ITSSD
INSTITUTE FOR TRADE, STANDARDS, AND SUSTAINABLE DEVELOPMENT

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Mr. Philippe Baechtold
Head, Patent Law Section
Sector of PCT and Patents,
Arbitration and Mediation Center, and
Global Intellectual Property Issues
World Intellectual Property Organization
34, chemin des Colombettes,
1211 Geneva, Switzerland

Re: Annex III of the Report on the International Patent System (SCP/12/3 Rev.2)

Dear Mr. Baechtold,

The Institute for Trade, Standards and Sustainable Development (ITSSD) wishes to thank you and the SCP for considering and including some of our organization's comments within the recently released Annex III - "Comments on the Report on the International Patent System Received from Members and Observers of the SCP" (SCP/12/3 Rev.2).

The ITSSD believes that most of the chapters contained with this Annex compilation incorporate a broad representation of the various perspectives of SCP members and observers on given issues. "Chapter II. Economic Rationale for Patents and Different Interests and Needs in the International Patent System", however, could benefit from additional research findings that discuss and analyze several of the many dimensions of the socio-economic value of patents.

For this purpose, the ITSSD, its Advisory Board and I are pleased to share with SCP representatives, member nations and fellow observers our research findings concerning the following related subject matters:

1. The economic rationale for patents and trade secrets, and their related legal underpinnings;
2. The importance of knowledge-based foreign direct investment (FDI) to emerging and developing country national governments, and its relationship to intellectual property right protection; and
3. The national, regional and local socio-economic spillover benefits that host countries may derive from knowledge-based foreign direct investment (FDI).

We request that the SCP and its members take into account these additional ITSSD research findings, as set forth below, for possible inclusion as an addendum to Annex III.

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ITSSD
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Thank you, once again, for your thoughtful consideration.

Sincerely,

Lawrence A. Kogan

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President/CEO

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The following discussion is comprised of excerpts from *Rediscovering the Value of Intellectual Property Rights: How Brazil's Recognition and Protection of Foreign IPRs Will Stimulate Domestic Innovation and Generate Economic Growth*, [1] a manuscript published by the International Journal of Economic Development.[2]

I. The Economic Rationale for Patents and Trade Secrets and Their Related Legal Significance [3]

A. PATENT-BASED INTELLECTUAL PROPERTY IS ECONOMICALLY VALUABLE

Intellectual Property is the Key to Innovation

During 2003, the Multilateral Investment Fund (MIF) of the Inter-American Development Bank (IADB) issued an insightful report analyzing the effectiveness of institutional reform projects it had previously funded during the 1990s to ensure the proper functioning of Latin American markets. These projects identified the protection of private *intellectual property rights* as one of the "key factors" needed to ensure the competitiveness of firms operating within regional markets.[4]

> "*Intellectual property is an asset, and as such, has an economic value*. Whoever creates, invents, or designs something can protect that creation by using the legal tools contemplated for that purpose by law. By using those tools, legal recognition of the creative activity can be obtained in the form of an intellectual property 'right' which allows us to protect what we have created and prevent others from exploiting it without our consent" (emphasis added). [5]

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

> …During the 1990s, most of the…projects in the region aimed to reform and modernize intellectual property registries. They…channel[ed] funds for buildings, personnel training courses, the introduction of information technologies and software, and dissemination activities…These projects have played an important role given that *intellectual property registries are components in the system*. It is they that are called upon to register patents, trademarks, and industrial designs, analyze applications for new registrations, and keep the records on file" (emphasis added). [6]

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

> "*Innovation is essential for creating intellectual property*. The two basic factors of understanding innovation are: (i) *the enterprises themselves as creators and administrators of knowledge*; and (ii) *the national innovation system, as the provider of the environment and resources to generate this know-how*" (emphasis added). [7]

Moreover, the report noted the economic benefits that can be derived from various productive uses

of innovations protected by intellectual property rights. They include improved brand and market differentiation, acquisition and development of valuable economic assets that may be financially leveraged and increased access to new markets through licensing, franchising, etc.[8] [9]

Interestingly, the economic freedom and benefits that can be realized by intellectual property owners that have officially 'registered' their rights and collateralized or otherwise exploited (e.g., licensed franchised) their assets, are analogous to those benefits thus far realized by individuals who have officially registered their informal claims to real property throughout Latin America. In this regard, the SCP, its members and observers should carefully study the successful program of Latin American economist Hernando de Soto. That program has secured official registration and recognition of informal title (deeds) to land held by poor people living in various Latin American countries.[10] [11]

Lastly, the IADB report concluded that many of the obstacles faced in promoting the value of intellectual property in Latin America do not stem not from any lack of appreciation by the *private sector* for the *legal* concepts of intellectual property and private property rights in general. Rather, it found that the failure of governments to coordinate with and enhance the ability of (i.e., to enable) local enterprises and academic institutions to develop, convert, and commercialize their know-how has effectively denied them the economic benefits from such ownership.[12]

A recent (2005) OECD report concluded that the economic value of patents, especially those secured by knowledge-intensive companies operating within the ICT, pharmaceuticals, and biotech sectors,[13] has been rapidly rising.

> "…*The economic value of patents is increasing*. Spurred by increasing competition from low-wage countries, firms in OECD countries are putting more emphasis on innovation and the creation of intellectual property as a means of generating comparative advantage and are filing a growing number of patents. *Economic studies show an order-of-magnitude increase in the estimated value of patents, although considerable variation remains in the value of individual patents*, with a large share of the total value of patent portfolios deriving from a small number of patents. *Value is strongly influenced by the novelty of the invention and the availability of alternative routes to the same solution (i.e. inventing around a patent*" (emphasis added). [14]

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

> "*[The economic value of patents]…is highly context-dependent and relates to the ability of a firm to extract the value from its patents through competent management, as well as on the particular market environment facing a patent holder*. Differences across sectors are driven by factors such as patent strength, market structure, technology characteristics, company strategies and firm size…*Management of intellectual assets, notably patents, has become a central issue in the knowledge-based economy. An increasing share of the market value of firms appears to derive not from tangible assets as reported in financial statements but from intangible, intellectual assets that firms are attempting to manage more actively*. Technology markets, which facilitate the exchange of patented inventions (via sale or licensing), are an important part

> of the economic infrastructure for exploiting patents and can help improve the efficiency of innovation processes by putting inventions in the hands of those most able to *commercialise* them" (emphasis added). [15]

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

> "…Public institutions have an important role to play. *While the development and implementation of technology markets is largely a private-sector activity, there is general consensus that governments play an important role in ensuring the efficient operation of markets and competition authorities monitor their functioning and prevent anticompetitive licensing behaviour*. The creation of markets takes time and governments can help remove obstacles to the development of technology markets to accelerate the process" (emphasis added). [16]

Moreover, the study observed that because of growing competition posed by technology- oriented companies from advanced as well as emerging economies, a new global business environment has evolved which engenders higher technology development costs, lower profit margins, shorter product lifecycles, and continuing market demand for new and more specialized technologies. As a result, companies' use of patents has assumed a more central and strategic character in their daily business that varies according to the idiosyncrasies of the industry sector in which they operate.[17] Thus, industry actors are compelled to rely increasingly on strong patent protections internationally to both defend their most valuable assets and expand their already vulnerable market shares.

> "In recent years, the globalisation of marketing and manufacturing has brought in stronger competition, lower profit margins and shorter product life cycles. Technology has become more complex, raising the cost of R&D and demanding specialised technology suppliers. As a result, returns to the investments in the development of new products and services are less certain, and *emphasis has shifted away from manufacturing as the key to competitiveness and towards R&D as a source of new ideas* and to build better relationships with customers. As IP protection has strengthened (especially in the United States), patents and trademarks have become strategic weapons for many businesses. *Companies protect their inventions via patents and build up their patent portfolios for strategic purposes*. Wise management of IPRs through technology marketing and licensing strategies is increasingly seen as a strategic way to generate revenues and profits. *Such changes are leading to an intellectual economy in which IP becomes the basis for value creation for firms, whether through its incorporation into innovation products and services or through its sale in the market place*" (emphasis added).[18]

Apparently, the U.S. Congressional Research Service had drawn similar conclusions regarding the economic utility of patents in a report it released earlier during 2005[19] as had the European Commission.[20] Also, at least one (2004) study has noted how competition-minded Asia-Pacific-based agro-businesses have increasingly focused on the economic value of establishing strong IPR (i.e., patent) regimes to enhance the protection of their evolving life science technologies – e.g., new plant and animal varieties, biologically based inputs for agriculture, and crop-based nutritional and pharmaceutical goods. [21]

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

The General Case for Protecting Test Data and Trade Secrets

In addition to securing patent protection, life sciences companies rely significantly on their ability to protect, as a separate intellectual property right, the costly know-how or other undisclosed information they have generated, compiled, analyzed, organized and submitted, at their own expense, to government regulators. This usually occurs, subsequent to or in lieu of a patent's issuance, in order to secure commercial marketing approval for the ultimate product.[22]

There are good public policy reasons for recognizing and protecting such private property rights. First, it results in the development and distribution of new, more specialized, and higher quality drug and medicinal products that can improve the healthcare and enhance the quality of most citizens' lives. Second, it encourages inventors and producers of data and other information to create new incremental innovations that spawn new uses that can ensure continuous future *societal* progress and well-being. Third, it is both equitable and fair for life sciences companies to be able to recoup their economic outlays (return on capital)[23] *and* to earn a reasonable profit to boot (return on sales),[24] which they can later reinvest in search of new breakthrough and incremental medicines.[25] Fourth, it attracts greater research and development-related foreign direct investment.[26]

The Economic Underpinnings

Most countries require that innovative drugs undergo lengthy examination procedures to ensure that they are effective and safe for public use before they are granted marketing approval.[27] Drug innovators (originators) must provide regulators with a great amount of confidential and proprietary information during this examination process, much of it being the result of very costly experiments and clinical trials spanning many years.[28] Drug innovators are motivated to endure this painful process because they anticipate earning enough revenue and profit once their drug enters the market to recover their considerable investment of time and money. Generic manufacturers, however, typically do not undergo such a timely and costly development process. Nor are generic copies of patented drugs usually subject to such an exhaustive examination before they are granted country marketing approval. Generic manufacturers need only establish that their version of the innovative drug is 'bioequivalent' to the already approved original drug. It is mostly from this discrepancy in cost, time, and effort, and the otherwise undisclosed ('secret') know-how generated in the process, that drug innovators hope to derive a competitive advantage in the marketplace.

It is easy to see how allowing a generic applicant to utilize bio-equivalence-related information previously obtained by regulators about an innovative drug during the course of an earlier examination, would be viewed as commercially unfair, especially if it occurs without the drug originator's consent and fair compensation. Arguably, absent the need to conduct its own clinical trials and to produce independent evidence of bioequivalence, a generic drug manufacturer is effectively provided with a significant competitive advantage over the drug originator – the ability

to obtain fast and cheap marketing approval through other than its own efforts.[29] While an innovative drug is usually accorded a period of exclusivity, as it is protected by patents which assist the originator in recouping the inordinate expense of undergoing many years of costly *basic* research and development, those sunk costs are separate and *apart from*, and are often *incurred before*, the subsequent clinical testing activities the details of which are ultimately reported in the confidential data submitted to regulators. For this reason, many countries, beginning with the United States, have created a complimentary mechanism of 'data exclusivity' the objective of which is to eliminate the competitive market advantage that would otherwise inure to the generic manufacturer as the result of using such a 'fast-lane' approach. "In essence, data exclusivity refers to a period during which no third party applicant can rely on data filed by the original applicant for a marketing authorization."[30]

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

Data exclusivity sometimes has the effect of protecting innovative drugs the underlying patents of which have expired, or for which patent protection is unavailable. In fact, data exclusivity may serve as the sole protection for the innovative drug manufacturer in that case. It can therefore be said that the grant of data exclusivity, like other pharmaceutical regulation and authorization, reflects "an attempt[] to protect the investment of companies in their innovations."[31]

The Legal Underpinnings

Data exclusivity derives its legal significance as private property from two areas of the common law which have since been codified into uniform state statutes in the U.S. – namely, that of trade secrets and unfair competition. [32]

Trade Secrets at Common Law

Data exclusivity can be said to be in the nature of an affirmative common law property right of 'trade secret', [33] insofar as it protects from disclosure and unauthorized use information that the drug originator has developed over considerable time and as a result of significant expenditure which it otherwise made a reasonable effort to keep secret (from public knowledge), and that has, in fact, remained undisclosed ('secret') at the time it is submitted to regulators. In other words, the information or clinical testing data for which exclusivity is sought is not in the public domain. Typically, such information is not protected by a patent, because a patent requires, as a condition for its issuance, that the applicant publicly disclose (fully and clearly) in its application all technical information about the product or process for which patent protection is sought.[34]

A trade secret is legally "anything that gives a competitor an advantage [,edge] or head-start" that is not in the public domain. It includes various opportunities that present themselves to a business, is generally developed through substantial time, cost, and effort and often consists of the knowledge possessed by company executives and key employees.[35] In other words, the economic value of a trade secret resides in the pecuniary and human outlays (costs) associated with its development, along with the effort expended to prevent its disclosure to others – i.e., to maintain its exclusivity. The nondisclosure of a trade secret is protected for a temporary period against both the acts of commercial competitors AND the acts of government officials if properly designated as such.[36]

> "Statutory provisions have been enacted that are designed to *prevent unwarranted administrative disclosure of trade secrets*. Thus, when companies submit license applications for regulatory review, officials at the FDA are prohibited from improperly disclosing confidential information, including trade secrets." [37]

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

> "[I]t is an inexorable fact that much of the information that is submitted to the FDA is subject to production under the Freedom of Information Act ("FOIA"). Although FOIA's underlying policy is public disclosure, trade secrets are protected from disclosure by 5 U.S.C. §552(b)(4) ("Exemption 4"), in addition to the statutory provisions cited above. *This exemption to FOIA protects "trade secrets and commercial or financial information obtained from a person and privileged or confidential"* (emphasis in original).[38]

This safe harbor protection, however, is not absolute as it is subject to 'public interest' exceptions.[39]

Furthermore, the disclosure, divulgence, or making known of commercial trade secrets or any information relating thereto by any federal employee in any manner not authorized by law can constitute a criminal offense punishable by fine and/or imprisonment.[40]

Unfair Competition at Common Law

The character and nature of the affirmative right to data exclusivity is also shaped, in part, by the common law of torts ('unlawful wrongs'). Section 757 of the Restatement of Torts First (1939), provided the first broad widely accepted definition of a trade secret: "Any formula, pattern, device or compilation of information which is used in one's business, *and which gives him an opportunity to obtain an advantage* over competitors who do not know how to use it" (emphasis added).[41] And, this definition can be traced back to the common law 'right of prospective economic advantage'. In the environment of free and fair competition evolving during the early twentieth century, the unlawful and willful interference with this right gave rise to an action in tort.[42]

As a matter of law, the burden of proof (i.e., the burden to show causation) is placed upon the plaintiff, who must establish "that it is reasonably probable that the lost economic advantage [i.e., an evolving economic interest that has not yet matured] would have been realized but for the defendant's interference. This means, in other words, that "it must be reasonably probable that the prospective economic advantage would have been realized 'but for' defendant's interference." [43]

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

> "…[I]n a civilized community which recognizes the right of private property among its institutions, the notion is intolerable that a man should be protected by the law in the enjoyment of property once it is acquired, but left unprotected by the law in his effort to acquire it; and that since *a large part of what is most valuable in modern life depends upon 'probable expectancies'* as social and industrial life becomes more complex the courts must do more to discover, define and protect them from undue interference" (emphasis added). [44]

In addition, this right is partly based on the privilege of individuals to engage in free competition by 'all fair and reasonable means' in pursuit of that reward. [45] The conduct of 'unfair competition' refers generally to "all dishonest or fraudulent rivalry in trade and commerce, but is particularly applied to the practice of endeavoring to substitute one's own goods or products in the markets for those of another."[46] It also encompasses 'unfair *methods* of competition'.[47]

It can be said that the modern law of unfair competition evolved, at least in part, from the need to protect this right of prospective advantage, since it "is intended to resolve the natural conflict between the need for competition in the commercial arena and the opposing need for reasonable restraints on methods of competition." [48] The tort of unfair competition now includes the tort of 'misappropriation', which "consists of three basic elements: 1) the plaintiff has made a substantial investment of time, effort, and money to create a thing misappropriated; 2) the defendant has appropriated[49] the thing at little or no cost; [and] 3) The defendant has injured the plaintiff by the misappropriation."[50] [51]

In effect, "any *improper* method used to obtain [misappropriate] a competitor's trade secret is an infringement [of the right of prospective economic advantage] and is subject to injunction and damages" (emphasis added). [52] This interpretation is reinforced by Section 39 of the Restatement (Third) of Unfair Competition (1995), which defines a trade secret as: "any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford *an actual or potential economic advantage* over others" (emphasis added). And, it embodies the principles of trade secrecy codified in the Uniform Trade Secret Act (USTA).[53] Consequently, "The UTSA, as adopted by various states, together with the Restatement (Third) of Unfair Competition §39, provides a basis for companies to obtain equitable and injunctive relief for the appropriation of information that is not necessarily tied to the productive process."[54] [55]

II. Knowledge-based Foreign Direct Investment (FDI) is Important to Emerging and Developing Country National Governments and is Related to Intellectual Property Right Protection [56]

IPR Protections Are Important to Foreign Investors

Due to the significant and growing economic value of patents, it is understandable why developing countries have undertaken considerable efforts to acquire such tools of innovation. One way to do so is to through foreign direct investment. Arguably, FDI flows are even more important than trade flows in today's rapidly expanding technology and information society.

As noted by the World Bank,

> "what makes FDI especially important is that unlike trade in goods, where developing countries try to glean whatever information they can from the products and services imported or import capital goods that embody modern technology, FDI involves explicit trade in technology…" [57]

One recent (2005) study identifying secure property rights as a *key* concern of foreign investors,[58] examined the impact of developing country institutional efforts to attract FDI. It found a positive correlation between a developing country's adoption of open and transparent domestic capital account control policies and its participation in international treaty regimes (including WTO membership, and preferential trade and bilateral investment agreement participation) on the one hand, and positive FDI flows on the other.

> "Developing countries can domestically enact policies that are attractive to private foreign investors, or they can employ international strategies, such as entering into international agreements [such as WTO membership, preferential trade agreements and/or bilateral investment treaties] that promote policy orientations seen as reassuring by foreign investors…Each of these provides a direct or indirect mechanism *for reassuring foreign investors that the country will protect its property rights and allow profitability*. They serve as credible signals to private investors of the government's intentions because, at least for the international agreements, they are costly to renege on" (emphasis added). [59]

The study viewed the protection of investor property, including IPRs, as critical to securing such flows, given the substantial, long-term, capital-intensive and immobile nature of the types of investments being made (i.e., plant and equipment and research and development). [60] It also admonished foreign investors to be weary about committing significant investments to any one of a number of developing and emerging economies that do not have a well established property rights regime.[61] [62] The study concluded that developing country membership and participation within international treaty regimes that promoted physical and intellectual property right protections (e.g., TRIPS) was more likely than not to contribute to its ability to secure FDI. This result obtains because such diplomatic engagement *usually* requires complimentary domestic reforms.[63] At least one more recent (2006) study seems to have confirmed that U.S. and OECD bilateral investment agreements have stimulated greater FDI flows to developing countries "with a high quality of institutions *and strong local property rights*" (emphasis added). [64]

These conclusions were also confirmed within a recent (2005) United Nations study. It found that the setting of minimum IPR standards at the international level via the TRIPS Agreement had been effective in facilitating domestic reforms that can lead to actual R&D-related FDI flows to certain emerging and developing countries.

> "[Although m]any international agreements give special attention to investment in R&D activities...[by focusing on] [k]ey issues [that] relate to the entry and establishment of R&D-related FDI, the treatment of R&D performance requirements (whether by restricting or explicitly permitting them), incentives encouraging investment in R&D activities [,etc.]…[m]ost international investment agreements do not have provisions that specifically protect R&D-related FDI; they protect FDI in general…[Consequently,] [*t]he protection of IPRs at the international level and minimum standards set by international treaties are of particular relevance for R&D related FDI. The most important instrument in this area is the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)*" (emphasis added). [65]

Furthermore, one recent (2005) study has documented how a developing country's adoption of domestic TRIPS-compliant IPR reforms has resulted in increased IP-related foreign corporate manufacturing investments.[66] And, another recent (2005) study found that the degree and scope of such investments and technology transfer activities largely depends on the nature of those reforms, i.e., the extent to which they expand/strengthen IPRs.[67] This latter study also evaluated the magnitude of the economic impacts in terms of technology transfer. It did this by measuring the changes in the value of inter-company licensing (royalty) payments and allocations of inter-company R&D expenditures among corporate affiliates.[68] The study found that following a developing country's adoption of IPR reforms, the amount of royalty payments made by an affiliate to its parent for the use or sale of transferred technologies, like the amount of local R&D expenditures the affiliate incurred related to such transferred technology, increased in excess of 30 percent.[69]

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

> "[*W]hen technology transfer considerations are accounted for it is **not rational** for governments in these countries **to oppose IPR protection***…In a North-South trade environment, the South sets its IPR policy strategically to manipulate multinationals' decisions on innovation and location…As the Southern government sets the IPR protection level before the Northern firm makes its multinational decision, it can influence this choice by inducing technology transfer or encouraging innovation… Firms can protect their technology by exporting, or risk spillovers by undertaking FDI to avoid tariffs…*In relatively low technology intensive industries, attracting foreign investment as a channel of technology transfer is the motive behind protecting IPR*. The level of protection is chosen such that exporting is never strictly preferred to FDI by the North. *Although the South may desire a lower level of IPR protection to reach its first-best welfare, the Northern firm's credible threat of exporting rather than undertaking FDI restricts the latter to a stricter IPR regime*.
>
> …*For more R&D intensive industries, innovation as opposed to technology transfer is the key concern for protecting IPR in the South*. The South stimulates innovation by tempting the

multinational to deter entry by means of substantial R&D efforts. Although the South does not imitate the complex technology to compete with the North, it benefits from the enhanced innovation it induces by protecting the IPR of the Northern multinational. Therefore a rational South would never strictly prefer to violate international IPR, as the optimal level of protection for the South is always very high...[Much to the contrary, a] stringent IPR regime is always optimal for the South as it triggers technology transfer by inducing FDI in less R&D-intensive industries and *stimulates innovation by pushing multinationals to deter entry in high-technology sectors*" (emphasis added). [70]

IPR Protections and the Enabling Environment Can Influence Investment Composition

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

One early (1993) study involving Brazil and Argentina revealed that, despite the lack of adequate patent protections in those countries, U.S. pharmaceutical companies continued to invest there.[71] It found that such behavior was likely a predatory response from rival companies (competitors), which were eager, in the face of weak patent protection, to move in (by establishing a manufacturing facility) and capitalize on (reproduce) products not protected by patents. Alternatively, as was the case in Turkey, during the early 1960's, U.S. pharmaceutical company FDI increased despite that government's abolishment of product and process patent protection. It was later concluded that other factors had played a larger role in those companies' foreign investment decisions. They included more favorable foreign exchange rates, and lower taxes, regulatory costs, and wage rates, than was then available in the U.S. and other venues.[72]

Even if a foreign company's decision concerning whether to invest in a given country has already been made, it can still be influenced by the degree of IPR protection afforded. One recent (2006) study [73]examined how the level of protection a developing country provides to foreign IPRs would affect the nature of an MNC's investment in that country. In particular, it focused on two possible scenarios: direct investment via an independent venture (i.e., FDI), and indirect investment through a joint venture (JV) arrangement with a local company. Since joint ventures usually provide local rivals with the opportunity to gain market share at the expense of co-venturers, the study found that the MNC would need to undertake an amount of research & development per dollar invested (R&D intensity) that would allow itself to benefit economically from the venture and also to compensate the local co-venturer for its market share loss. The study found, incidentally, that this same R&D intensity level would also produce technology spillover benefits for local firms not involved in the JV. Most importantly, the study concluded that, by strengthening its IPR regime consistent with the TRIPS Agreement, a developing country could reduce the losses to the JV caused by local outside firm imitation of JV technology, and facilitate the formation of more JVs that could increase MNC R&D intensity, local spillover benefits, and total developing country firm profits.[74]

This new study's findings support those of earlier studies, including a (1994) study which surveyed 100 major U.S. firms operating across a spectrum of different industries about their views towards intellectual property protection and foreign direct investment. It found that the level of a developing country's IPR protections would most substantially affect the FDI decisions of high technology, research-intensive industries with products or processes that are relatively easy to imitate. [75] In particular, it concluded that these companies would most likely be dissuaded from investing in countries with weak IPR protections.[76] As concerns the 'composition' of their investment, once the decision to invest had already been made, the U.S. high-tech firms interviewed indicated that their investments would more likely assume the form of sales and distribution outlets or rudimentary production and assembly facilities rather than R&D facilities and component or finished goods manufacturing plants. And, if it they were to engage in any technology transfer at all, it would likely be with older rather than newer technologies.[77]

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

> "[On the one hand,]… stronger IPR protection provides title holders with increased market power and could, at least theoretically, cause firms to actually *divest and reduce* their service to foreign countries…[On the other hand,]…*higher levels of protection* may cause TNCs to *switch their preferred mode of delivery* from foreign production to licensing. *[Companies may] prefer foreign investment over licensing* in the case of *weak protection* because internalized foreign production helps firms to maintain direct control over their proprietary assets." [78]

Alternatively, cautious companies may ultimately decide to invest in developing countries through corporate *affiliates*. In this situation, however, firms are usually more covetous of their technologies and know-how, and less willing to share them with local companies. As a result, there are potentially fewer opportunities to engage in *collective* R&D at the local level, and thus, much less of a possibility for technology transfer/diffusion and knowledge spillovers to domestic firms.

In effect, the decision of *how* a company decides to use its IPR assets within a given developing country boils down to a choice between 'internalizing' (keeping within the corporate group) or 'externalizing' (outsourcing to third parties) them. It often also entails a choice between undertaking 'horizontal' (where firms establish plants abroad to produce the same or similar goods for local or regional markets) and 'vertical' FDI (where plants in different countries produce outputs that serve as inputs in other plants). When a company has decided to *internalize* its IPR assets but has not decided how (and where) to produce them, the question essentially becomes one of FDI *composition* – i.e., the apportionment or allocation of production resources among firm affiliates. [79]

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

> extent to which the title holder is able to maintain control over its proprietary assets in the absence of protection." [80]

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

> "…IPR protection [was found] to be more relevant in making decisions related to investment in R&D facilities than in decisions related to FDI in sales and distribution outlets… Companies in the chemical, pharmaceutical, machinery and electrical equipment industries reported that IPRs played a major role in their decisions with respect to investment in joint ventures abroad. In contrast, companies in the transportation equipment, metals, and food industries considered IPR protection to have marginal significance on FDI." [81]

> "…We conclude that…although one could argue that almost all FDI stocks and flows are indirectly affected by IPRs protection, the *direct impact* of IPRs protection is likely to be confined to selected FDI stocks and flows (e.g., foreign investment in *pharmaceutical R&D facilities*)" (emphasis added). [82]

These observations were confirmed, yet again, in a subsequent (2000) World Bank study that evaluated how IPR protections affect the composition of FDI.

> "[W]hat makes FDI especially important is that unlike trade in goods, where developing countries try to glean whatever information they can from the products and services imported or import capital goods that embody modern technology, FDI involves explicit trade in technology… It is well known that multinational firms are concentrated in industries that exhibit a high ratio of R&D relative to sales and a large share of technical and professional workers…By encouraging FDI, developing countries hope not only to import more efficient foreign technologies but also to generate technological spillovers…[i.e.,] the facilitation of technology adoption… for local firms…" [83]

> "…[T]he level of IPR protection in a country… affects the *composition of FDI* in two different ways. First, *[in] industries in which IPRs are crucial (pharmaceuticals for example)*, firms may refrain from investing in countries [with] a weak regime of IPR protection. Second, regardless of the industry in question, multinationals are *less* likely to set up manufacturing and R&D facilities in countries with [weak] IPR regimes and more likely to set up sales and marketing ventures, since the latter run no risk of technology leakage… [Consequently,]…*IPR policy may also affect the mode of technology transfer (licensing, joint ventures, or establishment of wholly owned subsidiaries*)" (emphasis added). [84]

Similar conclusions were drawn in a more recent (2004) study in which this same author participated.[85]

Another (2004) study produced analogous findings. It showed that, although most (84%) executives interviewed in an Economist Intelligence Unit survey had generally considered the lack of IPR protections in emerging economies to pose a serious challenge to R&D investment, R&D spending in countries such as Brazil, China, India and Mexico had actually increased. In addition, it found that, the nature of the R&D conducted in such countries often exceeded the level required by local law or for local market use and diffusion. [86] Apparently, the companies in question had filed thousands of patents with the *U.S.* Patent and Trademark Office based on technologies

developed in those countries in anticipation of pursuing more lucrative national and global markets. [87]

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

> "[T]echnologies developed in countries with weak IPR protection are used more *internally*, and technologies developed by firms with R&D in weak IPR countries show stronger *internal* linkages. The results suggest that firms may use *internal* organizations to substitute for inadequate external institutions. By doing so, they are able to take advantage of the arbitrage opportunities [88] presented by the institutional gap across countries" (emphasis added). [89]

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

> "MNEs' ability to conduct R&D in weak IPR countries stems from their efficiency in transferring, integrating, and quickly building on technologies developed in various IPR regimes. By keeping complementary resources well protected, MNEs can actually leverage the institutions in strong IPR countries for their operations worldwide. R&D-intensive MNEs, with their closely interlinked R&D activities worldwide, are in a unique position to arbitrage the difference in factor prices across national borders…" [90]

It found, for example, certain practices quite effective in enhancing both the value and protection of their internally derived intellectual property assets (patents), especially where low cost, talented, and underutilized labor in developing countries is plentiful.[91]

First, they compartmentalize or break down their technologies into components so that they cannot be imitated. Second, they disperse the units of knowledge geographically throughout their global organization and make them difficult to convey or otherwise share in standardized form.

> "[I]mitation [is] discourage[d]…by developing technologies that require complementary knowledge not readily available to imitators. For example, basic research still far from commercialization, or technologies that are firm specific, are usually less attractive to imitators. Second, the acquisition of complementary knowledge is subject to the constraints of geographic distance. It has long been realized that a multinational corporation is a geographically distributed innovation network, with the capacity to assimilate, generate and integrate knowledge on a worldwide basis (Bartlett and Ghoshal 1990). Knowledge that is difficult to codify or teach can be more efficiently transferred within the firm. Therefore, outside firms would have to face much higher costs…[or might even find it] impossible…to obtain complementary knowledge across country borders…" [92]

Third, they engage extensively in the practice of patent self-citation, which is a form of 'internalized knowledge transfer.' [93]

> "I find supportive results that patents developed in weak IPR countries are cited more internally

> than those developed in other foreign countries. In addition, firms doing R&D in weak IPR countries feature significantly stronger internal linkages among their technologies than those who do not. The results are consistent with the thought that the internal linkages allow firms to appropriate value from their knowledge even in weak institutional environments." [94]

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

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

> "[F]oreign affiliates are assuming more important roles in many host countries' R&D activities. Between 1993 and 2002 the R&D expenditure of foreign affiliates worldwide climbed from an estimated $30 billion to $67 billion (or from 10% to 16% of global business R&D). Whereas the rise was relatively modest in developed host countries, it was quite significant in developing countries: the share of foreign affiliates in business R&D in the developing world increased from 2% to 18% between 1996 and 2002. The share of R&D by foreign affiliates in different countries varies considerably. *In 2003 foreign affiliates accounted for more than half of all business R&D in Ireland, Hungary and Singapore and about 40% in Australia, Brazil…*" (emphasis added). [95]

And, it correctly recognizes, as did the previous studies noted above, that MNCs will still invest in R&D activities within developing countries such as Brazil, India and China, even if IPR protections are presently weak or otherwise lacking. This result obtains for several reasons. First, R&D may be conducted in a country to develop products directed at markets of different countries. Second, "a technology may be highly firm-specific and thus of limited value" to local competitors. Third, R&D may be too far advanced for the host country to exploit, i.e., to copy and use commercially. Fourth, the technology may "involve tacit and uncodifiable elements that are difficult for outsiders to imitate without intimate knowledge gained by working with that specific technology." [96]

Thus, an MNC's concern about the level of available IPR protections afforded in a given developing country does not always dominate the reasoning underlying its decision to invest there if, in the totality, there are other significant financial, legal, or economic issues also to consider. In addition, to IPR protection, such considerations would likely include the overall size of the potential market, the regulatory enabling environment, the level of taxation and attractiveness of tax-based incentives, the relative cost of labor, etc. [97]

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

III. Host Countries May Derive National, Regional and Local Socio-Economic Spillover Benefits from Knowledge-based Foreign Direct Investment (FDI) [98]

Indigenous Capacity-Building

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

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

> "[K]nowledge is a significant determinant of long-term economic growth. In particular, we find that the stock of human capital, the level of domestic innovation and technological adaptation, and the level of information and communications technologies (ICT) infrastructure all exert statistically significant positive effects on long-term economic growth. More specifically with regard to the growth effects of the ***human capital stock***, *we find that an increase of 20 percent in the average years of schooling of a population tends to increase the average annual economic growth by 0.15 percentage point*. In terms of *innovation, we find that a 20 percent increase in the annual number of USPTO* ***patents*** *granted is associated with an increase of 3.8 percentage points in annual economic growth*. Lastly, when the ICT infrastructure, measured by the number of phones per 1,000 persons, is increased by 20 percent, we find that annual economic growth tends to increase by 0.11 percentage point" (emphasis added). [99]

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

> "Innovative activity tends to be concentrated in a small number of advanced countries. In these countries stronger IPR protection would be expected to encourage innovation and subsequent growth. For many other countries however, and for middle-income countries in particular, imitation can be an important source of technological development and growth. [This result obtains, even though] providing stronger IPR protection to foreign firms could cripple [those] domestic industry[ies] previously relying on pirated technologies." [100]

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

between IPR protection and growth" (emphasis added). [101]

A more recent (2005) study addressed the concern of the previous study's authors, regarding the potential negative impact of IPR protections on imitation-oriented domestic industries ('technology opportunists'). It found, to the contrary, that following IPR reforms, local affiliate output, employment levels and capital stocks had expanded significantly, and that "this expansion…[led] to a higher net level of production shifting to developing countries [which] more than offset[] any possible decline in the imitative activity of indigenous firms." [102]

Furthermore, a recent (2005) United Nations study acknowledged, albeit reluctantly, that FDI flows precipitated by a developing country's adoption of IPR protections can lead to the types of critical knowledge development (learning) that will raise such country's ability to innovate and, hence, to grow economically.

> "Innovation is essential for economic growth and development. Research and development [103] is only one source of innovation *but it is an important one*" (emphasis added). [104]
>
> …Developing countries could increase their attractiveness as locations for conducting R&D *by strengthening their protection of intellectual property*, but it is not necessarily considered a prerequisite in the decision-making process of TNCs. Other factors, such as the availability of human resources, infrastructure and the domestic innovative capacity in general, appear to be more important. *However, the development of domestic innovative capacity, which does affect TNCs' location decisions, is partly influenced by the IPR regime*. Furthermore, *to the extent that such a regime facilitates sharing of knowledge and learning, it can also help enhance the benefits of FDI in R&D*" (emphasis added). [105]

What each of these studies indicates, but which many intellectual property opponents, health advocates, and 'open source' missionaries are loathe to admit, is that beyond the more narrowly focused MNC benefits sought (i.e., protection of their private intellectual property interests against unauthorized imitation and expropriation), there are even greater benefits that await developing countries savvy enough to recognize IPRs as they keep their R&D-related FDI spigots open.

> "It is well known that multinational firms are concentrated in industries that exhibit a high ratio of R&D relative to sales and a large share of technical and professional workers…By encouraging FDI, developing countries hope not only to import more efficient foreign technologies but also to generate technological spillovers…[i.e.,] the facilitation of technology adoption… for local firms…" [106]

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

Defined narrowly, the term 'spillover' includes only "pure externalities (such as the facilitation of technology adoption) that may [directly] accompany FDI" flowing from a single company.[107]

> "…[I]f FDI spurs innovation in the domestic industry by increasing competition, we do not view that as a 'spillover' from FDI but rather a benefit enjoyed by the host country that works its way through the price mechanism and the market equilibrium. *Of course, [however,] it is very difficult to empirically isolate the pure externalities from FDI from its other effects that work through the market. Furthermore, policy ought to be based on the aggregate effect of FDI on welfare, not just on the extent of positive externalities from FDI*" (emphasis added). [108]

However, it could be persuasively argued that spillovers should be defined more broadly to include also "pecuniary externalities (that result [indirectly] from the effects of FDI on market structure)…" [109] A broader definition of the term spillover would better be able to take into account any 'follow the leader' or 'copycat' behavior that might and often does occur among corporate competitors who later enter and invest in developing country markets.

> "An old tradition in the management literature describes the interdependence between the decision making of large multinationals as 'follow the leader' behavior...For example [in the present case], when two firms are exporting to a foreign market, a switch from exports to FDI by one creates an incentive for FDI on the other firm's part, who finds itself at a competitive disadvantage…Thus, if such trade is indeed pervasive, one should expect a strong complementary relationship between exports and FDI at the *aggregate* level" (emphasis added). [110]

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

A recent (2004) Inter-American Development Bank report sheds light on these problems and opportunities in the context of SME technology 'clusters'[111] (networks).[112] It found that, among the factors that can contribute significantly to the creation of Latin American country SME innovative capabilities, are: 1) the establishment of a business-friendly, market-based enabling environment, replete with institutions that attract MNC FDI [113] and foster MNC embeddedness and know-how exchanges; [114] 2) a well functioning and integrated national innovation system that encourages R&D investment and a stable *property rights (i.e., intellectual property/patents)*, regulatory, and dispute settlement (judiciary) systems; [115] and 3) effective 'good governance' (ant-corruption) mechanisms.[116]

Unfortunately, "[d]espite overall acknowledgement of the positive effects that interaction with foreign firms can have on the competitiveness of domestic companies, including smaller firms, only Mexico, Chile, Costa Rica and Nicaragua have adopted specific instruments to promote such an interaction.[117] As a result, within these and other Latin American countries, "domestic firms

seem largely unable to provide the high qualitative standards that MN[C]s ask of their suppliers." [118]

Clustered SMEs Realize Potentially Greater Benefits

The IADB report identifies a number of specific benefits that Latin American cluster-based SMEs[119] can expect to derive from targeted FDI. They include improved "host economy[] productivity and wages generating [local] investment opportunities and production variety in both upstream [supplier] (backward linkages) and downstream [customer] (forward linkages) industries." [120]

> "…[B]ackward and forward linkages might be a powerful channel *through which FDI knowledge might spill over to [the] host economy*. The main spillover channels are imitation, competition, worker turnouts and exports. *FDI knowledge spillovers are said to take place when local firms increase their productivity by copying the technology of affiliates of foreign firm*s. Given the foreign firm's strong interest in protecting their competitive edge, and therefore, minimizing technology transfer, spillovers would most likely be 'vertical' (among their clients and suppliers) [rather than] 'horizontal' (among their competitors). [121] FDI is also believed to generate positive pecuniary externalities (linkages effects) to local firms improving the local supply (quality and variety) of intermediate goods…The most relevant form of linkage for FDI is the backward one – that is, the link between MN[C]s and local upstream suppliers" (emphasis added). [122]

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

"Several empirical studies [have found] a positive correlation between the [local] presence of…MN[C]s and the acquisition of human capital – that is, the training or upgrading of workers and the transfer of knowledge that makes possible the generation of new [entrepreneurial] firms via spin-off mechanisms."[123] Such learning may occur by way of exposure to foreign affiliates, through testing and diagnostic feedback related to the use of quality-control techniques.[124] Local companies may also acquire valuable technological knowledge from 'the competition effect'. "[This] occurs when FDI pushes indigenous firms to use existing technology more efficiently and increases the speed of adoption/imitation of new technology. Further competition between domestic firms and MNEs in both the home and foreign markets can induce domestic firms to improve their export performance." [125]

In addition, MNC FDI flows may facilitate many other types of knowledge spillovers to local SMEs. They include transfers of product and process technology, financial, management and marketing skills, business practices, know-how, information, and enhanced social and environmental standards.[126]

Benefits Depend on Local SME-MNC Dynamic

Available evidence adduced from Latin American country 'cluster' studies suggests that an MNC's ability to successfully facilitate knowledge spillovers, and an SME's ability to successfully

benefit from them, depends on certain conditions.

Such success "depends to a large extent on the degree [to which the MNC is] embedded[] in the local relational fabric."

> "Embeddedness and…local acquisition of knowledge cannot take place unless several requirements are met…namely, geographical proximity, appropriate soft and hard infrastructure, and entrepreneurial activities in the private and public sector. Hence, …[F]oreign-owned subsidiaries only contribute to cluster dynamism if they are embedded in the local economy and are autonomous enough to interact freely with entities in the cluster." [127]

Usually, a good amount of time must pass before a multinational company becomes embedded within a developing country. For example, it must first familiarize itself with the local conditions and develop relationships of trust with local suppliers.[128] In addition, such success depends upon the existence of any technology gaps between local and foreign firms. "Wide technological gaps…lessen the attractiveness of outsourcing, subcontracting, and other forms of interconnections."[129] Furthermore, the success or failure in effecting such a transfer is determined by the 'absorptive capacity' of the local firms which, in turn, depends on the level of their human capital. Gaps in human capital between MNCs and local firms "can make the knowledge transfer itself difficult or impossible."[130]

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

> "*Several studies (both theoretical and empirical) indicate that absorptive capacity in the host country is crucial for obtaining significant benefits from FDI. Without adequate human capital or investments in R&D, spillovers from FDI may simply be infeasible*…Thus, liberalization of trade and FDI policies may need to be complemented by appropriate policy changes with respect to education, R&D, and human capital accumulation, if developing countries are to take full advantage of increased trade and FDI" (emphasis added). [131]

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

> "FDI has a potential role in fostering development of clusters and the innovations therein…*FDI can…have both positive and negative effects on host countries, the overall net benefits being a variable that depends on the socioeconomic environment of the recipient country.* In Latin American countries, the capacity of clustered firms to interlink with external sources of knowledge is therefore critical…[T]he capacity to absorb extra-cluster knowledge and diffuse it at the local level is important for fostering development and improving local performance…*In general, the capacity to absorb and implement external knowledge is higher for a cluster than for a firm*, and once a few firms in a cluster assimilate external knowledge its diffusion within the cluster becomes easier…MN[C]s usually have the potential to generate the external stimuli necessary to enhance learning and innovation locally" (emphasis added). [132]

Benefits May Ultimately Depend on Structural Policy Changes

In the event developing country SMEs suffer from huge technological deficits and absorption limitations, then transformational structural changes capable of facilitating MNC knowledge spillovers are in order. The creation of a business cluster-, regional cluster- or even a nation-based innovation system may thus be indispensable to promoting the types of innovative activities needed for such SMEs to compete domestically and globally.[133] These innovation frameworks[134] must involve MNCs as well as local public institutions, including universities, research centers, and technical institutes. And they must be organized consistent with foreign market requirements (as noted previously), be receptive of new technology imports, and be supported by the public.[135]

> "The whole bundle of innovative firms, clustered geographically and surrounded by a set of supportive organizations, leads us to the RIS [regional innovation system] concept. To restate, *an RIS is built on industrial clusters, supported by an adequate infrastructure made up of (i) universities, colleges and technical institutions that provide appropriate levels of human capabilities; (ii) research institutes and agencies, whether public or private, which provide R&D systems and S&T infrastructure; (iii) meso-institutions (chambers of commerce, associations, consultancy systems), providing appropriate communication channels between firms, and between firms and the public sector; (iv) business incubators, which stimulate entrepreneurial activities; and most importantly, the overall regional system exhibits a dynamic path in terms of both innovation and business startups.* There is a complex two-way relationship of mutual embeddedness between these institutions and organizations within an RIS, which govern the innovation processes. International success in advanced industries is interpreted as a direct function of the conduct and the articulation of the RIS" (emphasis added). [136]

In summary, this recent (2004) IADB report emphasizes that in order for developing country firms to remain globally competitive in today's knowledge-based information society, their governments must not only focus their efforts on attracting external R&D-related FDI as part of their regional or national development strategies, but they must also design innovation-centric education and training policies aimed at enhancing internal market fundamentals that enable local SMEs to absorb MNC FDI spillovers.[137] At least one Latin American country (Brazil) has taken several steps down the path towards creating a new innovation system and industrial development policy capable of unleashing the creative potential trapped within its many IP-rich industries. Whether it or other South American countries are ultimately successful in this endeavor, however, will depend on its (their) ability to increase FDI flows, strengthen official bilateral science and technology partnerships, secure continuing official project development funding and import financing and insurance underwriting, and maintain important export trade preferences with significant trading partners, such as the U.S.

The Importance of Science and Technology R&D to Emerging and Developing Countries

Case Example: Brazil

Brazil obviously considers science and technology R&D to be of the utmost importance. For example, during the years 1999-2002, the Government of Brazil created 14 'sectoral funds' financed from a portion of national tax revenues to promote high-quality science and technology (S/T) research and development (R&D) in Brazil's industrial sectors.[138] The funds have been co-managed by government, academia and industry in the areas of aeronautics, agriculture,

biotechnology, energy, health, hydrology, informatics, infrastructure, minerals, petroleum, space sciences, telecommunications, transportation, and university-industry research.[139]

In addition, reforms were made to several federal government bodies. For example, a new division was created within the national agency for technology development and innovation [(FINEP)[140], which focuses on supporting private sector R&D activities. Its purpose is to improve national venture initiatives, and change has already resulted in the growth of a number of start-up and venture capitalist firms, and the creation of a private venture national association. Furthermore, "a new National Secretary's [federal cabinet] position was created within Brazilian government's S/T ministry to improve planning, managing, and coordinating the National Research Institutes…[and to promote] the introduction of 'innovation' in the core of S&T public policies, with a great emphasis in public-private cooperation."[141] Also, a new national public-private organization, the Management and Strategic Studies Center, was created to support more strategic actions and coordinate technological forecast for Brazilian's [National Institute of Science] NIS.[142]

Lastly, the Government of Brazil "has established a regional agenda for S&T in Brazil that supports [approximately] …100 local innovation systems and local cooperative clusters."[143] This perhaps dovetails with Brazil's participation in the global Millennium Science Initiative (MSI), funded equally by the Brazilian government and the World Bank. The MSI

> "seeks to strengthen science and technology capacity in developing countries by supporting locally planned and executed programs that provide new opportunities for talented scientists to excel through research, training, networking, and outreach… Local leadership helps ensure continuity, political acceptance, and familiarity with local challenges."[144]

Two Brazil-based MSI's are currently in operation. One is comprised of 15 S&T institutes that include specialists in mathematics, the nanosciences, tissue bioengineering and climatology. The other is comprised of two S&T institutes that include geographic specialists in semi-arid and coastal regions.[145]

In the field of pharmaceuticals, the Brazilian Ministries of Health and Science are planning to finance a number of university-based research projects focusing on the production of drugs obtained from Brazilian flora and fauna. The program is expected to continue through 2008. In particular, the research will seek to: 1) implement a process to develop an anti-malarial drug from the sagebrush plant Artemesia; 2) start pre-clinical studies of prototypes originated from Spectaline for the treatment of Alzheimer and other cerebral vascular diseases; 3) develop herbal medicine extracted from the Vernonia Condensata Baker bush; 4) the purification of and research into the nociceptic portion of the poison from the Durissus Collilineatus snake; 5) develop phytomedicines for the treatment of asthma and depression; 6) conduct pre-clinical studies on phytomedicines for pharmacology and toxicological effects; 7) study biodrugs associated with nanotechnology tools for treating cancer; and 8) study the use of Bauhinia Ungulata plant for the treatment of diabetes and cholesterol alterations.[146]

Brazil is among the most S&T proficient of the developing nations. For the year ended 2002, Brazil allocated approximately .91 percent of its GDP towards research and development,[147] while for the year ended 2004, it devoted 1.6 percent of its GDP to R&D – a sizeable increase in

investment.[148] Of the total amount of resources spent on R&D during 2004, *60.2% was derived from government sources*, 38.2% from industry sources, and **1.6% from academia** and other sources (e.g., nonprofits).[149]

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

> "The R&D efforts in…countries of special interest—such as…Brazil…provide a context within which to gauge *the manner in which localized and specialized resources should play an important role in two major types of activities.* First, there is the question of being able to *provide technology-based solutions to problems* that are specific to the local environment and resources. Second, there is the issue of the *establishment and maintenance of a capacity to provide technical support* to industries that are growing from within and those that are immigrating from without… [While] …efforts are being directed toward *expansion of the inherent capabilities in both facilities and personnel*…[and R&D]…growth rates suggest that science and technology policy goals can be set and met, assuming stability…[there remain challenges].
>
> *…One of the major challenges facing the R&D establishment in Brazil is said to be the fact that too little of the local industry looks toward R&D as one of the integral inputs to their overall processes*. Government initiatives are underway to encourage greater participation by industry. These initiatives include emphasis on education, incorporation of new technology— in both products and processes—with the objective of job creation and enhanced world-standard exports" (emphasis added). [150]

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

> "In many cases, the initial government support of industry-targeted research institutes had been made with the anticipation that a funding shift—from predominant government funds to those provided by industry—would occur as the relationship between industry and the technology resources grew. *To a significant degree, the transformation did not occur 'naturally' until changes occurred overriding government policies, such* ***as liberalization and openness to foreign investment and ownership.***
>
> *This is not to say that there is an insufficient amount of government funding* to support the development of modern research and high-tech manufacturing capability in emerging areas. There is a continuing effort to capture shares of the worldwide market in high-tech materials, biotechnology, aerospace, and semiconductor devices, and a commitment toward establishing the technology base that is required to support these industries" (emphasis added). [151]

Case Example: The United States

The U.S., by contrast, devoted approximately 2.59 percent of its 2003 GDP to research and development,[152] and 2.7 percent of its 2004 GDP to R&D.[153] Of the total amount of resources spent on R&D during 2004, *31.3% was derived from government sources*, 61.2% from industry

sources, and **7.3% from academia** and nonprofits.[154] With respect to the distribution of the overall national R&D effort ('R&D performance') during 2004, 67% of all R&D was performed by industry, 9.1% by government, and 23.9% by academia and nonprofits.[155] In other words, while universities and nonprofits approximately funded only 7 percent of the R&D performed in the U.S. during 2004, they actually undertook approximately 24% of the work involved in those activities. This data implies that approximately 17% of the R&D conducted by these institutions was funded from either industry or government sources or both. According to at least one report, such data suggests the continuation of a trend reflecting "significant changes in the manner in which U.S. companies acquire [both directly and indirectly] their technological assets…"[156] Indeed, perhaps it is the growing R&D cooperation between U.S. industry and the U.S. academic and nonprofit communities that enables the U.S. to remain "the world's undisputed leader in science and technology."[157]

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

A recent survey that analyzed the top 100 global corporate spenders in research and development found that 41 percent of them were based in the U.S.[158] It also found that during 2004, the global *pharmaceutical and healthcare* sector invested more on R&D than any other of the fifteen sectors considered – a reported $59,332,000,000 ($59.3 billion).[159] In addition, it found that, during 2004, the pharmaceutical and healthcare sector achieved the second highest level of R&D intensity (i.e., R&D $ spent as a percentage of $ gross sales) of all the industries surveyed – 12.5%. The computer software industry scored highest achieving an R&D intensity of 18.2%. [160]

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

> "…another major development…[is]…*the extent to which U.S. companies* (and others) *are outsourcing R&D activities to independent, non-captive performing entities*…one of the more striking trends as of late has been the marked increase in funding from abroad that has been supporting the performance of R&D in private industries. Italy, The Netherlands, Turkey, and Denmark have all experienced considerable increases in funding from foreign sources...The amount of R&D arising from insourcing was, within the period 1998-2002, as high as 7.6% of total funding in Switzerland and Ireland…What is more important, especially in the context of well-publicized actions taken by U.S. and other companies, is the amount of R&D that is insourced in major burgeoning R&D enterprises in, for example, China and India…Over the past few years, *there has been a remarkable growth in the amount of research and development funding that has funneled into China and India, with such funding originating primarily in the U.S.*…Furthermore…it is noteworthy that the outsourcing activities go beyond software back-office operations, software development, and strictly research; it has begun to become much more involved in product development, thereby expanding the entire scope of services in support of manufacturing and operational activities" (emphasis added). [161]

The Important Role Served By Bilateral Science and Technology Agreements

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

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

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

> "*Memorandums of Understanding should only be used for binding agency-to-agency international agreements that commit both parties to specific actions,* ***such as the protection of intellectual property***. This type of agreement is typically broad in scope and would cover any cooperative activity between NIST and the foreign entities. [It] must be signed by the Deputy Director of NIST or higher" (emphasis added). [162]

It is therefore likely that other U.S. federal agencies, including the U.S. Departments of Agriculture (USDA) and Energy (USDOE), the U.S. Food and Drug Administration (FDA), and the U.S. Nuclear Regulatory Commission (NRC), have relied upon this same rationale when deciding to enter into MOUs with their Brazilian government counterparts.

Brazil – U.S. Science and Technology Cooperation is a Related Spillover Benefit

The United States was the first country to recognize Brazil's independence in 1822. The two countries have traditionally enjoyed friendly, active relations encompassing a broad political and economic agenda,[163] including joint science and technology cooperation.

As a result of the growing consensus between Brazil and the U.S. concerning the benefits of sharing science and technology know-how and protecting the intellectual property rights that underlie it[164], a number of joint projects and initiatives between the two countries have evolved. And they have included the participation of both governmental and private (industry, university and nonprofit) institutions.

The basis for such cooperation resides in the periodic renewal of the long-term Brazil-US bilateral science and technology agreement.[165] Under the auspices of this S/T "umbrella agreement", other institutional agreements have been reached pursuant to which a number of joint Brazil-US R&D technical capacity and knowledge-building activities have proceeded. A variety of joint research projects and academic exchanges are being pursued, for example, in the areas of energy, earth and space science, biotechnology, engineering, and agriculture.[166] They include:

1) The execution of a cooperation agreement between NASA and the Brazilian Space Agency;

2) The execution and extension of an MOU and other cooperation agreements providing for the exchange of technical information relating to energy regulatory affairs between the Brazilian National Commission of Nuclear Energy (CNEN) and the U.S. (NRC), and resulting in other joint energy research projects focuses on renewable energy sources.[167] In fact, Brazil and the U.S. are working together on two major international initiatives to develop energy technologies that will address common energy challenges, the Carbon Sequestration Leadership Forum[168] and the International Partnership for the Hydrogen Economy"[169] [170];

3) The progression of regulatory cooperation between Brazil and the U.S. on health care issues, including exchanges of information on how to create a drug regulatory agency modeled after the U.S. FDA;

4) The execution of research and development (R&D) cooperation agreements between national health institutes to pursue joint health care and medical research, including one that focuses exclusively on foot-and-mouth disease;

5) The continuation of cooperative dialogues between research institutes concerning the development of drugs against developing country diseases such as dengue fever and Chagas disease;

6) The execution of U.S. government-approved technology-sensitive contracts between U.S. industry and the Brazilian government to provide Brazil with the satellite surveillance capabilities to pursue climate and pollution research over the Amazon and other locations within Brazil[171];

7) The commencement of joint university-level cooperation projects in the areas of space services, engineering, biotechnology, public health and agriculture;[172]

8) The execution of joint cooperation initiatives, including an MOU between the USDOC – NIST) and the Brazilian Ministry of Science and Technology, to promote bilateral cooperation and learning opportunities between and among national science and technology institutions, and industries in both countries that operate in the science, technology and innovation (ST&I), manufacturing, engineering and life sciences sectors. The MOU endeavors to ensure the development and improvement of consistent national systems of scientific, industrial, and legal metrology (measurement standards) in the chemicals, physics and engineering sciences; [173] [174]

9) The formation of a partnership between the Brazilian Agricultural Research Endeavor's Virtual Library in the United States (EMBRAPA-LABEX), "staffed by Brazilian senior researchers in the United States, in partnership and the USDA/ARS (United States Department of Agriculture/Agricultural Research Service), which seeks to strengthen and broaden the scientific and technological cooperation between EMBRAPA researchers and Brazilian universities and their American partners in the area of agricultural biotechnology"[175] [176].

[1] *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*, International Journal of Economic Development (IJED) Vol. 8, Nos. 1-2 (©SPAEF 2006), at: http://www.itssd.org/White%20Papers/ijed-8-1-2-kogan.pdf .

[2] *See* International Journal of Economic Development, Southern Public Administration Education Foundation (SPAEF) website at: http://www.spaef.com ; http://www.spaef.com/ijed.php .

[3] *Ibid., at* pp. 137-152.

[4] *See* "Evaluation of MIF Projects – Market Functioning: Promotion of Competition and Consumer Protection" MIF/GN-78-14, Office of Evaluation and Oversight, OVE, Multilateral Investment Fund, the Inter-American Development Bank (Dec. 2003), Executive Summary at p. ii. The Bank describes such projects as promoting 'second generation' institutional reforms…aimed at enhancing the capacity of the State to perform its regulatory functions appropriately [to] ensure the sustainability of [prior macroeconomic] market reforms…The confluence of interests between the government and the private sector with respect to these reforms is even more apparent in the connection with competitiveness. The current conception is based on a comprehensive vision of the business environment, including such factors as the quality of macroeconomic policy, the availability of financial resources, infrastructure and human capital services, *and the capacity of enterprises and think tanks to innovate*" (emphasis added). *Ibid.*

[5] *Ibid*., at p.18.

[6] *Ibid*., at p. 19.

[7] *Ibid*., at p. 20.

[8] "One core feature of intellectual property is that it can help differentiate products. This is a key factor in the marketing challenges faced by [small and medium enterprises] SMEs. Brand names, patents, and designs can help to position a product on the market because they make it possible to distinguish its specific characteristics from those of competing products and to locate it in specific segments…An adequate grasp of intellectual property…may…[also]… increase the… commercial]…value of an enterprise in the eyes of potential investors. *Alternatively, the intellectual property assets can be used as collateral security to obtain external funding.* Many entrepreneurs, especially the owners of small businesses, are unaware of the value of brand names, designs, and patents. Proper valuation of those assets can raise the value of an enterprise in the event of a sale, merger, or acquisition"…Intellectual property…[can also be used]…to access new markets, export, or to open branches… Franchising is an instrument that allows a business to expand by granting a brand name license together with authorization to use specific know-how and an agreement to provide ongoing technical assistance…In short, franchising is a commercial expansion tool based exclusively on the sale of intellectual property rights" (emphasis added). *Ibid*., at pp 20-21.

[9] "In Brazil, the Arab food chain 'Habib'…ranked one of the most outstanding enterprises in Latin America by Global Finance magazine…has a vast network of 200 outlets created over the past 14 years [1989-2003]…A report by the Brazilian Franchising Association states that the [franchise] business grew 12 percent in 2002. Annual billing increased from US$ 8.3 billion in 2001 to approximately US$ 9.3 billion in 2002. Together, franchising operations have generated 350,000 jobs in the country as a whole." *Ibid*., at pp. 21-22. A very recent study focused on how franchise operating systems can help to establish respect for intellectual property rights and rule of law in developing countries. "[F]ranchise operating systems can serve many of the same functions as a rule of law while franchise networks can be wonderfully supportive social institutions…The franchise business model is all about brand protection. International franchise consultants are quick to point out that entrepreneurs abroad do not strictly 'buy and sell franchises'. They 'license a brand'. It is in the self-interest of everyone associated with a franchise network – the franchisor, master franchisee and local franchisee – to protect the brand which delivers ongoing mutual value. Proliferating MicroFranchises throughout an economy will be an effective way to educate large numbers of people about the benefits of IPP as local owners work to protect and strengthen their co-owned brands." *See* Kirk Magelby, "MicroFranchises as a Solution to Global Poverty" at pp. 31-32, at: (http://www.nextbillion.net/files/Micro%20Franchises%20as%20a%20Solution%20to%20Global%20Poverty.pdf); (http://www.omidyar.net/group/poverty/file/7.35.11055472357/get/Micro%20Franchises%20as%20a%20Solution%20to%20Global%20Poverty.pdf).

[10] Hernando De Soto is the best-selling author of *The Other Path: The Economic Answer to Terrorism (1989) and Mystery of Capitalism: Why Capitalism Triumphs in the West and Fails Everywhere Else* (2000). He is also founder/director of Peru's Institute for Liberty and Democracy, a champion of market economics and property rights. According to Dr. De Soto, "in Peru there indeed exists a private sector, but it exists largely on the basis of competing for government favors, contracts, and privileges, and its economic approach is to try to exclude or marginalize

competitors--not by out-producing them in quantity, quality, or prices, but through political means, from legislation to outright use of the many resources of legal coercion at the disposal of a modern state… The informal economy is much closer than the formal to what we call a market economy. Not only does it not function on the basis of political favors, but it often functions in spite of a government opposition incited by participants in the formal economy…We pointed out that the problem which both formals and informals had to face was not a 'class struggle' but rather how to handle the intrusion of the government in the activities of all businessmen in Peru…[T]he difference between the institute's agenda of granting official property rights to their land to the informals and the old left-wing idea of 'agrarian reform' [is that] *Agrarian reform is a process by means of which government assigns lands to the peasants*. But when we talk about titling and registering those who have already occupied the lands, the 'squatters,' we are talking about a different phenomenon. The squatters have already created their own revolution. They do not need anybody, neither a party nor a government agency, to carry out a revolution for them… Private property constitutes a formidable bastion against socialism… (emphasis added). *See* Dario Fernandez-Morera, Reason Online "Interview with Hernando de Soto", (?), at: (http://reason.com/DeSoto.shtml). .

[11] Dr. De Soto, in effect, "works with heads of state to implement institutional reforms that give the poor access to formal property rights for their real estate holdings and businesses along with the tools to release the capital locked up in those assets… 'Extralegal is something that cannot be readily used as a guarantee to obtain credit, invest, or make accountable by a third party. The "under-the-table" economy is part of the extralegal sector… If they own assets, these assets are not working for them because they are not registered; they cannot borrow against their assets to create wealth... Once you're in the legal system, you become more interested in the political system'…[M]icrocredits will only work if the borrower has something to loose by not paying back their loan, and they will only have something to lose if they have title deed, legal ownership of their house, their car, their family farm, whatever.'" *See* Kenneth Rapoza, "Interview: Peruvian Economist Hernando de Soto", World Press Review (Oct. 15, 2003) at: (http://www.worldpress.org/Americas/1602.cfm).

[12] "Some of the region's shortcomings with respect to innovation have to do with the enterprises themselves. Innovation tends to be informal, since only 15.7 percent of enterprises have a formal in-house R&D facility. Another aspect of informality is that most enterprises have no idea how much they invest in R&D. Another problem is lack of coordination among enterprises and the other generators of innovation. Empirical data in the region suggest 'limited and inadequate cooperation among the companies themselves and among the business community, universities, and research institutions. This constitutes a bottleneck for the generation of new knowledge and for determining enterprises' innovation needs." *See* "Evaluation of MIF Projects – Market Functioning: Promotion of Competition and Consumer Protection" *supra*, at p. 20.

[13] "[A]vailable evidence indicates that technology markets (essentially licensing transactions) are expanding rapidly, in particular in the United States and in the ICT and biopharmaceutical sectors. This expansion reflects a shift toward more open innovation processes that make firms more eager to use licensing to gain access to needed inventions in a timely fashion and to generate additional revenues from inventions they do not plan to exploit themselves. It has been facilitated by governments, which are encouraging universities and other public research organisations to enter patent markets, licensing inventions to the private sector and engaging in more co-operative research with industry. Expansion is further fuelled by globalisation, as reflected in increased international licensing of technology. While the majority of licensing transactions remain within affiliated groups of companies, evidence suggests that the share of open trade between unaffiliated firms is increasing." *See* "Intellectual Property as an Economic Asset: Key Issues in Valuation and Exploitation", EPO-OECD-BMWA Conference Summary Report, Organisation for Economic Co-Operation and Development (6/30-7/1/05), at p. 6.

[14] *Ibid*., at pp. 5-6.

[15] *Ibid*., at p. 5.

[16] *Ibid*., at p. 7.

[17] "It is highly context-dependent and relates to the ability of a firm to extract the value from its patents through competent management, as well as on the particular market environment facing a patent holder. Differences across sectors are driven by factors such as patent strength, market structure, technology characteristics, company strategies and firm size. Firms exploit the value of their patents through multiple channels. Firms capture the value of their patents not only by embedding protected inventions in new products, processes and services while excluding competitors from the market place, but also by using patents as a source of additional revenue (e.g., via royalties from outward licensing) and a mechanism for accessing technology (e.g., via cross-licensing and inward licensing). Increasingly, they view their patents as assets that can provide markets with information about their technological

capabilities and enhance their bargaining power in various types of transactions, such as establishing joint ventures, negotiating mergers and acquisitions, and accessing financial markets. Different strategies are followed by firms in different industries, often reflecting differences in innovation processes and markets: cross-licensing to get freedom of action and access to complementary technologies, direct licensing to extract royalty revenues, asset in mergers and acquisitions, exclusive rights on leading products, etc. In some low-margin, high-volume industries, such as ICT manufacturing, firms increasingly license their patents to generate revenues that finance R&D and innovation. Start-up firms find licensing an effective means improving the commercialisation prospects of their inventions, as well as of attracting financing from venture capitalists and banks." *Ibid*., at p. 6

[18] *Ibid*., at p. 11, paraphrasing Ruud Peters, Chief Executive Officer at Philips Intellectual Property and Standards. By way of contrast, "In the 1970s a company's strategic effort was typically based on investing in product development and manufacturing with the objective of making better products at lower cost. Success was based on manufacturing high-volume products at low prices." *Ibid*.

[19] "*The utility of patents to companies varies among industrial sectors. Patents are perceived as critical in the drug and chemical industries. That may reflect the nature of R&D performed in these sectors, where the resulting patents are more detailed in their claims and therefore easier to defend*. In contrast, one study found that in the aircraft and semiconductor industries patents are not the most successful mechanism for capturing the benefits of investments. Instead, lead time and the strength of the learning curve were determined to be more important. *The degree to which industry perceives patents as effective has been characterized as '. . . positively correlated with the increase in duplication costs and time associated with patents.' In certain industries, patents significantly raise the costs incurred by non-patent holders wishing to use the idea or invent around the patent – an estimated 40% in the pharmaceutical sector, 30% for major new chemical products, and 25% for typical chemical goods – and are thus viewed as important*. However, in other industries, patents have much smaller impact on the costs associated with imitation (e.g. in the 7%-15% range for electronics), and may be considered less successful in protecting resource investments" (emphasis added). *See* Wendy H. Schacht and John R. Thomas, "Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ('The Hatch-Waxman Act')", Congressional Research Service, Order Code RL30756 (Updated 1/10/05), at p. 5, at: (http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL3075601102005.pdf).

[20] "The six motives for patenting are the following: commercial exploitation of the innovation, licensing, cross-licensing, prevention from imitation, blocking rivals, and reputation…The most important reasons for patenting are the commercial exploitation of the innovations and the prevention from imitation. *In other words, inventors and organisations patent because* ***they seek exclusive rights to exploit economically***. By patenting the "inventions around" they prevent others to imitate their valuable innovations. Another reason for patenting is to block competitors that might patent similar innovations, which suggests that patents are important for competitive reasons more than for evaluating or motivating people working in the organization" (emphasis added). *See* "Study on Evaluating the Knowledge Economy: What Are Patents Actually Worth? – The Value of Patents for Today's Economy and Society", Tender n° MARKT/2004/09/E, Final Report for Lot 1 for the European Commission, Directorate-General for Internal Market (5/9/05), at p. 44. at: (http://ec.europa.eu/internal_market/indprop/docs/patent/studies/patentstudy-report_en.pdf). "Different types of employers have different motivations to patent…[C]ommercial exploitation of a patent is more important for small and medium firms…Licensing is more important for private and public research organizations, including universities…Cross-licensing is an important reason for patenting for large firms. Large and medium firms also consider prevention from imitation and blocking rivals as important motives to ask for patent protection. Finally reputation is an important reason to patent for public research organizations and universities." *Ibid*., at p. 45. The report, furthermore, cites the findings of at least one 2003 study which concluded that "patents have the greatest positive incentive effect on research and development (in the sense that an increase in the premium generates a positive a substantially positive response in R&D) in pharmaceuticals, biotechnology, medical instruments, and computers. In semiconductors and communications equipment the premium and the incentive effect are much lower, although still positive and not negligible." *Ibid.* at p. 14, *citing* Ashish Arora, Marco Ceccagnoli, Wesley M. Cohen, "R&D and the Patent Premium", National Bureau of Economic Research Working Paper No. 9431 (Jan. 2003), at: (http://papers.nber.org/papers/W9431). "[T]here are technologies in which the probability of inventing valuable patents is higher than in others. If we consider the innovations that are worth more than 10 million Euros, the technological sectors with the highest share of patents in this class are: Pharmaceuticals & Cosmetics (17.48%),

Semiconductors (12.81%), Organic Fine Chemistry (13.07%), Chemical, Petrol & Basic Material Chemistry (12.54%), and Material Processing, Textile & Paper (9.90%). *Ibid.*, at p. 30.

[21] "An important, and sometimes overlooked, feature of farm policy is that agriculture is a technologically dynamic sector. Agriculture is in the midst of two ongoing technological revolutions -- crop genetics and livestock industrialization -- and is in the early stages of a third -- gene modification through recombinant DNA. These technological changes have a number of implications. First, the evolution of large agrobusiness firms devoted to life science has generated substantial industrial concentration and vertical integration in the sector. Second, while research in agricultural product development is increasingly undertaken in the private sector, the relationships between public research agencies and private firms in establishing basic scientific results are growing in complexity. Third, there is increasing product innovation through the development of new plant and animal varieties, biologically based inputs for agriculture, and crop-based nutritional and pharmaceutical goods. Taken together, these factors mean that the *industry places growing reliance on formal means of protecting new technologies, including intellectual property rights (IPRs), and there are strong interests pushing for further strengthening and international harmonization in this regard. There are three major forms of IPRs that affect such protection and the willingness to invest in agricultural technologies. These are patents* on life forms, plant variety rights, and geographical indications. Also relevant is competition policy, including the treatment of exhaustion (parallel imports)" (emphasis added). *See* Keith E. Maskus, "Intellectual Property Rights in Agriculture and the Interests of Asian-Pacific Economies", Discussion Paper No. 59, Institute of Economic Research Hitotsubashi University, Tokyo, Japan (Dec. 2004), at pp. 1-2, at: (http://hi-stat.ier.hit-u.ac.jp/research/discussion/2004/pdf/D04-59.pdf); (http://www.fordschool.umich.edu/rsie/Conferences/CGP/Mar2004Papers/Maskus.pdf).

[22] "IPRs in the pharmaceutical industry rely mainly on two instruments, patents and data exclusivity. Patents are usually given for 20 years from the day the patent is accepted by the national patent office. For most innovations, holding a patent is equivalent to holding a marketing authorization and market exclusivity for a certain period of time, until a newer, better alternative is introduced. For NCEs, however, having a patent can be quite disconnected from having marketing authorization. In fact, it is ten years, on average, before a newly patented medicine reaches the patient's bedside. After receiving a patent, the innovator must prove the safety and efficiency of the new drug to the regulatory authority. In order to prove safety and efficiency of a new drug, pre-clinical and clinical tests must be performed. The results of tests on animals and humans are systematically reported in the registration dossier prepared for the regulatory authority. Because of the large investment in money and time needed to successfully gain marketing approval through clinical trials, the data generated during testing phases is kept confidential and cannot be exploited by potential competitors for a certain number of years. This protection is referred to as both data protection and data exclusivity…*For most drugs, patent protection goes beyond data protection. However, if the testing period has been extremely long, or if the drug does not have full patent protection, data exclusivity can be the only form of IP*" (emphasis added). *See* Corinne Sauer and Robert M. Sauer, Reducing Barriers to the Development of High Quality, Low Cost Medicines - A Proposal for Reforming the Drug Approval Process", IPN Working Papers on Intellectual Property, Innovation and Health (©2005), at: (http://www.who.int/intellectualproperty/submissions/Sauerbarriers.pdf).

[23] 'Return of capital' is essentially a return of one's actual cost (outlay) investment in a 'capital asset' – i.e., "a long-term asset that is not bought or sold in the normal course of business." In a broader sense, it can be viewed as a return on invested capital, including both contributed equity and incurred debt, "or return on investment', or ROI, [which] is a useful means of companies or corporate divisions in terms of efficiency of management and viability of product lines." *See* John Downes and Jordan Elliot Goodman, Finance and Investment Handbook, Barrons (© 1987) at pp. 199 and 431.

[24] 'Return of sales' is essentially "net pretax profits as a percentage of net sales…[figured after returns, allowances, and discounts]...a useful measure of overall operational efficiency when compared with prior periods or with other companies in the same line of business. *It is important to recognize, however, that a return on sales varies widely from industry to industry*" (emphasis added). *Ibid*., at p. 431.

[25] IPRs are crucial in pharmaceutical innovation because of the high cost of innovation relative to the cost of imitation. Patent protection and data exclusivity provide innovators with a period of market exclusivity that allows them to recoup their large initial investments and earn a profit. Without such protection, innovative products would be quickly imitated at a very low cost, rendering the original R&D effort worthless…[A]mong the 118 new chemical entities (NCEs) introduced to the market between 1990 and 1994, only 30% of them had a present value of net revenue that exceeded their R&D costs. For the median drug, the cost of R&D was not recovered. It was only among the few high

selling drugs, known as blockbusters, that the return to R&D was substantial (five times greater than the return to all other drugs). This wide range of returns in new drug investment led the authors to conclude that R&D effort in the pharmaceutical industry is mainly driven by the search for a blockbuster. In fact, research-based pharmaceutical companies need to have some top selling drugs in order to cross-subsidize other R&D investments. Legislative enactments that weaken IPRs and lower the price of blockbusters, without lowering their costs of development, could cause a cascading reduction in pharmaceutical innovation. *Ibid*., at p. 8.

[26] "For R&D — and innovation in general — the most relevant types of intellectual property are patents and trade secrets. *Trade secrets may in fact be even more important than patents for a country to be able to attract FDI in R&D.* To the extent that the R&D process involves sensitive information, TNCs will always seek to protect trade secrets against disclosure. A 1994 survey of 1,478 R&D labs in the United States manufacturing sector found that trade secrecy was effective for 51% of innovations, while the corresponding figure for patents was only 35%" (emphasis added). *See* "Transnational Corporations and the Internationalization of R&D", United Nations Conference on Trade and Development (UNCTAD) World Investment Report, UNCTAD/WIR/2005 (Sept. 2005), at p. 209, at: (http://www.unctad.org/en/docs/wir2005_en.pdf).

[27] As a condition for registering pharmaceutical products, national authorities normally require registrants to submit data relating to a drug's quality, safety and efficacy as well as to its physical and chemical characteristics.

[28] "In addition to test data, national authorities require information on the quantitative and qualitative composition and other attributes of the product, as well as on manufacturing methods. Marketing approval is generally granted for a specific drug used for a specific therapy. Changing the composition of the drug, combining it with other drugs in a single product or selling the drug for a different therapeutic purpose requires new approval." *See* Carlos María Correa, "Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement", The South Centre (2002), at pp. 17, at: (http://www.southcentre.org/publications/protection/protection.pdf).

[29] For example, in *Ruckelshaus v. Monsanto, Co.*, the U.S. Supreme Court noted the District Court's finding that "Monsanto had incurred costs in excess of $23.6 million in developing the health, safety, and environmental data submitted by it under FIFRA…The information submitted with an application usually has value to Monsanto beyond its instrumentality in gaining that particular application. Monsanto uses this information to develop additional end-use products and to expand the uses of its registered products. The information would also be valuable to Monsanto's competitors." *Ruckelshaus v. Monsanto, Co.*, 467 U.S. at __.

[30] *See* Alfred Adebare, "Data Exclusivity: The Implications for India", LexCounsel India (11/22/05), at: (http://www.articlealley.com/article_16562_18.html).

[31] *Ibid*.

[32] Pursuant to U.S. law, a trade secret is a protectable intellectual property right that meets the following definition: "information, including a formula, pattern, compilation, program, device, method, technique, or process that: (i) derives independent economic value, actual or potential, from not being generally known, and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." *See* "The Uniform Trade Secrets Act", Sec. 1(4)(1985), 14 U.L.A. 286 (Supp. 1987). Factors that should be considered when ascertaining whether information is covered under this definition are set forth within the U.S. Restatement of Torts (Sec. 757 comment b (1939). 'Trade secrets' may include pending patent applications. *See* Robert C. Dorr and Christopher H. Munch, Protecting Trade Secrets, Patents, Copyrights and Trademarks, Wiley Publications (© 1990), at pp 4 and 9. "[T]he Uniform Trade Secrets Act ("UTSA") essentially 'codifies the basic principles of common law trade secret protection'...The UTSA has been adopted by most states. In addition to injunctive relief, the UTSA provides for the award of monetary damages, including exemplary damages. Reliance on the UTSA may be compelling because it codifies a broad enough definition of trade secret that: 1) comports with the Restatement (Third)… of Unfair Competition §39 (1995); and 2) covers a wider array of categories of information beyond what is contemplated by federal statutes like [the Freedom of Information Act] FOIA." *See* Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, "Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation", RX for the Defense (Winter 2004), at p. 23, at: (http://www.orrick.com/fileupload/298.pdf). That restatement defines 'trade secret' as "any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others." *Ibid*.

[33] *See* Meir Perez Pugatch, "Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access", Presentation made at the *ICTSD-UNCTAD Dialogue on Ensuring Policy*

Options for Affordable Access to Essential Medicines (10/12-10/16/04), at: (http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf). "The underlying logic of data exclusivity *suggests* that it is an expression of trade-secrets, and that as such, data exclusivity should be independent of patents. Compared with patents, the market power of data exclusivity is, in theory, less restrictive, mainly because it does not legally prevent other companies from generating their own registration data" (emphasis added). [D]ata exclusivity is becoming increasingly dominant as an additional IP layer of protection which affects both research-based and generic-based companies…Trade retaliation policy tools are also currently being used by the US and the EU against developing countries, such as Israel, Turkey and India, in which the absence of data exclusivity legislation results in a serious commercial clash between research-based multinational pharmaceutical companies and powerful local generic-based companies that are often perceived as 'national champions'…[S]ince data exclusivity is a new form of protection, there are still significant disagreements on what this form of IP protection encompasses." *Ibid*.

[34] According to the U.S. Supreme Court, "patent application shall include a full and clear description of the invention and 'of the manner and process of making and using it' so that any person skilled in the art may make and use the invention." *Kweanee Oil Co. v. Bicron Corp*., 416 U.S. 470, 480-81 (1974). "The information contained in a patent application is kept by the Patent and Trademark Office as a trade secret as long as the application is pending…[However,] …[t]he day the patent is printed by the Government Printing Office, all trade secrets contained therein become public knowledge ...Issued patents are good examples of technical information that no longer constitutes trade secrets…When a chemical composition falls within this category, it is a wise business decision to protect the chemical formulation as a trade secret and not publicly disclose it in an issued patent." *See* Dorr and Munch at p. 6.

[35] *See* Dorr and Munch at pp. 5-6. Prior the enactment of the Uniform Trade Secrets Act (USTA) the definition of trade secret was narrowed down by the courts with respect to information submitted to regulatory authorities. For example, in *Public Citizen Health Research Group v. Department of Health and Human Services*, 704 F.2d 1280 (D.C. Cir. 1983), the federal circuit court defined a 'trade secret' as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." As a result of the *Public Citizen* court's ruling, the U.S. Food and Drug Administration amended its operative regulations to read as follows: "a trade secret: may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process… This requirement means that sensitive information, like marketing projections, customer or supplier lists, or pricing information, not directly related to the productive process, would be not be deemed to be trade secret. Rather, these categories would fall under the definition of confidential commercial or financial information, found in 21 C.F.R. §20.61(b), and risk being afforded a reduced level of protection." *See* Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, "Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation", *supra*, at p. 22

[36] For example, "Whenever a company submits information to the FDA…[several] statutory and regulatory provisions ostensibly provide reassurance that any confidential information will be protected. Still, the protections afforded in these provisions require companies to properly designate their information as trade secret, or confidential." *See* Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, "Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation", *supra*, at p. 22; Robert C. Dorr and Christopher H. Munch, Protecting Trade Secrets, Patents, Copyrights and Trademarks, *supra*, at p. 31.

[37] "For instance, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §331(j), prevents: [t]he *using* by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, *any information…concerning any method or process which as a trade secret is entitled to protection*… Additionally, 18 U.S.C. §1905 prohibits government officials and employees *from publishing, divulging, disclosing or making known, 'to any extent* not authorized by law' a wide array of confidential information, 'except as provided by law.' Violators of this provision will be subject to fines, and even possible imprisonment. However, these punitive provisions do nothing to undo the probable economic damage of disclosure of a trade secret that a company would suffer. FDA regulations also prohibit the disclosure of trade secret information: Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure" (emphasis added). *See* Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, "Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation", RX for the Defense (Winter

2004), at p. 21, at: (http://www.orrick.com/fileupload/298.pdf).
[38] *Ibid*., at p. 22.
[39] "[U]nder 21 C.F.R. §20.83, the FDA will disclose information pursuant to a final court order, even if that information is otherwise not available for public disclosure[;]21 C.F.R. §20.86 permits the release of confidential information in an administrative proceeding or a court proceeding, "where data or information are relevant" to that proceeding[;] [T]he FDA…is authorized to release trade secrets and commercial or financial information to other federal government departments and agencies *if* the FDA satisfies certain provisions of the United States Code. One such provision is Section 331(j) of Title 21, which permits disclosure of trade secrets to "courts when relevant in any judicial proceeding[;] [and] [T]he FDA Commissioner also has the discretionary authority to disclose otherwise exempt information based on a finding that disclosure would be "in the public interest, promote the objectives of the act and the agency, and is consistent with rights of individuals to privacy, the property rights of persons in trade secrets, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities" (emphasis added). *Ibid*., at p. 23.
[40] "The Federal Trade Secrets Act covers only the specific criminal acts of federal employees." *See* Dorr and Munch at p. 9, *citing* The Federal Trade Secrets Act, 18 U.S.C. Sec. 1905 (Supp. 1988).
[41] *See* Restatement First of Torts, comment b (1939). "The Restatement…historically was relied upon by courts and federal agencies when considering whether to withhold confidential information from production." *See* Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, "Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation", at p. 22.
[42] "The elements of that tort of are: '(1) an economic relationship between [the plaintiff and some third person] containing the probability of future economic benefit to the [plaintiff], (2) knowledge by the defendant of the existence of the relationship, (3) intentional acts on the part of the defendant designed to disrupt the relationship, (4) actual disruption of the relationship, [and] (5) damages to the plaintiff proximately caused by the acts of the defendant.' *Buckaloo v. Johnson* 14 Cal.3d 815, 827 (1975)." *See* "The Lectric Law Library's Lexicon On Intentional Interference With Prospective Economic Advantage", at: (http://www.lectlaw.com/def/i084.htm).
[43] *Ibid*., citing *Youst v. Longo* 43 Cal.3d 64, 71 (1987). "In New Jersey, '[w]hat is actionable is the luring away, by devious, improper and unrighteous means, of the customer of another.' *Printing Mart-Morrison v. Sharp Elecs. Corp.*, 563 A.2d 31, 36 (N.J. 1989). 'A complaint based on tortious interference must allege facts *that show some protectable right* – a prospective economic or contractual relationship. Although the right need not equate with that found in an enforceable contract, *there must be allegations of fact giving rise to some 'reasonable expectation of economic advantage*.'' Id. at 37 (emphasis added); see *Democratic State Comm. v. Bebchick*, 706 A.2d 569, 573 (D.C. 1998) ('In order to survive a motion to dismiss on a claim of intentional interference with prospective economic advantage a plaintiff must allege business expectancies, not grounded on present contractual relationships, but which are commercially reasonable to anticipate.'); *Walker v. Sloan*, 529 S.E.2d 236, 242 (N.C. Ct. App. 2000) ('[T]o state a claim for wrongful interference with prospective advantage, the plaintiffs must allege facts to show that the defendants acted without justification in inducing a third party from entering into a contract with them which contract would have ensued but for the interference.')" *See United Educational Distributors, LLC v. Educational Testing Service*, (SC CA 2002), at: (http://www.law.sc.edu/ctapp/3436.htm).
[44] "For the most part, the 'expectancies' thus protected have been those of future contractual relations, such as the prospect of obtaining employment, or employees or the opportunity of obtaining customers. In such case[] there is a background of business experience on the basis of which it is possible to estimate with some fair amount of success both the value of what has been lost [e.g., prospective profits] and the likelihood that the plaintiff would have received it if the defendant had not interfered." *See* William L. Prosser, Handbook of the Law of Torts, 4th ed., 'Interference With Prospective Advantage' Sec. 130, West Publishing Co., at pp. 949-950, (© 1971).
[45] "[F]ree competition…proverbially is the life of trade. So long as the plaintiff's contractual relations are merely contemplated or potential, it is considered to be in the interest of the public that any competitor should be free to divert them to himself by all fair and reasonable means." *Ibid*., at p. 954. "Though trade warfare may be waged ruthlessly to the bitter end, there are certain rules of combat which must be observed. 'The trader has not a free lance. Fight he may, but as a soldier, not as a guerilla.' In the interests of the public and the competitors themselves, boundaries have been set by the law, and numerous practices have been marked out as 'unfair' competition, for which, in general, a tort action will lie in favor of the injured competitor, although very often the tort is given some other name." *Ibid*., at p. 956, citing Hammond, J., in *Martell v. White*, 185 Mass. 255, 260, 69 N.E. 1085, 1087; Grismore, "Are Unfair Methods of Competition Actionable at the Suit of a Competitor", 33 Mich. L. Rev. 321 (1935).

[46] *See* Black's Law Dictionary Special Deluxe Fifth Edition at p. 93 (© 1979) West Publishing Co. at p. 1371. "The torts of intentional interference with contractual relations, with lawful business, and with prospective business advantage are closely related. . . The general wrong involved in each tort consists of intentional and improper methods of diverting or taking away ongoing or prospective business or contractual rights from another, which methods are not within the privilege of fair competition." *See* 45 Am. Jur. 2d Interference § 36 (1999).
[47] "[A] method was said to be an unfair method if its does not leave to each actual or potential competitor a fair opportunity for play of his contending force engendered by an honest desire for gain. *California Rice Industry v. Federal Trade Commission*, C.C. A. 9, 102 F.2d 716, 721." *Ibid*., at p. 1372.
[48] *See* Dorr, and Munch, *supra*, at p. 104.
[49] The term 'appropriation' is defined as "To make a thing one's own; to make a thing the subject of property; to exercise dominion over an object to the extent, and for the purpose, of making it subserve one's own proper use or pleasure." *See* Black's Law Dictionary, *supra* at p. 93.
[50] The term 'misappropriation' has been defined as "the taking and use of another's property for [the] sole purpose of capitalizing unfairly on good will and reputation of [the] property owner." *Ibid*., at p. 901.
[51] *Ibid*., at p. 108.
[52] *See* Dorr and Munch, *supra*, at p. 111.
[53] *See supra*.
[54] *See* Raymond G. Mullady, Jr., Scott D. Hansen and James C. Pelletier, "Protecting Trade Secrets and Other Intellectual Property in Drug and Medical Device Litigation", *supra*, at p. 24.
[55] *See also* Andrew Beckerman-Rodau, "Are Ideas Within The Traditional Definition of Property? A Jurisprudential Analysis", *supra*, at pp. 12-21.
[56] Id., at pp.
[57] *See* Kamal Saggi, "Trade, Foreign Direct Investment, and International Technology Transfer: A Survey", The World Bank Development Research Group (May 2000), at p.17.
[58] *See* Tim Büthe and Helen Milner, "The Politics of Foreign Direct Investment into Developing Countries: Increasing FDI through Policy Commitment via Trade Agreements and Investment Treaties?" Circulation Draft (3/24/05), at (http://polisci.ucsd.edu/calendar/ButheMilner_FDI_24mar05.pdf), at p. 2.
[59] *Ibid*.
[60] "FDI involves the acquisition or creation of productive capacity, which implies a long-term perspective and inherently involves at least some assets that are highly specific to the location and cannot be moved in the short run without considerable loss. *Effective property rights safeguard such investments*" (emphasis added). *Ibid*., at p. 9. "Once the MNC undertakes a foreign direct investment, some bargaining power inevitably shifts to the host country, because the investment is by definition not perfectly mobile and depends upon local property rights." *Ibid*., at p. 1.
[61] "[Since few developing countries have well established property rights regimes… [p]otential foreign investors should therefore be expected to be weary about committing significant investments to any developing countries. Although outright expropriation of foreign investments has become much less likely over time, it remains a possibility. More important, however, are the myriad mechanisms that exist for changing the terms of an investment and thus reducing its profitability and/or changing its ownership. *Governments can pose far more subtle threats to property rights through* changes in taxation, tariffs, and fees, as well as *government toleration of* crime and *intellectual property theft*" (emphasis added). *Ibid*.
[62] *Ibid*., at pp. 9-10. In this regard, the study found "strong empirical [anecdotal] support for the centrality of property rights concerns. In a survey of its members in the late 1990s, the U.S. chamber of commerce found property rights to rank first among the factors noted by U.S. businesses as important to their allocation of investment abroad (U.S. Chamber, "12 Rules for Investors"). And this does not appear to be just an American preoccupation: In a series of interviews with German senior managers—conducted by one of us in 2000-2002, on, inter alia, the factors that make for a good investment climate in a given country, interviewees tended to distinguish first between countries where physical *and intellectual property* is essentially secure and countries where it is not. For the latter category, in which interviewees tended to include countries outside Western Europe and North America, measures that would enhance property rights guarantees were always the first concern" (emphasis added). *Ibid*., at p. 40.
[63] "International institutions may allow governments to make more credible commitments. Why? In our view, international institutions, while certainly not determining government behavior, affect the incentives that governments face when choosing between alternative policies by changing the relative cost of the policy choices (making some more costly than they would be in the absence of the institutions*…[P]articipation in international agreements, treaties*

and organizations that institutionalize the country's commitment to property rights and a liberal economic policy should make this commitment more credible" (emphasis added). *Ibid*., at pp. 12 and 13.

[64] *See also* Kim Sokchea, "Bilateral Investment Treaties, Political Risk, and Foreign Direct Investment", International University of Japan (2006), at p. 8, at: (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=909760). "The study analyzes the effects of bilateral investment treaties on foreign investment in…10 Asian countries from 1984 to 2002…[T]his study provides evidence that BITs play a significant role in stimulating the inflows of investment… BITs can function as a credible framework to promote FDI, and countries with higher political risk seem to be better able to receive more FDI with BIT ratification. While the effects of BITs with OECD countries are not likely to depend on the quality of political condition, those of BITs with non-OECD countries might be likely to…As BITs are viewed as the commitment of a host country to provide a stable legal framework to investors, signing BITs is a signal to not only signatory countries, but also the international business community. The result concludes that the commitment is credible even with BITs signed with non-OECD countries although conditional on BITs signed with OECD countries. Thus, a message to a developing country is that a BIT is really worth negotiating, signing, ratifying, and complying. In addition, using 2004 political risk data, the study provides evidence that an additional BIT ratified raises FDI inflows by an average of 2.3 percent in South, East, and South-East Asian nations…Lastly, the overall findings in this study add to the literature on the determinants of FDI. As shown in the empirical results, the market size, political stability, the quality of infrastructure, wage, the degree of openness, APEC membership are the important factors for stimulating FDI inflows." *Ibid*., at pp. 30-31.

[65] *See* "Transnational Corporations and the Internationalization of R&D", United Nations Conference on Trade and Development (UNCTAD) World Investment Report, UNCTAD/WIR/2005
(Sept. 2005), at pp. 33-34, at: (http://www.unctad.org/en/docs/wir2005_en.pdf).

[66] "[There is now] evidence on the response of U.S. multinationals to a series of well-documented IPR reforms by developing countries in the 1980s and 1990s. Our results indicate that U.S.-based MNCs expand the scale of their activities in reforming countries after IPR reform, and this effect is disproportionately strong for affiliates whose parents rely strongly on patented intellectual property as part of their global business strategy." *See* Lee Branstetter, Ray Fisman, Fritz Foley, and Kamal Saggi, "Intellectual Property Rights, Imitation, and Foreign Direct Investment: Theory and Evidence", National Bureau of Economic Research (NBER) (Aug. 2005), at p. 1, at: (http://faculty.smu.edu/ksaggi/IPR-LEE.pdf). A prior 1999 study had found that "international trade flows consisting of knowledge-intensive or high technology products rose sharply following the enactment of intellectual property reforms by developing countries", but not as much as for manufacturing trade flows. *See* Carsten Fink & Carlos A. Primo Braga, "How Stronger Protection of Intellectual Property Rights Affects International Trade Flows," The World Bank, Policy Research Working Paper Series 2051, (1999), at p. 2.

[67] "Each reform can be classified according to whether or not it expanded and strengthened patent rights along five dimensions. These dimensions include: 1) an expansion in the range of goods eligible for patent protection, 2) an expansion in the effective scope of patent protection, 3) an increase in the length of patent protection, 4) an improvement in the enforcement of patent rights, and 5) an improvement in the administration of the patent system. While the 16 patent reforms are not identical, there is a surprising degree of similarity in these reforms, with 15 out of 16 exhibiting expansion of patent rights along at least 4 of the 5 dimensions described. These are the kind of substantive reforms that are likely to have a material impact on intrafirm technology transfer…" *See* Lee Branstetter, Raymond Fisman, and Fritz Foley, "Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence From U.S. Firm-Level Panel Data", National Bureau of Economic Research (NBER) Working Paper # 11516 (**July** 2005), at p. 14, at: (http://weblog.ipcentral.info/IPRs%20&%20Tech%20Trans.pdf).

[68] "*Changes in the value of licensing payments could reflect changes in the volume of technology transferred or merely changes in the price charged for that technology*. Analyzing changes in the R&D expenditures of affiliates is helpful in distinguishing between these two possibilities". *Ibid*., at p. 6. "[Prior studies reveal that]…co-location of R&D with foreign manufacturing facilitates the 'transfer of knowledge and prototypes from the firm's home location to actual manufacturing.' Viewed in this light, affiliate R&D and technology transfer from the parent may be considered complements. Given this complementary relationship, IPR reform should also prompt an increase in R&D spending" (emphasis added). *Ibid*., at p. 7. "In addition to reporting extensive information on measures of parent and affiliate operating activity including R&D expenditures, multinationals must also report the value of royalties paid by affiliates to parents for the sale or use of intangible property. *Royalty payments are reported at the affiliate level, and they include payment for industrial products and processes, which capture technology licensing fees, as well as franchise fees, fees for the use of trademarks, and payments for other intangibles*" (emphasis added). *Ibid*., at p. 9. "Section 482

of the U.S. tax code requires affiliates to make royalty payments for intrafirm technology transfer and to ascribe a value to these transfers that would be equivalent to what the firm would charge an unaffiliated party. These legal reporting requirements *meaningfully constrain the discretion the firm can exercise in reporting transfers*, as demonstrated by a number of high profile legal cases" (emphasis added). *See* Lee Branstetter, Raymond Fisman, and Fritz Foley, "Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence From U.S. Firm-Level Panel Data", National Bureau of Economic Research (NBER) Working Paper # 11516 (**Jan**. 2005), at p.10. *****(Presumably, this was an earlier version of the July study cited above).

[69] *See* Lee Branstetter, Raymond Fisman, and Fritz Foley, "Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence From U.S. Firm-Level Panel Data" (**July** study), *supra*,,at pp. 1, 2 and 25.

[70] *See* Alireza Naghavi, "Strategic Intellectual Property Rights Policy and North-South - Technology Transfer", Fondazione Eni Enrico Mattei, NOTA DI LAVORO 18.2005 (Jan. 2005), at pp. 1 and 21, at: (http://www.feem.it/NR/rdonlyres/CCCC4C73-1C23-41AC-9046-A1463A39EE51/1440/1805.pdf).

[71] *See* Belay Seyoum, "The Impact of Intellectual Property Rights on Foreign Direct Investment", citing "United Nations Center for Transnational Corporations, World Investment Report" (New York: UNCTC, 1993), *supra*, at 57.

[72] *Ibid*.

[73] *See* Dermot Leahy and Alireza Naghavi, "Intellectual Property Rights and Entry into a Foreign Market: FDI vs. Joint Ventures", NOTA DI LAVORO 97.2006 (June 2006), at: (http://www.feem.it/NR/rdonlyres/B1B45A6F-70BD-4B77-BEEB-928ED383851D/2051/9708.pdf).

[74] *Ibid*., at pp. 31-33.

[75] *See* Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment and Technology Transfer*. International Finance Corporation, Discussion Paper No. 19, The World Bank (1994), at p. vii, at: (http://www.bvindecopi.gob.pe/colec/emansfield2.pdf).

[76] *Ibid*., at p. 19.

[77] *Ibid*., at p. 20.

[78] *See* Carlos A. Primo Braga and Carsten Fink, "The Relationship Between Intellectual Property Rights and Foreign Direct Investment", 9 Duke J. of Comp. & Int'l L. 163 at 172 (Fall 1998).

[79] *Ibid*.

[80] *Ibid*., at 174.

[81] *Ibid*., at pp. 175-176.

[82] *Ibid*., at p. 180.

[83] *See* Kamal Saggi, "Trade, Foreign Direct Investment, and International Technology Transfer: A Survey", The World Bank Development Research Group (May 2000) at p. 17.

[84] *Ibid*. at pp. 37 and 39. A more recent (2004) study drew similar conclusions with respect to how developing country adoption of various levels of copyright protections impacted the FDI flows of companies operating within the U.S. feature film and video industry. *See* Phillip McCalman, "Foreign Direct Investment and Intellectual Property Rights: Evidence from Hollywood's Global Distribution of Movies and Videos" Journal of International Economics 62 (2004) 107 – 123. "Due to the technological characteristics of its output, the chief issue facing Hollywood studios is the internalization question (FDI or license) rather than the location question (export or produce abroad). So, the main decision that a studio has to make is whether its presence in a foreign market is most profitable in the guise of an affiliate or an agent." *Ibid*., at p. 109. "…While Hollywood studios are likely to service a foreign market through an affiliate if the standards are either low or high, they are more likely to enter into a licensing agreement if a country offers a moderate degree of IPR protection. This pattern characterizes Hollywood's behavior in both feature film distribution and video distribution markets." *Ibid*., at pp. 121-122). This study was notable because it examined the impact of such protections at the *firm* rather than at the aggregate industry level, which enabled it to take into account the idiosyncrasies of each industry sub-sector.

[85] "[I]n theory a strengthening of patent rights in developing countries could reduce or expand access to foreign technologies. The former problem would arise essentially because of enhanced market power on the part of technology developers, who could choose not to offer certain technologies or to raise access fees. It would be exacerbated by the higher cost of imitation in recipient countries. *However, stronger IPRs may be expected also to reduce the costs of reaching and enforcing contracts, while raising the returns to FDI and licensing, thereby expanding the aggregate flows of technology*. While the empirical evidence on this issue remains somewhat murky, *the preponderance of results from econometric studies suggests the impact could be large and positive in developing*

economies with the ability to absorb technology. In this regard, ***developing countries may wish to focus resources on improving their absorptive capacities through improved governance, strengthened education programs, targeted technology inducements, and competition policies.*** Turning to substitution effects, standard economic theory argues that as a country's IP regime is strengthened, multinational enterprises would choose to shift away from FDI and toward licensing at the margin. Again, there is evidence to support this claim. However, we have put forward a simple model focusing on the relative impact of IPRs on reducing contracting costs in FDI and licensing. We find that the standard prediction holds only in sectors with rapid innovation rates, which presumably are higher-technology industries. In lower-technology industries it is more likely that stronger patents would induce firms to shift toward greater use of FDI and lesser use of licensing. To the extent that lower-income developing countries hope to attract FDI in such sectors, which presumably are more important in the medium term as a means of exploiting comparative advantage in international trade, strengthened IPRs would have this additional benefit" (emphasis added). *See* Keith E. Maskus, Kamal Saggi and Thitima Puttitanun, "Patent Rights and International Technology Transfer Through Direct Investment and Licensing" Revised Draft (6/28/04), at p. 23, at: (http://spot.colorado.edu/%7Emaskus/papers/MSP-paper_6-04.doc).

[86] "My conversations with managers and researchers in China also indicate that many of the labs are developing specific technologies which are later integrated into large R&D projects for global applications… For instance, AutoMovie, a video-editing technology developed at Microsoft Research (MSR) Asia in Beijing, was later integrated into Movie Maker, a feature of the new Windows XP. Other examples at MSR Asia include the Mobile HTML Optimizer used in FrontPage and the Ink Parsing technology used in Tablet PC." *See* Minyuan Zhao, "Conducting R&D in Countries with Weak Intellectual Property Rights Protection" (July 2004), at p.1 and fn1, at: (http://www.isnie.org/ISNIE04/Papers/zhao%20paper.pdf).

[87] *Ibid*.

[88] "…[This] study directly illustrates the arbitrage framework: institutional gaps across countries can be an important source of opportunity for firms possessing the right capabilities. Just as globalization is not for every firm, neither is establishing R&D centers in China and India. To take full advantage of such opportunities, a firm must have the ability to efficiently transfer, integrate and further develop knowledge on a global basis… In the face of international competition, a firm's competitive advantage resides not only in its proprietary knowledge and resources, which may be vulnerable to imitation, but also in its dynamic organization that matches the internal resources with the external environment." *See* Minyuan Zhao, "Conducting R&D in Countries with Weak Intellectual Property Rights Protection", at pp. 21-22.

[89] *Ibid*., at pp. 1-2. " MNEs are substituting internal organization for external IPR protection in countries with poor institutional environments. Firms with closely-knit internal technology structures can thereby take advantage of the underutilized human capital in weak IPR countries without exposing themselves to excessive risk." *Ibid*., at p. 21.

[90] *Ibid*., at pp. 2-3.

[91] *Ibid*., pp. 2-3, 10.

[92] *Ibid*., at p. 4.

[93] *Ibid*., at p. 12. "There is no direct measure for the internalized value of technologies, but value can be proxied by usage. Technologies whose values are highly dependent on internal resources are more likely to be utilized within the firm…Presumably, the more a patent is cited by the same firm, the more its value is being retained inside the firm boundary. Because I am more interested in the firm as an integrated organization, any citations that occur among affiliated entities are considered self-citations." *Ibid*., at p. 13.

[94] *Ibid*., at p. 21.

[95] *See* "Transnational Corporations and the Internationalization of R&D", United Nations Conference on Trade and Development (UNCTAD) World Investment Report, UNCTAD/WIR/2005
(Sept. 2005), at p. 22, at: (http://www.unctad.org/en/docs/wir2005_en.pdf).

[96] "Some developing countries like *Brazil*, China and India have attracted significant amounts of FDI in R&D; despite being perceived as having relatively lax IPR regimes. *There are four main reasons why IPR protection may have a limited impact on the location of TNC R&D*: [(1)] R&D may be conducted for a completely different market. For example, it has been noted that IPR issues for TNC R&D labs in China are mostly handled in the home country as these labs work on technologies aimed at world markets. Since a patent gives its assignee a monopoly on both production and sales, the TNC can protect its intellectual property by obtaining patents in the countries for which the product was developed rather than in the country where the R&D is undertaken. [(2)] A technology may be highly firm-specific and thus of limited value to others. For example, if different technologies developed by a firm are

complementary to one another and can only be used jointly, a particular innovation in the host economy may have little value on its own. TNCs may structure their international R&D activities so that a foreign affiliate in a country with weak IPR protection undertakes only R&D with strong complementary elements. [(3)] TNC R&D in a host economy may deal with technologies that are too advanced for local competitors to copy and use commercially. [(4)] Certain types of technology involve tacit and uncodifiable elements that are difficult for outsiders to imitate without intimate knowledge gained by working with that specific technology" (emphasis added). *Ibid*., at p. 164.

[97] "The extent to which international technology flows would increase as a result of strengthening IPRs depends importantly on the state of access to technological information. Such access is determined by a variety of factors. Impediments may come from many sources in the recipient country, including weak domestic absorption capacities, poor infrastructure, restrictions on inward technology, trade, and investment flows, and inadequate regulatory systems. In this context, strengthening intellectual property (IP) protection could play a positive and important role in mitigating the costs such factors raise for investors and thereby expanding technology flows. It should be evident from this brief description, however, that *simply strengthening IPRs alone cannot suffice to improve access significantly. Rather, the intellectual property regime needs to be buttressed by appropriate infrastructure, governance, and competition systems in order to be effective*" (emphasis added). *See* Keith E. Maskus, Kamal Saggi and Thitima Puttitanun, "Patent Rights and International Technology Transfer Through Direct Investment and Licensing", *supra*, at pp. 2-3.

[98] *Ibid*., at pp. 235-248;

[99] *See* Derek H.C. Chen and Carl Dahlman, "Knowledge and Development: A Cross-Section Approach, World Bank Policy Research Working Paper No. 3366, (Aug. 2004), at p. 44, at: (http://info.worldbank.org/etools/docs/library/117333/37702_wps3366.pdf). "We postulate that there exist four preconditions that lead to knowledge becoming an effective engine of growth. These four preconditions, or four pillars of the knowledge economy, are: [1] An economic and institutional regime to provide incentives for the efficient use of existing and new knowledge and the flourishing of entrepreneurship; [2] An educated and skilled population to create, share, and use knowledge well; [3] A dynamic information infrastructure to facilitate the effective communication dissemination, and processing of information; [4] An efficient innovation system of firms, research centers, universities, consultants, and other organizations to tap into the growing stock of global knowledge, assimilate and adapt it to local needs, and create new technology. In essence, we postulate that the amount of knowledge and how it is used are key determinants of total factor productivity. Strengthening the above four pillars of the knowledge economy will lead to an increase in the quantity and quality of the pool of knowledge available for economic production. This will consequently increase productivity and thus economic growth." *Ibid.*, at p. 4. .

[100] *See* Rod Falvey, Neil Foster, and David Greenway, "Intellectual property Rights and Economic Growth," Research Paper 2004/12, University of Nottingham, (2004), at p. 1. "…[Prior studies have shown] a positive and significant relationship between IPR protection and growth only when countries reach a certain level of development as measured by initial GDP. For countries below this level no significant relationship between IPR protection and growth exists…Our results suggest that the relationship between IPR protection and growth depends upon the level of development, as proxied by initial GDP per capita. For low- and high-income countries we find that stronger IPR protection significantly improves growth, but for middle-income countries no such relationship is found…The results for high-income countries are largely as expected; these countries undertake the vast majority of innovation and where strong IPR protection should encourage further innovation by allowing innovators to profit from their inventions. For low-income countries the positive relationship between IPR protection and growth clearly doesn't reflect a relationship between IPR protection and innovation, but more likely that strong IPR protection in these countries encourages imports and inward FDI that encourage growth without adversely affecting domestic imitative activities." *Ibid*.

[101] *Ibid*.

[102] *See* Lee Branstetter, Ray Fisman, Fritz Foley, and Kamal Saggi, "Intellectual Property Rights, Imitation, and Foreign Direct Investment: Theory and Evidence", National Bureau of Economic Research (NBER) (Aug. 2005), at pp. 1 and 32-33, at: (http://faculty.smu.edu/ksaggi/IPR-LEE.pdf).

[103] "It takes various forms: basic research, applied research and product and process development. While basic research is mainly undertaken by the public sector, the other two forms are central to the competitiveness of many firms. In the early stages of technological activity enterprises do not need formal R&D departments. As they mature, however, they find it increasingly important to monitor, import and implement new technologies. The role of formal R&D grows as a firm attempts significant technological improvements and tackles product or process innovation. For complex and fast-moving technologies it is an essential part of the technological learning process." *See* "Transnational Corporations and the Internationalization of R&D", (UNCTAD), *supra* at Executive Summary, pp. xxiv-xxv.

[104] *Ibid*., at p. xxiv.
[105] *Ibid*., at p. 209.
[106] *See* Kamal Saggi, "Trade, Foreign Direct Investment, and International Technology Transfer: A Survey", The World Bank Development Research Group (May 2000), at p. 17.
[107] *Ibid.* at p. 18.
[108] *Ibid*., at fn 28.
[109] *Ibid*., at p. 18. Actually, one may even argue that a broader definition of FDI spillover may include indirect benefits such as greater access to institutional capital markets, bilateral governmental science and technology exchanges, industrial and scientific tourism, international treaty waivers, extension of preferential trade status, export bank financing and insurance underwriting of critical developing country firm import purchases, etc.
[110] *Ibid*., at p. 12.
[111] "In general, we refer to clusters as the geographic concentration of business activities (OECD, 2004). However, we further discuss more sophisticated versions, such as places where inter-firm communication, common social and cultural patterns and the institutional environment stimulate socially- and territorially embedded collective learning and continuous innovation". *Ibid*., at p. 7, fn #2.
[112] *See* Lucas Ferrero and Alessandro Maffioli, "The Interaction between Foreign Direct Investment and Small and Medium-sized Enterprises in Latin America and the Caribbean: A Look at Regional Innovation Systems", Inter-American Development Bank, Working Paper, Series No. 6A (Nov. 2004), at: (http://www.iadb.org/europe/Working_Papers/SOE_WP_6A_Interaction_FDI-SMEs.pdf). "…[T]his paper…focus[es] on the interaction between FDI-clusters of SMEs and regional innovation systems (RIS)…[W]e uphold the notion that clusters and RIS can provide a better environment to exploit linkages and spillovers between firms…From a policy standpoint, we address a particular dimension of FDI-related policies: embeddedness policies. *Thus the concern is with improving the capacity of local firms to absorb spillovers and develop linkages with MNEs…[O]bstacles fac[e] Latin American clusters in view of the complete lack of government responsiveness. Similarly…even when there is an upgrading in Latin American clusters, despite government inaction and the virtual absences of business support systems, there is substantial evidence that the development of external economies and cooperation mechanisms is still minimal*…FDI-oriented policies are meaningful only if seen as a complement to a broader and coherent set of strategies geared to stimulating and improving regional performance. In other words, attracting and embedding MNEs should be matched to address the particular weaknesses of a cluster ([e.g.], in the value chain), with local institutions and associations playing a crucial role in the process of FDI selection, information transmission and so on" (emphasis added). *Ibid*., at pp. 5-6.
[113] "FDI can provide SMEs with access to information, know-how and technologies, increasing their innovative capabilities and improving their positioning on international markets. *In many Latin American and Caribbean countries, weak institutions and an inadequate business environment impede the development of innovative SMEs and of clusters*…" *Ibid.*, at p. 5.
[114] "More than larger firms, SMEs need access to external sources of information, knowledge, know-how and technologies in order to build their own innovative capability and reach their markets. Multinational enterprises (MNEs) usually have the potential to generate the external stimuli necessary to enhance learning and innovation locally. The overall impact on welfare depends on several factors subsumed to the degree to which the MNE is embedded in and linked to the local economy…*Latin American countries…need…to develop a broader set of policies, institutions and organizations so that they can screen, select and attract FDI while trying to absorb and maximize its potential benefits.*…[T]he ability of most SMEs to survive, achieve efficient scale levels and create new jobs depends on a number of factors, including their capacity to innovate and engage in collective activities. In order to build their innovative capabilities, *SMEs need to engage in innovative activities, which are fostered by the mass of (explicit/implicit) information, knowledge, and technology exchanges.* Clustering and interconnections among SMEs can be considered major facilitating factors" (emphasis added). *Ibid*. at p. 1.
[115] "*[C]ommon indicators of knowledge intensity* (research and development [R&D] as a share of GDP, ***patent rates***, relative employment or valued added in knowledge intensive sectors, educational attainment), as well as, joint actions and interconnectivity among firms, suggest that *Latin American and Caribbean (LAC) countries are far behind their…OECD… counterparts*…These features are not…the single most important obstacle to SMEs' development. Rather, *a highly volatile environment* (both economically and politically), limited access to factor services (credit, skilled labor…) and overall governance (including the quality of regulation, dispute settlement, ***property rights***…) *are often cited as the main barriers to firms' development in the region*" (emphasis added). *Ibid*., at p. 2.

[116] "Traditionally, there are three main broad areas related to the definition of governance. The first one refers to the process by which authorities are selected, monitored and replaced. The second tries to address governments' capacities to effectively formulate and implement sound policies. And, finally, the general respect for the institutions that govern economic and social interactions among members in the society…*Regulatory quaity* stresses the features of policies and legal frameworks, usually measured as perceptions of the burden imposed by excessive regulation in areas such as business development, **patenting**, foreign trade and the like. The *Rule of law* dimension focuses on the level of confidence in and compliance with the rules of society (the incidence of crime, the effectiveness and predictability of the judiciary, and the enforceability of contracts). *These indicators try to measure the extent to which the socioeconomic environment is predictable and fair and, importantly, the extent to which property rights are protected* (***by patents laws, for example***)" (emphasis added). *Ibid*, at pp. 41-42.
[117] *Ibid.*, at p. 3.
[118] *Ibid*., at p. 4.
[119] "The relative economic strength of firms within clusters of sectors and industries is important in shaping bargaining positions, and thus the way in which interactions are governed – including information and knowledge flows. For example, in *hub-and-spoke clusters* a number of non-locally embedded key firms act as anchors (hubs) with suppliers and related activities spread around them. The dynamism of the region is dependent on the position of hub organizations in national and international markets. Suppliers and hub firms engage in substantial trading. Intra-district cooperation, however, is driven by the willingness of hub firms, which is generally low and of a vertical nature. Internal scale and scope economies are relatively high, whereas labor market flexibility is low. Fear of specific knowledge leakage is a clear constraint on interactions." *Ibid*., at p. 13.
[120] *Ibid*., at p. 20.
[121] A prior World Bank study observed that, because multinationals can take actions to limit technology diffusion and maximize profits when deciding where to establish subsidiaries, developing countries should not expect the spillover effects of FDI to be uniform. According to the study, "spillovers to local firms that directly compete with the multinational would indeed be the most elusive of benefits that host countries may expect to enjoy from FDI…[T]he very act of curtailment of spillovers, may sometimes imply that local agents other than domestic competitors of multinationals (for example local workers) may enjoy positive extemalities from FDI. If so, the total welfare effect of FDI on local welfare may be positive despite the lack of technology spillovers. *See* Kamal Saggi, "Trade, Foreign Direct Investment, and International Technology Transfer: A Survey", *supra*, at p. 27.
[122] *See* Lucas Ferrero and Alessandro Maffioli, "The Interaction between Foreign Direct Investment and Small and Medium-sized Enterprises in Latin America and the Caribbean: A Look at Regional Innovation Systems", Inter-American Development Bank,, *supra*, at p. 20-21.
[123] *Ibid*., at p. 27. "MNEs tend to demand relatively skilled labor in the host country and to invest in training. The movement of labor from MNEs to existing firms or the start-up of new firms can generate outflows of specific knowledge, and the localization of MNEs in a particular area generates new training opportunities for local workers." *Ibid*., at p. 25.
[124] *Ibid*., at p. 26.
[125] *Ibid.*, at p. 25.
[126] "*Knowledge spillovers* may be related to…technology, management skills, business practice, know-how, information, and enhanced social and environmental standards. MNEs can generate spillovers by transferring technology directly or indirectly. The transfer of *product technology* may occur through: the provision of proprietary product know-how; the transfer of product designs and technical specifications; technical consultations with suppliers (to help them master new technologies); feedback on product performance (to help suppliers improve performance); collaboration on R&D by involving local universities or research institutes. The transfer of *process technology* may occur through: the provision of machinery and equipment to suppliers; technical support on production planning, quality management, inspection and testing; visits to supplier facilities to advise on layout, operations and quality; the formation of 'cooperation clubs' for interacting with or among suppliers on technical issues (quality control presentations, value analysis and cost reduction activities); assistance to employees to set up their own firms; organizational and managerial know-how (assistance with inventory management and the use of just-in-time and other systems, assistance in implementing quality assurance systems, including ISO certification); the introduction of new practices (management, financial, marketing) [etc.]" (emphasis added). *Ibid*., at p. 24.
[127] *Ibid*., at p. 28. "More specifically, clusters can be distinguished across the scale of international embeddedness, not simply by the presence and strength of MNEs but also by the extent and nature of linkages between them and local

actors. This depends both on the "willingness" of the multinational firms to participate in mutual learning-adaptation processes – that is, the degree to which a multinational is responsive and interacts with local actors – and on local conditions in terms of capabilities, governance and the overall business environment." *Ibid*., at p. 13.

[128] *Ibid*., at p. 24.

[129] *Ibid*., at p. 28. "…[I]t seems that foreign affiliates making standardized products with mature, non-proprietary technologies tend to prefer externalized, arms-length procurement…Where products are specialized and technologically advanced, affiliates tend to prefer in-house production or to retain relationships with a few selected suppliers…[e.g., Electronics, pharmaceuticals, biotechnology, precision instruments, aerospace [p.13]]…MNEs evaluating the potential technological gap between foreign firms and local providers make reference to the development gap between the home and the host countries in terms of technology, structure, reliability, regulation, trust relationships and the flexibility of local suppliers relative to suppliers abroad." *Ibid*., at pp. 22-23.

[130] *Ibid*., at p. 28.

[131] *See* Kamal Saggi, "Trade, Foreign Direct Investment, and International Technology Transfer: A Survey", *supra*, at p. 39.

[132] *See* Lucas Ferrero and Alessandro Maffioli, "The Interaction between Foreign Direct Investment and Small and Medium-sized Enterprises in Latin America and the Caribbean: A Look at Regional Innovation Systems", Inter-American Development Bank", *supra*, at p. 19.

[133] "Naturally, RIS, as clusters, can be quite different from each other along several dimensions – for instance, in their specialization of production, governance, and the like. *More specific dimensions of heterogeneity can be grouped into two categories: regional and business innovation structures*. The first includes *the amount of resources spent on R&D and its origin (public, corporate, MNE-led), initiation and concentration of innovative activities, role of support systems, governance of R&D and the science and technology infrastructure (funding, responsiveness to firms' demands) and so on.* The business-innovation *category refers to firms' attitudes towards innovation and its governance structure, addressing the characteristics of interactions between firms, with customers, R&D and development agencies.* Other aspects must be taken into account, such us the characteristics of the labor force, labor mobility, financial assistance, hard infrastructure, knowledge leakages , institutions regulating dispute-settlement and property rights protection, and so on" (emphasis added). *Ibid*., at p. 16.

[134] "Innovation policy comprises strategies to build basic and applied research capabilities; and raise the rate of technology adoption and product innovation among home country firms. [They] generally increase the number of higher wage, knowledge- and technology-intensive industries in a country or region." *Ibid*., at p. 32.

[135] *Ibid*., at p. 29. "[T]he nature of public support…merit[s] attention…First, overall and sectoral regulations [must] provide[] a stable and appropriate framework that [does] not hamper[] the development of activities in the sector. Second…public promotion institutes and funds [must] help[] to stimulate innovation, cooperation among firms and between firms and universities, and the development of appropriate infrastructure. Finally, tax credits for worker training [must] provide[] additional flexibility and capacities to the existing pool of specialized labor." *Ibid*., at pp. 28-29.

[136] *Ibid*., at p. 15.

[137] *Ibid*., at pp. 32-33.

[138] *See* "Inventing a Better Future - A Strategy for Building Worldwide Capacities in Science and Technology", InterAcademy Council (Jan. 2004), at p. 79, at: (http://www.interacademycouncil.net/Object.File/Master/6/720/0.pdf). "…[A] percentage of [national] corporate tax [revenues] are targeted to funding specific research and development objectives…No new taxes are involved, just the redirection of already-established government levies…The sectoral-funds program serves four major government objectives - to promote: [1] Stability of financial resources for medium- and long-term research and development; [2] Transparency in funding decisions, merit review, and evaluation; [3] Reduction of regional inequalities; [4] Interaction between universities, research institutes, and companies." *Ibid*. The "…income tax…incentives [promoting]…private sector…R&D activities that result in patents were created…[pursuant to] (Laws 10.332/01 and 10.637/02)…" *See* "2004 World Technology Awards Winners & Finalists", Carlos Pacheco, Deputy Minister of Science and Technology of Brazil from 1999-2002, The World Technology Network,
(http://www.wtn.net/2004/bio224.html).

[139] *See* "2004 World Technology Awards Winners & Finalists", *supra*.

[140] "The purpose of FINEP (study and project financing institution), a government-owned agency under the Ministry of Science and Technology, is to promote technological development and innovation in Brazil. Its role is to foster

support to companies and institutions investing in new products and processes, continuously striving for technological innovation and leadership." *See* "Developing an Institutional Structure to Create and Develop Technology-based Companies in Brazil", Capital de Risco Brasil, Ministerio da Ciencia e Tecnologia, at: (http://www.capitalderisco.gov.br/VCN_ING/EN_oquee_PI.asp)

[141] *Ibid*.

[142] *Ibid*.

[143] *Ibid*.

[144] *See* "Inventing a Better Future - A Strategy for Building Worldwide Capacities in Science and Technology", InterAcademy Council, *supra*, at p. 68.

[145] *Ibid*.

[146] *See* "Projects for Biotechnology and Pharmaceuticals", U.S. Commercial Service Brazil Market Research (Aug. 2005).

[147] *See* "Inventing a Better Future - A Strategy for Building Worldwide Capacities in Science and Technology", InterAcademy Council, *supra*, at pp. 23 and 32. By comparison, Brazil devoted 1.24% of GDP to science and technology R&D in 1997. *See* "Key Facts", Embassy of Brazil in Washington, at: (http://www.brasilemb.org/science_tech/tech2.shtml).

[148] *See* Jules Duga and Tim Studt "2005 Global R&D Changes in the R&D Community Report" R&D Magazine (Sept. 2005), at p. G3, at: (http://www.battelle.org/globalrd.pdf).

[149] *Ibid*., at p. 12.

[150] *Ibid*.

[151] *Ibid*., at p. G4.

[152] "European Union R&D represented 1.93 percent of EU gross domestic product in 2003, compared to…3.15 percent in Japan." *See* George Parker and Clive Cookson, "EU Urged to Put More Into Research Spending", Financial Times (1/20/06), at p. 2. EU R&D dropped to approximately 1.75 percent of EU GDP in 2004. *See* "2005 Global R&D Changes in the R&D Community Report" at p. G1.

[153] *See* "2005 Global R&D Changes in the R&D Community Report", supra, at p. G1.

[154] *Ibid*., at p. G12.

[155] *Ibid*., at p. G13.

[156] *Ibid*., at p. G1.

[157] "It is no secret that the US "is the world's undisputed leader in science and technology. US industry funds roughly two-thirds, and the federal government, one-third, of an approximately US$ 300 billion/year R&D enterprise… [I]n FY2001, R&D spending in the US was estimated to be approximately US$270 billion, comprising US$ 180 billion spent by industry and US$ 90 billion by the federal government. In FY2002, the federal government's contribution had increased to US$ 103 billion, and it continues to rise. The US dominates the world in total R&D spending, contributing approximately 44 % of OECD R&D, and 39% of world R&D. R&D is carried out by four main sectors: industry, government, universities and colleges, and non-profit institutions. Industry: continues to dominate the field, funding two thirds of all R&D in the US, amounting to approximately US$ 180 billion in FY2001. It performs most of its R&D in-house and also carries out R&D for the government. The federal government funds one third of the total R&D enterprise, amounting to approximately US$ 90 billion in FY2001 (and US$ 103 billion in FY2002). Significantly, it funds most basic research, particularly high-risk ventures. Nearly three-quarters of industrial patents cite publicly funded research as the basis for their invention. Most of publicly-funded R&D is carried out by industry, universities, non-profits and federally-funded research and development centers (FFRDCs). Universities and non-profit institutions fund less than 5 percent of research, but they perform almost 15% of the total R&D in the US." *See* Lisette Ramcharan, "Science and Technology Overview 2003: United States of America", Canadian Embassy in Washington DC (9/17/04), at: (http://www.infoexport.gc.ca/science/UnitedStates_2003-en.htm).

[158] These counties happen all to be in developed countries: Canada, Finland, France, Germany, Italy, Japan, Netherlands, Sweden, Switzerland, United Kingdom, United States, South Korea. *See* Andrew Dunn, "Global R&D Spending Survey 2002-2004", Cientifica (Oct. 2005), at p. 3 at: (http://www.cientifica.com/www/summarys/Global%20R&%20D%20survey.pdf).

[159] Including pharmaceuticals and healthcare, the fifteen sectors surveyed include: aero-defense, automotive, chemicals, computer hardware, conglomerate, consumer products, electronics, food, IT, office equipment, photography, semiconductors, computer software, and telecom. *Ibid*., at p. 5.

[160] *Ibid*., at p. 7.

[161] *See* Jules Duga and Tim Studt "2005 Global R&D Changes in the R&D Community Report" R&D Magazine, *supra* at pp. G14-G15.

[162] *See* "International Agreements", National Institute of Standards and Technology (NIST) at: (http://www.nist.gov/oiaa/intragre.htm).

[163] *See* "Background Note – Brazil", U.S. Department of State, Bureau of Western Hemisphere Affairs (July 2005), at: (http://www.state.gov/r/pa/ei/bgn/35640.htm).

[164] As the result of growing "mutual trust grew out of the Brazilian accession to the various multilateral control regimes such as the MTCR (Missile Technology Control Regime), NSG (Nuclear Suppliers Group), the Conventions on Chemical and Biological Weapons, the NPT (Nuclear Non-proliferation Treaty), the CTBT (Comprehensive Test Ban Treaty), and the Safeguards Agreement between Brazil, Argentina, IAEA (International Atomic Energy Agency) and the ABACC (Brazilian-Argentine Agency for the Control and Accounting of Fissile Materials). These major accomplishments, combined with the approval of modern legislation on intellectual property, facilitated the establishment of a new and highly productive agenda of cooperation in several scientific and technological areas, among governmental, commercial and academic entities." *See* "Brazil-US Cooperation", Brazilian Embassy in Washington, at: (http://www.brasilemb.org/science_tech/tech4.shtml).

[165] "The Agreement between the Government of the United States of America and the Federative Republic of Brazil Relating to Cooperation in Science and Technology. (Signed 2/6/84; EIF 5/15/86; extended by written agreement of the two contracting parties; amended and extended 3/21/94; EIF 1/30/96; automatically renewed for 5-year periods)." "U.S. Department of State Fact Sheet – List of Umbrella Science and Technology Agreements", Bureau of Oceans and International Environmental and Scientific Affairs (Updated 8/9/05), at: (http://www.state.gov/g/oes/rls/fs/46482.htm).

[166] *See* "U.S.-Brazilian ESTH Cooperation", Embassy of the United States Brasilia, Brazil, at: (http://www.embaixada-americana.org.br/index.php?action=materia&id=2470&submenu=esth.php&itemmenu=174)

[167] "During June 2003, the United States and Brazil formalized cooperative energy efforts today with the signing of two agreements. The U.S. Secretary of Energy signed a Memorandum Of Understanding with Brazilian Mines and Energy Minister to formally initiate energy cooperation with Brazil. In addition, the U.S. Secretary of Energy and the Brazilian Minister of Science and Technology *signed the U.S. - Brazil International Nuclear Energy Research Initiative (I-NERI).* The U.S. - Brazil I-NERI agreement will foster collaborative research and development on advanced nuclear technology that will improve cost performance, enhance safety and increase proliferation resistance of future nuclear energy systems. Additionally, both countries will cooperate on advanced technologies for nuclear power. …'This partnership will strengthen bilateral cooperation on energy modernization and new technologies for both countries, promoting economic growth and energy security, as called for in President Bush's National Energy Policy,' Secretary Abraham said. 'This dialogue will advance areas of mutual cooperation and help expand trade and investment between the U.S. and Brazil, enhance regional energy security and promote the use of clean energy technologies.' *See* "Secretary Abraham Announces Energy Partnership with Brazil - Supports President Bush's Call for International Energy Cooperation", U.S. Department of Energy Press Release PR-03-132 (6/20/03), at: (http://energy.gov/engine/content.do?BT_CODE=PR_PRESSRELEASES&TT_CODE=PRESSRELEASE&PUBLIC_ID=13532); (http://fossil.energy.gov/international/International_Partners/Brazil.html).

[168] "The charter sets the framework for international cooperation in research and development for the separation, capture, transportation and storage of carbon as a means of reducing greenhouse gas emissions." *See* "Brazil: Environmental Issues", Country Analysis Briefs, Energy Information Administration, U.S. Department of Energy (Aug. 2003), at: (http://www.eia.doe.gov/emeu/cabs/brazenv.html).

[169] "The U.S. and Brazil are two of the founding members of the International Partnership for the Hydrogen Economy (IPHE). On November 20, 2003, Secretary Abraham and representatives from Australia, Brazil, Canada, China, the European Commission, France, Germany, Iceland, India, Italy, Japan, Korea, Norway, Russia and the United Kingdom signed an agreement formally establishing the IPHE as an international mechanism to coordinate hydrogen research and technology development…The IPHE will allow participating countries to leverage limited resources, bring together the world's best intellectual skills and talents to solve difficult problems, and develop interoperable technology standards…President Bush has committed the U.S. to invest $1.7 billion for the first five years of a long-term research and development program for hydrogen, hydrogen infrastructure, fuel cells, and hybrid vehicle technologies." *See* **"**Secretary Abraham Announces Agreement with Brazil on Hydrogen Energy Research - Supports President Bush's Hydrogen Initiative, International Partnerships", U.S. Department of Energy Press Release (4/19/04), at:

(http://energy.gov/engine/content.do?BT_CODE=PR_PRESSRELEASES&TT_CODE=PRESSRELEASE&PUBLIC_ID=15621).

[170] *See* "Energy Secretary Looks Forward to Brazil Meetings Aimed at Expanding Energy Cooperation - Visit Follows Energy Partnership Launched By President Lula and President Bush Last June", U.S. Department of Energy Press Release (4/15/04), at: (http://energy.gov/engine/content.do?BT_CODE=PR_PRESSRELEASES&TT_CODE=PRESSRELEASE&PUBLIC_ID=15598). "On October 18, 2005, the Office of Nuclear Energy, Science and Technology's (NE) and the National Nuclear Energy Commission (CNEN) agreed under the NERI to collaborate on one new joint project on October 18, 2005. This collaboration will begin in January 2006, be jointly worth about $1.8 million over three years, and will be in the area of International Near Term Deployment (INTD)". *See* "United States and Brazil Agree on Joint Nuclear Energy Research Projects", International Nuclear Energy Research Initiative (I-NERI) Bilateral Collaborations", U.S. Department of Energy, at: (http://www.ne.doe.gov/ineri/ineriagreementsbrazil2.html).

[171] For example, "the Large Scale Biosphere-Atmosphere Experiment in Amazonia (LBA), an international research initiative led by Brazil and NASA that is designed to create the new knowledge needed to understand the climatological, ecological, biogeochemical, and hydrological functioning of Amazonia, the impact of land use change on these functions, and the interactions between Amazonia and the Earth system." *Ibid*. It is possible that this program includes or is related to an initiative known as the National Renewable Energy Laboratory (NREL), an effort in Brazil to develop integrated climate change and air pollution strategies for São Paulo led by the São Paulo State Environmental Sanitary Company and including the participation of the U.S. DOE. *Ibid*.

[172] *Ibid*.

[173] *See* "Memorandum of Understanding Between NIST and INMETRO…" executed on April 10, 2002, at: (http://www.nist.gov/oiaa/nistinmetro.pdf). "This Memorandum is being implemented within the framework provided by the Agreement Relating to Cooperation in Science and Technology between the United States of America and the Federative Republic of Brazil (hereinafter referred to as the "Agreement") signed February 6, I984, as amended and extended." The MOU is scheduled to terminate unless otherwise renewed on April 9, 2007. *Ibid*. *See also* "Technical Cooperation – Inmetro X NIST (United States of America), INMETRO Technical Barriers to Trade" website at: (http://www.inmetro.gov.br/english/international/cooperation.asp); "Brazil-US Technology Open House", NIST Technicalendar (6/30/04), at: (http://ois.nist.gov/techcal/search/display.cfm?uniqueID=085633Magda0.00949143); "Brazil-US Technology Open House", NIST Office of International and Academic Affairs (6/30/04), at: (http://www.nist.gov/oiaa/btdsumm.htm); "Brazil Technology Day", Speech by Arden Bement (2/25/03), at: (http://www.nist.gov/speeches/bement_022503.htm).

[174] *See* "U.S. Department of State Fact Sheet – List of Umbrella Science and Technology Agreements", Bureau of Oceans and International Environmental and Scientific Affairs, *supra*.

[175] "The areas of LABEX research will be: (i) bioinsecticides and other pest management techniques; (ii) new uses of commodities and value-added; (iii) global climate change; (iv) genetic improvement; (v) biotechnology; (vi) agrifood and agribusiness technologies; (vii) natural resource management; and (viii) agricultural economies." *See* "Brazil - Technological Innovation and New Management Approaches in Agricultural Research – AGROFUTURO", BR-L1001 Loan Proposal, Inter-American Development Bank at p. 18, at: (http://www.iadb.org/exr/doc98/apr/br1595e.pdf).

[176] *See* "U.S.-Brazilian ESTH Cooperation", Embassy of the United States Brasilia, Brazil, *supra*.