether a conditional copyright license like the GPL can bind anyone who uses the licensed software, whether they have voluntarily entered a contract with the copyright owner or not." (footnote omitted)).

347. See RECORD, *supra* note 340, at 326 ("The Association is firmly of the view that, when it comes to GPL, ambiguity should be dispelled to the maximum extent possible. [On the one hand] . . . activity that is arguably violative of Version 2 of the GPL has not been challenged, or not been challenged consistently, in order not to discourage the widespread use of open source software. On the other hand, rather than concede the desirability of compromise with free software principles, there appears to be a reluctance to expressly clarify the GPL to make such activity permissible. The hope seems to be that ambiguity will discourage and limit the extent of such activity. The Association believes that there is too much at stake to perpetuate such ambiguity in Version 3. While there may be a 'gentlemen's agreement' in some quarters of the free software community that certain types of activity will be tolerated, even if in technical violation of the GPL, not every contributor to an open source program necessarily subscribes to such a 'gentlemen's agreement,' and the potential for being subjected to copyright infringement litigation, and monetary and injunctive relief, is a significant risk for potential licensees.").

348. See Stoltz, *supra* note 340, at 1441-42, 1444 ("The limitations and exceptions of copyright also limit copyleft. In particular, the boundaries of copyright law's definition of a derivative work determine to which versions and revisions the GPL applies. For software, the definition of a derivative work is uncertain, because the boundaries separating one distinct 'work of authorship' from another are hard to fix in a computer system of many tightly interwoven components. Under what circumstances can two programs be said to combine into one, instead of simply being two programs that interact with each other? When two programs interact closely enough to be considered a new, hybrid program (a derivative work of both programs), the GPL's terms dictate that it must apply to the whole. The legal question of when two interacting programs form a derivative work will determine how broadly the GPL

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ino effect of copyright infringements (and/or perhaps contract breaches) along the entire chain of creations, and thus, a potential litigation free-for-all amongst its members.<sup>349</sup>

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.<sup>350</sup> However, once a company reduces such services to a uniform, standardized and repeatable process, thereby commoditizing them, its cost of developing them and the price it may charge clients for providing them should 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 service companies to establish their individual niches. 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.<sup>351</sup> The hope is that companies can and will develop new proprietary value-added consulting services for which clients are willing to pay higher fees.

Pursuant to the BSD model, on the other hand, businesses

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applies, and whether it can help preserve the cooperative values of FOSS development. If copyright law does not recognize a derivative work where two programs interact in common ways, the GPL copyleft regime may contain an enormous loophole for proprietary exploitation. . . This Note focuses on one ambiguity that affects the GPL: the scope of what constitutes a derivative work.”)

349. See e.g., Robert Jacques, *SCO Slams IBM's GPL Linux Defense*, INFOMATICS, Sept. 30, 2003, <http://www.infomaticsonline.co.uk/vnunet/news/2123380/sco-slams-ibm-gpl-linux-defence>; Robert McMillan, *SCO: IBM Cannot Enforce GPL*, INFO WORLD, Oct. 27, 2003, [http://www.infoworld.com/article/03/10/27/HNScoenforce\\_1.html](http://www.infoworld.com/article/03/10/27/HNScoenforce_1.html); Jay Lyman, *SCO Claims Linux GPL is Unconstitutional*, TECHNEWSWORLD, Oct. 28, 2003, <http://www.technewsworld.com/story/31975.html>; Sean Michael Kerner, *GPL Awaits Test in SCO Group/IBM Dispute*, ENTERPRISE, Jan. 23, 2004, <http://www.internetnews.com/ent-news/article.php/330280>; *IBM Goes for SCO Jugular in Test of GPL Validity*, LINUXDEVICES.COM, Aug. 19, 2004, <http://www.linuxdevices.com/news/NS9902827613.html>; *SCO Group, Inc. v. Int'l Bus. Machines Corp.*, No. 2:03CV0294 DAK, 2006 WL 2938820 (D. Utah Sept. 1, 2006); Eric Raymond, *OSI Position Paper on the SCO-vs.-IBM Complaint*, OPEN SOC'Y INST., <http://www.opensource.org/sco-vs-ibm.html>.

350. Blakeslee & Ferguson, *supra* note 334.

351. See Richard Waters, *IBM Repackages Its Brain Power*, FIN. TIMES, July 11, 2006, at 12 (arguing that Mr. Palisano of IBM is trying to reinvent the services industry by “[t]urning services, which by definition are delivered by people, into repeatable processes where IBM can get economies of scale” by isolating and standardizing many of the components that go into such assignments. This “mak[es] it easier to apply the same processes to subsequent projects”, resulting in the blurring of the line between the services and software business models, which in turn means that “revenue growth is no longer limited by the number of consultants that IBM can throw at projects.”).



are permitted to “build upon free software to create proprietary software.”<sup>352</sup> This means that, the BSD License allows proprietary commercial use, and the software released under the license can be incorporated into proprietary commercial products. In addition, any works based on and/or derived from the free software may be released under its own proprietary license.<sup>353</sup>

Legal experts have noted how ‘open source purists’ (GPL supporters) object to the BSD License. “[O]pen 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.”<sup>354</sup> The objection arises because “[t]he 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.”<sup>355</sup> BSD supporters refer to their model as ‘copyleft’ – between copyleft and copyright.<sup>356</sup>

Established software companies seemingly have embraced the BSD model. One example of this model is the Macintosh Operating System, which runs partly on BSD-licensed code.<sup>357</sup> BSD

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352. Blakeslee & Ferguson, *supra* note 334; *see also* Wikipedia.org, Berkeley Software Distribution, [http://en.wikipedia.org/wiki/Berkeley\\_Software\\_Distribution](http://en.wikipedia.org/wiki/Berkeley_Software_Distribution) (last visited Aug. 30, 2006) (describing the origins of BSD, sometimes called Berkeley Unix, and its wide identification with versions of Unix available for workstation-class systems during the 1970's due 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, which originated from using familiar systems such as DEC's Ultrix and Sun's SunOS).

353. Blakeslee & Ferguson, *supra* note 334.

354. *See id.*; RECORD, *supra* note 340, at 326 (“We recognize that there is a tension in the free software community regarding the use of open source in commercial products, especially when commercial developers wish to preserve the proprietary nature of all or some of their enhancements, extensions and compatible software. In principle, advocates of free software believe that any retention of proprietary rights is inconsistent with the concept of free software.”).

355. OpenBSD.org, OpenBSD Copyright Policy, <http://www.openbsd.org/policy.html> (last visited Nov. 22, 2006) (emphasis in original).

356. *Id.*

357. *See* Mac OS X for UNIX Users – The power of UNIX with the simplicity of Macintosh, at 3, [http://images.apple.com/macosx/pdf/MacOSX\\_UNIX\\_TB.pdf](http://images.apple.com/macosx/pdf/MacOSX_UNIX_TB.pdf) (last visited Dec. 13, 2006) (touting BSD as one of the most widely respected UNIX implementation systems that provides Mac OS X with stability, performance, and compatibility. “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, and has built on top of this rich Mach/BSD heritage with a number of powerful innovations, including well-defined, future-proof kernel programming

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code has also been detected operating in some Microsoft products, though it is not quite clear whether it was self-generated or it simply migrated there.<sup>358</sup> More recently, IBM has licensed some of its code under BSD.<sup>359</sup>

Unfortunately, the movement has more stridently challenged those within industry and the scientific community that continue to maintain the traditional proprietary view.<sup>360</sup> 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.<sup>361</sup> Given the lower 4th quarter of 2005 and forecasted 1st quarter of 2006 expected revenues reported by at least two of these companies,<sup>362</sup> however, one must seriously question the authenticity of their motivations for migrating to open source methods, as well as the economic viability of the open source business model itself.<sup>363</sup>

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interfaces (KPIs) supporting dynamically loadable file systems, network extensions, and packet filters, as well as I/O Kit drivers.”).

358. See Greg Lehey, *Does Microsoft run BSD Code?*, DAEMON NEWS, <http://ezine.daemonnews.org/200108/dadvocate.html>; see also David Sims et al., *Microsoft Plans Shared Source.NET*, O'REILLY NET., Jun. 27, 2001, <http://www.ondotnet.com/lpt/a/972>.

359. See Posting of George Kraft, *IBM TTS SDK now BSD Licensed*, to GNOME.ORG, <http://mail.gnome.org/archives/gnome-accessibility-list/2006-March/msg00048.html> (Mar. 27, 2006).

360. See *IBM to Give Away 500 Patents – Move Marks Major Shift of Intellectual-Property Strategy*, REUTERS, Jan. 11, 2005, available at [http://www.findarticles.com/p/articles/mi\\_zd2970/is\\_200501/ai\\_n8671221](http://www.findarticles.com/p/articles/mi_zd2970/is_200501/ai_n8671221) (reporting that IBM's plans to donate 500 patents for free use by software developers in order to encourage other patent holders to donate their own intellectual property in order to form what IBM calls a “patent commons” puts it in the vanguard of a movement to redefine patent laws in less restrictive ways, but is in contrast to zealous patent defenders such as pharmaceutical and media companies); see also Cukier, *supra* note 328 (Dr. Lita Nelson, Director of the Massachusetts Institute of Technology's Patent Transfer Office, believes that the term ‘open source biotech’ is so broad that it is meaningless, that “trying to adapt intellectual property approaches for different classes of technology, such as processes versus products, would be impossible [given that] ‘one man's infrastructure is another man's product or biotech company,’” and thus open source would negate the incentive to invest in patents.).

361. See Cukier, *supra* note 328.

362. See Dan Roberts & Richard Waters, *High-Tech Giants Fall Short of Forecasts*, FIN. TIMES, Jan. 18, 2006, at 1 (discussing earnings of IBM, Yahoo, and Intel); see also IBM, *IBM Reports 2006 First-Quarter Results*, IBM.COM, Apr. 18, 2006, <http://www.ibm.com/investor/1q06/1q06earnings.phtml>.

363. See Richard Waters, *The Prophet of Oracle's Evolving Future*, FIN. TIMES, Apr. 17, 2006, at 7 (reporting that while open-source companies benefit from a low-cost approach to developing and distributing software that threatens to disrupt established software companies, the lack of control over their own intellectual property in turn makes open-source companies vulnerable to take over by companies

Apparently, Brazil has been successful in advocating on behalf of the free and open source movement because of its ideological predisposition<sup>364</sup> towards communal sharing and bias against private property and free markets rooted in the United States.<sup>365</sup> And, the movement-at-large has seemingly embraced the Machiavellian tactic of 'divide and conquer' to pit the leaders of different governments and different industries against one another to promote such ideology abroad within the market and to government procurement agencies.<sup>366</sup> Companies, therefore, have increasingly turned towards their national governments in an

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such as Oracle, which in turn have also dissuaded companies such as Oracle from buying open-source companies such as Redhat for fear of seeing the software wiped off the map); see also Richard Waters, *Oracle Considers New Linux Venture*, FIN. TIMES, Apr. 17, 2006, at 15; John Gapper, *A Threat to the Fragile Linux Ecosystem*, FIN. TIMES, Apr. 24, 2006, at 19 (reporting that open-source companies such as Linux which do not hold intellectual property rights over its software cannot charge for the software, but make money by providing support and upgrades to make sure it works with other corporate software, are part of a delicate ecosystem comprising of open-source volunteers and software companies and distributors, who all have a stake in taking out more than they put in, thereby resulting in cheap and open operating platform, but which in turn also curtails the profits that Linux distributors can make).

364. See JAMES V. DELONG, PROGRESS & FREEDOM FOUND., THE ENIGMA OF OPEN SOURCE SOFTWARE (VERSION 1.0) (Mar. 2004), <http://www.pff.org/issues-pubs/pops/pop11.8opensource.pdf>. At least one commentator has cited the economic and ideological issues surrounding whether governments, in the first place, should give preference to open source software in making purchases. See also *id.* at 4 ("Connected to this limited debate are . . . disputes over the proper way to ensure the production of intellectual products in the computer age, ranging from music to movies to games to books to pharmaceuticals. The Free Culture Movement, which is based primarily in academia, regards the production of open source software as a pilot program for non-property-based, non-market production of these other forms of intellectual creativity.").

365. See MacPherson, *supra* note 333 ("When Brazil migrated to open source software, IBM stepped in to pledge local assistance in writing software for the Linux operating system. Microsoft's veteran competitor declared its intention to raise Brazil as a role model for other Latin American countries looking to cut their computer costs, according to Vania Curiati, IBM's software director in Brazil . . . . The lessons of recent history mean open source attitudes in South America are coloured by anti-US sentiment. Citizens of Ecuador, Guatemala, Chile, Colombia and Argentina have had fatal encounters with US foreign policy, and US multinationals are often viewed with as much suspicion as the White House itself. Brazil is no exception . . . . Therefore it is hardly surprising that ardent nationalism and anti-US tension have left an imprint on national politics.").

366. Although IBM's move was primarily against Microsoft, it was apparently applauded and embraced by Sun Microsystems. See Scott McNealy, *Share the 'Crown Jewels' and Create New Markets*, FIN. TIMES, Feb. 16, 2006, at 17. It also seemed to trigger concerns among 'open source' companies. See Richard Waters, *Red Hat Buys JBoss in Boost to Open-Source*, FIN. TIMES, Apr. 11, 2006, at 27. It is arguable whether Sun's reliance on this business model contributed to its negative financial results. See Richard Waters, *McNealy Steps Down as Sun Microsystems CEO*, FIN.

effort to employ this doctrine to their competitive advantage and for protectionist purposes.<sup>367</sup>

## 2. Brazil's Efforts to Nationalize OSMs

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 Brazilian Government has undertaken a series of popular initiatives at the national and international levels aimed at promoting FOSS business methods that, admittedly, "imply a political risk to Brazil."<sup>368</sup> The risk to which this expert obliquely refers is that the United States may view Brazil's adoption of the FOSS model as another new form of disguised trade protectionism, which may be punishable by withdrawal of U.S. GSP status and/or susceptible to challenge and retaliatory sanctions at the WTO.<sup>369</sup>

The populist rationale underlying the Brazilian Government's push for 'open source' methods has also been discussed by Brazil's Minister of Culture:

*[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.*

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TIMES, Apr. 24, 2006, at 1; Richard Waters, *McNealy Takes the Hits and a Backseat at Sun*, FIN. TIMES, Apr. 25, 2006, at 26.

367. See *United States v. Microsoft*, 87 F. Supp. 2d 30 (D.D.C. 2000); see also Wikipedia.org, *United States v. Microsoft*, [http://en.wikipedia.org/wiki/Microsoft\\_antitrust\\_case](http://en.wikipedia.org/wiki/Microsoft_antitrust_case) (last visited Dec. 13, 2006).

368. Brazilian Studies, *supra* note 14, at 5 (stating that the Brazilian Government has taken four actions regarding innovative intellectual property perspectives: (1) adoption of free software by both the private and public sectors; (2) the Creative Commons, "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"; (3) access to medicines initiative; and (4) the Development Agenda proposed at the World Intellectual Property Organization by Argentina and Brazil).

369. See Kingstone, *supra* note 336; Carlos Ball, *Why is There No Free Trade in the Americas?*, TCSDaily.com, Feb. 25, 2004, <http://www.tcsdaily.com/022504B.html>.

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.<sup>370</sup>

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.<sup>371</sup> Accordingly, one of the prime directives of Brazil's Federal Institute for Information Technology is to promote the adoption of free software throughout the government and ultimately the nation.<sup>372</sup>

The idea of extending the open source business methods paradigm from software to healthcare originally arose during Brazil's 'market-friendly' Cardoso administration, which, for political reasons, had guaranteed distribution of HIV/AIDS drugs to all infected Brazilians, free of charge.<sup>373</sup> And, this same model and policy rationale has since been embraced by the current socialist Lula administration.<sup>374</sup> The main downside of the drug program, as both administrations ultimately discovered, however, has been its extremely high, unsustainable cost.<sup>375</sup> As a result, from 1999 to the present, both administrations became skilled in the art of issuing periodic royalty-free compulsory licensing threats to foreign life sciences companies.<sup>376</sup> For example, in the spring of 2005,

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370. Julian Dibbell, *We Pledge Allegiance to the Penguin*, WIRED, Nov. 2004, (emphasis added) (internal quotations omitted) (quoting Cultural Minister, and former pop star, Gilberto Gil).

371. *See id.* (noting that Brazil, in its approach to drug patents and in its support for the free software movement is transforming itself into an open source nation, yet also noting that 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, and that sooner or later some country was bound to square off with the IP empire and be the first to insist, as a matter of state policy and national identity, on an alternative).

372. *See id.*

373. *See id.* (noting that this policy unfolded under the watchful eye of former Health Minister and politician José Serra, who has been said to be the individual who set Brazil on the path to IP independence).

374. *See id.*

375. *See id.*

376. *See id.*; Decreto No. 3.201, Dispõe Sobre a Concessão, de Ofício, de Licença Compulsória Nos Casos de Emergência Nacional e de Interesse Público de que Trata o art. 71 da Lei No. 9.279, de 14 de maio de 1996, de 6 de outubro de 1999 [Presidential Decree on Compulsory Licensing Establishing Rules Concerning the Granting, Ex Officio, of Compulsory Licenses in Cases of National Emergency and Public Interest Provided for in Art. 71 of Law No. 9,279 of May 14, 1997] (Braz.); *see also* Paulo Rebêlo, *Brazil Targets Another AIDS Drug*, WIRED NEWS, Aug. 29, 2001, <http://www.wired.com/wired/story/010829brazil/>.

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the Government of Brazil declared that it possessed the moral and legal authority, under both national and international law, to 'take' the HIV/AIDS drug Kaletra from its U.S. owners (patent-holders) *without* 'just compensation,' because the issue of health care is a matter of 'public interest' (i.e. a 'public use').<sup>377</sup>

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 also within its own national law to bail itself out. The Brazilian Government, however, had been suffering from an *economic* 'emergency' or 'urgency' that was 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.'

Economic emergencies or urgencies of the kind experienced by Brazil or any other emerging economy are often better addressed through balance of payment borrowings or project-related financings obtained from official international development and sovereign lending institutions, official *export*-promoting financial institutions, or from private banks, or even private aid. Health emergencies or urgencies experienced by impoverished least developed countries such as those from sub-Saharan Africa with respect to HIV/AIDS, malaria and tuberculosis are, by contrast, often better addressed by 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.<sup>378</sup> However, the jury is still out on whether such aid has actually been as transformational as envisioned.<sup>379</sup>

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wired.com/news/politics/0,1283,46353,00.html; Shasta Darlington, *Brazil Makes Demands in Roche AIDS Drug Dispute*, REUTERS, Aug. 23, 2001, [http://www.globaltreatmentaccess.org/content/press\\_releases/a01/082301\\_R\\_HGAP\\_brazil.html](http://www.globaltreatmentaccess.org/content/press_releases/a01/082301_R_HGAP_brazil.html).

377. See PR Newswire, *The Government Declares Anti-Retroviral Kaletra to Be of Public Interest and Will Produce it in Brazil*, PRNEWSWIRE.COM, Jun. 24, 2005, <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/06-25-2005/0003950348&EDATE>.

378. See *Bush Touts Foreign HIV/AIDS Funding*, *supra* note 204; see also Kenya, *Brazil Press for Funds for Neglected Diseases*, MEDIA CORP PRESS, May 17, 2006, <http://www.todayonline.com/articles/118794print.asp>.

379. See, e.g., Andrew Natsios, Adm'r of the U.S. Agency for Int'l Dev. [USAID],

It is more likely that Brazil suffers from a perennial *knowledge* emergency or urgency. This type of deficit is preferably corrected by improving national and local education capabilities, by attracting foreign private direct investment and by voluntarily negotiating arms-length, market-based arrangements (or procurement contracts) with the very private industry participants that can help it to acquire such knowledge.<sup>380</sup>

Brazil still has the option, in the words of Hernando De Soto, to act wisely and choose the 'other path.'<sup>381</sup> 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.

### 3. Brazil's Efforts to Internationalize OSMs

Brazil, in addition to proposing the so called 'Development Agenda' at the WIPO, is in the "forefront of several proposals regarding intellectual property, such as embracing free software and creative commons, as well as struggling for the for the proper balance of patent rights in order to promote access to medicines."<sup>382</sup> It is arguable that open source methods, especially as applied to the life sciences and information and communication technology industries, are intended to impair seriously the significantly higher value of U.S. and other OECD member intellectual property assets and the related commercial products and processes that incorporate them.<sup>383</sup>

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Five Debates on International Development – The US Perspective, Speech at a Meeting Hosted by the Overseas Development Institute (Oct. 12, 2005) (transcript available at [http://www.odi.org.uk/speeches/apgood\\_oct05/apgood\\_oct12/HLnatsios.pdf](http://www.odi.org.uk/speeches/apgood_oct05/apgood_oct12/HLnatsios.pdf)) (noting that some scholars have begun to doubt the power of aid packages by themselves to promote self-sufficiency in countries unwilling to emancipate themselves from the philosophy of welfare dependency).

380. Cf. Pachovski & Kogan, *supra* note 109 (discussing the dangers of Brazil's current approach).

381. HERNANDO DE SOTO, *THE OTHER PATH: THE ECONOMIC ANSWER TO TERRORISM* (1989).

382. Brazilian Studies, *supra* note 14, at 1.

383. See JANE HOPE, *OPEN SOURCE BIOTECHNOLOGY PROJECT, OPEN SOURCE BIOTECHNOLOGY?*, <http://rsss.anu.edu.au/~janeth/OSBiotech.html> (arguing that part of the appeal to open source approach to biotechnology research and development may be its capacity to weaken government and industry control over the rate and

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These assets provide the OECD nations, including the United States, with a considerable comparative trade advantage over emerging WTO member economies, including Brazil. Brazil has indirectly sought to impair the value of U.S. IP assets in two ways. First, Brazil has successfully persuaded diplomats, policymakers, and non-U.S. businesses that the current WTO IP system suffers from serious market and ethical failures.<sup>384</sup> Second, it has successfully cast those failures as a threat to developing countries' national sovereignty, cultural identity and ability to benefit equitably from the science and technology transfers.<sup>385</sup> In this regard, many believe that the UN Millennium Development Goals, a primary purpose of which is to ensure sustainable development, incorporate such a mandate. Third, as the following discussion will show, Brazil has also strongly recommended (i.e., demanded, as a matter of 'fundamental fairness'), that the FOSS replace this system as the benchmark for internationally harmonized IP rules. This will ensure that Brazil and its developing country comrades obtain 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, without doubt, the *most vocal*. Apparently, Brazil's message has resonated loud and clear among other developing countries, particularly those located in Latin America.<sup>386</sup> Suffering from even

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especially the direction of scientific progress); *see also* Robin Bloor, *South America Warms to Open Source*, THE REGISTER, Feb. 10, 2005, [http://www.theregister.co.uk/2005/02/10/south\\_america\\_open\\_source](http://www.theregister.co.uk/2005/02/10/south_america_open_source) (noting that 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." Da Silva appointed Sergio Amadeu, a "former economics professor and Open Source enthusiast . . . [who] wants Open Source to permeate government software usage, educational software usage and home computer usage" to head Brazil's National Information Technology Institute, after taking office last year).

384. *See* Brazilian Perspective, *supra* note 14, at 6 ("Dr. Lemos provided some numbers about the traditional copyright-based cultural industry in Brazil. The numbers demonstrate 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.").

385. *See id.* at 4.

386. *See* Bloor, *supra* note 383 ("The trend to Open Source in South America seems to be stronger than it is anywhere else." Examples include Chile, "where Open Source is being deployed extensively in schools through the governments high school internet access network;" Venezuela, where "President Chavez issued a decree . . . mandating



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 line for the purpose of dancing to what they will hope to be a new international genre of open-source music.<sup>387</sup>

For all intensive purposes, therefore, the outlines of an international open source alliance have begun to emerge. Besides Brazil, it consists of India, which has mustered a political commitment to free software, developing nations that are poor in IP rights and lacking in the power to enforce them, and certain developed nations which have a vested (political and economic) interest in the success of the open source paradigm. To some, this alliance is a natural response to the rapid rate of technological change and the chaotic nature of today's modernization process.<sup>388</sup>

*a. Brazil's Efforts at the World Summit on the Information Society*

The Government of Brazil also challenged the international IPR framework during both phases of the UN WSIS. The WSIS meetings had been convened by the International Telecommunications Union (ITU), a UN-based international standards body.<sup>389</sup> The first of the two phases took place in Geneva, Switzerland during December 10-12, 2003.<sup>390</sup> During the first phase, Brazil led<sup>391</sup> a

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Venezuela's public administration to switch to Open Source;" and Peru, "where the government recently introduced a bill mandating the use of Open Source software by the state.").

387. See Colin McMahon, *2 Nations United on AIDS Care: Argentina, Brazil Vow to Make Generic Drugs*, CHI. TRIBUNE, Aug. 25, 2005, at 4 ("[O]fficials 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 . . .").

388. See Dibbell, *supra* note 370.

389. See ITU - About Us, <http://www.itu.int/aboutitu/overview/index.html> (last visited Dec. 13, 2006) (summarizing the history of the ITU and its objectives, mandates and activities).

390. See WSIS: Geneva 2003 - Tunis 2005, <http://www.itu.int/wsis/index.html> (last visited Jan. 3, 2007); see also WSIS, G.A. Res. 56/183, ¶ 1, U.N. Doc. A/Res/56/183 (Jan. 31, 2002), available at [http://www.itu.int/wsis/docs/background/resolutions/56\\_183\\_unga\\_2002.pdf](http://www.itu.int/wsis/docs/background/resolutions/56_183_unga_2002.pdf), (recognizing Council of the International Telecommunication Union's decision to endorse same).

391. See Marcelo D'Elia Branco, WSIS, *World Summit on Information Society: The Rich and the Rest of the World*, <http://cyber.law.harvard.edu/wsis/Branco.html> ("The main controvers[y] [at] WSIS ha[d] been around the alternative of Free Software as an instrument to digital inclusion, incentive to innovation and technological development. In that point, the Brazilian delegation ha[d] been firm and le[d] the discussion. . . . A second controversy ha[d] been on the emphasis to deepen the intellectual property laws about digital stuff vs. the knowledge sharing as a

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bloc of developing countries including India, South Africa and China<sup>392</sup> in seeking to define the scope of IPRs in an effort to prevent the United States and its OECD allies from ‘hardening’ the UN line in support of them.<sup>393</sup> Fortunately, they were unsuccessful. The United States was able to ensure that “the official WSIS Declaration of Principles include[d] a section promoting intellectual property rights” and “only support[ing] ‘increas[ed] awareness . . . offered by different software models, including proprietary, open-source and free software,’”<sup>394</sup> although the final

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mechanism to guarantee the permanent technological innovation and the digital inclusion. Brazil and India [led] the group that understands that the emphasis to knowledge sharing among the people is more appropriate to the development of a democratic information society and it’s the unique opportunity for the in growth and poor countries to overcome the technological delay.”)

392. See ROBIN D. GROSS, IP JUSTICE EXEC. DIR., WORLD SUMMIT TO CREATE ‘PAY-PER-USE’ SOCIETY: HUMAN RIGHTS IGNORED AS BIG BUSINESS DOMINATES IN GENEVA (Dec. 21, 2003), [http://www.ipjustice.org/WSIS/IPJ\\_WSIS\\_Report.html](http://www.ipjustice.org/WSIS/IPJ_WSIS_Report.html) (“India and Brazil among other countries unsuccessfully attempted to insert language into the official WSIS documents that called into question the lack of balance in current international standards for intellectual property rights, such as the TRIPS Agreement. But the US flexed its muscle and calls for balance were ignored . . . . Another controversial issue in the official WSIS documents was [the lack of] any mention of Free or Open Source Software development models. An increasing number of governments have announced plans to switch from proprietary software to Free and/or Open Source Software to save money and improve quality and security. Already Governments in Brazil, Peru, India, Australia, Vietnam, South Korea Korea, China, and South Africa have taken steps to reduce their dependence on Microsoft software products by announcing support for Free or Open Source Software . . . . But Microsoft lobbyists fought hard on this point.”).

393. See Kenneth Cukier, *Source vs. Force: Open Source Meets Intergovernmental Politics*, SOC.SCI. RES. COUNCIL, [http://www.ssrc.org/wiki/POSA/index.php?title=source\\_vs.\\_Force:\\_Open\\_Source\\_Meets\\_Intergovernmental\\_Politics](http://www.ssrc.org/wiki/POSA/index.php?title=source_vs._Force:_Open_Source_Meets_Intergovernmental_Politics) (“The hard US line on open source is widely interpreted as a reflection of Microsoft’s lobbying power, and behind it the broader, US-dominated proprietary software industry. Much of this lobbying occurs through surrogate trade associations . . . . These organizations are closely connected to the office of the U.S. Trade Representative, and several are accredited observers at WIPO. Responsibility for scuttling the first planned WIPO meeting on open source, for example, is usually attributed to the Business Software Alliance, which played the leading role in applying pressure on the US Patent and Trademark Office.” (citation omitted)); U.S. DEP’T OF STATE, BUREAU OF ECON. AND BUS. AFFAIRS, COMMENTS OF THE UNITED STATES OF AMERICA ON INTERNET GOVERNANCE, Aug. 15, 2005, <http://www.state.gov/e/eb/rls/othr/2005/51063.htm>.

394. GROSS, *supra* note 392 (internal citations omitted); see also WSIS, Geneva 2003, *Declaration of Principles, Building the Information Society: a global challenge in the new Millennium*, ¶ 42, U.N. Doc. WSIS-03/GENEVA/DOC/4-E (Dec. 12, 2003) [hereinafter *Declaration of Principles*], available at [http://www.itu.int/dms\\_pub/itu-s/md/03/wsis/doc/S03-WSIS-DOC-0004!!PDF-E.pdf](http://www.itu.int/dms_pub/itu-s/md/03/wsis/doc/S03-WSIS-DOC-0004!!PDF-E.pdf) (“Intellectual Property protection is important to encourage innovation and creativity in the Information Society . . . .”); *id.* ¶ 27 (“Access to information and knowledge can be promoted by increasing awareness among all stakeholders of the possibilities offered by different software models, including proprietary, open-source and free software . . . .”); WSIS, Geneva 2003, *Plan*



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Secretariat of the UNCTAD.<sup>401</sup> The MOU provided for UN training and education in the use of FOSS in an effort to support the promotion of such paradigm in the developing world.<sup>402</sup>

Apparently, Brazil had also been previously successful, with the assistance of free and open method advocates, in discretely inserting additional anti-IPR references within an ITU Report on WSIS Stocktaking released approximately one month prior to the WSIS' second phase meeting.<sup>403</sup> This report cites the prior efforts of the UNESCO to promote open source over proprietary software as a way to ensure cultural diversity.<sup>404</sup> As far back as 2003, for example, UNESCO had incorporated numerous open source and universal access references within a recommendation to promote multilingualism and universal access to cyberspace.<sup>405</sup> Indeed, the UNESCO website corroborates these and other past activities, as well as reveals numerous additional ways in which UNESCO continues to influence the WSIS discussion about the *need* for open source software.<sup>406</sup>

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401. See UNCTAD & WSIS, *UNCTAD and Brazil Support Free and Open-Source Software*, Nov. 16, 2005, <http://www.unctad.org/Templates/Page.asp?intItemID=3603&lang=1>.

402. See *id.*

403. See WSIS, Tunis 2005, WSIS Executive Secretariat: Report on the WSIS Stocktaking, ¶¶ 16, 20-32, U.N. Doc. WSIS-05/TUNIS/DOC/5 (Oct. 18, 2005), available at <http://www.itu.int/wsis/docs2/tunis/off/5.pdf> (describing several Brazilian Government initiative/programs that are actively promoting open source methods within Brazil).

404. See *id.* ¶¶ 74-76; see also ¶ 68 (“The WSIS Plan of Action recognises that cultural and linguistic diversity, while stimulating respect for cultural identity, traditions and religions, is essential to the development of an Information Society based on dialogue among cultures and regional and international cooperation.”).

405. See UNESCO General Conference, 32d Sess., Oct. 2003, *Recommendation concerning the Promotion and Use of Multilingualism and Universal Access to Cyberspace*, ¶¶ 7, 13, 15, 17, 19, 23, available at [http://portal.unesco.org/ci/en/ev.php-URL\\_ID=13475&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/ci/en/ev.php-URL_ID=13475&URL_DO=DO_TOPIC&URL_SECTION=201.html).

406. See UNESCO, UNESCO and the WSIS, <http://www.unesco.org/wsis> (last visited Jan. 3, 2007) (“UNESCO with its unique mandate to promote the free exchange of ideas and knowledge has played a key role in WSIS. UNESCO’s contribution incorporated the ethical, legal and sociocultural dimensions of the Information Society and helped to grasp the opportunities offered by the ICTs by placing the individual at its centre.”); see also UNESCO, Consultation meeting on WSIS Action Line C8 Cultural Diversity and Identity, Linguistic Diversity and Local Content, May 12, 2006, available at [http://portal.unesco.org/ci/en/ev.php-URL\\_ID=21663&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/ci/en/ev.php-URL_ID=21663&URL_DO=DO_TOPIC&URL_SECTION=201.html) (“In accordance with the Tunis Agenda for the Information Society and the Consultation Meeting of Possible Action Line Moderators/Facilitators (Geneva, 24 February 2006), which designated UNESCO as provisional focal point of WSIS Action Line C8, the first consultation meeting on Action Line C8 was convened by UNESCO on 12 May 2006.”).



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law<sup>411</sup> and industry standards<sup>412</sup> intended to pollute trade and economic fora. A perfect example of this is the effort now underway to ‘import’ (regime-shift) the ‘soft’ *non*-science-based Precautionary Principle from health and environmental fora into the ‘hard’ scientific and technical ICT fora.<sup>413</sup>

The Precautionary Principle in the information society can be articulated as follows: In order to enable society now and in the future to make relevant choices in the use of Information and Communication Technologies, as well to minimize harm for human health and the environment caused by ICT, ICT-related decisions under uncertainty should favor [] lower complexity over higher complexity[,] open standards over proprietary standards[,] and adapting the technology to humans over adapting humans to the

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*technology*, together with technical assistance programs to harmonize developing countries’ legislation to the standard of developed countries.” (emphasis added)).

411. See MARK W. JANIS & JOHN E. NOYES, INTERNATIONAL LAW – CASES AND COMMENTARY 39 (2d ed., West Group 2001) (“Some international lawyers distinguish between ‘hard’ and ‘soft’ law, a distinction with 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).”).

412. The EU is now apparently seeking to require open source and royalty-free software ‘inter-operability’ 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’*, 10 INT’L J. COMM. L. & POL’Y 8 (2005), available at [http://www.ijclp.org/10\\_2005/pdf/ijclp\\_08\\_10\\_2005.pdf](http://www.ijclp.org/10_2005/pdf/ijclp_08_10_2005.pdf) (discussing mandatory royalty-free licensing and unfettered sublicensing and prohibition of other reasonable licensing terms in favor of ‘FRAND’ – fair, reasonable and non-discriminatory); Benoit Müller, THE EUROPEAN INTEROPERABILITY FRAMEWORK: AN INDUSTRY PERSPECTIVE, BUSINESS SOFTWARE ALLIANCE 6-8 (Dec. 2005), [http://www.politech-institute.org/review/articles/MULLER\\_Benoit\\_volume\\_3.pdf](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 is 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 regarding open-source software.”); ESTEBAN BURRONE, WIPO, STANDARDS, INTELLECTUAL PROPERTY RIGHTS (IPRS) AND STANDARDS-SETTING PROCESS, [http://www.wipo.org/sme/en/documents/ip\\_standards.htm](http://www.wipo.org/sme/en/documents/ip_standards.htm); Priscilla Caplan, *Patents and Open Standards*, INFO. STANDARDS Q. (Oct. 2003), [http://www.niso.org/press/whitepapers/Patents\\_Caplan.pdf](http://www.niso.org/press/whitepapers/Patents_Caplan.pdf).

413. See Claudia Som, et al., *The Precautionary Principle in the Information Society – Impacts of Pervasive Computing on Health and the Environment*, 10 HUMAN & ECOLOGICAL RISK ASSESSMENT, 787–99 (2004). “We advocate precautionary measures directed towards pervasive applications of ICT (Pervasive Computing) because of their inestimable potential impacts on society.” *Id.* at 787.

technology.<sup>414</sup>

Apparently, anti-private property activists and 'enlightened' academics believe that open international ICT standards are essential in order to protect industries and peoples against the evils of 'pervasive computing.'<sup>415</sup> In other words, they are necessary to "avoid[] strong path-dependency and trends toward market dominance, which destroy diversity."<sup>416</sup>

Thus, if not carefully monitored, these seemingly innocuous statements and declarations could conceivably be assembled, recombined, or otherwise used with or within documents already produced to develop an overly broad non-economic framework from which to reconsider the role of intellectual property law in international affairs.

*b. Brazil's Efforts at the World Intellectual Property Organization*

These issues also have been debated at the WIPO. In late August 2004, for example, Brazil and Argentina submitted to the WIPO Secretariat a formal detailed proposal relating to the establishment of a new development agenda within WIPO.<sup>417</sup> Subsequently, the WIPO General Assembly convened an extraordinary session to consider it that spanned from September 27 to October 5, 2004.<sup>418</sup>

Brazil's proposal requested that the WIPO General Assembly consider eight issues: 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

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414. *Id.* at 796.

415. *Id.* at 791 ("The application of ICT is expected to become pervasive within about a decade, that is, all aspects of daily life may be influenced by networked ICT components (Pervasive Computing). From the perspective of technology assessment, the combination of the following characteristics of ICT is important for their potential implications. . . .").

416. *Id.* at 796. Will this not serve as but another oblique basis for disguised industry protectionism?

417. See Secretariat of the WIPO, *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, U.N. Doc. WO/GA/31/11 (Aug. 27, 2004), available at [http://www.wipo.int/documents/en/document/govbody/wo\\_gb\\_ga/pdf/wo\\_ga\\_31\\_11.pdf](http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_11.pdf).

418. See *id.*

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 least developed countries (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 and 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.<sup>419</sup>

The proposed amendment to the WIPO Convention calls for each country's stage of development to be taken into account to ensure that intellectual property protections do not impede access to culture and technology.

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 lead 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.<sup>420</sup>

At least one representative of the Brazilian Government who attended the special session noted that the amendment had received strong support from other developing nations.<sup>421</sup>

On September 29, 2004, shortly following the commencement

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419. *See id.* at app. 1-2.

420. *Id.* at 2.

421. *See* Juliana César Nunes, *Brazil Wants New Rules for Intellectual Property*, BRAZZIL MAG., Sept. 29, 2004 (Allen Bennett trans.), available at <http://www.brazzilmag.com/content/view/279/2> (referring to is Roberto Jaguaribe, the president of the Brazilian Institute of Intellectual Property (INPI)).



of the 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 World Intellectual Property Organization*.<sup>422</sup> 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.”<sup>423</sup> It focused on the perceived inequities surrounding access to innovations and the scientific and technical know-how underlying medical, information, and other essential technologies.<sup>424</sup> It also called for WIPO to ensure universal access to all such knowledge as a matter of both morality and international law.<sup>425</sup>

Following the Geneva Declaration, other European activists submitted their own objections, equating these inequities with human rights violations, and calling for a reinterpretation of the WIPO Convention’s mandate.<sup>426</sup> The Brazilian and Argentine Governments, along with NGOs, have also recently called for greater NGO participation in WIPO’s enforcement committee, which, fortunately, the U.S. Government has opposed.<sup>427</sup>

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. That order is designed to protect exclusive private property, including IPRs, and to preserve the role of free markets in financing and commercializing scientific and technological knowledge. The open source approach, if adopted, will fundamentally change for the worse the entire international system of research and development, scientific and technological innovation, foreign trade and FDI. An organized effort should therefore be mounted

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422. See Geneva Declaration on the Future of the WIPO, <http://www.cptech.org/ip/wipo/futureofwipodeclaration.pdf> (last visited Dec. 15, 2006) [hereinafter Geneva Declaration on the Future of WIPO].

423. Open Soc’y Inst. & Soros Foundns. Network, *Declaration on the Future of WIPO*, Sept. 30, 2004, [http://www.soros.org/initiatives/information/news/wipo\\_20040929](http://www.soros.org/initiatives/information/news/wipo_20040929).

424. See Geneva Declaration on the Future of WIPO, *supra* note 422, at 1.

425. See *id.*

426. See *e.g.*, Ovet, *supra* note 223.

427. See Posting of Thiru Balasubramaniam, *US Delegation Opposes Consumer Groups’ Inclusion On WIPO ACE Panels*, to FromGeneva, <http://fromgeneva.blogspot.com/2006/05/us-delegation-opposes-consumer-groups.html> (May 17, 2006, 11:44).

to resist the implementation of these ideas in every international organization and in every country, beginning with Brazil.<sup>428</sup>

*c. 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 hardly stellar, and it 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.<sup>429</sup> Its ostensible objective is to procure well-recognized branded drugs, medical services and medical devices and technologies at *cost or below-cost* prices from reputation-vulnerable multinational pharmaceutical and biotechnology companies to protect the health and lives of all Brazilian AIDS victims.<sup>430</sup> The Government of Brazil, with the assistance of health care extremists, 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.<sup>431</sup>

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428. See e.g., Frances Williams, *Fears of Polarisation If Bush Nominee Takes Top WIPO Post*, FIN. TIMES, (Asia), May 12, 2006, at 5, available at <http://news.ft.com/cms/s/fcb83c38-e10e-11da-90ad-0000779e2340.html>.

429. See discussion *supra* Part III.A.

430. The Brazilian Government no doubt cites the TRIPS agreement as justification. See Andrew Beckerman-Rodau, *Patent Law - Balancing Profit Maximization and Public Access to Technology*, 4 COLUM. SCI. & TECH. L. REV. 48-49 nn.187-88 (2002) ("[T]he TRIPS Agreement specifically allows signatories to exclude from patent protection certain inventions that are protected in other countries. Additionally, it also provides for the withholding of patent rights for inventions that are necessary to protect human life or health. In light of this, the law already embodies the concept of excluding certain types of inventions from being eligible for patent protection." (footnotes omitted)).

431. See discussion *supra* Part II.B.4. Other countries have observed and copied Brazil's tactics. See Posting of Tove Iren S. Gerhardsen, [tgerhardsen@ip-watch.ch](mailto:tgerhardsen@ip-watch.ch), *Thailand Compulsory License on AIDS Drug Prompts Policy Debate*, to INTELL. PROP. WATCH, <http://www.ip-watch.org/weblog/index.php?p=499&res=1280&print=0> (Dec. 22, 2006, 5:01 pm) ("On 29 November, the Thai Government announced that it would issue a compulsory license to the Government Pharmaceutical Organization of Thailand . . . [entitling] the government-owned company [to] produce HIV/AIDS product, efavirenz (Stocrin), despite it still being under patent by Merck . . . . In the announcement, the government said that under the Doha Declaration (agreed to at a WTO ministerial in Doha, Qatar in 2001), and the TRIPS, 'member countries have a right to issue a safeguard measure to protect public health, especially for universal access to essential medicines using compulsory licensing on the patent of pharmaceutical products.' It also referred to the Thai Patent Act, saying that the government had the right to use any patent rights 'for non-commercial public uses.'" (emphasis added) (citations omitted)).

These threats have provided Brazil, an emerging economy, as well as developing country governments such as the new 'democratically' installed military Government in Thailand, with the political capacity to override *any* pharmaceutical patents they choose "for public health concerns [or interests]."<sup>432</sup> It has also enabled such countries to insist that market-based royalty rates for licensed patented drugs not apply,<sup>433</sup> i.e., in no case should an 'adequate' rate of compensation exceed five percent for purposes of computing a much lower (nearly zero) compulsory licensing roy-

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432. See Darren Schuettler, *Activists Hail Thai Move to Make Generic AIDS Drugs*, REUTERS, Nov. 30, 2006, [http://www.pamf.org/health/healthinfo/reutershome\\_top.cfm?fx=article&id=33242](http://www.pamf.org/health/healthinfo/reutershome_top.cfm?fx=article&id=33242) ("Thailand, faced with ballooning costs for HIV-AIDS drugs, has issued its first compulsory license to make a cheap version of a foreign-made drug and fired a shot across the bow of big pharmaceutical companies. The action drew a swift riposte from U.S. drug maker Merck & Co Inc, which holds the patent on Efavirenz. The firm denounced the Health Ministry decision . . . But AIDS activists and health experts cheered loudly . . . Merck will receive a 0.5 percent royalty on sales of the locally produced drug . . . Thailand's state-owned drug maker, said it would import generic Efavirenz until the GPO made its own version in June 2007." (emphasis added)). This would more than suggest that previous Merck below-market royalty rate of 1% was too high, and that practically anything more than a zero royalty rate would be too much!

433. See WHO, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, Health Economics and Drugs, TMC Series No. 18*, at 81-82, U.N. Doc. WHO/TCM/2005.1 (2005), prepared by James Love, Consumer Project on Technology, available at [http://www.who.int/medicines/areas/technical\\_cooperation/WHOTCM2005.1\\_OMS.pdf](http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf) ("WTO gives its Members very broad latitude in determining remuneration. The TRIPS Agreement does not require a country to make up the lost profits that the patent owner would have enjoyed with a monopoly and pricing freedom. Under Article 31, countries have discretion to consider private market licensing transactions, as well as other data, and to consider also a wide range of policy objectives in determining remuneration for use of patented inventions. Countries are not required to mimic market results, and indeed, may set royalties at levels that are plainly designed to change market outcomes, such as to lower market prices, and make medicines more affordable . . . . A determination of what is 'adequate' remuneration may vary between countries. Very low royalty rates will be appropriate in cases of low income countries, especially for medical technologies that are used to treat diseases of high incidence, and/or when the cost of the treatment poses an economic hardship . . . . In recent cases involving remuneration for the use of patents on medicines, governments have set royalties between 0.5 and 5% of the price of the generic product."); see also Consumer Project on Technology, CPT Page on Royalties on Patents for Health Care Inventions, <http://www.cptech.org/ip/health/royalties> (last visited Jan. 4, 2007); see also *id.* at 6 ("There is extensive experience of voluntary technology licensing in the private sector. The evidence of compensation for private, market-based license arrangements provides an important context for making determinations of royalty and remuneration arrangements in cases of compulsory licensing. There is some conflicting evidence on cross-industry licensing averages, but there seems to be agreement in reports from the pharmaceutical industry and others that licensing fees for the pharmaceutical industry congregate at 4-5%.").

alty rate.<sup>434</sup>

Yet, arguably, for all of the international recognition that its HIV/AIDS 'universal access to medicines' program has received, including from international financial institutions,<sup>435</sup> 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.<sup>436</sup> These purposes include: 1) gaining negotiating leverage at the WTO Doha Round against developed countries on the issue of agricultural subsidies;<sup>437</sup> 2) exercising its legal option to cross-retaliate against the United States if the latter fails to comply with a prior adverse WTO ruling on cotton subsidies;<sup>438</sup> 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;<sup>439</sup> 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.<sup>440</sup> In other words, Brazil, an aspiring member of the UN Security Council, is arguably seeking a leader-

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434. It may be argued, however, that activist James Love has intentionally 'low-balled' what an 'adequate' royalty rate would be. This would help him to establish a framework for the much lower *non-market* compulsory licensing royalty rates he has cited. At least one IP practitioner has noted how 'adequate' market-based royalty rates for pharmaceutical products may be much higher than the 4-5% cited by Mr. Love, depending on various factors, including its stage of development (i.e., whether a patented discovery is in the research and development, clinical trial or commercialization stage when it is licensed). See Posting of Stephen Albainy-Jenei, *What's a Reasonable Royalty Rate?*, to Patent Baristas Blog, <http://www.patentbaristas.com/archives/2005/11/17/whats-a-reasonable-royalty-rate/#comments> (Nov. 17, 2005).

435. See generally CHRIS BEYRER, VARUN GAURI AND DENISE VAILLANCOURT, WORLD BANK OPERATIONS DEP'T, EVALUATION OF THE WORLD BANK'S ASSISTANCE IN RESPONDING TO THE AIDS EPIDEMIC: BRAZIL CASE STUDY 25 (2005), [http://www.worldbank.org/ieg/aids/docs/case\\_studies/hiv\\_brazil\\_case\\_study.pdf](http://www.worldbank.org/ieg/aids/docs/case_studies/hiv_brazil_case_study.pdf) (discussing Brazil's program's interactions with the World Bank).

436. See Pedro da Motta Veiga, *Brazil and the G-20 Group of Developing Countries*, in MANAGING THE CHALLENGES OF WTO PARTICIPATION 109 (Peter Gallagher, et al. eds., 2005), available at [http://www.wto.org/english/res\\_e/booksp\\_e/casestudies\\_e/case7\\_e.htm](http://www.wto.org/english/res_e/booksp_e/casestudies_e/case7_e.htm).

437. See *id.*

438. See generally Pachovski & Kogan, *supra* note 109 (discussing Brazil's breaking of U.S. drug patents).

439. See generally *id.*

440. See generally *id.*

ship role in international affairs through acts of IP opportunism rather than innovation.<sup>441</sup>

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.<sup>442</sup>

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 that has thus far been done to long-term diplomatic and Brazilian industry interests.

Ideology has indeed been an important part of Brazil's 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

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441. See Natasha T. Metzler, *Brazil Uses Compulsory Licensing Threat in Negotiations*, PHARMEXEC DIRECT, July 18, 2005, <http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=170954>; Nadezhda Pitulova, *Abbott Criticizes Brazil's Move to Copy Company's HIV/AIDS Drug*, KANSAS CITY INFOZINE, June 28, 2005, <http://www.itssd.org/media> (follow link to article's title); Nadezhda Pitulova, *U.S. Delegation to Brazil Will Discuss Proposal to End Drug Patents*, SCRIPPS HOWARD FOUND. WIRE, June 16, 2005, <http://www.itssd.org/media> (follow link to article's title); Mary Ann Liebert, *Brazil, Abbott Reach Tentative Deal on Kaletra – Threat to Suspend Antiretroviral Patents in Abeyance for Now*, 24 BIOTECHNOLOGY L. REP. 583 (2005).

442. Mário Marconini, *Brazil's Trade Policy 2004: The Good, The Bad, and the Uppity*, VIEWPOINT BRAZ., Jan. 17, 2005, available at <http://www.counciloftheamericas.org/coa/publications/ViewPointBrazil/ViewPointBrazilindex.html> (follow link to Marconini piece) (emphasis added).

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 . . . .

. . . .  
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 . . . 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.<sup>443</sup>

Consequently, if the OECD nations, including the United States, 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 this important dynamic into account.

*C. Brazil Aims to ‘Take’ U.S. Private Property for Brazilian ‘Public Use’ Without ‘Just Compensation’*

1. Introduction

‘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: “as 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.<sup>444</sup>

It is evident that Brazil has invested substantial time, energy and

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443. *Id.*

444. See Roger Pilon, Sr. Fellow and Dir. of the Ctr. for Const. Stud. at the Cato Inst., Testimony Before the Subcommittee on Constitution Committee on Judiciary

resources into reforming the current global IPR framework, or the established international order. It has arguably done so in order to create an environment in which it may systematically and legitimately 'take' the exclusive private property owned by American and other OECD nation citizens for Brazilian 'public use' *without* paying 'just compensation.' If Brazil is permitted to succeed in this endeavor, it will have accomplished that which no U.S. president or Congress is legally sanctioned to do.

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

In the United States, an individual's 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), is recognized and protected by the U.S. Constitution and its accompanying Bill of Rights. These documents also guarantee individuals that their private property will be protected against arbitrary and wanton government interference,<sup>445</sup> ostensibly intended to serve the public good.<sup>446</sup>

## 3. Individual Natural Rights Include the Right to Private Property

Many of the provisions of the TRIPS Agreement and the WIPO Agreement are informed by 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 exclusive right to own and enjoy private property.<sup>447</sup> The history surrounding the drafting of the U.S. Constitution and its accompanying Bill of Rights instructs us that an individual's rights, including his or her exclusive property rights, must be preserved

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United States House of Representatives (Feb. 10, 1995), *available at* <http://www.cato.org/testimony/ct-pi210.html> (footnote omitted).

445. See Laurence H. Tribe, *AMERICAN CONSTITUTIONAL LAW* 1-2 (1978) ("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)).

446. See also PETER GOLDSMITH ET AL., *FOOD SAFETY IN THE MEAT INDUSTRY: A REGULATORY QUAGMIRE* 8 (2002), *available at* <http://www.ifama.org/conferences/2003Conference/papers/goldsmith.pdf> (discussing the role of the individual in the U.S. Constitutional system in the context of food safety, "[t]he 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*." (citation omitted) (emphasis added)).

447. See TRIBE, *supra* note 447, at 427-28.

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and protected by *and* from government.<sup>448</sup> “Property is not, however, entirely a natural right. The Founders understood that it would need to be further defined in statute.”<sup>449</sup> 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.<sup>450</sup>

#### 4. Patents are Exclusive Private Personal Property

Every U.S. citizen possesses an exclusive inalienable right to his or her discoveries and inventions that is recognized by Article I, Section 8, Clause 8, of the U.S. Constitution.<sup>451</sup> The founders understood that *temporary* exclusive rights granted in property served as an adequate incentive to encourage the research and innovation by inventors and creators<sup>452</sup> needed to “propel [the United States] from a small, agrarian colony into an advanced and

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448. See *Knapp v. Schweitzer*, 357 U.S. 371, 376-77 n.4 (1958); TRIBE, *supra* note 445, at 3-4 (“[A] Bill of Rights directed against federal abuses was thought necessary in addition to separation and division of powers. . . institutional boundaries in the absence of such a list of liberties were not deemed quite sufficient to preserve individual rights.” (footnote omitted)); see also Letter from Thomas Jefferson to James Madison (Dec. 20, 1787), in 12 THE PAPERS OF THOMAS JEFFERSON, Aug. 1787 – Mar. 1787, at 438-40 (Julian P. Boyd ed., 1955); Letter from James to Thomas Jefferson (Oct. 17, 1788), in 14 THE PAPERS OF THOMAS JEFFERSON, Oct. 1788 – Mar. 1789, at 16,18 (Julian P. Boyd ed., 1958); Letter from Thomas Jefferson to James Madison (Mar. 15, 1789), in 14 THE PAPERS OF THOMAS JEFFERSON, Oct. 1788 – Mar. 1789, at 659-61 (Julian P. Boyd ed., 1958).

449. Douglas W. Kmiec, *The Takings Clause*, in THE HERITAGE GUIDE TO THE CONSTITUTION 342 (Edwin Meese III et al. eds., 2005).

450. See *Lynch v. Household Finance Corp.*, 405 U.S. 538, 552 (1972) (“[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.” (footnote omitted)).

451. See U.S. CONST. art. I, § 8, cl. 8 (“The Congress shall have power . . . [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.”).

452. A series of correspondences between Thomas Jefferson and James Madison reflects the framers’ justifiable concern with promoting innovation through excessive grants of copyright monopoly. Yet they seemed to agree that a limited monopoly term was necessary. See Letter from Thomas Jefferson to James Madison (Dec. 20, 1787), in 12 THE PAPERS OF THOMAS JEFFERSON, Aug. 1787 – Mar. 1788, at 438, 440 (Julian P. Boyd ed., 1950); Letter from Thomas Jefferson to James Madison (July 31, 1788), in 13 THE PAPERS OF THOMAS JEFFERSON, Mar. 1788 – Oct. 1788, at 440, 442-43 (Julian P. Boyd ed., 1956); Letter from James Madison to Thomas Jefferson (Oct. 17, 1788), in 14 THE PAPERS OF THOMAS JEFFERSON, Oct. 1788 – Mar. 1789, at 14, 21 (Julian P. Boyd ed., 1958); Letter from Thomas Jefferson to James Madison (Sept. 6, 1789), in 15 THE PAPERS OF THOMAS JEFFERSON, Mar. 1789 – Nov. 1789, at 392 (Julian P. Boyd ed., 1958).



prosperous country.”<sup>453</sup> Such progress would not have been possible had the U.S. Government appropriated or retained for itself the rights to own and use patented inventions without first obtaining inventor consent or providing them with an economic return for their efforts.

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.*<sup>454</sup>

Thus, in the United States, the right conferred by a patent grant is a form of exclusive personal private property *anticipated* by the U.S. Constitution.<sup>455</sup> It is a right to temporarily exclude others from making use, offering for sale, selling, or importing an ‘invention’ into the United States, and it has long been recognized as falling within the protection of the Fifth Amendment’s Takings Clause.<sup>456</sup> Once the statutory conditions for obtaining a patent have been satisfied, only the patent owner or other authorized party possesses the affirmative right to exercise and enforce the patent in the marketplace to derive benefits from it.<sup>457</sup>

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453. James E. Rogan, Under Sec’y of Commerce for Intell. Prop. and Dir. of the U.S. Patent and Trademark Office, Remarks at the Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Feb. 6, 2002, <http://www.ftc.gov/opp/intellect/rogan.htm> [hereinafter Rogan Remarks].

454. *James v. Campbell*, 104 U.S. 356, 358 (1881) (emphasis added); *see also Hollister v. Benedict*, 113 U.S. 59, 67 (1885).

455. *See* Rogan Remarks, *supra* note 453.

456. *See generally James*, 104 U.S. at 356; *Hollister* 113 U.S. at 59.

457. *See* U.S. Patent and Trademark Office, General Information Concerning Patents, <http://www.uspto.gov/web/offices/pac/doc/general/#ptsc> (last visited Dec. 15, 2006) (“A patent for an invention is the grant of a property right to the inventor . . . . 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.”).

## 5. 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 the otherwise undisclosed 'invention.'<sup>458</sup> The U.S. Supreme Court recognized over twenty years ago that trade secrets have legal significance deserving of protection.<sup>459</sup> In *Ruckelshaus v. Monsanto Co.*, the Court held that,

Trade secrets have many of the characteristics of more tangible forms of property . . . [T]o the extent that [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.<sup>460</sup>

## 6. The Bill of Rights Limits Government Action Against Exclusive Private Property

### a. *Federal Government Action – 'Just Compensation'*

The 'just compensation' requirement was added in 1791, as the Fifth Amendment to the U.S. Constitution.<sup>461</sup> It effectively limits the powers of the federal government otherwise conferred by Articles I and II of the U.S. Constitution, including the power of eminent domain, which is the power to take private property for public use by federal, state, or local government.<sup>462</sup> This limitation

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458. See *Ruckelshaus v. Monsanto*, 467 U.S. 986, 1001-02 (1984) ("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.' . . . 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.").

459. See *id.* at 1003-04.

460. *Id.* at 987, 1003-1004.

461. See U.S. CONST. amend. V ("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.").

462. See *Kmiec*, *supra* note 449, at 342 ("[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. 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. 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." (citations omitted)).

is intended to prevent government from sacrificing the rights of individuals for the public good.<sup>463</sup>

Several rationales have been advanced to explain the intention underlying the Bill of Rights' "no taking without just compensation" clause: 1) to prevent the government from deliberately redistributing wealth, directly or indirectly; 2) to prevent the government from indirectly reallocating property among citizens by generating a uniformly desired good or by reducing a uniformly disliked public bad, without otherwise affecting the distribution of wealth; and 3) to prevent government from acting out of some high sense of morality to forbid a formerly accepted and tolerated use of property.<sup>464</sup>

The U.S. Supreme Court has defined the 'just compensation' requirement as ensuring payment that amounts to 'full and adequate compensation'<sup>465</sup> or 'a full and perfect equivalent for' whatever interest in or share of real or personal property has been taken.<sup>466</sup> 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 . . . ."<sup>467</sup> In other words, just compensation must reflect the fair market value of the property, or what a willing buyer would pay a willing seller.<sup>468</sup>

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.<sup>469</sup> A similar

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463. See *TRIBE*, *supra* note 445, at 463 ("[T]he just compensation requirement appears to express a limit on government's power to isolate particular individuals for sacrifice to the general good."); *Armstrong v. United States*, 364 U.S. 40, 49 (1960) ("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.").

464. See *TRIBE*, *supra* note 445, at 463.

465. *Backus v. Fort Street Union Depot Co.*, 169 U.S. 557, 573 (1898).

466. *Monongahela Navigation Co. v. United States*, 148 U.S. 312, 326 (1893).

467. *Chicago B. & Q. R. v. Chi.*, 166 U.S. 226, 250 (1897).

468. See *United States v. Miller*, 317 U.S. 369, 374 (1943).

469. See *Miller*, 317 U.S. at 374; *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, Hamilton & Buffalo Navigation Co.*, 338 U.S. 396 (1949).

standard, as applicable to patents,<sup>470</sup> has since been codified into federal law.<sup>471</sup> Calculating ‘just compensation’ 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 or seriously undermine patent or trade secrets rights) actually results in an artificial or irregular diminution in the fair market value of such property.<sup>472</sup>

The due process of law to which the Fifth Amendment refers relates to both substantive and procedural safeguards guaranteed to individuals against arbitrary governmental actions.<sup>473</sup> An individual’s due process rights are deemed to be implicated “whenever government action seemingly conflict[s] with substantive individual rights.”<sup>474</sup> It has thus been said that 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.<sup>475</sup> Procedurally speaking, the due process clause guaranteed, at a minimum, the right to notice and a hearing prior to deprivation of such a substantive right.<sup>476</sup>

#### *b. State and Local Government Action – ‘Takings’*

The notion of ‘due process of law,’ and its application to the Takings Clause, was extended to the States by the 14th Amendment to the U.S. Constitution in 1868.<sup>477</sup> The 14th Amendment has been interpreted by the U.S. Supreme Court as requiring the protection, at the state and local level, of virtually all of the rights

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470. *See* *Leasona Corp. v. United States*, 599 F.2d 958, 968-69 (Ct. Cl. 1979) (illustrating that where a government 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.”).

471. *See* 28 U.S.C. § 1498 (2000) (allowing the U.S. Government to use a patentee’s invention without his permission in exchange for paying “reasonable and entire compensation”).

472. *See* *Brazil, Gilead Agree AIDS Drug Price Cut*, TODAY ONLINE, May 10, 2006, <http://www.todayonline.com/articles/117593.asp>.

473. *See* TRIBE, *supra* note 445, at 501 (“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.” (footnote omitted)).

474. *Id.* at 507.

475. *See id.* (citing *Tumey v. Ohio*, 273 U.S. 510, 523 (1927)).

476. *See id.* at 507-08.

477. *See* U.S. CONST. amend. XIV (“[N]or shall any State deprive any person of life, liberty, or property, without due process of law . . .”).

guaranteed to individuals by the Bill of Rights at the Federal level.<sup>478</sup> This entails both procedural and substantive rights, including those protected by the 'takings' clause.<sup>479</sup> The U.S. Supreme Court recently affirmed the purpose behind the 'takings clause' in the very recent case of *Lingle v. Chevron USA, Inc.*<sup>480</sup> 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."<sup>481</sup>

*c. Direct and Indirect 'Takings'*

The U.S. Supreme Court's 'takings' jurisprudence has addressed the issue of private property 'takings' mostly in disputes involving states and local municipalities, where it was alleged that real property had been unfairly appropriated without adequate compensation.<sup>482</sup> The Court has held that a taking can occur even in the absence of a direct physical appropriation of, or ousting from, private property.<sup>483</sup> If a government regulation

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478. See *TRIBE*, *supra* note 445, at 507 ("Thus, apart from the specific declarations of the Bill of Rights – virtually all of which later came to be applied to the 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." (footnote omitted)).

479. See *id.* at 508 ("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.").

480. See *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528 (2005).

481. *Id.* at 537 (quoting *First English Evan. Luth. Ch. v. Los Angeles*, 483 U.S. 304, 315 (1987)) (emphasis in original omitted); see also *id.* ("As its text makes plain, the Takings Clause 'does not prohibit the taking of private property, but instead places a condition on the existence of that power.'" (quoting *First English*, 482 U.S. at 314)).

482. See *Lingle*, 544 U.S. at 538-39. The *Lingle* decision has already prompted at least one legal scholar to debate the Court's holding that a 'takings' analysis should not and does not incorporate a 'due process' analysis – i.e., they are separate and independent of one another. See STEVEN J. EAGLE, *LINGLE V. CHEVRON AND ITS EFFECT ON REGULATORY TAKINGS 1-5* (2005), available at [http://d2d.ali-aba.org/\\_files/thumbs/course\\_materials/SL012-CH09\\_thumb.pdf](http://d2d.ali-aba.org/_files/thumbs/course_materials/SL012-CH09_thumb.pdf); see *id.* at 1 ("[C]ontra 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.").

483. See *Lingle*, 544 U.S. at 538 ("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. A second categorical rule applies to regulations that completely deprive an owner of 'all economically beneficial us[e]' of her property." (emphasis in original) (citation omitted)).

deprives an owner of substantially all of the beneficial use, enjoyment, or value of his or her private property, then a taking is deemed to have occurred.<sup>484</sup> In *Lingle v. Chevron USA, Inc.*, for example, former Justice Sandra Day O'Connor discussed how both "the permanent physical invasion" of private property and "the complete elimination of a property's value", i.e. the "total deprivation of [its] beneficial use," are equivalent in that they both "eviscerate the owner's right to exclude others from entering and using her property."<sup>485</sup> 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 advance legitimate state interests.<sup>486</sup>

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 government appropriation (a 'taking') and may be entitled to Fifth Amendment protection.<sup>487</sup> This type of taking, however, has typically been found to occur indirectly via regulation.<sup>488</sup> The U.S. Supreme Court has ruled that a regulation that compels the disclosure of otherwise undisclosed proprietary trade secrets amounts to an unauthorized taking of intangible private property where it impairs, in a substantial manner, the bene-

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484. *Id.* at 539 ("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. . . . In the *Lucas* context, of course, the complete elimination of a property's value is the determinative factor." (citations omitted)).

485. *See id.* at 539 (emphasis added) (citations omitted) (quoting *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1117 (1992)).

486. *See id.*

487. *See* discussion *supra* Part III.C.5; *Ruckelshaus v. Monsanto, Co.*, 467 U.S. 986, 987 (1984) ("To the extent [a private company] has an interest in its health, safety, and environmental data cognizable as a trade-secret property right under [state] law, that property right is protected by the Taking Clause of the Fifth Amendment.").

488. *See Zoltek Corp. v. United States*, 58 Fed. Cl. 688, 705 (2003) ("Today, there are at least two categories of takings where just compensation is due: (1) a physical occupation of the property at issue, the traditional idea of a taking; and (2) a regulatory taking. Regulatory takings are governed by the legal standards outlined in *Monsanto*. In *Monsanto*, the Supreme Court held that the appropriation of an intellectual property interest by a government action requires just compensation for its use when a federal law deprives the intellectual property owner of virtually all investment-backed expectations in the intellectual property. The Supreme Court's decision in *Monsanto* . . . makes clear that an intellectual property interest is deserving of protection under the Fifth Amendment tantamount to real property." (citation omitted)).

ficial use, value, and enjoyment of that property.<sup>489</sup> Indeed, the U.S. Federal Court of Claims has gone so far as to analogize a U.S. Government infringement of a privately held patent to a compensable taking under Fifth Amendment eminent domain theory.<sup>490</sup> At least one legal commentator has characterized compulsory licenses as “the eminent domain of intellectual property.”<sup>491</sup>

*d. Takings for ‘Public Use’*

Another very recent and extremely controversial U.S. Supreme Court decision, *Kelo, et al. v. New London*, has temporarily placed the U.S. Supreme Court’s takings jurisprudence in conflict with itself.<sup>492</sup> 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 (for the private use of future purchasers and lessees newly constructed dwellings and commercial office space), incident to a municipal economic redevelopment plan.<sup>493</sup> The Court’s majority ruled that it was *not* necessary for the replacement property to be actually used by the general public

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489. *Id.*; see also Ruckelshaus, 467 U.S. at 998 (“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.”). Consequently, the Supreme Court agreed with the District Court’s determination that the government regulation had “appropriated Monsanto’s fundamental right to exclude, and that the effect of that appropriation [had been] substantial.” *Id.* at 989.

490. See *Leesona Corp. v. United States*, 599 F.2d 958, 964 (Ct. Cl. 1979) (discussing how 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); *Zoltek Corp. v. United States*, 58 Fed. Cl. 688, 696 (Fed. Cl. 2003) (finding that patent rights are property that may be taken by eminent domain pursuant to 28 U.S.C. § 1498); see also Bradley M. Taub, *Why Bother Calling Patents Property? The Government’s Path to License Any Patent and Maybe Pay for It*, 6 J. MARSHALL REV. INTELL. PROP. L. 151, 154 (2006) (“Government takings via eminent domain in a patent context come in the form of intangible compulsory licenses to use or manufacture patented inventions.” (citation omitted)).

491. 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, July 30, 2001, [http://writ.news.findlaw.com/commentary/20010730\\_chander.html](http://writ.news.findlaw.com/commentary/20010730_chander.html).

492. See *Kelo v. New London*, 125 S. Ct. 2655 (2005).

493. See *id.*

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to be considered a 'public use.'<sup>494</sup> Rather, redevelopment use need only have a conceivable public character or serve a public purpose to be deemed legitimate.<sup>495</sup>

This decision is troubling, in the first instance, because contrary to prior court jurisprudence it focused on the legitimate state interests that the particular regulation sought to advance rather than the burden that it placed on private property rights. It then proceeded to effectively liberalize the 'legitimate state interest' requirement. The majority explained that a *conceivable* public character or public purpose would be inferred if the economic development plan had either eliminated some undesirable 'social and economic evil,' such as crime, time-consuming and costly data research, etc., or had 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").<sup>496</sup> It does not matter whether some private individuals would benefit at the expense of others in the process.<sup>497</sup>

In response to the public outcry following the *Kelo* decision and the growing number of state and municipal-led economic redevelopment plans resulting in real property takings, President Bush issued a new Executive Order (EO) entitled, *Protecting the Property Rights of the American People*.<sup>498</sup> This EO is largely based on prior EO 12630,<sup>499</sup> which had been issued during the

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494. *See id.* at 2662-64.

495. *See id.* at 2665.

496. *Id.* at 2663 (quoting *Berman v. Parker*, 348 U.S. 26, 33 (1954)); *id.* at 2664. This reasoning was apparently consistent with the rationale underlying the Court's earlier decision in *Ruckelshaus*, where the Court held that there was a compensable 'taking' of private property for a 'public use,' even though some private persons would benefit at the expense of others. *See Ruckelshaus v. Monsanto*, 467 U.S. 986, 1014-15 (1984).

497. *See Kelo*, 125 S. Ct. at 2666 ("Quite simply, the government's pursuit of a public purpose will often benefit individual private parties . . . . 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." (quoting *Berman*, 348 U.S. at 34)).

498. Exec. Order No. 13,406, 71 Fed. Reg. 36,973 (June 23, 2006) ("It is the policy of the United States to protect the rights of Americans to their private property, including by limiting the taking of private property by the Federal Government to situations in which the taking is for public use, with just compensation, and for the purpose of benefiting the general public and not merely for the purpose of advancing the economic interest of private parties to be given ownership or use of the property taken.").

499. *See id.* § 4(c) ("This order shall be implemented in a manner consistent with Executive Order 12630 of March 15, 1988."); *see also* Exec. Order No. 12,630, 53 Fed. Reg. 8,859, §§ 1(c), 3(b-c) (Mar. 15, 1988).



Reagan administration to deal with the much larger problem of state and local environmental regulatory-based takings that had plagued the U.S. countryside during the 1970s and early 1980s.<sup>500</sup> It 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.”<sup>501</sup>

Beyond the impact that the Supreme Court’s *Kelo* decision has already had on the U.S. law of real property takings, it has since also encouraged U.S. state and local governments to propose laws that would allow for the issuance of compulsory licenses to control drug prices.<sup>502</sup> More importantly, however, it is arguable that this decision will have much broader and serious ramifications internationally. For example, foreign governments are

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500. See Harvey M. Jacobs, *The Politics of Property Rights at the National Level – Signals and Trends*, 69 J. AM. PLAN. ASS’N. 2, 181, 181-182 (2003) (“[T]hrough the 1988 Executive Order 12630 . . . the administration sought to initiate a national level process analogous to environmental impact assessments (EIAs) called takings impact assessments. 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.”).

501. Exec. Order No. 12, 630, 53 Fed. Reg. 8, 859, § 1(a) (Mar. 15, 1988). EO 12630’s guidelines were updated after the release of a 2003 General Accounting Office report which found that federal agencies had conducted few 12630 takings implications assessments during the 1990s. See U.S. GEN. ACCOUNTING OFFICE, 162 CONG., REPORT TO THE CHAIRMAN, SUBCOMMITTEE ON THE CONSTITUTION, COMMITTEE ON THE JUDICIARY, HOUSE OF REPRESENTATIVES, REGULATORY TAKINGS: IMPLEMENTATION OF EXECUTIVE ORDER ON GOVERNMENT ACTIONS AFFECTING PRIVATE PROPERTY USE 2 (Sept. 2003), available at <http://www.gao.gov/new.items/d031015.pdf>; see also William G. Laffer, *Realistic Options for Reducing the Burden of Excessive Regulation*, HERITAGE FOUND., Jan. 19, 1993, <http://www.heritage.org/Research/Regulation/CM15.cfm> (“[Federal] agencies [could have] easily circumvent[ed] EO 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.”).

502. See Tamsen Valoir, *Legal: State Compulsory Licenses*, PHARMACEUTICAL EXECUTIVE, Nov. 1, 2005, at 44, available at <http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=197791> (“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.”); see also Tim Shorrock, *Capital Appropriations: One Man’s Plan For High-Concept Health Care Legislation*, MOTHER JONES, July/Aug. 2005, at 19, available at [http://www.motherjones.com/news/outfront/2005/07/capital\\_appropriations.html](http://www.motherjones.com/news/outfront/2005/07/capital_appropriations.html).

likely to rely on the majority's misreading of precedent when considering how to treat intellectual property rights, such as patents, 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?

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

The U.S. Supreme Court has held that the U.S. Government cannot act against, and must affirmatively protect, outside of the territory of the United States, any and all of the constitutional rights guaranteed to U.S. citizens by the U.S. Constitution and the Bill of Rights within the United States.<sup>503</sup> The Fifth Amendment right against the taking of private property for public use without just compensation falls within this obligation.<sup>504</sup> This has remained the law of the land for over 150 years.<sup>505</sup>

*f. Constitutional Limitations on the Federal Treaty-Making Power*

The obligation of the federal government to protect the private property rights held by U.S. citizens outside of U.S. borders against unlawful appropriation also extends to takings effect-

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503. *See Reid v. Covert*, 354 U.S. 1, 5-9 (1957) ("[R]eject[ing] 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.").

504. *See id.*

505. *See Mitchell v. Harmony*, 54 U.S. 115, 135 (1851).

ated pursuant to treaties.<sup>506</sup> 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.<sup>507</sup> The U.S. Supreme Court recognized this hierarchy almost fifty years ago, in the case of *Reid v. Covert*.<sup>508</sup> Thus, according to the Court, it is arguable that the President cannot execute and that Congress can neither ratify nor enact legislation implementing a treaty with another nation that effectively violates *any* of the Constitutional protections afforded U.S. citizens.<sup>509</sup> Furthermore, “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 [constitutional] limitations on the treaty power.”<sup>510</sup>

Consequently, the President, in the exercise of his Article II powers, and the Congress, in the exercise of its Article I powers, would therefore be constitutionally precluded from executing and

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506. See U.S. CONST. art. VI, § 2 (The Supremacy Clause provides that “[t]his 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.”).

507. “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.” Legal Info. Inst., *Constitutional Limitations on the Treaty Power*, CORNELL L. SCH., [http://www.law.cornell.edu/anncon/html/art2frag18\\_user.html#fnb328](http://www.law.cornell.edu/anncon/html/art2frag18_user.html#fnb328) (quoting *Whitney v. Robertson*, 124 U.S. 190, 194 (1888)); *id.* at n.329 (“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.” (citations omitted) (omissions in original)).

508. See *Reid v. Covert*, 345 U.S. 1, 16-17 (1957) (“There is nothing in this language [Article VI, Section 1] 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 Constitution 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.” (footnote omitted)).

509. See *id.* at 18 (“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.” (footnote omitted)).

510. Curtis A. Bradley, *The Treaty Power and American Federalism*, 97 MICH. L. REV. 390, 413 (1998) (footnote omitted).

implementing a treaty the provisions of which did *not* adequately protect U.S. citizens against non- or poorly compensable takings of their intellectual property by a foreign treaty party's government.<sup>511</sup> Indeed, this is perhaps why the U.S. Government has insisted that a takings clause be included within Article 31 of the TRIPS Agreement,<sup>512</sup> Chapter 11 of North American Free Trade Agreement (NAFTA), the recently executed Central American Free Trade Agreement (CAFTA), and approximately 2,200 bilateral investment treaties it has consummated or is currently negotiating with other nations around the world.<sup>513</sup>

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 (the substantial diminution in the value) of private investments via oppressive regulation<sup>514</sup> or outright threat of expropriation once considerable upfront costs have already been sunk.<sup>515</sup> Legal commentators have noted that the 'investor-to-state' provisions of NAFTA Chapter 11 broadly define the term 'expropriations' so that it includes both

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511. See Exec. Order No. 12,630, 53 Fed. Reg. 8, 859, §§ 2(a)(1), 2(c)(2) (Mar. 15, 1988). A Takings Impact Assessment would be required if a treaty obligation results in the adoption of administrative, regulatory, and legislative policies and actions that affect, or may affect, the use of any real or personal property. *Id.* However, "[a]ctions taken . . . in preparation for or during treaty negotiations with foreign nations . . . qualify neither as 'policies that have takings implications' under § 2(a)(1), nor as 'Actions' under § 2(c)(2)." *Id.*

512. See Council for TRIPS, *Implementation of Paragraph 11 Of The General Council Decision Of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, art. 31, § 2, U.N. Doc. IP/C/41 (Dec. 6, 2005) ("Where a compulsory license is granted by an exporting Member . . . adequate remuneration . . . shall be paid . . . taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member.").

513. See EMMA AISBETT ET AL., *REGULATORY TAKINGS AND ENVIRONMENTAL REGULATION IN NAFTA'S CHAPTER 11 1-2*, Oct. 25, 2005, available at [http://are.berkeley.edu/courses/EEP131/old\\_files/lectureNotes/CarolEmmafragment.pdf](http://are.berkeley.edu/courses/EEP131/old_files/lectureNotes/CarolEmmafragment.pdf).

514. See Thomas Waelde & Abba Kolo, *Multilateral Investment Treaties and Environmental Expropriation of Foreign Investment*, 5 *CTR. FOR ENERGY, PETROLEUM AND MINERAL L. & POL'Y INTERNET J.* 2 (2000), available at <http://www.dundee.ac.uk/cepmlp/journal/html/vol5/article5-2.html>.

515. See AISBETT, *supra* note 513, at 2 ("Signing a treaty with an expropriation clause is one way a government can pre-commit not to expropriate foreigners' assets . . . 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." (emphasis in original)).

direct nationalization measures and indirect creeping expropriations – i.e., regulatory takings.<sup>516</sup> No matter the form, therefore, a government taking for *any* ‘public use’ is still subject to compensation requirements, as a matter of due process.<sup>517</sup>

The Government of Brazil is aware of and likely seeks to exploit a new model international investment agreement that challenges this kind of thinking. Anti-private property NGO activists and academics have embraced the new model because it would provide developing country governments with the sovereign right to take indirectly (through legislation and/or 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.<sup>518</sup> Such an agreement only adds to the confusion over the scope of private property rights that has been triggered by several 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 towards the scope of private property rights, have made a considerable effort to protect the private property rights of U.S. citizens doing business abroad. And, this may have included conducting ‘takings impact assessments’ with respect to, and/or by actually incorporating Fifth Amendment-type takings clauses within many of the multilateral and bilateral treaties they have negotiated with foreign nations.

However, are such efforts enough, from a U.S. constitutional

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516. *Id.* at 1 (“[NAFTA Chapter 11] entitles investors to take expropriation claims against the host country directly to international courts . . . [It also defines the term] 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.”).

517. *See id.* at 6 (“[A]ccording 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.”).

518. *See* HOWARD MANN ET AL., IISD MODEL INTERNATIONAL AGREEMENT ON INVESTMENT FOR SUSTAINABLE DEVELOPMENT 17, available at [http://www.iisd.org/pdf/2005/investment\\_model\\_int\\_agreement.pdf](http://www.iisd.org/pdf/2005/investment_model_int_agreement.pdf); *see also* Daniel M. Price, Partner at Sidley, Austin, Brown & Wood, Remarks at the Carnegie Endowment Workshop on the IISD’s Model International Agreement on Investment for Sustainable Development (May 5, 2005) (transcript available at <http://www.carnegieendowment.org/events/index.cfm?fa=eventDetail&id=808>) (“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.*” (emphasis added)).

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, and this has had the effect of substantially diminishing the value of such IPRs and weakening the negotiating leverage of the IP holders. Furthermore, the Brazilian Government has pursued this approach through exercise of its police power for the ostensible purpose of benefiting the Brazilian 'public interest.' Or in other words, in the interests of Brazilian citizens and companies, Brazil 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 in the form of 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?

#### IV. BRAZIL MUST STOP UNDERMINING U.S. PRIVATE PROPERTY RIGHTS

##### A. *Brazil's Efforts Against Counterfeits do not Compensate for its Continued IP Opportunism*

##### 1. Brazil Has Made Some Progress Against Counterfeits

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 up IPR enforcement along its border with Paraguay, and increased its seizure rate of copyrighted materials.<sup>519</sup> Prior to these efforts,

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519. See U.S. COM. SERV., INT'L TRADE ADMIN. IN THE U.S. DEP'T OF COM., COUNTRY

the Brazilian Congress' Deputies had formed a Commission of Parliamentary Inquiry on piracy and amendments to the criminal code.<sup>520</sup> Foreign inventors and investors should applaud the Brazilian government's efforts because they reflect an official acknowledgement that IP piracy is no longer tolerable as national policy.

## 2. Brazil's Institutions and Ideology Must Change to Stem IP Opportunism

Notwithstanding these efforts, U.S. Government officials remain concerned that Brazil continues to fall short in providing adequate and effective protection of U.S. IPRs.<sup>521</sup> Despite Brazil's enactment of modern copyright legislation, significant challenges to effective copyright enforcement, particularly with respect to optical media and internet piracy, remain.<sup>522</sup> Furthermore, Brazil continues to be 'one the world's largest pirate markets'<sup>523</sup> and thus poses a real risk to patent as well as copyright-based technology owners.<sup>524</sup>

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.<sup>525</sup> As of January 2006, however, it was revealed that the patent backlog was actually as large as 130,000 patents.<sup>526</sup> Of these, 17,000 are for pharmaceutical patents, each bearing an upfront

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COM. GUIDE FOR BRAZ. 6 (Jan. 2006) [hereinafter CCG 2006], *available at* <http://www.focusbrazil.org.br/ccg/> (follow Entire CCG in One Document hyperlink, open PDF file).

520. *Id.*; see also U.S. COM. SERV., INT'L TRADE ADMIN. IN THE U.S. DEP'T OF COM., COUNTRY COMMERCIAL GUIDE FOR BRAZ. 28 (Jan. 2005) [hereinafter CCG 2005], *available at* <http://strategis.ic.gc.ca/epic/internet/inimr-ri2.nsf/en/gr-01304e.html> (follow hyperlink for Doing Business in Brazil: The 2005 Commercial Guide for US Companies (PDF)).

521. See CCG 2006, *supra* note 519, at 6.

522. See *id.*

523. CCG 2005, *supra* note 520, at 28.

524. See BRAZIL MARKET RESEARCH, *supra* note 7, at 2 ("Software piracy continues to be a large problem for Brazil. In March of 2005, the Business Software Alliance (BSA) estimated that 64 percent of all software used in Brazilian computers was pirated. In March 2004, the estimate was 55 percent, and in 2003, BNamericas estimated the problem at 61 percent. . . . Beyond increased internet accessibility, the Government of Brazil's insistence that government agencies use free open source software is hurting the development of the domestic industry and some U.S. software suppliers.").

525. See CCG 2005, *supra* note 520, at 28.

526. See CCG 2006, *supra* note 519, at 7.

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U.S. \$30,000 filing fee, and some have been pending for several years.<sup>527</sup>

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.<sup>528</sup> One such failure concerns the inability of Brazil's health infrastructure to efficiently distribute medicines to rural communities and to effectively treat and care for those patients whom it can reach.<sup>529</sup> Another such failure concerns Brazil's lack, until very recently, of a national innovation system<sup>530</sup> that could support Brazil's less than efficient<sup>531</sup> national industrial development pol-

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527. *See id.*

528. *See id.* at 6 (“[D]ebate continues within the Brazilian Government, legislature and society over issues relating to patents, compulsory licensing and access to medicines.”)

529. *See* Margareth Crisóstomo Portela & Michel Lotrowska, *Health Care to HIV/AIDS Patients in Brazil*, 40 REVISTA SAÚDE PÚBLICA (April 2006), available at [http://www.scielo.br/scielo.php?script=sci\\_arttext&pid=S0034-89102006000800010&lng=&nrm=&tlng=en](http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0034-89102006000800010&lng=&nrm=&tlng=en) (“The Brazilian health care system is undermined by serious operational problems and several different local realities, many of them below the desired care standards.”); *Looking at Health Care*, CITIZENSHIP AND IMMIGRATION CANADA, CULTURE PROFILES PROJECT: BRAZIL, available at <http://www.cp-pc.ca/english/brazil/health.html> (“Health and sanitary conditions in Brazil vary widely from region to region. The big cities have many physicians who have trained abroad. In smaller towns and interior areas of Brazil however, there is a shortage of doctors, nurses and hospitals. While Brazil offers a public health care system, its coverage is not extensive.”).

530. *See* Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil's Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, INT'L J. ECON. DEV. [hereinafter Kogan, *Rediscovering*]; Maria Beatriz Amorim Páscoa, *In Search of an Innovative Environment – The New Brazilian Innovation Law*, WIPO, [http://www.wipo.int/sme/en/documents/brazil\\_innovation.htm](http://www.wipo.int/sme/en/documents/brazil_innovation.htm); Maria Jose Amstalden Sampaio, *Perspectives From National Systems and Universities*, in INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURE – THE WORLD BANK'S POSSIBLE FUTURE ROLE IN ASSISTING BORROWER AND MEMBER COUNTRIES 50 (Uma J. Lele et al. eds., 1999).

531. For example, in a paper released during 2004, one commentator noted that during Brazil's import substitution era (1940-1980) and its 'quasi-stagnation' period (1981-2003), “[the] Brazilian state was incoherent in spelling out and implementing its policies; 3) pre-existent institutions made the economic system less flexible; 4) in particular, still today, there are only seven big banks in Brazil; 5) industrial structure remained by and large the same during the whole period; 6) imitation during the first stage has been harmed by very low standards of education, which only recently have started to change only recently.” Michele di Maio & Mario Sylos Labini, *Notes from the Initiative for Policy Dialogue, Industrial Task Force Meeting*, INITIATIVE FOR POLY DIALOGUE (Shana Hofstutter ed., Mar. 17-19, 2004), at 13, available at <http://www0.gsb.columbia.edu/ipd/pub/IPMarch2005Notes.pdf> [hereinafter Initiative for Policy Dialogue Notes]; Donald Hay, *Instituto de Pesquisa Econômica Aplicada*, INDUSTRIAL



icy.<sup>532</sup> Furthermore, Brazil's ideological reluctance to recognize private IPRs in the field of life science technologies, despite the existence of national patent and data exclusivity legislation, has placed its drive towards innovation-based development at risk and ignited international passions in the pharmaceutical and biotechnology industries.<sup>533</sup>

The Government of Brazil has, with the assistance of anti-private property and anti-free market activists, academics, and bureaucrats, continued to employ opportunistic policies and practices<sup>534</sup> to compel international, primarily U.S., pharmaceutical companies to significantly reduce their drug prices to an at-or-below-cost level.<sup>535</sup> If the companies refuse, Brazil then threatens to break, i.e. to take, their patents via issuance of a compulsory license that it argues is sanctioned as a permissible flexibility within the TRIPS Agreement.<sup>536</sup> 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.<sup>537</sup>

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POLICY IN BRAZIL: A FRAMEWORK 1-2, 7-8, 10-11, 15 (Mar. 1998), <http://www.ipea.gov.br/pub/td/td0551.pdf>.

532. Brazil only recently introduced its newly updated national industrial policy. See Patricia Marega, *Brazil's New Industrial Policy*, PINHEIRO NETO ADVOGADOS, available at <http://strategis.ic.gc.ca/epic/internet/inimr-ri.nsf/en/gr124394e.html> ("On March 31, 2004, President [Lula], and the Minister of Development, Industry and Foreign Trade, Luis Fernando Furlan, launched a new industrial, technological and foreign trade policy entitled *Building the Brazil of the Future*. . . . The main goals . . . consist in promoting the smooth and steady economic growth of Brazil by implementing a more efficient and versatile national production, increasing the export of goods (such as software and pharmaceuticals), decreasing the external vulnerability, and boosting investment rates. The New Industrial Policy does not call for any immediate measures, nor does it intend to rush toward reaching its goals.")

533. See CCG 2006, *supra* note 519, at 7 ("Invoking TRIPS provisions, Brazil has at times threatened to issue compulsory licenses for anti-retrovirals used to treat HIV/AIDS if satisfactory supply agreements, including reductions in price, could not be reached; to date, Brazil has not issued a compulsory license."); BRAZIL MARKET RESEARCH, *supra* note 7, at 3 ("The [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 . . . . To justify its threats, the GOB refers to a WTO clause that allows compulsory licensing in cases of national health emergencies."); Kogan, *Rediscovering*, *supra* note 530, at 179-187.

534. See Initiative for Policy Dialogue Notes, *supra* note 531, at 9-13, 16, 26-28.

535. See discussion *supra* Part II.B.5.

536. See *id.*

537. Chamas, *supra* note 7 ("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 . . . degree of

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Indeed, it is arguable that 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. Brazilian Government and industry have made no secret of their desire to develop a strong generic drug manufacturing capacity in order to preserve the domestic market for Brazilian companies, and 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 law liberally in order to achieve this objective. 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.<sup>538</sup> This has permitted Brazil to reverse engineer many foreign drugs and to then reconstitute them through application of new synthetic processes, as a completely unique molecule or product susceptible to national patenting.<sup>539</sup> The Brazilian Government, with NGO support, has

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freedom offered by the international agreements for the conformance of rights (the TRIPs Agreement, for example) to undertake a more equitable implementation at the 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. . . . Safeguards such as compulsory licensing are vital. . . .* (emphasis added).

538. See Lei No. 9279, de 14 de maio de 1996, art. 42, available at <http://www.araripe.com.br/law9279eng.htm#patcap5> ("A patent entitle [sic] its owners the right to prevent third parties from manufacturing, using, offering for sale, selling or importing the following: I - a *product* that is the subject of a patent; II - a *process*, or product directly obtained by a patented process." (emphasis added)).

539. See Maurice Cassier & Marilena Correa, *Patents, Innovation and Public Health: Brazilian Public-Sector Laboratories' Experience in Copying AIDS Drugs*, in *ECONOMICS OF AIDS AND ACCESS TO HIV/AIDS CARE IN DEVELOPING COUNTRIES, ISSUES AND CHALLENGES* 91 (2003), available at <http://www.iaen.org/papers/anrs.php> (follow hyperlink for Chapter 3) ("The Brazilian experience of AIDS drug production has shown that reverse engineering is a source of acquisition of knowledge for a laboratory."); EUR. FED'N OF PHARMACEUTICAL INDUSTRIES AND ASS'NS [EFPIA], POSITION PAPER – BRAZIL 1 (Nov. 2004), available at [http://www.efpia.org/4\\_pos/Brazil2004.pdf](http://www.efpia.org/4_pos/Brazil2004.pdf) ("In 1996, Brazil enacted an overall good patent law; unfortunately, Brazil has not enforced its patent law consistently and has allowed for a slow erosion of the law. The principle concern of the research-based pharmaceutical industry is Article 229-C of the 1999 amendment to the patent law, which gives the National Sanitary Supervision Agency (ANVISA) authority to approve pharmaceutical patents before they are issued. Other concerns include the large patent backlog, the lack of respect for data confidentiality and the lack of linkage between ANVISA and the patent office resulting in copies of pharmaceutical products receiving sanitary registrations as well as compulsory licences in case of public interest.").

continued to justify a policy that favors the use of legal 'safeguards' by referring to the extreme economic hardships that it would endure if it were otherwise required to pay the higher prices that patents usually demand.<sup>540</sup>

According to one prominent Brazilian scientist and intellectual property expert, IPRs are dispensable and may be wielded as both a sword and a shield by the Brazilian Government, if, and when, it is convenient and in the national interest to do so.<sup>541</sup> Interestingly, some within Brazil's pharmaceutical industry agree that maintaining strong protection of foreign patents works against their economic interests. They see the protectionist benefits that may be gained from the Brazilian Government's emphasis of the possible health risks engendered by according unnecessary protection to foreign patents and trade secrets.<sup>542</sup> Based on this evidence, one may credibly argue that some Brazilian Government regulators and domestic companies seek for Bra-

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540. See CLAUDIA INES CHAMAS ET AL., CTR. FOR THE MGMT. OF INTELL. PROP. IN HEALTH RES. & DEV. [MIHR], *Developing Innovative Capacity in Brazil to Meet Health Needs*, in INNOVATION IN DEV. COUNTRIES TO MEET HEALTH NEEDS – EXPERIENCES OF CHINA, BRAZIL, SOUTH AFRICA AND INDIA: COUNTRY REPORTS FOR SUBMISSION TO THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 98-99 (Ingrid Hering ed., Apr. 2005) available at <http://www.who.int/intellectualproperty/studies/MIHR-INNOVATION%20EXPERIENCES%20OF%20South%20Africa,%20CHINA,%20BRAZIL%20AND%20INDIA%20MIHR-CIPIH%20REPORTS%2014-04-05.pdf> ("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 [HIV medications] 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 [Brazilian] 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."); see also Posting of James Love, james.love@cpotech.org, *AIDS: Expenses Reignite Discussions Over Patents*, O GLOBO, Apr. 16, 2006, to IP-Health, <http://lists.essential.org/pipermail/ip-health/2006-May/009499.html> (May 8, 2006, 16:28:19).

541. See CHAMAS, *supra* note 540, at 105-106 ("*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." (emphasis added)).

542. See Marcos Oliveira, *Patentes: Tempo de Crise, Tempo de Mudança* [Patents: Time of Crisis Time of Change], ABIFINA INFORMA (Jan. 2006), available at <http://www.abifina.org.br/informaNoticia.asp?cod=62>.

zil to acquire foreign, particularly U.S., technologies opportunistically to advance both its evolving national industrial and innovation agenda and its international economic/trade interests. All of this leads one to believe that Brazil must change its ideology and reform its institutions to stem IP opportunism.

### 3. The Old Ways Are Simply No Longer Acceptable

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 than the opportunistic practices of other countries during past industrial eras. However, there are three crucial differences that must be emphasized. First, there are now binding multilateral treaties (the GATT/WTO/WIPO 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 time-tested industry and mercantile customs and industry standards codes in place that may be referenced as precedent to determine the shape and direction of evolving industry practices surrounding new hi-technologies.<sup>543</sup> Third, there is documentary evidence of successful national systems of innovation that recognize and protect exclusive private property rights, including IPRs.<sup>544</sup> 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 since largely evolved.

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543. See National Institute of Standards and Technology, National Standards Bodies, <http://www.nist.gov/oiaa/stnd-org.htm> (last visited Jan. 7, 2007) ("International standardization is well-established for many technologies in such diverse fields as information processing and communications, textiles, packaging, distribution of goods, energy production and utilization, shipbuilding, banking and financial services. International standards will continue to grow in importance for all sectors of industrial activity for the foreseeable future. International standards can facilitate world trade by effectively removing technical barriers to trade, leading to new market opportunities and economic growth. . . . [WTO] Agreement on Technical Barriers to Trade (TBT) explicitly recognizes that international standards play a critical role in improving industrial efficiency and facilitating world trade. . . . There are a diversity of bodies involved in the preparation of standards used globally. . . . [I]n certain technology sectors, consortia organizations are popular means for the development of global standards. Consortium technical categories include areas such as e-commerce, the Internet, multimedia, web services and so on.").

544. See Kogan, *Rediscovering*, *supra* note 530, at 157-74, 200-209, 227-248.

*B. Continued IP Opportunism May Cost Brazil Significant Bilateral and Regional Benefits*

Apart from commencing an action at the WTO, the U.S. Government possesses a portfolio of bilateral and regional options to address Brazil's continuing IP opportunism.

1. Brazil-United States Science & Technology Cooperation

Brazil and the United States have "traditionally enjoyed friendly, active relations encompassing a broad political and economic agenda"<sup>545</sup> including joint science and technology cooperation. There has even been a growing consensus between Brazil and the United States concerning the benefits of sharing science and technology know-how and the importance of protecting the intellectual property rights that underlie it.<sup>546</sup> As a result, a number of joint projects and initiatives between the two countries have evolved; they have included the participation of both governmental and private (industry, university and nonprofit) institutions.<sup>547</sup>

The basis for such cooperation resides in the periodic renewal of the long-term Brazil-U.S. bilateral science and technology agreement.<sup>548</sup> Under the auspices of this science and technology (S/T) 'umbrella agreement,' other institutional agreements have been reached. A number of joint Brazil-U.S. R&D technical capacity and knowledge-building activities have proceeded under these agreements. In fact, there are a broad variety of joint research projects and academic exchanges currently being pursued, for example, in the areas of energy,<sup>549</sup> earth and space science,<sup>550</sup> and agricultural biotechnology.<sup>551</sup> In addition, the technical standards

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545. U.S. DEP'T OF STATE, BUREAU OF W. HEMISPHERE AFF., BACKGROUND NOTE: BRAZIL (Aug. 2006), available at <http://www.state.gov/r/pa/ei/bgn/35640.htm>.

546. See Brazilian Embassy in Washington D.C., Brazil-U.S. Cooperation, [http://www.brasilemb.org/science\\_tech/tech4.shtml](http://www.brasilemb.org/science_tech/tech4.shtml) (last visited Dec. 18, 2006).

547. See Kogan, *Rediscovering*, *supra* note 530, at 257-59.

548. See Science and Technology, U.S.-Braz., Feb. 6, 1984, 35.5 U.S.T. 5116.

549. See Press Release, U.S. Dep't of Energy, Secretary Abraham Announces Energy Partnership with Brazil - Supports President Bush's Call for International Energy Cooperation (June 20, 2003), <http://www.energy.gov/news/1071.htm>; Press Release, U.S. Dep't of Energy, Secretary Abraham Announces Agreement with Brazil on Hydrogen Energy Research - Supports President Bush's Hydrogen Initiative, International Partnerships (Apr. 19, 2004), <http://www.energy.gov/news/1324.htm>.

550. U.S. DEP'T OF STATE, EMBASSY OF THE U.S. - BRAZIL, U.S.-BRAZILIAN ESTH COOPERATION (2006), <http://www.embaixada-americana.org.br/index.php?action=materia&id=2470&submenu=esth.php&itemmenu=174>; U.S. DEP'T OF ENERGY, ENERGY INFO. ADMIN., COUNTRY ANALYSIS BRIEFS - BRAZIL: ENVIRONMENTAL ISSUES, (2003), <http://www.eia.doe.gov/emeu/cabs/brazenv.html>.

551. ADIRANA DELGADO ET AL., IADB, BRAZIL: TECHNOLOGICAL INNOVATION AND

agencies of the U.S. and Brazilian Governments have executed MOU to ensure the development of consistent science-based national measurement standards in the chemistry, physics and engineering fields.<sup>552</sup>

The Bush administration, however, can be persuaded not to fund further bilateral S/T collaborations, and to even terminate others, if Brazil's IP opportunism is seen as threatening the economically valuable IPRs of innovative U.S. companies and inventors, and hence, America's scientific, technological and economic competitive advantages.

## 2. Inter-American Development Bank Program Financing

The Inter-American Development Bank (IADB) has long been instrumental in encouraging private investment, supporting small businesses, and promoting economic growth in the Latin American region, including Brazil.<sup>553</sup> For example, in the past the IADB earmarked loans for Brazil that focused on promoting S/T infrastructure capabilities and improving *market sector* participation in such programs.

Although the IADB's early support for national S/T policies focused mostly on government 'institution-building,' they have since placed "a greater emphasis on supporting the *business sector's efforts* at technological modernization."<sup>554</sup> The primary objective has been to raise competitiveness by enhancing enterprise

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NEW MANAGEMENT APPROACHES IN AGRICULTURAL RESEARCH—AGROFUTURO (2004), <http://www.iadb.org/exr/doc98/apr/br1595e.pdf>.

552. See Memorandum of Understanding Between the National Institute of Standards and Technology of the Department of Commerce of the United States of America and the National Institute of Metrology, Standardization, and Industrial Quality of the Ministry of Development, Industry and Foreign Trade of the Federative Republic of Brazil, U.S.-Braz., Apr. 10, 2002, available at <http://www.nist.gov/oiaa/nistinmetro.pdf>. The MOU will terminate unless otherwise renewed on April 9, 2007. See *id.*

553. The Bank has made 371 loans totaling approximately \$28.4 billion and bank disbursements to Brazil have totaled approximately \$27.4 billion. See IADB, Brazil and the IDB, [http://www.iadb.org/countries/home.cfm?language=english&id\\_country=br&parid=1](http://www.iadb.org/countries/home.cfm?language=english&id_country=br&parid=1) (last visited Jan. 7, 2007); *id.* (follow disbursement hyperlink to see disbursement data). (last visited Jan. 2, 2007); see also ANTONIO GIUFFRIDA, IADB, LEARNING FROM THE EXPERIENCE: THE INTER-AMERICAN DEVELOPMENT BANK AND PHARMACEUTICALS 17, available at <http://www.iadb.org/sds/doc/SOC123.pdf>.

554. Alberto Melo, *The Innovation Systems of Latin America and the Caribbean* (IADB Working Paper No. 460, 2001), available at <http://www.iadb.org/res/publications/pubfiles/pubWP-460.pdf> (emphasis added). The loan proposal for the Science and Technology Program (880/OC-BR) of \$320 million, of which \$160 million, was approved by the IADB. See IADB, SCIENCE AND TECHNOLOGY PROGRAM, BRAZIL (1995), available at <http://www.iadb.org/EXR/doc98/apr/br880e.htm>.

level innovation.<sup>555</sup> In 1996 and 1999, for example, 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 public procurement and distribution of medicines.<sup>556</sup> The project was also to have resulted in the preparation of a study that would yield recommendations concerning how to improve human and institutional capacities.<sup>557</sup> And more recently, the IADB approved funding for a portion of a proposed Brazil agri-food project involving the development of intellectual property-rich biotechnology-based processes.<sup>558</sup> The project seeks an 80% increase in the rate of patent filings/registrations by 2007.<sup>559</sup>

It cannot be confirmed, however, that these funds were actually used in this manner. Previous Brazilian Government, IADB and World Bank oversight failures that have only recently come to light likely compromised these institutions' ability to monitor sufficiently whether good manufacturing practices were being followed, how imported pharmaceutical raw materials were being used, and if foreign patents were being protected during the terms of these loans.<sup>560</sup> In other words, there is no proof that Brazil had not diverted these subsidized medicines to local generic manufacturers to enhance their reverse-product engineering, production and national process patenting capabilities.<sup>561</sup>

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555. See MELO, *supra* note 554, at 45-46.

556. See GIUFFRIDA, *supra* note 553, at 5, 10 and App.; see also Jillian Clare Cohen, *Public Policies in the Pharmaceutical Sector: A Case Study of Brazil*, 54 LCSHD PAPER SERIES 1 (Jan. 2000).

557. See GIUFFRIDA, *supra* note 553; Cohen, *supra* note 556.

558. See DELGADO, *supra* note 551.

559. See *id.*

560. See Cohen, *supra* note 556, at 19 ("In the past, manufacturers in the public and private [pharmaceutical] sectors [of Brazil] have not been consistently subject to sufficient monitoring for GMP [good manufacturing practice] standards, nor rigorous testing of product quality. The same applies to raw materials. . . ."); see also CHRIS BREYER ET AL., WORLD BANK OPERATIONS EVALUATION DEP'T, EVALUATION OF THE WORLD BANK'S ASSISTANCE IN RESPONDING TO THE AIDS EPIDEMIC: BRAZIL CASE STUDY 25, available at [http://www.worldbank.org/ieg/aids/docs/case\\_studies/hiv\\_brazil\\_case\\_study.pdf](http://www.worldbank.org/ieg/aids/docs/case_studies/hiv_brazil_case_study.pdf) ("[T]he World Bank has taken the position that although the [National AIDS Program] 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.").

561. See Cohen, *supra* note 556, at 10-11. During this time period (1998), 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

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Furthermore, the IADB's Multilateral Investment Fund (MIF) arm has also been involved in funding Brazilian projects that promoted the development of open source computer software in Brazil.<sup>562</sup> Apparently, the policy objective underlying these small loan facilities was consistent with Brazil's evolving national policy of requiring all sectors of government to procure only open source software programs for their internal use.<sup>563</sup> And, it also seemed consistent with Brazil's call for open source software to become the new international standard during the 2005 WSIS.<sup>564</sup>

Since the United States has traditionally been a steward and supporter of the IADB and its project-related work, a high-ranking cabinet official (usually the U.S. Treasury Secretary) has retained a seat on the IADB's decision-making Board of Governors.<sup>565</sup> This seat has also served to represent U.S. national interests. The U.S. administration, therefore, need not continue its support for, and may even vote against, proposed IADB funding of Brazilian projects, if the Government of Brazil fails to cease its constructive takings of U.S. private property for public use without just compensation. In fact, the U.S. Government has already used its influence to prevent the IADB from disbursing previously

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within Latin America, the world's then-fastest growing regional pharmaceutical marketplace. *Id.* at 10, 11, 19. Although Brazilian pharmaceutical companies had secured only 30% of their domestic market (1997), they nevertheless possessed pharmaceutical reproductive capabilities with respect to both therapeutic ingredients and finished products, and could easily have drawn from the 60-70% of pharmaceutical raw materials they had then been importing.

562. The IADB administers the MIF, a technical assistance mechanism of the Bank, in accordance with an agreement with MIF's Donors Committee. *See* IADB, *How Does the MIF Work?*, [http://www.iadb.org/mif/v2/where\\_money.html](http://www.iadb.org/mif/v2/where_money.html) (last visited Dec. 18, 2006); *see also* IADB, *Project Database*, <http://www.iadb.org/mif/v2/projectsort.asp?Type=country&Param1=BR&C=8&Status=99> (last visited Dec. 18, 2006); IADB, *Project Database*, *SME Metasys (MIF/AT-474)*, <http://www.iadb.org/mif/v2/projectview.asp?ID=1874&C=8> (last visited Dec. 18, 2006) ("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.*" (emphasis added)); IADB, *Project Database*, *Competitive Support Program for Software SMEs (MIF/AT-649)*, <http://www.iadb.org/mif/v2/projectview.asp?ID=1925&C=8> (last visited Dec. 18, 2006).

563. *See* CCG 2005, *supra* note 520, at 32, 51; *Brazil Gives Nod to Open Source*, ASSOCIATED PRESS, Nov. 16, 2003, *available at* <http://www.wired.com/news/infrastructure/0,1377,61257,00.html>.

564. On November 16, 2005, Brazil's Minister of Culture and the Secretary-General of UNCTAD "signed a memorandum of understanding [] to support the promotion of free and open-source software (FOSS)." *UNCTAD and Brazil Support Free and Open-Source Software*, *supra* note 401.

565. *See* IADB, *About the IDB – Board of Governors*, [http://www.iadb.org/aboutus/IV/go\\_governors.cfm?language=english](http://www.iadb.org/aboutus/IV/go_governors.cfm?language=english) (last visited Dec. 18, 2006).



approved funding to an intended beneficiary government where that government's policies were determined to threaten U.S. national interests,<sup>566</sup> and it may even consider doing so again.<sup>567</sup>

### 3. U.S. Export-Import Bank Program Financing

Brazil has ranked as the U.S. Export-Import Bank's (Eximbank) second largest market in Latin America after Mexico.<sup>568</sup> The Eximbank is the official export credit agency of the United States.<sup>569</sup>

The Eximbank has enjoyed a productive relationship with Brazil since at least the 1940s, when it helped to finance the construction of Brazil's first steel manufacturing plant at Volta Redonda in the state of Rio de Janeiro.<sup>570</sup> From 1997 through 2005, Eximbank directly authorized for funding approximately \$3.17 billion, consisting of approximately, \$1.18 billion in loans, \$1.16 billion in loan guarantees and \$833 million in export credit insurance supporting Brazilian company purchases of U.S. goods and services.<sup>571</sup>

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566. See generally 108 CONG. REC. H3558-H3564 (Apr. 30, 2003) (discussing testimony before the House of Representatives reacting to the recommendation to the IADB President by the U.S. Representative to block disbursement of loans to Haiti).

567. See Christopher Swann & Richard McGregor, *Renminbi Weakness Tests U.S. Patience*, FIN. TIMES, Mar. 29, 2006, at 4 ("If the Treasury were to find that the renminbi was 'misaligned' and that this was damaging the US 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 . . . and less favorable status under US anti-dumping laws.").

568. See Ian Vásquez, *Re-authorize or Retire the Export Import Bank?*, CATO INST., May 8, 2001, available at <http://www.cato.org/testimony/ct-iv050801.html>.

569. See generally Eduardo Aguirre, Jr., *Export-Import Bank Financing for U.S. Exports to Latin America*, SETON HALL J. DIPL. & INT'L. REL. 135 (2003) (discussing financing for U.S. exports to Latin America).

570. See Embassy of Brazil in London, *Economy and Finance, Historical Perspective*, <http://www.brazil.org.uk/economy/historical.html> (last visited Dec. 18, 2006).

571. Annual reports detail EximBank funding by year: fiscal year (FY) 2005: (\$0 loans, \$43.2M loan guarantees, \$35M export credit insurance); FY 2004 (\$76.9M loans, \$81.2M loan guarantees, \$55M export credit insurance); FY 2003 (\$52.7M loans, \$120.1M loan guarantees, \$55.1M export credit insurance); FY 2002 (\$24.1M loans, \$20.5M loan guarantees, \$29.4M export credit insurance); FY 2001 (\$623.7M loans, \$69M loan guarantees, \$36.1M export credit insurance); FY 2000 (\$0 loans, \$404M loan guarantees, \$83.1M export credit insurance); FY 1999 (\$152.8M loans, \$50.7M loan guarantees, \$310.2M export credit insurance); FY 1998 (\$68.7M loans, \$171.4M loan guarantees, \$112.9M export credit insurance); and FY 1997 (\$177.2M loans, \$198.2M loan guarantees, \$116.2M export credit insurance). These reports can be found at the Export Import Bank of the U.S., Annual Reports website at <http://>

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The Eximbank has also supported a few large public infrastructure and private commercial projects during this period that have provided social as well as economic benefits to Brazilians. They have included a 469-megawatt combined cycle power plant in Araucaria, Brazil, a \$1.1 billion integrated ethylene and polyethylene complex in Rio de Janeiro, and a municipal water filtration and waste-water-treatment facility.<sup>572</sup> Since 2000, Eximbank has also operated a program (the 'Sub-sovereign Program') to provide Brazilian municipalities and state governments with the financing needed to procure essential infrastructure-related goods and services.<sup>573</sup> In addition, Eximbank financing and/or loan guarantees have helped to secure important goods and services purchases by Brazilian aircraft,<sup>574</sup> oil and gas production,<sup>575</sup> construction,<sup>576</sup> health care<sup>577</sup> and textile companies.<sup>578</sup>

Although the trade policy of the Eximbank is largely shaped by the U.S. Trade Representative (USTR), a cabinet official who is

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[www.exim.gov/about/reports/ar/index.cfm](http://www.exim.gov/about/reports/ar/index.cfm) (follow hyperlinks for annual reports) (last visited Jan. 2, 2007).

572. See Aguirre, *supra* note 569, at 137.

573. See *id.* at 138; see also Press Release, Export-Import Bank of the U.S., Ex-Im Bank Announces New Program to Accept the Credit of Emerging Market Cities, States (Aug. 11, 2000), <http://www.exim.gov/pressrelease.cfm/2000> (follow Aug. 11, 2000 hyperlink); Press Release, Export-Import Bank of the U.S., Ex-Im Bank Opens Financing in the Public Sector of Brazil, Increases Credit Limit for Brazilian Banks by \$1 Billion (Dec. 3, 1998), <http://www.exim.gov/pressrelease.cfm/1998> (follow Dec. 3, 1998 hyperlink).

574. See Press Release, Export-Import Bank of the U.S., Ex-Im Bank Supports Export of Sikorsky Commercial Helicopters to Brazil (Sept. 7, 2004), <http://www.exim.gov/pressrelease.cfm/2004> (follow Sept. 7, 2004 hyperlink).

575. See Press Release, Export-Import Bank of the U.S., Ex-Im Bank Finances U.S. Export Sale to Build High-Technology Deep Water Oil and Gas Production Platform Off Brazil (May 25, 2005), <http://www.exim.gov/pressreleases.cfm/2005> (follow May 25, 2005 hyperlink); see also Sustainable Energy & Economy Network, Project Profile: Petrobras Oil and Gas Developments, <http://www.seen.org/db/Dispatch?action=ProjectWidget:637-detail=1> (last visited Dec. 18, 2006); Sustainable Energy & Economy Network, Project Profile: Canoas 250MW Gas-Fired Power Plant, <http://www.seen.org/db/Dispatch?action=ProjectWidget:422-detail=1> (last visited Dec. 18, 2006).

576. See Press Release, Export-Import Bank of the U.S., Ex-Im Bank's Medium-Term Financing to Assist Brazilian Buyers in Purchase of U.S. Construction, Manufacturing, and Equipment (Feb. 16, 2000), <http://www.exim.gov/pressreleases.cfm/2000> (follow hyperlink to Feb. 16, 2000).

577. See Press Release, Export-Import Bank of the U.S., Ex-Im Bank Supports U.S. Exports to Equip New Hospital in Brazil (Aug. 3, 2000), <http://www.exim.gov/pressreleases.cfm/2000> (follow hyperlink to Aug. 3, 2000).

578. See Press Release, Export-Import Bank of the U.S., Ex-Im Bank Facilitates US Cotton Sales to Brazil (Mar. 23, 2000), <http://www.exim.gov/pressreleases.cfm/2000> (follow hyperlink to Mar. 23, 2000).

a non-voting member of the Eximbank,<sup>579</sup> the U.S. Congress, nevertheless, ultimately bears the legal and political responsibility for deciding whether to periodically reauthorize, through appropriations, the Bank's international lending activities<sup>580</sup> for a successive five-year period. Given the debate over HIV/AIDS drug patent rights that arose during the previous 2001-2002 reauthorization hearings<sup>581</sup> and the Senate's more recent concerns that Eximbank financing has been increasingly exploited by beneficiary countries, like Brazil, at the expense of U.S. jobs and economic competitiveness,<sup>582</sup> Brazil must recognize that the U.S. Congress is likely to take its responsibility very seriously. Indeed, Congress revisited Eximbank reauthorization in the fall of 2006, and passed legislation that was subsequently signed into law in late December.<sup>583</sup> It will provide the Bush administration with the

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579. See Office of the USTR, Who We Are, USTR Mission, [http://www.ustr.gov/Who\\_We\\_Are/Mission\\_of\\_the\\_USTR.html](http://www.ustr.gov/Who_We_Are/Mission_of_the_USTR.html) (last visited Dec. 19, 2006) [hereinafter Mission of the USTR].

580. See U.S. CONST., art. 1, § 9, cl. 7 (granting the Congress the power to make appropriations, "No money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . . ."); see also U.S. Government Printing Office, Congressional Appropriations: About, <http://www.gpoaccess.gov/appropriations/about.html> (last visited Jan. 7, 2007) ("The executive branch may not spend more than the amount appropriated, and it may use available funds only for the purposes established by Congress.").

581. California Representative Maxine Waters proposed legislation that would have "prohibit[ed] 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." California Congressman Ray Ose challenged this effort by proposing legislation that would deny 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 U.S. industry sectors. Neither of these bills ever made it out of committee. See Letter from Maxine Waters, California Congressional Representative, to Colleagues, The Export-Import Bank Should Not Oppose AIDS Drugs! (May 4, 2001), <http://www.cptech.org/ip/health/country/waters05042001.html>; U.S. House of Representatives Committee on Rules, Summary of Amendments Submitted to the Rules Committee on H.R. 2871 – Export-Import Bank Reauthorization Act of 2001 (Apr. 30, 2002), available at [http://www.rules.house.gov/archives/sum\\_exim\\_107.htm](http://www.rules.house.gov/archives/sum_exim_107.htm).

582. See 151 CONG. REC. S8, 408-409 (daily ed. July 18, 2005), Statement of Senator Grassley Press Release, U.S. Senate Committee on Finance; see also Senator Chuck Grassley of Iowa, Grassley Wins Initial Approval of Funding Ban for Project Benefitting Brazilian Ethanol Producers (July 20, 2005), <http://finance.senate.gov/press/Gpress/2005/prg071905.pdf> (Export-Import Bank's approval of credit insurance for ethanol dehydration plant in Trinidad using Brazilian ethanol found to violate the Export-Import Bank's authorizing statute by causing substantial injury to U.S. producers of the same commodity. Thus, no further taxpayer funds should be provided for this facility).

583. See Export-Import Bank Reauthorization Act of 2006, Pub. L. No. 109-438, 120

latitude needed to modify the Eximbank program consistent with U.S. national interests.<sup>584</sup> In effect, Brazil's eligibility to receive such preferential treatment may be subject to new conditions.

#### 4. Overseas Private Investment Corporation (OPIC) Program Financing and Underwriting

The OPIC, a U.S. government development agency, has helped Brazilian companies to procure the financing and associated insurance coverage needed to acquire essential capital assets and investments from U.S. sources without risk of impairment or loss. OPIC effectively complements the private sector in managing the political risks<sup>585</sup> associated with FDI.<sup>586</sup>

Brazil has been among the top recipients of OPIC-backed private investment between 1996 and 2004.<sup>587</sup> These contracts entailed the provision, installation and/or expansion of telecommunications, cellular and internet services and networks, the construction of gas pipelines and power plants, hydroelectric plants and hotels, the leasing of power plant turbines and railroad equipment, and the development of oil and gas fields.<sup>588</sup> Although OPIC's support for Brazilian projects has dropped off significantly during the past two years (2005-2006), at least one significant U.S. trade mission to Brazil was, nevertheless, organized during this period.<sup>589</sup> Yet, considering that the Brazilian Government

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Stat. 3268; White House, *Statement by the Press Secretary on Bill Signings* (Dec. 20, 2006), <http://www.whitehouse.gov/news/releases/2006/12/20061220-3.html>.

584. *See id.*

585. 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* OPIC, Insurance, <http://www.opic.gov/Insurance> (last visited Dec. 19, 2006).

586. *See* OPIC, About Us, Our Mission, <http://www.opic.gov/about/mission/index.asp> (last visited Dec. 19, 2006).

587. *See OPIC's Deep Pockets*, NEW AM., Aug. 4, 1997, at 9 ("Of the nations receiving U.S. private investment backed by OPIC, Brazil was the largest recipient.").

588. *See* U.S. DEP'T. OF STATE NEWSLETTER, OFFICE OF THE COORDINATOR FOR BUS. AFFAIRS, NATIONAL EXPORT STRATEGY UPDATE: U.S. EXPORTS = U.S. JOBS (June 1, 1995) [http://dosfan.lib.uic.edu/ERC/economics/Trade\\_Policy\\_Newsletter/9506.html](http://dosfan.lib.uic.edu/ERC/economics/Trade_Policy_Newsletter/9506.html) (indicating that during 1995, Brazil received over \$250 million of OPIC insurance and financing); David Ivanovich, *Enron Pipeline in Bolivia Gets U.S. Loan Guarantee*, HOUSTON CHRON., June 15, 1999; OPIC, Annual Reports 2000-2004, Investment Activities, <http://www.opic.gov/pubs/handbooks/annualreport/> (follow hyperlink links to Annual Reports from 2000 to 2004); Press Release, OPIC, U.S. Small Business Uses OPIC Loan to Expand Clean Energy Technology in Brazil (Jan. 11, 2006), <http://www.opic.gov/news/pressreleases/2006/pr011106.asp>.

589. During October 2005, the U.S. Commerce Department and OPIC representatives organized and attended a renewable energy trade mission to Brazil. The mission's purpose was "to help U.S. firms find business partners and sell

had threatened during the spring of 2005 to issue compulsory licenses against U.S. HIV/AIDS drug patent holders and to abrogate such patents altogether under a newly proposed Brazilian law, this drop-off was probably *not* a coincidence.<sup>590</sup> The Government of Brazil must remember that the USTR, a cabinet official, serves as the influential vice chairman of the OPIC.<sup>591</sup>

## 5. Continued U.S. Generalized System of Preference Status

Since, at least 1997, Brazil has enjoyed a growing trade relationship with the United States, which still remains Brazil's single largest trading partner. In 2003, Brazil's exports to the United States were valued at US\$ 21.3 billion, fourteen percent of which (approximately \$3 billion) enjoyed duty-free status pursuant to the U.S. Generalized System of Preferences (GSP).<sup>592</sup> From January to November 2005, Brazil exported overall approximately \$24 billion worth of goods to the U.S. spanning numerous industry sectors, fifteen percent of which (approximately \$3.6 billion) qualifying under the U.S. GSP program.<sup>593</sup>

At the recent Doha Round trade negotiations that took place in Hong Kong in late November and early December 2005, the United States and the EU became of one mind concerning the serious threat posed to their joint prosperity by widespread IP opportunism in developing countries.<sup>594</sup> However, recognizing that not all developing countries (especially those least developed countries) possess the means and capabilities to address that growing threat through regulation and law enforcement, U.S. Commerce Secretary Carlos Gutierrez and EU Trade Commissioner Peter Mandelson arrived at a temporary solution – to grant developing

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renewable energy equipment and services in Rio de Janeiro, São Paulo, and Salvador da Bahia.” See U.S. Commercial Service, Brazil Renewable Trade Mission Oct. 17-19, BUYUSA.GOV, <http://www.buyusa.gov/kern/brazilrenewabletrademission.html>.

590. See Pachovski & Kogan, *supra* note 109.

591. See Mission of the USTR, *supra* note 579.

592. See *Breaking Patents Is Not the Way to Go, Says US to Brazil*, BRAZZIL MAG., May 18, 2005, available at <http://www.brazzilmag.com/content/view/2470/49>.

593. See CCG 2006, *supra* note 519, at 2; AMCHAM BRAZIL, GENERALIZED SYSTEM OF PREFERENCES: FINAL REPORT 2 (Dec. 14, 2006), [http://www.amcham.com.br/update/2006/update2006-12-15d\\_dtml.pdf](http://www.amcham.com.br/update/2006/update2006-12-15d_dtml.pdf); see also U.S. CENSUS BUREAU, FOREIGN TRADE STATISTICS, TOP TRADING PARTNERS – TOTAL TRADE, EXPORTS, IMPORTS (Dec. 2005), <http://www.census.gov/foreign-trade/statistics/highlights/top/top0512.html>.

594. See Duncan Hooper & Kevin Costelloe, *US, EU Threaten 'Zero Tolerance' for Copyright Violations*, BUS. DAY, Dec. 1, 2005, <http://www.businessday.co.za/articles/world.aspx?ID=BD4A121407>.

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countries an extra seven and one-half years before they must protect copyrights and trademarks.<sup>595</sup> 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*.

Although Congress has renewed the U.S. GSP many times since its enactment, its renewal and Brazil's continued eligibility to benefit from it should *not* be taken for granted.<sup>596</sup> In fact, the USTR, on two recent occasions, requested public comments to determine "whether . . . the program should be changed so that benefits are not focused on trade from a few countries. . . ."<sup>597</sup> In

595. *See id.*

596. *See* VIVIAN C. JONES, CONGRESSIONAL RESEARCH SERVICE [CRS], GENERALIZED SYSTEM OF PREFERENCES: BACKGROUND AND RENEWAL DEBATE, (Sept. 26, 2006), <http://www.nationalaglawcenter.org/assets/crs/RL33663.pdf>, at Summary [hereinafter JONES, CRS] ("In previous years that the GSP was set to expire, its subsequent renewal was generally considered non-controversial. Even when the preference was allowed to lapse, as it has at several times in its history, it was widely expected that Congress would retroactively renew the preference, as in the Trade Act of 2002. However, this year, due, in part, to the present impasse in multilateral trade talks in the World Trade Organization Doha Development Agenda (DDA) and congressional concerns regarding the inclusion of certain more advanced developing countries such as India and Brazil in the program - renewal of the preference seems more tenuous. The Bush Administration favors GSP renewal, but also appears willing to review and modify the program in order to respond to congressional concerns."); *see also id.* at CRS 14-15 ("As early as January 2006, Senate Finance Committee Chairman Chuck Grassley commented that renewal of GSP was 'not a foregone conclusion' and that its extension was likely to be tied to the United States receiving certain reciprocal benefits as part of a successful conclusion of the Doha Round of trade talks. In . . . May 2006, Senator Grassley repeated these concerns, mentioning especially India and Brazil, two major beneficiaries of the GSP that he perceived as 'two of the countries most responsible for holding up the Doha negotiations.' On that basis, he warned that he might oppose GSP renewal as a result of their obstruction, or make sure that eligibility requirements are tightened so that more advanced developing countries, such as India and Brazil, are removed from the program." (footnotes omitted)); Mark Langevin, *U.S.-Brazil Trade Relations: Finding Post-Elections Overlap*, INFOBRAZIL.COM, Nov. 18-26, 2006, [http://www.infobrazil.com/Conteudo/Front\\_Page/Opinion/Conteudo.asp?ID\\_Noticias=1019&ID\\_Area=2&ID\\_Grupo=9](http://www.infobrazil.com/Conteudo/Front_Page/Opinion/Conteudo.asp?ID_Noticias=1019&ID_Area=2&ID_Grupo=9) (Phil English, U.S. Congressman and Co-Chair of the Brazil and Steel Caucuses stated "I think it's going to be a hard argument to pass GSP. . . preferences for Brazil, and at this point, the level of interest in Congress in indiscriminately extending trade preferences is pretty well exhausted. I do think that we will revive the GSP program because we recognize the importance of giving [LDCs] and takeoff economies access to our market and the ability to compete with China. I think Brazil is going to have a huge burden in arguing for inclusion in the future, on that basis."").

597. *See* JONES, CRS, *supra* note 596, at CRS 15; *see also* Generalized System of Preferences (GSP): Request for Public Comments, 70 Fed. Reg. 58502 (Oct. 6, 2005) [hereinafter GSP Public Comments Request] (requesting public comments to determine "whether the Administration's operation of the [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

2004 and 2005, Brazil was among the top ten recipients of U.S. GSP benefits.<sup>598</sup> It is quite possible, therefore, that Brazil's continued eligibility under the program may depend on whether or not the USTR and U.S. industry perceive the Brazilian government's failure to address rampant *patent or trade secret* opportunism as threatening.<sup>599</sup> According to the USTR, developing countries and their industry exports are entitled to receive GSP status as an *incentive* for promoting conduct consistent with U.S. trade policy, including recognition and protection of strong intellectual property rights.<sup>600</sup> During late December 2006, the Congress and the administration ultimately decided to extend GSP status for less

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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.

598. See GSP Public Comments Request, *supra* note 597 (“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.”); see also RENEE JOHNSON, CONG. RES. SERV. [CRS], GENERALIZED SYSTEM OF PREFERENCES RENEWAL: AGRICULTURAL IMPORTS 1,3,6 (Nov. 29, 2006), <http://fpc.state.gov/documents/organization/78423.pdf> (“Agricultural imports under the GSP totaled \$1.9 billion in 2005, about 7% of all U.S. GSP imports . . . . In 2005, the top six BDCs [beneficiary developing countries] ranked by import value - Thailand, Brazil, Argentina, India, the Philippines, and Turkey - accounted for 56% of agricultural imports under the GSP. Brazil and India accounted for nearly one-fifth of agricultural imports under the program. These countries are among those identified by critics of the current program as countries whose GSP benefits should be limited or curtailed. . . . If the administrative changes being evaluated by the TPSC are implemented by USTR, certain beneficiary countries, including Thailand, Brazil, Argentina, India, the Philippines, and Turkey, might be graduated from the program and no longer be eligible to receive benefits under the GSP.”).

599. See OFFICE OF THE USTR, U.S. GENERALIZED SYSTEM OF PREFERENCES GUIDEBOOK 16-19 (Jan. 2006), [http://www.ustr.gov/Trade\\_Development/Preference\\_Programs/GSP/Section\\_Index.html](http://www.ustr.gov/Trade_Development/Preference_Programs/GSP/Section_Index.html) (follow hyperlink to U.S. Generalized System of Preferences Guidebook); see also Letter from Lila Feisee, Director for Intellectual Property, Biotechnology Industry Organization (BIO), to Sybia Harrison, Office of the U.S. Trade Representative (Mar. 31, 2006), <http://www.bio.org/ip/international/20060331.pdf> (“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 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.”); JOHN H. JACKSON ET AL., LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS – CASES, MATERIALS AND TEXT 319-335 (4th ed. 2002); Greg Mastel et al., *Smart Pills: Protecting IP Rights Overseas*, IP L. & Bus., Sept. 2004, available at <http://www.ipww.com> (follow hyperlink to Smart Pills article).

600. See James E. Mendenhall, Acting Gen. Counsel, Office of the U.S. Trade Rep., Piracy of Intellectual Property, Testimony Before the U.S. Senate Committee on the Judiciary (May 25, 2005), available at [http://judiciary.senate.gov/print\\_testimony.cfm?id=1514&wit\\_id=4302](http://judiciary.senate.gov/print_testimony.cfm?id=1514&wit_id=4302).

developed countries for a temporary period - from six months to two years.<sup>601</sup>

## VI. CONCLUSION

### A. *Brazil Must Evolve for its Own Sake, and the World's*

Economists generally recognize that the national practice of industrial and technology IP opportunism is, to some extent, to be expected. Developing countries and emerging economies face enormous pressures to maintain an evolutionary track in a world that continually progresses. The current information society is taking shape much more rapidly than previous globalization eras due to significant and continuous scientific, technology and communication advances. Consequently, the acquisition of foreign advanced technologies through opportunistic abuse of intellectual property laws serves as the most effective means by which such countries may, at least initially, maintain a modicum of forward momentum.<sup>602</sup> However, such practices should neither continue nor be justified forever. Once developing countries rise to become emerging economies, such as Brazil, they must grow up and evolve!

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 extra-regional trade agreements or to recognize and enforce foreign intellectual property rights. While Brazil's bravado has garnered the applause and admiration of a group of impoverished nations and socialist-minded activists and advocacy groups, the indelible nature of its national and international activities likely threatens the interests

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601. See Press Release, House Committee on Ways and Means, House Approves Omnibus Trade Bill (Dec. 8, 2006) <http://waysandmeans.house.gov/News.asp?FormMode=print&ID=460> ("[T]he U.S. House of Representatives approved Omnibus Trade Bill H.R. 6406, a bill addressing a number of trade issues, by a 212-184 vote."); Press Release, White House, President Bush Signs the Tax Relief and Health Care Act of 2006 (Dec. 20, 2006), <http://www.whitehouse.gov/news/releases/2006/12/20061220-2.html>.

602. See Shapiro & Hassett, *supra* note 116, at 10.



of most other countries, the established global system of innovation and economic growth, and the economic prospects for Brazil itself.

*B. OECD Nations Will Not Pay for Brazil's Continued IP Opportunism*

Brazil's past failure and/or inability, like that of other emerging economies, such as Russia, India and China (the BRIC nations), to vigorously uphold the exclusive private intellectual property rights of foreign and domestic owners through well enforced national laws, 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 home country intellectual property laws.<sup>603</sup> Higher prices have resulted chiefly from OECD country industries' inability to recover their costs of investment in both R&D and commercialization, let alone, to earn a reasonable profit. Two cases in point are pharmaceuticals and computer software.

Anecdotal evidence suggests, for example, that prior to 2006, U.S. purchasers of patented/copyrighted software programs could often load their software onto three or more different computers within a defined workplace or home office 'user' space even if used by more than one registered user, which enabled many families to afford the purchase of such products.<sup>604</sup> The number of software product users and computers upon which software may be loaded has, over time, however, been restricted to only a single registered user and/or to a single computer.<sup>605</sup> The concern about piracy has,

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603. John Gardner, *Healthcare in the Developing World: Obstacles and Opportunities*, TCSDAILY.COM, May 19, 2006 ("[T]here 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?").

604. See e.g., Trend Micro Download License Agreement, <http://www.trendsecure.com/download/index.php> (last visited Jan. 7, 2007); Aid4Mail License Grant, <http://www.aid4mail.com/license.php> (last visited Jan. 7, 2006); Adobe End User License Agreement, <http://www.adobe.com/products/eula/central> (last visited Jan. 7, 2006); End-User Agreement for Microsoft Software, [http://download.microsoft.com/download/1/2/5/12538ba0-3d24-4f00-aab1-dd9ff4aacfc9/en\\_student\\_eula.pdf](http://download.microsoft.com/download/1/2/5/12538ba0-3d24-4f00-aab1-dd9ff4aacfc9/en_student_eula.pdf); see also Adney Patrizio, *Microsoft OneCare Jumps Out to a Big Star: Cut-Rate Pricing and Three-User License Spur Popularity*, WINPLANET, Aug. 14, 2006, <http://cws.internet.com/article/3348-.htm>.

605. See e.g., Overview for ACT! 2007, Single User by Sage, COMPUSA, [http://www.compusa.com/products/product\\_info.asp?product\\_code=341564](http://www.compusa.com/products/product_info.asp?product_code=341564) (last visited Jan. 7,

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in effect, caused an increase in the consumer cost of such items.<sup>606</sup> In addition, the cost of pharmaceuticals continues to rise and increase 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 platforms that lead to cheaper products can provide U.S. consumers with more 'bang for the buck,' they still do not address industry's difficulty of securing an adequate enough 'return on investment' to facilitate future investments in invention and innovation.

If OECD nation-based companies cannot protect their exclusive private intellectual property from exploitation by misplaced Brazilian and other foreign government policies, 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 incentives such as R&D credits and other rewards are helpful but not compensatory. Markets are profit-, not cost-driven. Government mandates provide even greater disincentives to invest and innovate. This is not rocket science, but simply, human nature.

Over the course of the 20th century, life expectancy increased by 30 years; 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 2.5 percent of the workforce; household auto ownership rose from one to 91 percent; household electrification rose from 8 to 99 percent; controlling for inflation, household assets rose from \$6 trillion to \$41 trillion between 1945 and 1998. These are but a few of the wonderful things that have occurred during the 20th century.

. . . .

. . . What human motivation accounts for the accomplishment of these and many other wonderful things? The answer should be obvious. It was not accomplished by people's concern for others but by people's concern for themselves. In other words, it's people seeking more for

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2007); Apple Computer, Inc. Software License Agreement Single Use License, <http://store.apple.com/Catalog/US/Images/singleuser.html> (last visited Jan. 7, 2007); Microsoft Windows XP Home Edition (Retail) End-User License Agreement for Microsoft Software, <http://www.microsoft.com/windowsxp/home/eula.msp> (last visited Jan. 7, 2007).

606. See BETTER BUS. BUREAU, *Computer Software Piracy*, <http://www.bbb.org/Alerts/article.asp?ID=434> (last visited Jan. 5, 2007).

themselves that has produced a better life for all Americans.

. . . .

What about all those people who've invented and marketed machines that do everything from diagnosing illnesses to controlling air flight? Were they basically motivated by a concern for others, or were they mostly concerned with their own well-being?

. . . .

One of the wonderful things 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.<sup>607</sup>

Since the United States has had the strongest level enforcement of IPRs among the OECD nations, an increasing number of know-how-rich industries, including those based within the Member States of the EU 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 within or to the United States. 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. And, in certain OECD countries, price controls, and parallel trade in below-cost and illicit generic drugs, as well, contribute to higher product prices.

Arguably, emerging and developing country governments' non- or limited protection of IPRs, strict price controls on health care and other products, and allowance of parallel trade should constitute the exception rather than the rule, and it should apply only to *least* developed countries suffering from actual health emergencies and lacking actual manufacturing capacity. 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, will only further threaten America's industries and innovation potential in the future.

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607. See Walter E. Williams, *The Economics of Caring vs. Uncaring*, CAPITALIST MAG., May 10, 2006, available at <http://www.capmag.com/article.asp?ID=4653>.

