Global Competition Versus Regional Interests: FDI and Pharmaceuticals in India

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Abstract. This essay explores the economic dynamics of global competition versus regional interests corresponding to the treatment of intellectual property rights (IPRs) in India and the relative effects of such policies on its domestic pharmaceutical industry. The scope of considerations are formally limited to variables implicative of the transnational flow of capital within the pharmaceuticals industry, most specifically those pertaining to foreign direct investment (FDI). India, as the second most populated country in the world, has been the focus of much discussion regarding patent violations in its pharmaceutical industry. International pressures and membership covenants of the World Trade Organization (WTO) have succeeded in structuring policy such that process patents are now legitimized. This has brought dilemmas between global and regional conflicts of interest to open discussion, and has become a pressing political agenda among various industry stakeholders. This paper discusses the history of Indian internal protection in the pharmaceutical industry and suggests ways in which India may continue to benefit when regulatory barriers are reduced and global trade covenants are abided. The essay first examines trends in global FDI and Knowledge Process Outsourcing (KPO). It highlights changes to Indian policy, and subsequently discusses other matters associated with the protection of IPRs including parallel imports, price discrimination, and corruption. Lastly, suggestions are made for viable ways of enabling India to comply with WTO mandates for participation in the global marketplace, while concurrently attending to its domestic needs as well.

1 Introduction

This essay explores the economic dynamics of global competition versus regional interests corresponding to the treatment of intellectual property rights (IPRs) in India and the relative effects of such policies on its domestic pharmaceutical industry. The scopes of considerations are formally limited to variables implicative of the transnational flow of capital within the pharmaceuticals industry, most specifically those pertaining to foreign direct investment (FDI).

India, as the second most populated country in the world, has been the focus of much discussion regarding patent violations in its pharmaceutical industry. Throughout much of the industry's history, neither pharmaceutical processes nor end products (such as a pill) patents have been considered legally valid within the internal legal structure of India. International pressures and membership covenants of the World Trade Organization (WTO) have succeeded in structuring policy such that process patents are now legitimized. In recent years, end product patents have also found legitimacy in Indian rule of law. This has brought dilemmas between global and regional conflicts of interest to open discussion, and has become a pressing political agenda among various industry stakeholders.

This paper discusses the history of Indian internal protection in the pharmaceutical industry and suggests ways in which India may continue to benefit when regulatory barriers are reduced and global trade covenants are abided. The structure of this essay is arranged as follows: it first examines trends in global FDI and Knowledge Process Outsourcing (KPO). It highlights changes to Indian policy, and subsequently discusses other matters associated with the protection of IPRs including parallel imports, price discrimination, and corruption. Lastly, suggestions are made for viable ways of enabling India to comply with WTO mandates for participation in the global marketplace, while concurrently attending to its domestic needs as well.

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2. World Pharmaceutical Investments, TRIPS, and FDI

The role of pharmaceutical trade in the global economy has increased substantially in recent years. Facilitated in part by advancing technology and the infinite need for cures and treatment options, world pharmaceutical industries are growing rapidly while becoming more globalized. According to the World Trade Organization (WTO) (2009), the world trade volume for pharmaceutical commodities increased from approximately USD 247.991 billion in 2004, to USD 426.672 billion during 2008 [See Figure 1A].1

Figure 1A

Merchandise Trade by Commodity
Units in US Dollars at Current Prices (Millions)

Reporter	Flow	Indicator	Partner	2004	2005	2006	2007	2008
World	Exports	Pharmaceuticals	World	247991	274419	312731	372457	426672
World	Imports	Pharmaceuticals	World	251001	277146	313091	372457	426672
China	Exports	Pharmaceuticals	World	3234	3778	4486	6000	8070
China	Imports	Pharmaceuticals	World	1899	2309	2715	3889	5508
India	Exports	Pharmaceuticals	World	2218	2713	3436	4523	5766
India	Imports	Pharmaceuticals	World	689	970	1180	1606	1866
United States	Exports	Pharmaceuticals	World	23980	25946	29265	33610	38339
United States	Imports	Pharmaceuticals	World	35371	39323	46222	53954	59868

Source: World Trade Organization: http://stat.wto.org/Home/WSDBHome.aspx
(Table manually created using statistics database.)

Consequential of such significant growth rates, many markets in which pharmaceutical products are developed and traded are affected by the evolving industry. Factors such as infrastructure, labour force characteristics, the need for capital, the number of firms in a given market, competition levels, and the prices of consumer products are only a small number of the considerations implicated by the growing industry. Naturally, such factors impact the behaviour of firms in the industry as companies seek new ways to adapt to a changing environment and remain competitive. As a result, many countries with markets affected by the trading of pharmaceuticals have a necessary concern for how factors of industry growth impact their domestic economies.

On one hand, many nations are quite receptive to the introduction of multinational pharmaceutical firms as a means of facilitating the flow of capital and luring foreign direct investment (FDI) into domestic markets. Seeking benefits often inherent of FDI such as increased efficiency in resource allocation, knowledge and technology transfers, or infrastructural improvements, developing nations have a strong desire, in this context, to maintain capital inflows for the cultivation of domestic industry.[2] On the other hand, motivated efforts to draw in FDI are often found to be associated with high drug prices in relative markets and result in an inadequate provision of medicines to poorer demographics. This means there is often an evident trade-off between the ability of nations to attract FDI and moderate the price of drugs to levels conducive for widespread distribution. Furthermore, there are additional concerns for the impact of FDI on indigenous industries relative to the displacement of domestically held equity as foreign firms enter the marketplace.

In view of such concerns regarding FDI, many nations' policies are reflective of attempts to attract capital to the degree that it is advantageous to domestic industries, yet restrain the inflow of FDI from reaching the extent that it becomes detrimental to domestic industry growth and healthcare as a result of higher competition and drug prices. For instance, if FDI is injected into a given industry to the extent that foreign firms hold the majority of equity in that industry, then the relative growth of domestic companies may be hindered by the inability to compete in said market.[3] As a result, many countries' policies seem to exhibit an inward focus, reflective of the attempt to safeguard national interests through the moderation of foreign capital in local trade and production,

[1] World Trade Organization, *International Trade Statistics*, Annual Trade Statistics, Statistics Database, World Trade Organization (Geneva: World Trade Organization, 2009).
[2] Susan E. Feinberg and Sumit K. Majumdar, "Technology Spillovers from Foreign Direct Investment in the Indian Pharmaceutical Industry," *Journal of International Business Studies* (Palgrave Macmillan Journals) 32, no. 3 (3rd Qtr. 2001): 421-437.
[3] This argument assumes that all different sizes of domestic firms will suffer the same fate with FDI. However, our observations show that large and efficient local firms go into joint ventures with foreign partners and actually benefit from FDI. Less efficient, small sized, and small scale economy firms do suffer.

which has often been apparent in Indian policy.[4] This argument assumes that different sizes of domestic firms will suffer the same fate in regards to FDI. However, observations show that larger and more efficient domestic firms often enter into joint ventures with foreign partners, causing those firms to actually benefit from FDI. Rather, it is many times the less efficient, smaller firms that suffer.

Relative to industry firms, the policies instituted by a particular nation bear heavy influence on the lucrativeness of producing and marketing products in that country. Further, due to the variability of laws between many nations, dissimilar policy regimes may affect the trading of pharmaceuticals on a global scale; an impact also felt by firms in the industry. Thus, the World Trade Organization (WTO) has a keen interest in the relative policy structures of member nations, and focuses efforts to support the trading of pharmaceuticals by reducing barriers to trade and standardizing regulatory practices that may otherwise serve as hindrances.[5]

For pharmaceutical companies, one of the largest concerns facing a firm in any country is that nation's treatment of intellectual property rights (IPRs). Accordingly, the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) signifies an attempt to address those concerns by attempting to reduce the variability of IPR protection between two or more countries' policy regimes. Conceived as part of the Uruguay Round, the goal of the TRIPS Agreement is to:

"Reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."[6]

Correspondingly, the protection of intellectual property is a key component in attracting FDI because it creates the *incentive* for such property to be developed in a particular country. For pharmaceuticals, such protection is often granted in the form of patents, whereby the patent holder retains the sole rights to produce, market, and thus profit from her invention.[7] Contrarily, a lack of patent protection provides a *disincentive* for pharmaceutical innovations to be developed in a certain country due to the inherent risk of that property being generically reproduced and marketed by other parties, thereby inhibiting the creator from profiting, or possibly even recouping the costs of developing the product.[8] In other words, as suggested by Jamie Feldman (2009), "intellectual property rights are the fundamental driving forces behind the pharmaceutical industry."[9]

Furthermore, an additional implication of patent protection for pharmaceutical IPRs is the monopolistic power often afforded to patent holders in corresponding markets. The exclusive right of a given entity to develop, produce, and market a particular product amidst the absence of competitors, affords that firm the potential to profit. Further, because profits are a necessary condition under which pharmaceutical companies are willing to develop products in a given nation, it is therefore the expected size of such profits that determines the degree of a firm's incentive to invest, and which ultimately dictates the level of FDI said country receives in that industry.

In addition, given the exclusive right to produce and market certain products, firms are inherently endowed with the ability to subjectively price such products.[10] While this often enables firms to act monopolistically, it also leads to pharmaceuticals being expensive and thus unattainable by poor populations like many of those in India, where patent protection means that much of the population is unable to enjoy the benefits of medical technology.[11] Although, without the rule of law providing protection to patent holders, developing nations would risk foregoing substantial amounts of foreign direct investment (FDI) in pharmaceutical markets, and thus the development of some medical technologies may be inhibited in the first place.[12]

However, sales are dependent upon the ability and willingness of consumers to pay, whereby the difference in the resulting revenue and cost to produce such a quantity represents a firm's profit margin. In recent years, many pharmaceutical companies have begun to pay attention to the opportunity cost of high-priced patented drugs, which fail to reach many consumer sectors of markets due to lack of affordability. Further, with consideration for the variability of IPR protection, as well as the inevitable expiration of patents on drugs and looming generic companies seeking to scoop up relative market shares, many firms in the pharmaceuticals industry have begun to

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[4] Susan E. Feinberg and Sumit K. Majumdar (2001): 421-437.
[5] Anna Lanoszka, "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries," *International Political Science Review* (Sage Publications) 24, no. 2 (April 2003): 181-197.
[6] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): Appendix 1A.
[7] Patents Act 1970: chap. 8(48).
[8] Shubham Chaudhuri, Pinelopi K Goldberg and Panle Jia, "Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India," *The American Economic Review* (American Economic Association) 96, no. 5 (December 2006): 1477.
[9] Jamie Feldman, "Compulsory Licenses: The Dangers behind the Current Practice," *Journal of International Business & Law* (Hofstra University School of Law) 8, no. 1 (2009): 139.
[10] Whether the prices are based on average cost plus markup or price discrimination depend on price elasticities of demand, or marginal cross pricing, relative to competitive conditions.
[11] Anna Lanoszka (2003): 182.
[12] Susan E. Feinberg and Sumit K. Majumdar (2001): 426.

look at generic drugs markets as containing the future of industry profits.[13] According to the Economist (2008), many of the world's top pharmaceutical companies that generate the majority of profits in the United States are now looking to generic and emerging markets in preparation for potential policy revisions. Part of the worry is that recent political transformations and relative healthcare reforms may soon expose U.S. markets to generic pharmaceutical imports from Canada, or allow for discounts to be negotiated with companies that could alleviate much of the profits associated with high drug prices.

Dynamics of patented drug pricing, whether in the developed home market such as the US or Switzerland, depends on costs, competitive conditions, and the bargaining power of the government and insurance companies with the firm. In developed countries, where 60-90 percent of workers and household members may be insured through public or private means, individuals' ability to pay becomes an issue for only a small percentage of the uninsured. In developing countries where public employee percentages are low and private medical insurance is nonexistent or haphazard, the ability to pay issue involves the majority of the respective populations.

The optimism however, for developing nations' drug markets, is high. Exemplifying this perspective is the world's largest pharmaceutical company, Pfizer, which announced its intent to reorient the company structure with a focus that prioritizes developing countries.[14] As Pfizer quoted in The Economist (2008), its participation in such markets is motivated now as "a business, not a charity," whereas in years past, deviating from the market of high-priced drug sales may have been considered a less profitable venture. Consistent with this attitude, Pfizer has established an agreement with Aurobindo Pharma, an Indian generic drug manufacturer, with expectations that generic drug sales will generate $1 billion in annual revenue by 2012.

In general, the opportunities apparent in developing countries are substantial, and serve as attractive lures for FDI. In fact, it is predicted by industry consultants that emerging markets will account for sales equal to those in the United States and top five EU markets combined by 2017.[15] Further, Pfizer believes that the current drug market for individuals with annual incomes below $3,000 is potentially worth $30 billion annually, which by 2012, may be as worth as much as $60-70 billon.[16] Such a forecast for growth in developing countries thus suggests that the incentive for companies to seek operational holdings in those nations is substantial, and will continue to increase in the future.

Furthermore, the changing market environment for globalized pharmaceutical investments also suggests that the incentive for developing countries to attract FDI may increase to provide for the transfer of technology and access to medicines for those nations' populations.[17] For India, FDI used for generic drugs has the potential to dissolve many concerns for the availability of medicines to the nation's poor—FDI that has previously represented a tradeoff between IPR protection and access to affordable drugs, and thus a disincentive for stringent patent security laws.[18]

Accordingly, the progression of the pharmaceutical industry into generic markets may present the possibility of patent protection and affordable drugs coexisting, creating interesting challenges for the treatment of IPR policies. Some of the most critical considerations for India in regards to the future of its pharmaceutical industry and the innovation of medical technology pertain to the stringency of its patent laws. Hopefully by acknowledging the evolution of the industry and understanding how firms respond economically to changes in policy, India may be able to appropriate its rule of law to find a more harmonious balance between facilitating FDI and addressing its domestic concerns for industry and public health.

3. Knowledge Process Outsourcing (KPO) and India

Consistent with the prevalence of globalized industries, knowledge-based firms are drawn to advantages afforded by the labour markets of many emerging economies. Often finding an abundance of highly trained and educated workers, many companies are able to experience the benefits of substantially lower labour costs, without sacrificing productivity. Such outsourcing efforts have thus come to be known as knowledge process outsourcing (KPO)[19]; a context in which emerging markets have become particularly appealing to specialized industries.

[13] The Economist, *Racing Down the Pyramid: Big Drugmakers' Love Affair with America is Coming to an End*, November 13, 2008, http://www.economist.com/businessfinance/displaystory.cfm?story_id=E1_TNGDTRVN (accessed November 2, 2009).
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] Susan E. Feinberg and Sumit K. Majumdar (2001): 421-437.
[18] *Id.*
[19] Sonia Baldia, "Knowledge Process Outsourcing to India: Important Considerations for U.S. Companies," in *Doing Business in India: Critical Legal Issues for U.S. Companies*, 171-209 (New York, New York: Practising Law Institute, 2007).

In particular, India provides one of the most conducive environments for firms looking to establish KPO operations. Infrastructural developments and policy revisions have spurred substantial economic growth in India over the last couple decades, and its uniquely desirable labor force enhances the viability of profits for foreign, knowledge-based firms. U.S. pharmaceutical companies such as Eli Lilly, GlaxoSmithKline, Pfizer, Novartis and AstraZeneca all hold sectors of their clinical testing departments in India as part of KPO operations.[20] According to Sonia Baldia (2006), such companies seek to establish operations in India in an effort to "tap into India's vast and diverse population and pool of highly-skilled, but lower-wage demanding scientists," maintaining that such efforts "can significantly accelerate the trial time and time to market for new drugs on top of potential cost savings of up to 40-60 percent". [21]

Such a combination of lower costs and higher productivity make India an attractive environment for many knowledge-based industries, including pharmaceuticals where the trade-off between qualified workers and wages can heavily affect marginal product and revenue. Compared to the United States, where the estimated cost is near one billion USD to develop and market a new pharmaceutical product, the cost of bringing a new drug to market in India is about half.[22] Further, a simultaneous increase in productivity and decrease in costs often means higher profits—measured relative to both the savings in labour costs, as well as the difference in time to market similar products in other countries.

In addition to an alluring labour market, foreign capital inflow is further propelled through KPO by India's strong economic environment. As of 2007, India had the world's second largest population and the second greatest purchasing power GDP among developing nations.[23] At the same time (2007), Indian markets were said to be growing at an annual rate of eight-percent.[24] In 2009, India's primary stock index, Sensex, has grown by close to one hundred percent since March, reflecting the $13.8 billion in foreign investment that has been injected into the markets from April to November.[25]

Accordingly, the advantages presented by India's economic environment are naturally conducive to research and development operations, providing opportunities for firms to profit from relative labour costs and continuous economic growth. Further, the prospects for KPO ventures in India are likely to increase, as India progressively becomes a more prevalent participant in world markets. In fact, while it currently holds roughly three percent of the global market for outsourcing, a study by the Organization of Pharmaceutical Producers in India (OPPI) and Ernst & Young (E&J) (2009) reports that the Indian outsourcing industry exhibits a high potential for growth and that the outsourcing of pharmaceutical services is expected to rise.[26]

However, regardless of its inherent economic advantages, India's policy regime remains a necessary concern for firms considering KPO, and the need for IPR protection in many KPO operations raises the degree to which FDI is impacted by patent policies. [27] Necessarily, firms that develop intellectual property and consider the stringency of IPR protection to be a variable in determining specific risk will consider how expected profits are impacted by the appropriation of relative policies. For instance, pharmaceutical companies that are dependent upon patent protection to secure the marketability of certain products are more exposed to risk if policies are less apt to maintain the exclusivity of those products in the marketplace. A lesser degree of patent protection enhances the ability of competing firms to produce and sell substitutable products, causing the original firm to lose shares of market revenue, which lessens its margin for profit. Such companies would associate the potential for IPR infringement with a certain level of risk, and treat any subsequent profit losses as a cost of doing business; hence, a disincentive for investing in India. Thus, India's treatment of IPR security may heavily impact the rate at which its outsourcing industry is expected to grow.

Correspondingly, the encompassing effect of patent policies in the context of KPO is that while India's economic climate has been known to foster a somewhat ideal environment for growing companies, its historical

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[20] *Id.*

[21] We stipulate in this paper that the ability to hold large sample trials in an ethical and industry standard mode is one of the primary attractions luring clinical studies to a country such as India due to both time and cost gains. Here however, we emphasize the word 'ethical'; there have been many known cases of unethical international trials where patients' rights were not upheld, thus exposing them to risks associated with the trials. Pharmaceutical companies are subject to the same moral rules that outsourced U.S. manufacturing and retailing companies subjected to. Just as in the case of manufacturing subcontractors unethically exploiting child labor (when alternative schooling for these children is available), the same ethical binding restrictions should be placed on clinical trials subcontracted to local medical communities to ensure that patients' rights and risks are clearly asserted.

[22] Sonia Baldia (2007): 171-209.

[23] *Id.*

[24] *Id.*

[25] The Economist (October 29, 2009).

[26] fe Bureaus, "The Financial Express," *The Financial Express*, August 14, 2009, http://www.financialexpress.com/news/emerging-mkts-to-boost-global-pharma-sector/501838/# (accessed December 2, 2009).

[27] Sonia Baldia (2007): 171-209.

structuring of patent laws has served to somewhat offset the benefits of that environment by implicating risk for firms whose profits are considerably dependent on IPR protection. Although revisions of patent laws since the 1990s and the introduction of the TRIPS agreement have dissolved much of this risk for companies and reduced the barriers for KPO operations in India,[28] the correlation between the protection of IPRs and incentive for FDI inevitably still exists..

4. Changes to Indian Patent Law and Impact

Patent law in India dates as far back as 1856, in which patent protection was provided to inventors of new manufacturing technology for up to 14 years.[29] Modelled after British policies, subsequent amendments to the act extended the privileges of patent protection to provide exclusivity to inventors in the making, marketing, and distribution of their innovations.[30]

It was not until 1911 that The Indian Patents and Designs Act allowed for patent policy to be controlled by the Controller of Patents in India, and not until India's independence that economic and political conditions motivated the reform of its patent laws for domestic protection.[31] According to the Controller General of Patents Designs and Trademarks (CGPDT) (2008), A committee was assigned by the Government of India in 1949 to contemplate an appropriation for patent laws that would be "conducive to the national interest," instituting what many considered a 'protectionist' stance towards policy structure. [32] However, the objective of this approach was to promote the development of domestic industries through the natural 'spillover' of technologies brought in by foreign firms,[33] and to safeguard the availability of affordable drugs for Indian consumers.[34] India institutionalized a lack of barriers for pharmaceutical patent infringement with consideration for the larger public interest (sometimes interpreted as cheap prices in accordance with the ability to pay) and for national emergency situations.

Consistent with such policy objectives, the committee later brought about the 1950 amendment, which provided for the implementation of compulsory licenses. Defined as a "license of right," compulsory licenses enable the government to discretionarily set aside the rights to a patent with regard to public necessity or national emergency without the permission of the patent holder.[35] In addition, a provision in 1953 called for medical innovations to be made publicly available, permitting compulsory licenses to be issued against patents involving food, medicines, germicides, fungicides or insecticides.[36] Although the bills containing these riders were repeatedly introduced and let to lapse, all of the aforementioned were brought into law by The Patents Act 1970.[37]

Effectively implemented in 1972, the Patents Act exclusively denied patent protection for pharmaceutical *products*, but rather made available the patenting of *processes* or methods of manufacturing for such products for seven years from the date of filing, or five years from the date the patent was granted.[38] However, this did not include processes for treatment.[39] According to the Patents Act of 1970, patentable property excluded "any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products," but permitted the patenting of manufacturing processes for "substances intended for use, or capable of being used, as food or as medicine or drug" [See Appendix 1B]. [40] The development of end-product drugs using

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[28] *Id.*
[29] Controller General of Patents Designs and Trademarks, "History of Indian Patent System," *Government of India*, July 15, 2008, http://www.patentoffice.nic.in/ipr/patent/patents.htm (accessed October 9, 2009).
[30] *Id.*
[31] Controller General of Patents Designs and Trademarks (2008).
[32] Violeta I.: Prasad, Ashish S. Balan, "Strategies for U.S. Companies to Mitigate Legal Risks from Doing Business in India," in *Doing Business in India: Critical Legal Issues for U.S. Companies*, 9-60 (New York, New York: Practising Law Institute, 2007), 24.
See Also Susan E. Feinberg and Sumit K. Majumdar (2001): 421-437.
[33] Susan E. Feinberg and Sumit K. Majumdar (2001): 421-437.
[34] Shubham Chaudhuri (December 2006): 1477-1514.
[35] Feldman, Jamie (2009): 137-167.
See also Controller General of Patents Designs and Trademarks (2008).
[36] Controller General of Patents Designs and Trademarks (2008).
[37] *Id.*
[38] Shubham Chaudhuri (December 2006): 1477-1514.
See also Jacob Arfwedson, *Re-importation (Parallel Trade) in Pharmaceuticals*, Policy Report, IPI Center for Tehcnology Freedom, Institution for Policy Innovation (Lewisville: Institute for Policy Innovation, 2004).
[39] The Patents Act 1970, Chapter 2.
[40] *Id.*

different processes than the patented ones came to be loosely termed as "reverse engineering", whereby a pharmaceutical firm devises a new process to manufacture an existing patented drug.

Subsequently, the culmination of policy changes implicated by the 1970 Patent Act had a substantial impact on FDI in India's pharmaceutical industry, due largely to the sizeable ratio of foreign-to-domestic firms comprising the industry. According to Prasad (2007), foreign pharmaceutical firms held 75-90 percent of India's domestic market prior to the 1970 act, and patent applications were over three times as frequent by foreign nationals as Indian nationals. Further, considering that the average time for developing and testing a new drug can take as long as fifteen years,[41] the 5-7 years of protection provided by the act effectively offered little or no marketing advantages to companies creating new medical technologies. Thus, a patent could expire and allow for the process to be reproduced by other firms before the drug could even be completely developed; essentially granting 5-7 years of 'free-rider' status to firms reproducing generic substitutes, while straddling the innovating firm with sunk costs and a low return on invested capital as it enters the competitive market.

Accordingly, while the proportions of foreign-to-domestic firms certainly helped propagate the initial passing of the act in line with national interests,[42] its implications virtually eliminated incentives for foreign firms to develop pharmaceutical products in India. The subsequent inflow of medical technology and FDI slowed drastically, hindering the progression of India's pharmaceutical industry overall. In fact, by the late 1980s, the average annual flow of FDI into India was merely about $100 million in total, compared to relative inflows into China, which were roughly $3.5 billion despite its economy having been liberalized only about a decade earlier, in 1978.[43] Therefore, while the decrease in IPR protection enabled India to protect itself from foreign monopolies, it also caused India's pharmaceutical industry to be less competitive in world markets, and virtually absent of innovation.

Furthermore, while India was supporting protectionist policies of internal markets in the pharmaceutical industry, the pharmaceutical firms and industries of developed nations did not act in a timely manner to address the issues of affordability in emerging countries.[44] Many protectionist policies were implemented with the consumer in mind, on whom the entire cost of medical care often falls in developing nations. Accordingly, political protectionism is not often viewed as a weapon against the implementation of TRIPS, nor is it seen as an attempt to bypass patent laws, but looked at by many Indians in the context of diminishing costs to the consumer. The protectionist argument is that when a patent drug is marketed in a developed country, most of the time the cost is not directly borne by the consumer but by his/her insurance company. In India however, the absence of healthcare insurance is highly prevalent amongst the general population, often causing the entire expense of medical treatment to fall on the consumer.

Subsequently however, India observed the need to step away from its 'protectionist' policy structure, and enacted several reforms in 1991 aimed at liberalizing its economy to create a market environment more conducive to FDI.[45] Although, the most significant change to its patent policies, and arguably the most impactful to its pharmaceutical industry, was India's membership in the WTO and corresponding adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Implemented as part of the General Agreement on Tariffs and Trade (GATT) Uruguay Round Agreement in 1994, TRIPS was fashioned as part of the WTO to standardize IPR policies and facilitate trade amongst member nations.[46]

4.1 . TRIPS and FDI in India

In contrast to the inward focus of past Indian policies, the TRIPS agreement provides mandates for India's patent laws with the objective to create a more nurturing environment for industry growth and innovation. Unlike the 1970 Patents Act, one of the stipulations of TRIPS is that it provides patent protection not only to *processes*, but to the resulting *products* as well; requiring also that the duration of protection be no less than twenty years from the date the patent is initially filed (as opposed to the previous seven-year allotment).[47] As a result, not only are new

[41] Cheri Grace, *The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines*, Government, Department for International Development, DFID Health Systems Resource Centre (London: Fretwells Ltd, 2004).
[42] Violeta I.: Prasad, Ashish S. Balan (2007): 24.
[43] Susan E. Feinberg and Sumit K. Majumdar (2001): 421-437.
[44] The affordability-to-pay argument came into global consciousness with AIDS related pharmaceutical costs in Africa in the 1990s, where the high prices of patented drugs caused medicines to be unattainable to many victims of the HIV virus.
[45] Sonia Baldia (2007): 171-209.
[46] Hemant N Joshi, "Analysis of the Indian Pharmaceutical Industry: With Emphasis on Opportunities in 2005," *Pharmaceutical Technology*, January 2003: 74-94.
[47] TRIPS: Article 27, par 1; Article 33.

innovations more able to be developed without the risk of infringement, but the protection of the resulting products may offer profitable rewards to the innovator.

Particular to pharmaceutical industries, expanding the breadth and length of IPR protection under the TRIPS agreement has enabled India to exploit many of its intrinsic economic advantages, as the lack of patent protection is no longer presented as a formal hindrance to FDI. Further, because India is one of 132 WTO countries for which the TRIPS agreement is intended, its standardized provisions naturally make India's IPR policies more transparent to foreign firms.[48] Considering that risk is associated with the predictability of a given outcome, the degree of conformity that TRIPS requires of Indian patent laws serves to alleviate much of the risk that pharmaceutical firms had prior to its implementation. By mandatory levels of patent protection being upheld per the TRIPS agreement, a firm's reliance on IPR policy as part of an investment ensures that it is not relying solely on the policies of the country in which it invests (i.e. India), but on the common policies of the 132 countries that comprise the WTO. Thus, IPR protection provided by the TRIPS agreement and the security that its provisions render to pharmaceutical companies enhances the facilitation of FDI in Indian markets as a result of its compliance.

Though the TRIPS agreement has strengthened India's ability to procure FDI, there are some risks to patent protection that still remain. While the TRIPS agreement does uphold the protection of patents and other IPRs, it also allows for the exception of patents for particular items, which are ultimately designated at the discretion of the issuing country. Per article 27 of the TRIPS agreement,

> "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect 'order public' or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

In the case of India, exceptions to patents are often issued in the form of compulsory licenses, which represent the rights that many nations reserve to act in the interest of the public for protection against the abuse of a patent by its holder.[49] Though a compulsory license may be necessary in situations such as an epidemic (i.e. AIDS in Africa), where unlimited patent protection could threaten entire populations, the risk such a license otherwise poses to patent holders is dependent upon the definition of circumstance that compels its use.[50]

For example, the necessity for compulsory licenses was highlighted during the AIDS epidemic in Africa when some companies refused to provide drugs at subsidized rates. At that time the cost of a single course of treatment for AIDS in Africa was greater than most individuals' annual earnings. Even though there were companies in India that were willing to produce and supply the drugs at one-tenth the cost, the patent holders often refused to allow for parallel exports. From a company's perspective, in an industry such as pharmaceuticals where firms' cost structures generally consist of high fixed and low marginal costs, the risks imposed by compulsory licenses often have a greater impact on profit margins and thus, may reduce the incentive to produce in a such a political environment.

Relative to TRIPS, the agreement's failure to definitively stipulate conditions under which compulsory licenses may be used effectively provides an avenue through which countries may undermine the rights afforded by patent protection.[51] For example, if a foreign firm develops a new drug for which the demand is sure to be high, a country could potentially contend that it is necessary to protect the public (aka, domestic firms) from the inability to compete with the prices of the patentee. Although, such a practice would likely be avoided because it would raise concerns about preferential treatment, it is nonetheless possible, implicating considerable risk for patent holders. Therefore, while the dependability of laws governing IPR protection may be accredited by the WTO, the risk associated with compulsory licensing is reflected in the credibility of the relative country; in this case, India.

Accordingly, acknowledging the 'protectionist' demeanor of India's previous policies, if credibility is a relevant variable implicative to the risks posed by compulsory licensing, then the lack of transparency that TRIPS provides for patent exceptions may be a major cause for the impediment of FDI in India.[52] Companies are less capable of predicting the future returns on investments in the presence of ambiguous policies like compulsory licensing which, in turn, makes said investments more risky. Consequently, the vagueness of compulsory

[48] Hemant N Joshi (January 2003): 74-94.
[49] Subhasis Saha, "Patent Law and TRIPS: Cumpulsory Licensing of Patents and Pharmaceuticals," *Journal of the Patent and Trademark Office Society* (Patent and Trademark Office Society) 91, no. 5 (May 2009): 364-374.
[50] *Id.*
[51] Feldman, Jamie (2009): 137-167.
[52] *Id.*

licensing policies (or "exclusions from patentability inventions" in TRIPS)[53] enables the purpose of TRIPS to be undermined by member nations in direct contradiction to the stated objectives of the agreement.[54]

Holistically, the changes to Indian patent law have had various levels of impact on the state of India's domestic industries. Observable however, is the correlation between the degree of protection afforded by patent policies and the level of foreign capital that India is able to accumulate (which is further exemplified by its adoption of TRIPS). Further, though receiving WTO membership in 1994, because India was considered to be one of the lesser developed of the 132 member nations, it was not required by the WTO to fully comply with the conditions of the TRIPS agreement until January 1, 2005.[55] Thus, because the most recent of vital changes to Indian patent policy have taken place in the last five years,[56] it is likely that the true effects of changes to Indian patent policy are yet to be seen.

5. Parallel Imports of Pharmaceuticals

Parallel imports (also known as grey-market imports or goods that are 're-imported')[57] may be described as "goods produced genuinely under protection of a trademark, patent or copyright, placed in to circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property rights."[58]

Though the trading of parallel imports remains controversial by signifying yet another threat to IPR protection, such goods do not directly infringe upon IPRs in the form of piracy or counterfeiting. Instead, in the case of pharmaceuticals, a patented product that is exported and re-imported may disrupt the discriminatory pricing of that product in its original market due to the price differential between the market where it was developed, and the market from which it was re-imported.[59] Further, when the cost of buying, transporting and marketing goods is below the price of the same good in another market, there exists an arbitrage opportunity to profit from said differential.[60] Thus, participants in the trading of parallel imports have an incentive to target markets where such an opportunity for arbitrage is presented.[61]

Accordingly, variations in pharmaceutical prices between two different markets can result from a number of factors including transport costs, relative demand and supply, tariffs and import fees, etc.[62] However, considering that parallel importing is a legal practice, it is therefore, often the lack of conformity between different countries' IPR policies that allows it to take place.[63] Thus, the prices of patented products in one country may not only accentuate the opportunity for arbitrage by heightening the price differential between two markets, but will also be subsequently affected by respective re-importation.[64]

Hypothetically, if a product produced in the United States is protected by a patent when it is exported to another country say, pre-2005 India (where pharmaceutical *products* were not yet patentable), it would thus be exposed to the open market where it may be reproduced by generic manufacturers.[65] Accordingly, the reproduction of the patented product and its re-importation back into the U.S. would decrease the price of the branded product in the U.S. by serving as a lower-priced substitute. Therefore, although no legal infringements may be made relative to the patent policies of two countries, there is still potential for the re-importation of products to perpetuate the undermining of IPRs.[66]

Consistent with pharmaceutical companies' concern for IPR protection, parallel importing inherently poses the same risks as other threats, adding to the deterrence of capital. Considered by the International

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[53] TRIPS: Article 27.
[54] *Id*: Article 7.
[55] Hemant N Joshi (January 2003): 74-94.
[56] Jacob Arfwedson (2004).
[57] Keith E Maskus, "Parallel Imports," in *The World Economy: Global Trade Policy 2000*, 179-193 (Malden, Massachusetts : Blackwell Publishing, 2000).
[58] Jacob Arfwedson (2004).
[59] *Id.*
[60] Katherine M. Sauer, "Wholesale Pricing under Parallel Imports," *Journal of International and Global Economic Studies* (University of Southern Indiana) 1, no. 1 (June 2008): 60-82.
[61] *Id.*
[62] Jacob Arfwedson (2004).
[63] Katherine M. Sauer (June 2008): 60-82.
[64] *Id.*
[65] The Patents Act 1970: chap. 2(5).
[66] Jacob Arfwedson (2004).

Federation of Pharmaceutical Manufacturers Association (IFPMA) to be "detrimental to intellectual property rights,"[67] new products may be vulnerable to open-market pricing similar to how products would be priced in many generic markets, or in the absence of IPR protection all together (not accounting for import costs).[68] By creating a greater supply of generic substitutes at lower prices than patented products, parallel imports may interfere with the ability of patent holders to profit in said markets by alleviating exclusivity.[69] Thus, considering the necessity for the progression of pharmaceutical innovations, there may exist a trade-off similarly inherent to that of formal IPR policies; between short-term costs and long-term benefits in the regulation of parallel imports and the prices of pharmaceutical products.[70] In other words, parallel importing decreases the prices of drugs for consumers,[71] yet decreases the innovation of new medical technologies by firms.[72]

Exemplary of its impact on innovation, studies estimate parallel imports to have comprised up to 10% of pharmaceutical market volume in 2006, and to have generated revenues of approximately $7.4 billion in the EU alone (This is thought to be part of an increasing trend, signifying that estimates for today may be substantially higher). [73] Further, because re-imported goods are generally sold in generic markets, the estimated profit losses endured by developing firms may be more than double the corresponding revenue generated by parallel importing.[74] Accordingly, the disincentive firms have to develop and market new products is evidenced by the undermining affects that re-importation has on patents, and the losses potentially endured by participating in relative markets.

In terms of regulatory measures, though WTO efforts to harmonize trade amongst the differing policy environments of member countries has been oriented in IPR protection, little consideration has been given in the context of parallel imports. Referring to re-importation as "exhaustion" (in the sense that it exhausts patents' rights to market exclusivity)[75], the TRIPS agreement expressively excludes such practices from discussion. Per Article six of TRIPS:

> "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

Accordingly, though the objective of the TRIPS agreement to standardize IPR protection policies seemingly applies to the control of parallel imports between member nations,[76] its lack of consideration for nations' independent policies, or for other countries involved in the re-importation of patented products may erode the effectiveness of WTO objectives. Consequently, so long as the parallel importing of goods creates generic markets where patents are held by parent substitutes, the patent laws mandated by TRIPS are likely to be less effective in facilitating FDI and the development of medical technology in those domestic markets.[77]

Consistent with the absence of re-importation provisions in the TRIPS agreement, it is arguable that the treatment of compulsory licensing per the agreement serves as an additional variable that perpetuates the opportunity for parallel importing to take place. As discussed previously, the TRIPS agreement effectively leaves the required parameters for the granting of compulsory licenses to the subjectivity of an issuing country.[78] As it is written:

> "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary…"[79]

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[67] *Id.*
[68] Katherine M. Sauer (June 2008): 60-82.
[69] Feldman, Jamie (2009): 137-167.
[70] Jacob Arfwedson (2004).
[71] Katherine M. Sauer (June 2008): 60.
[72] Jacob Arfwedson (2004).
[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] TRIPS: Article 7.
[77] Shubham Chaudhuri (December 2006): 1477-1514.
[78] Feldman, Jamie (2009): 137-167.
[79] TRIPS: Article 27.

Nations therefore have the option (and possibly the incentive) of exercising these 'licenses of right' against the patents of pharmaceutical products that are not only produced domestically, but are imported as well. Thus, because exclusions from patentability (compulsory licenses) are able to be determined by governments "within their territory" even WTO members are not entirely barred from participating in, or even facilitating parallel importing as a means of profiting from the margin that generic reproduction might create. Therefore, not only does parallel importing pose risks to companies and thus potentially deter FDI, but the treatment of compulsory licenses per the TRIPS agreement may heighten those risks and further disrupt the same trading practices it is designed to facilitate.

Particular to India in the context of parallel imports, its ability to appropriately moderate its policy regime to generate the inflow of capital is not strictly dependent on its own treatment of patent protection, but is necessarily influenced by the IPR policies of countries with which it trades; specifically those from which it imports. However, while modifications to the TRIPS agreement might be the most viable means of regulating parallel importing, India's treatment of its own policies regarding compulsory licensing and the re-importing of pharmaceuticals may afford it the greatest opportunity to promote FDI in its domestic industries in the short and medium run.

6. Is Regional Price Discrimination the Answer?

Emerging country policy makers have accused the patent-holding pharmaceutical companies of ignoring the affordability factor of [low income] households and have accused such companies of setting pricing mechanisms that are often deemed 'too high to afford'. Therefore, many nations justify patent infringement cases on the grounds of citizens' rights to healthcare and drugs. This, of course, has created a disincentive for pharmaceutical FDI to be injected into countries that have adapted protectionist policies such as India, causing a lag in medical research and technology. Price discrimination[80], where lower prices are charged to poorer nations and where lost revenue in recovered through economies of scale, may work well provided there are no parallel imports. This is where the institutional factors take over: pharmaceutical companies must accept 'losing a region' (in market share) to parallel imports as a result of issuing local patents and using regional, cheaper price points, or they will be forced to fight such losses through lobbying and WTO efforts.

In all, one may say, that pertinent to patent infringement arguments, the pharmaceutical industry has also been very slow to responding to the 'real' needs of emerging nations in terms of healthcare provisions. One outcome of such high pharmaceutical costs has been the popularity of any party or political movement that will dispense free drugs in exchange for radical politics.

7. Is Corruption a Factor?

Corruption, which might be considered a form of private taxation, is prevalent throughout the world. When risk/reward/penalty ratios of public officials are not in line, corruption becomes institutionalized. In some countries, it is sanctified and institutionalized across all levels of public service. In others, it is penalized only in regional or local services, if observed. Corrupt business practices offer an additional disincentive for companies to participate in a particular market.

In the context of the pharmaceutical industry, corruption is another barrier that could potentially disrupt the inflow of FDI via the inherent risk of illegitimacies such as bribery and piracy remaining prevalent in Indian commerce.[81] In the same way that weak IPR protection may provide a disincentive by increasing risk and thus potential costs for pharmaceutical firms, the prevalence of corruption deters FDI under the same consideration.

According to Transparency International (2009), the Corruption Perceptions Index (CPI), which indicates the amount of perceived corruption in the public sector of a country or territory, denotes India as 3.4 on a scale of ten, where ten is the least corrupt.[82] An additional survey conducted by an independent committee for the Government of India (2000) found that of all Indians utilizing government services, nearly half admitted to using

[80] Price discrimination in economics is where, depending on the demand elasticity of consumer groups, the firm can charge differential prices to maximize the consumer surplus. In this case, households who have more elastic demands (ie, have more substitute goods) are charged a lower price and households who have inelastic demands are charged the higher price. In emerging countries such as India where folk and herbal medicines are still used as a very strong substitute to medical drugs, lower prices can be charged even if the household incomes are the same.

[81] Violeta I.: Prasad, Ashish S. Balan (2007): 9-60.

[82] Transparency International, "Corruption Perceptions Index 2009," *Transparency International*, December 10, 2009, http://www.transparency.org/policy_research/surveys_indices/cpi/2009/cpi_2009_table (accessed January 13, 2010).

bribes as part of doing business.[83] In fact, according to an article by Business Standard (2008), Transparency International ranks India as one of the world's five worst bribe payers, sharing the ranks with Brazil, Mexico, China and Russia.[84] The extent of this subornment not only lessens the transparency of Indian policy, but it undermines the rule of law and questions the ability of Indian regulators to see that it be enforced. Further, in terms of the perception of foreign firms, the pervasiveness of corruption may propagate the notion that Indian policy lacks credibility, which amplifies the risk associated with conducting operations in such an environment.

In contrast, it is evident that the government of India has shown extraordinary efforts over the past decade to adopt the TRIPS agreement and enforce its policies. It is also true that the physical presence of multinational firms may help to alleviate corrupt practices per the natural course of serving self-interests (i.e. monitoring and controlling specific risk). However, the overall presence of corruption in India remains high relative to other countries, which inherently poses risks to foreign firms. As a result, not only do such risks correspond to costs in company projections, there is a blatant cost incorporated with a firm devoting private efforts to securitize its assets.[85]

In addition, perpetuating the rifeness of corruption is the treatment of perpetrators under Indian law, in which no disincentive exists to deter individuals from bribing public officials. According to Prasad (2007), "the Indian Penal Code specifically prohibits bribery of public servants, but prosecutes the individual receiving the bribe, not the other party involved in the act of bribery itself". This asymmetric application of penalty promotes and incentivizes bribery schemes. In addition, anti-bribery laws do not apply to private citizens doing business, but merely to those individuals who are or are about to become public servants.[86] Thus, one may argue that absent the risk of prosecution, there is no reason for individuals *not* to offer bribes as tools of persuasion in dealings with governmental officials. In fact, a survey by India's Central Vigilance Commission (2000) reveals that bribes may be used in as many has half of all government service transactions.[87]

Recently, much progress has been made in dealing with large-scale corruption in India, as national and regional tolerance for such activity has dissipated. Increased objectivity in journalism has disseminated information, resulting in large retail, refinery, and telecom companies being penalized for acts of bribery. Nonetheless, there still remains many institutional factors that have yet to be changed. Considering that the recipient of a bribe in India (assuming prosecution is rendered) is punishable merely by a fine and-or imprisonment of up to three years,[88] it is questionable the extent to which such a punishment discourages a bribe's acceptance. To give a comparative perspective, the acceptance of a bribe by a U.S. public official is punishable by up to fifteen years in prison, with fines as high as triple the value of the bribe, or both, as well as the possible disbarment from any public position thereafter [See Appendix 1C].[89] Accordingly, the disincentive for a public authority to accept a bribe is likely to be much higher under a penal code such as that of the United States as opposed to that of India.

In the context of foreign investment, the extent to which a domestic government entity or public authority is motivated to act in accordance with the law is negatively correlated with the degree of risk borne by the foreign party with which it interacts. In other words, the less variability presented between expressed policy and applied policy, as differentiated by corrupt practices, the more accurately firms will be able to forecast future returns on investments—the market will be considered less risky and thus more attractive for FDI. As suggested by Hemant N. Joshi (2003), associate director of pharmaceutical R&D at Barr Laboratories, "Transparent policies are essential to attract long-term investments;" "widespread corruption and a deeply integrated system of bribery make every transaction complicated and expensive." In fact, it is reported that U.S. companies in India lost upwards of $500 million in 2004 from the piracy of copyrighted materials.[90] Of course, while copyrights do not have a specific application in the protection of pharmaceuticals, the prevalence of corruption in IPR-related industries is nonetheless illustrated by such losses.

Consistent with risks implied by the opaqueness of policies, the unpredictability of markets resulting from corrupt practices is similarly implicative to the provision of economic incentives for investment. Foregone profits as high a half-billion dollars for instance, illustrate a large scope of unforeseeable, potential costs. Accordingly, even though India boasts an economic environment conducive for firms attaining optimum profits, so long as the

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[83] Violeta I.: Prasad, Ashish S. Balan (2007): 9-60.

[84] Business Standard, "India Remains One of the Five Worst Bribe-Payers in the World," Business Standard, December 10, 2008, http://www.business-standard.com/india/news/india-remains-onethe-five-worst-bribe-payers-inworld/342772/ (accessed January 13, 2010).

[85] Business Standard (December 10, 2008).

[86] Violeta I.: Prasad, Ashish S. Balan (2007): 9-60.

[87] *Id.*

[88] *Id.*

[89] ***18 U.S.C. § 201 : US Code - Section 201: Bribery of public officials and witnesses.***

[90] Sonia Baldia (2007): 171-209.

variability of profits remains high, risk averse companies are likely to opt to invest in a more reliable market where similar or even slightly less profits may be achieved with greater certainty.

8. Proposed Solutions to Appropriating FDI in India

Due to trade-offs inherent in the appropriation of patent policy, there is a delicate balance that must be reached—a sort of equilibrium—in which India is able to foster a healthy amount of economic growth without jeopardizing regional interests, its domestic industries, or human welfare.[91] Exemplified by prior Indian policies, laws too heavily centred on facilitating only the growth or protection of one particular facet such as FDI (pre-1970) or domestic equity and affordable healthcare (post-1970), can be economically detrimental. In other words, it creates an imbalance in India's institutional environment. Accordingly, it is necessary to take into consideration the degree of impact that the treatment of such policies has in correspondence to the creation of incentives (or disincentives) for pharmaceutical firms.

Fundamental to managing incentives with policy application is the notion that firms are profit seeking, and thus drawn to an investment with the expectation of realizing greater returns than would be made by investing in a comparable alternative. This means that the more risks seemingly associated with investment in India, the more disincentives firms have to invest. Therefore, as patent protection in pharmaceutical markets is often a precondition for profiting from the development of new drugs, threats to IPRs such as parallel importing or compulsory licensing may pose huge risks to profitability; hence, largely contribute to the deterrence of capital. Therefore, in order to provide incentives that not only attract FDI, but also promote the production of medical innovations, India must use its policy regime to diminish the risks associated with investment in its pharmaceutical industry.

First, procedures for honouring exceptions to patentability and the issuance of compulsory licenses must be clearly and thoroughly defined by India. Although, acknowledging the purposefulness of compulsory licensing in highly extraordinary or disastrous circumstances (i.e. patented medicines needed to fight a plague-like epidemic), it is imperative that such intrusive options remain. However, it is equally important that such circumstances be defined in a way to ensure that the criteria for issuing compulsory licenses be as standardized and transparent as possible, and limited to highly exceptional cases such as those that may arise, say, once in a decade. The central focus for standardizing compulsory license issuance is to perpetuate the notion that such licenses are not granted subject to casual interests of the issuing country, but rather, to earnestly serve the public welfare independent from political motive.

In view of concerns for companies, the relative risks implicated by compulsory licenses are not so much derived from the potential for patent rights to be negated, but the unpredictability of how, when, and to what extent such licenses are implemented. Comparatively, the United States uses compulsory licenses against patents, yet has seen little deterrence in the innovation of pharmaceutical products. In fact, while the U.S. retains its right to void patents, it remains a world leader in medical innovations (producing fifteen Nobel prizes in medicine 1996 and 2006, compared to seven issued to researchers elsewhere).[92]

Accordingly, the reason that compulsory licenses are evidently perceived as being less risky to patent-holders in the United States is due in part to its attempt to assign licenses based on "objective, verifiable criteria."[93] As explained by Makan Delrahim, Deputy Assistant Attorney General for the Anti-Trust Division at the U.S. Department of Justice (2004), "when uncertainty increases, innovation often decreases, which is exactly opposite of what should be the long-term goal of competition law."

In terms of sustaining medical innovation and attracting FDI, heightening the transparency of its compulsory licensing procedures and abiding by a continuous, consistent regiment for issuing such licenses may decrease the perceived risk associated with relative Indian policies. Consequentially, it may increase the incentive for foreign firms to invest in India's pharmaceutical industry. If, like in the United States, the option for compulsory licenses exists but the parameters for issuance are clearly identified, then the uncertainty of patent protection as a result of those licenses is diminished.

Secondly, India must protect its domestic patents from the undermining effects of parallel importing. While there is no doubt that diluting its markets with substitute products makes certain drugs more affordable to Indian consumers, the Indian pharmaceutical industry simultaneously suffers because of it. Similar to the risks

[91] Cheri Grace, *The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines*, Government, Department for International Development, DFID Health Systems Resource Centre (London: Fretwells Ltd, 2004), 55.

[92] Tyler Cowen, "Poor U.S. Scores in Health Care Don't Measure Nobels and Innovation," *The New York Times*, October 5, 2006, http://www.nytimes.com/2006/10/05/business/05scene.html (accessed December 9, 2009).

[93] Makan Delrahim, *Forcing Firms to Share the Sandbox: Compulsory Licensing of Intellectual Property and Antitrust*, Presentation, Antitrust Division, U.S. Department of Justice (London: U.S. Depatment of Justice, 2004).

presented by vague compulsory licensing policies, parallel importing increases the uncertainty for firms to generate profits in markets to which products are re-imported by negating patent holders' rights to exclusivity. Thus, it may be beneficial for India, in the context of its industries, to restrict products identified to be substitutes of domestically patented products from being imported into the country. Doing so may help to protect the revenues of indigenous and foreign firms alike from the threat of anticompetitive substitutes.

Thirdly, imperative to the success of the two aforementioned policy changes is the eradication of the high degree of corruption in India's political system. In terms of associating predictability with risk, rule of law is only as reliable as the stringency with which it is enforced. Further, if corruption is as prevalent in Indian government as studies suggest, then it may be inferred that the lack of congruency between policies and procedures makes reliance on India's policies considerably risky. Therefore, even if India revises its policies to offer more protection for IPRs by controlling compulsory licensing and parallel importing, such policies will not effectively alleviate the risks for investors so long as it remains uncertain as to whether or not those laws will be upheld.

Holistically, the primary consideration for India in terms of generating FDI is fundamentally centred in its control of risk. Any amendment to policy that affects patents or IPR protection, in turn affects the risks faced by companies in India's pharmaceuticals industry. Accordingly, the higher the risk firms face, the lower the incentive will be to invest. Thus, to the extent that India wishes to attract FDI, the degree of capital inflow it receives is likely to be reactive to its treatment of those policies that influence the predictability of profits.

Conversely, often contrasting the attempt to generate FDI is the concern for the provision of drugs to India's poorer populations. The problem exists, that while it is discernable that appropriate amounts of FDI are beneficial to India in terms of stimulating industry development and facilitating economic growth, the patent protection required to attract such capital often leads to drugs being priced at levels which are unaffordable by much of the population. Thus, in trying to find a balance between FDI and the provision of low-priced drugs, it would seem logical, at least theoretically, to reciprocate the yields created by patent pricing to help provide drugs to India's poor and thus attain a balance between the incentive for firms to innovate and the wellbeing of the Indian people.

Comprising this theory is the notion that tax revenue generated from pharmaceutical sales might be used to establish programs in which patented drugs are made affordable to Indian consumers through government subsidies (a form of healthcare for the consumer) and other sources of aid such as the World Health Organization (WHO). The idea is that funding such a program might create a cyclical cash flow; in which a portion of firms' revenue is collected by the Indian government in the form of taxes, and reinvested in the industry via subsidies on patented drugs. Accordingly, firms would be able to profit and thus maintain the incentive to develop new medical innovations, while Indian citizens would be afforded the benefits of those innovations without hindering the progression of technology.

To elaborate, assuming that industry revenues would be higher if patent protection were increased as a result of the policy amendments mentioned above, then it is likely that the amount of relative tax revenue generated by the Indian government would increase as well. Also, according to Bureaus (2009), India, being a developing economy with limited affordability, currently spends only 0.8% of its total GDP on research and development for new innovations, compared to more developed countries such as Germany (2.5%), Japan (3.1%), France (2.2%), or the U.S. (2.8%). Thus, consistent with establishing a system more conducive to innovation, comparison suggests that an increased financial effort from the Indian government might be helpful in facilitating growth. Such a subsidy would serve as an economic stimulant initiated at the consumer level; a sort of 'trickle-up' approach to government spending.

In addition, more sources of funding may be available to further the affordability of drugs in India by contributing to subsidy programs. According to ELab Medical (2008), a study by the Institute for Health Metrics and Evaluation (IHME) reveals that the amount of health funding for developing countries totaled $21.8 billion in 2007, mentioning India specifically as a recipient of "huge amounts of health aid." Therefore, if such aid were coupled with government funds to subsidize the purchasing of patented medicines for lower income individuals, then the cost for drugs borne by Indian consumers could be substantially decreased. Further, depending on the degree of consumer demand for drugs and the contributing proportion of drug costs provided by subsidies, it might even be possible to lower the consumer-paid portion of drug prices to levels comparable with the prices of generic substitutes. If so, such an approach might also help to alleviate the impact of parallel imports by providing a branded drug (often perceived as higher quality) at a price comparable to that of its generic substitute.

Although, it may be proposed that using tax revenue or charitable donations to further the profits of pharmaceutical companies is not an appropriate use of such funds. Moreover, some may argue that such subsidies would only entice firms to increase prices, enabling subsidy programs to be treated like American insurance companies (i.e. moral hazard resulting from subsidies that contribute to lower consumer prices, thereby enticing firms to use such contributions as sources of revenue). However, it can be argued conversely that the profit-seeking behaviour of firms is unending, and without the ability to generate profits pharmaceutical companies would not innovate new technologies. Therefore, the purpose of using charitable funds and taxes to pay for

patented drugs is not with the interest of advancing firms' profits, but with the intent to promote medical innovation and develop new possibilities for saving lives.

Furthermore, it is likely that firms would be more apt to reduce the prices of patented products with a government subsidy as opposed to seeking profits through price increases. Consistent with economic theory, the reason for this is because firms will seek to maximize profits where marginal revenue equals marginal cost, and would likely be exposed to opportunities through economies of scale. Initially, lower prices of drugs for consumers would cause the quantity demanded to increase (along with the price), but simultaneously cause the proportion paid for by subsidy programs to decrease (along with the price). However, as firms increase the supply of patented drugs in the market, the price of those will go down, and the quantity demanded by both consumers and subsidy programs will increase. Accordingly, because the quantity of drugs that firms are able to sell will increase as the price of drugs decrease (demand is price elastic), firms have the incentive to lower prices to a level that equates the marginal cost of producing a drug with the marginal revenue associated with marketing and selling it.

9. Conclusions

As part of the outlook for India, achieving a scenario that will provide for its industries and residents to receive simultaneous benefit is the key to enabling healthy, long-term economic growth. On one hand, India's need for foreign capital makes it necessary for the rule of law to protect IPRs and pharmaceutical patents. On the other, India must utilize resources afforded by increased FDI to ensure that its people are not deprived of healthcare as a consequence to the country's economic endeavours. By maintaining such a consciousness of balance, it may be feasible to reconcile India's global verses regional interests in its pharmaceutical industry.

Regardless, imperative to its success in either category is India's ability to make its policies clearly defined, and void of influence from corrupt government entities. Though the absence of corruption and thus risk is necessary condition for achieving an optimal inflow of capital, it is also vital to ensure the efficacy of any further remedies to appropriate the balance between human and economic interests. Overall, the growing prominence of India's economic environment projects the potential for a bright future. Nonetheless, it is how India chooses to treat its policies that may determine just how bright that future will be.

India has the potential to benefit in the future from its new political environment, even in the absence of regional protectionism. It has comparative cost advantages in producing intermediate pharmaceutical products and selling them to patent-honouring countries such as Japan. It may find end product, as well as market-size advantages by designing ethical, large-scale drug trials for companies around the world, which would benefit India, its domestic industry, and the world pharmaceutical industry by expediting drug discoveries on a larger scale. This is especially true in the development of 'orphan drugs' where the diseases are severe but occur rather infrequently in most countries.

Furthermore, India's large population may be seen as asset in providing larger samples for drugs so that trials can be conducted fairly accurately. Emphasizing the need for *ethical* drug trials, ultimate liability and the proper conduction of such trials remains the responsibility of the administering pharmaceutical firm (not necessarily the local subcontractor). Accordingly, in expecting regional price discrimination, India can examine its potential in producing licensed generic drugs and subsidies to its poor while simultaneously honoring international patents.

Inevitably, the dilemma of regional interests versus global patents is ongoing for pharmaceutical products in the world. India however, has the opportunity to establish a leadership role in this dialogue. By appropriating policies that create win-win situations for its domestic industry and social welfare, it has the potential to create positive, future gains all around.

Appendix 1A

AGREEMENT ON TRADE-RELATED ASPECTS OF
INTELLECTUAL PROPERTY RIGHTS
Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.94 Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[95]

Appendix 1B

The Patents Act 1970

(39 of 1970)
(Chapter 2) 5. Inventions where only methods or processes of manufacture patentable
(1) In the case of inventions-

a. claiming substances intended for use, or capable of being used, as food or as medicine or drug, or
b. relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds),

[94] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.
[95] It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.
[(2) Notwithstanding anything contained in sub-section (1), a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug, except the medicine or drug specified under sub-clause (v) of clause (1) of sub-section (1) of section 2, may be made and shall be dealt, without prejudice to the other provisions of this Act, in the manner provided in Chapter IVA.]

(Chapter 8) 48. Rights of patentees
(1) Subject to the other provisions contained in this Act, a patent granted before the commencement of this Act, shall confer on the patentee the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute the invention in India.
(2) Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted after the commencement of this Act shall confer upon the patentee -

a. where the patent is for an article or substance, the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute such article or substance in India;
b. where a patent is for a method or process of manufacturing an article or substance, the exclusive right by himself, his agents or licensees to use or exercise the method or process in India.

Appendix 1C

18 U.S.C. § 201 : US Code - Section 201: Bribery of public officials and witnesses

(a) For the purpose of this section - (1) the term "public official" means Member of Congress, Delegate, or Resident Commissioner, either before or after such official has qualified, or an officer or employee or person acting for or on behalf of the United States, or any department, agency or branch of Government thereof, including the District of Columbia, in any official function, under or by authority of any such department, agency, or branch of Government, or a juror; (2) the term "person who has been selected to be a public official" means any person who has been nominated or appointed to be a public official, or has been officially informed that such person will be so nominated or appointed; and (3) the term "official act" means any decision or action on any question, matter, cause, suit, proceeding or controversy, which may at any time be pending, or which may by law be brought before any public official, in such official's official capacity, or in such official's place of trust or profit.
(b) Whoever - (1) directly or indirectly, corruptly gives, offers or promises anything of value to any public official or person who has been selected to be a public official, or offers or promises any public official or any person who has been selected to be a public official to give anything of value to any other person or entity, with intent - (A) to influence any official act; or (B) to influence such public official or person who has been selected to be a public official to commit or aid in committing, or collude in, or allow, any fraud, or make opportunity for the commission of any fraud, on the United States; or (C) to induce such public official or such person who has been selected to be a public official to do or omit to do any act in violation of the lawful duty of such official or person; (2) being a public official or person selected to be a public official, directly or indirectly, corruptly demands, seeks, receives, accepts, or agrees to receive or accept anything of value personally or for any other person or entity, in return for: (A) being influenced in the performance of any official act; (B) being influenced to commit or aid in committing, or to collude in, or allow, any fraud, or make opportunity for the commission of any fraud, on the United States; or (C) being induced to do or omit to do any act in violation of the official duty of such official or person; (3) directly or indirectly, corruptly gives, offers, or promises anything of value to any person, or offers or promises such person to give anything of value to any other person or entity, with intent to influence the testimony under oath or affirmation of such first-mentioned person as a witness upon a trial, hearing, or other proceeding, before any court, any committee of either House or both Houses of Congress, or any agency, commission, or officer authorized by the laws of the United States to hear evidence or take testimony, or with intent to influence such person to absent himself therefrom; (4) directly or indirectly, corruptly demands, seeks, receives, accepts, or agrees to receive or accept anything of value personally or for any other person or entity in return for being influenced in testimony under oath or affirmation as a witness upon any such trial, hearing, or other proceeding, or in return for absenting himself therefrom; shall be fined under this title or not more than three times the monetary equivalent of the thing of value, whichever is greater, or imprisoned for not more than fifteen years, or both, and may be disqualified from holding any office of honor, trust, or profit under the United States.
(c) Whoever - (1) otherwise than as provided by law for the proper discharge of official duty - (A) directly or indirectly gives, offers, or promises anything of value to any public official, former public official, or person selected to be a public official, for or because of any official act performed or to be performed by such public official, former public official, or person selected to be a public official; or (B) being a public official, former public official, or person selected to be a public official, otherwise than as provided by law for the proper discharge of official duty, directly or indirectly demands, seeks, receives, accepts, or agrees to receive or accept

anything of value personally for or because of any official act performed or to be performed by such official or person; (2) directly or indirectly, gives, offers, or promises anything of value to any person, for or because of the testimony under oath or affirmation given or to be given by such person as a witness upon a trial, hearing, or other proceeding, before any court, any committee of either House or both Houses of Congress, or any agency, commission, or officer authorized by the laws of the United States to hear evidence or take testimony, or for or because of such person's absence therefrom; (3) directly or indirectly, demands, seeks, receives, accepts, or agrees to receive or accept anything of value personally for or because of the testimony under oath or affirmation given or to be given by such person as a witness upon any such trial, hearing, or other proceeding, or for or because of such person's absence therefrom; shall be fined under this title or imprisoned for not more than two years, or both. (d) Paragraphs (3) and (4) of subsection (b) and paragraphs (2) and (3) of subsection (c) shall not be construed to prohibit the payment or receipt of witness fees provided by law, or the payment, by the party upon whose behalf a witness is called and receipt by a witness, of the reasonable cost of travel and subsistence incurred and the reasonable value of time lost in attendance at any such trial, hearing, or proceeding, or in the case of expert witnesses, a reasonable fee for time spent in the preparation of such opinion, and in appearing and testifying. (e) The offenses and penalties prescribed in this section are separate from and in addition to those prescribed in sections 1503, 1504, and 1505 of this title.

http://codes.lp.findlaw.com/uscode/18/I/11/201

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