How India Can Attract More Foreign Direct Investment, Create Jobs, and Increase GDP: The Benefits of Respecting the Intellectual Property Rights of Foreign Pharmaceutical Producers

Robert J. Shapiro and Aparna Mathur

January, 2014

SONECON

Table of Contents

How India Can Attract More Foreign Direct Investment, Create Jobs, and Increase GDP: The Benefits of Respecting the Intellectual Property Rights of Foreign Pharmaceutical Producers[1]

Robert J. Shapiro and Aparna Mathur

I. Introduction

As the effective application of new technologies has become increasingly important to most nations' economic growth and development, the significance of intellectual property (IP) rights has also increased. Most technological innovations come from the world's most advanced countries; and the transfers of those technologies to developing nations, mostly through the foreign direct investments (FDI) of multinational companies, are critical to efforts to modernize their economies. The economic returns on these transfers depend on the foreign investor's ability to claim the profits from its innovations. As a result, a willingness to respect and enforce the IP rights of those foreign direct investors has become a prerequisite for modernization in most developing countries.

This study examines the economic impact of India's current approach to intellectual property rights, as it affects pharmaceutical products and FDI. We begin by reviewing the economic effects of FDI generally on the growth and development of developing nations. In countries as disparate as Mexico, Indonesia, China and Russia – as well as India -- FDI has been shown to have strong, positive effects on a country's growth, productivity and incomes. These positive effects reflect not only the direct benefits from applying the technologies and business methods brought in through FDI, but also spillover effects from domestic workers learning new skills and domestic companies adopting the new technologies and business methods.

Next, we turn to the impact of IP rights and enforcement on where pharmaceutical firms locate their FDI. Most researchers in this area have found that the technology and other transfers from FDI, considered generally, tend to increase as a country strengthens IP rights and enforcement. Using the standard Ginarte-Park (G-P) index of nations with regard to IP rights and enforcement, we demonstrate a strong relationship between how much FDI a nation attracts and the strength of its IP regime, and an even stronger relationship for pharmaceutical FDI.

Next, we turn to India and review its history of IP rights and enforcement. Until the early 1990s, IP rights in India were notably weak by international standards, and especially in the pharmaceutical sector. In 1995, however, India joined the World Trade Organization (WTO) and agreed to adopt the IP rights set forth in the WTO's Trade Related Aspects of Intellectual Property Rights (TRIPS), following a ten-year transition period. During this transition period, India reformed its patent laws to generally accord with TRIPS, but it also adopted a number of provisions which effectively weaken the IP rights of foreign direct investors.

We examined the impact of these legal changes on flows of pharmaceutical FDI to India. As expected, such investments were negligible until India joined the WTO in 1995. However,

[1] We gratefully acknowledge the superb research assistance of Doug Dowson and financial support provided by the Pharmaceutical Research and Manufacturers of America. The views and analysis are solely those of the authors.

they increased four-fold over the ten-year transition period to TRIPS (1995-2005), and then grew 16-fold more since 2005. However, we also track recent sharp declines in these investments as Indian courts have overturned the IP rights of several foreign-based pharmaceutical companies.

It is clear that India could still make substantial progress in its IP regime. In the second part of this study, we examine the range of economic gains India could achieve by doing so. We start by comparing IP rights and enforcement in India, China and the United States, as measured by the G-P index. We show that pharmaceutical FDI to India could increase sharply if it adopted stronger IP rights and enforcement. If India adopted an IP regime comparable to China – which itself has considerable room for improvement -- annual FDI flows in pharmaceuticals to India would increase an estimated 33 percent. If it adopted a system of IP rights and enforcement comparable to the United States, these FDI flows could rise by 83 percent per-year.

Next, we explore the economic effects of such improvements in India's IP regime. First, we estimate how much those improvements would increase pharmaceutical FDI to India: Under an IP regime comparable to China's and which started this year, we estimate that annual pharmaceutical FDI flows to India would grow from $1.5 billion in 2014 to $8.3 billion in 2020. Under an IP system comparable to the United States, India could become the leading, developing country for pharmaceutical FDI: Those flows would increase from $2.1 billion in 2014 to $77.2 billion in 2020. We also examine the links between these FDI flows and the R&D activities in foreign markets of those foreign direct investors. We find that substantial improvements in India's IP regime could make the country a center for innovative pharmaceutical R&D. Under a system of IP rights merely comparable to China, innovative pharmaceutical R&D in India would double from 2014 to 2020, rising from $645 million to $1.3 billion. Under an IP regime comparable to the United States, such R&D would grow nearly six times, from $760 million in 2014 to $4.2 billion in 2020.

With greater pharmaceutical FDI and R&D, the Indian people's access to the latest pharmaceutical treatments should increase. To estimate the effects of such increased access, we first analyze the relationship between improvements in India's G-P index score and the availability of new patented drugs, and show how access to new drugs has increased with greater IP protections. Next, we review research which has explored the relationship between such access to new drugs and changes in life expectancy. Using these findings, we can estimate the impact on the longevity of Indians if their government adopted a stronger IP regime.

The results: We estimate that if India adopts an IP regime comparable to China, its access to new innovative drugs should increase by about 5 percent. Based on research in this area across many countries, we further estimate that such increased access to new pharmaceutical treatments could raise the average life expectancy of working-age Indians by four weeks. We estimate the long-term economic benefits of a four week increase in life expectancy at roughly $32 billion. Similarly, if India adopted an IP regime comparable to the United States, the increased access to new pharmaceuticals would extend the average life expectancy of working-age Indians by an estimated 10 weeks, with long-term benefits totaling some $80 billion.

An IP system that promoted greater access to new pharmaceuticals could also lead to other benefits, through lower costs for other forms of medical treatment, lower government subsidies for medical care, and lower income losses from illnesses. Drawing on research analyzing such cost savings from early adoption of new innovative drugs, we project those

indirect savings under three scenarios. We find that those savings could range from $5.2 billion per-year to $12.8 billion per-year – and conceivably reach as much as $19.2 billion annually.

Next, we estimate the impact of higher FDI on the total output and workforce of the Indian pharmaceutical sector. First, we calculate the impact of greater pharmaceutical FDI on the sector's total capital investment. We also establish how increases in pharmaceutical FDI and the sector's total capital investment affect employment in the sector. Based on these relationships, we estimate that if India adopted an IP regime comparable merely to China, the increased FDI would generate some 18,000 additional jobs in the pharmaceutical sector by 2020. Similarly, under a system of IP rights and enforcement comparable to the United States, the increased FDI would lead to nearly 44,000 additional jobs in the sector by 2020.

Finally, we examine the impact of stricter IP protections on FDI flows and the economic performance of other, selected Indian industries. Based on data availability, we focused on services generally and, within manufacturing, on computer software and hardware, chemicals (other than fertilizers and not including pharmaceuticals), automobiles, and metallurgical industries. Together, they account for 74 percent of India's GDP and 38 percent of FDI inflows.

First, we estimate the impact of improved IP rights and enforcement on the FDI flows to these industries and sector, using two scenarios. We find that if India improved its IP regime sufficiently to raise by 20 percent the annual FDI flows to Indian services and the four manufacturing industries, service sector output would increase by more than $2.2 billion per-year, and the annual output of the four selected industries would expand nearly $4 billion. We further estimate that those increases in FDI and output would lead to some 20,000 additional jobs in services, per-year, and an estimated 31,500 additional jobs in the four manufacturing industries. Similarly, if India improved its IP regime sufficiently to increase annual FDI inflows by 40 percent, yearly output in services would increase by an estimated $4.5 billion, and annual output in the four manufacturing industries would rise nearly $8 billion. Accompanying those increases, the service sector workforce would increase by nearly 40,000 jobs, per-year, and employment in the four manufacturing industries would rise by nearly 63,000 jobs.

The research and analysis presented in this study establish that inflows of foreign direct investment vitally affect the pace of development and growth in India's pharmaceutical industry and across much of the rest of the nation's economy. Those inflows, in turn, depend substantially on the strength and integrity of India's commitment to protect and enforce the intellectual property rights of foreign direct investors. By strengthening its IP regime to the level of China or, better, the United States, India could well become a global center for innovative drug development and production, increase the life expectancy of its people, expand output and employment, and achieve considerable cost savings in medical care and government subsidies.

II. Intellectual Property Rights, Foreign Direct Investment, and Modernization

In a period in which innovations seem to drive and dominate the economic progress of many nations, the economic importance of IP rights has received great attention. It has been long recognized that without strict protections for the returns from new ideas, the incentives for companies and individuals to devote scarce capital and labor to developing new technologies, materials, goods and services would quickly erode. The economic utility of IP rights and their enforcement also informs the dominant approach to modernization, in which developing nations

encourage multinational companies (MNCs) to locate their FDI in their countries. In this way, developing economies can gain access to technologies and business methods that, in turn, support large in productivity and growth which otherwise might be unattainable for decades.

MNCs generally protect their returns on their new technologies and other innovations by locating them, through their FDI, in countries which respect their IP rights, lest other firms appropriate those innovations and reduce the MNC's market and returns. While developing nations have strong incentives to encourage MNCs to locate the FDI in their countries, the benefits of FDI to developing economies were not so obvious a generation or more ago. To begin, it was clear that many MNCs took home with them much of the additional wealth earned by their FDI. Indeed, many early studies of FDI focused on a single firm, and those studies found that FDI appeared to produce modest benefits, at best, for many developing nations. One influential study, for example, found no evidence of growth and productivity benefits from foreign firms investing Venezuela from 1979 to 1989.[2] Only later did economists focus on the benefits associated with certain "spillovers" from FDI, in which the advanced technologies and ways of doing business are adopted by native companies. Analysts began to study these benefits by moving beyond firm-based studies to macroeconomic analyses using aggregate FDI flows across a number of countries. In most cases, they have found that FDI in developing economies generates faster or greater economic growth. [3]

While the evidence of this effect is strong, there is less consensus about the magnitude of the effects.[4] One reason is that a number of factors influence whether and to what degree FDI contributes to broader economic gains. One study, for example, found that FDI promotes stronger economic growth in countries with developed financial markets, and another analysis found that the growth effects of FDI are associated with trade openness.[5] More generally, the effectiveness of FDI in increasing a country's future growth appears to be much higher in countries with more open economies.[6] In addition, the ability of a developing nation to apply the advanced technologies and business methods introduced through FDI in ways that enhance growth, especially through spillovers, depends on factors such as the supply of educated workers capable of making effective use of the innovations. [7] There is also debate among experts about FDI's impact on native companies. Some developing-nation critics of FDI, for example, point to the risk that FDI will "crowd out" access by domestic firms to finance and domestic markets.[8] However, most economists would agree with the analyst who wrote, "One of the greatest benefits of FDI is the injection of new technologies and competition that leads to the exit of inefficient enterprises and the raising of efficiency in others. Without such a process, the economy can lack dynamism and flexibility, and lose competitiveness over time."[9]

[2] Aitken and Harrison (1999). See also, Germidis (1977); Haddad and Aitken (1993); Mansfield and Romeo (1980); and Carkovic and Levine (2002).
[3] Carkovic and Levine (2002).
[4] Blomstrom, Globerman, and Kokko (2000)
[5] Alfaro, Chandra, Kalemli-Ozcan, and Sayek (2000); and Balasubramanyam, Salisu, and Dapsoford (1996)
[6] Usha and Weinhold (2000).
[7] Sanjaya Lall (2000).
[8] Cited by Lall (2000).
[9] Lall (2000).

Studies of the economic effects of FDI span most of the world. Scholars have found econometric evidence of positive spillovers from FDI, for example, in countries as disparate as Mexico,[10] Uruguay,[11] and Indonesia.[12] Similarly, one recent study applied econometric analysis across the provinces of China to test whether FDI contributed to higher productivity growth in those provinces that received the greatest FDI.[13] The researchers found that areas with the most FDI not only had higher income gains,[14] but that much of China's export growth in the 1990s was attributable to FDI.[15] Another study found that the capital investment, technologies and management know-how brought by FDI into Malaysia have been important factors in that country's growth gains over the 35 years from 1970 to 2005.[16] Every 1 percent increase in FDI was associated with a 0.05 percent increase in the nation's growth and national income.[17] And two studies of FDI in African countries found that those places with macroeconomic and political stability, policy credibility, and relatively open economies attracted FDI, which in turn contributed to higher growth.[18]

These effects are also evident in studies of FDI across regions. An analysis of the effects of FDI on growth in 25 Central and Eastern European and former Soviet Union economies from 1991 to 2000, for example, found a significant positive effect on growth in each country.[19] Another study of FDI and growth across 12 Asian economies from 1987 to 1997 found that FDI in manufacturing industries had a strong, positive effect on growth in the host economies.[20] Other studies, however, report that the link between FDI and growth is stronger in service sectors than in manufacturing, and that the impact differs across manufacturing industries.[21] As one scholar concluded, "At present, the consensus view seems to be that there is a positive association between FDI inflows and growth provided receiving countries have reached a minimum level of educational, technological and/or infrastructure development."[22]

This view is also held by the OECD, which concluded that developing countries have to achieve a certain level of advancement in education and infrastructure in order to capture the potential benefits linked to FDI.[23] More generally, the OECD reported that based on its review of 14 studies, there seems to be "a strong relationship between FDI and growth."[24] The literature also suggests that other domestic conditions also help determine whether FDI will promote growth.[25] Three recent studies, for example, found that countries with more developed

[10] Blomstrom (1986); Kokko (1994).
[11] Blomstrom, Kokko and Zejan (1994).
[12] Sjoholmn (1999).
[13] Graham and Wada (2001).
[14] *Ibid.*
[15] *Ibid.*
[16] Wai-MunHar, Teo and Yee (2008).
[17] *Ibid.*
[18] Anyanwu (1998) Obwona (2001).
[19] Kinoshita and Campos (2002).
[20] Wang (2001).
[21] Nunnekamp and Spatz (2003).
[22] Iihan Ozturk (2007).
[23] *Ibid.*
[24] *Ibid.*
[25] Carkovic and Levine (2002).

financial systems and financial regulation exploit FDI more effectively and capture greater growth benefits.[26]

While most of these studies focus on factors which affect a developing nation's capacity to take advantage of FDI in ways that boost its overall growth, mainly through spillovers, a number of other scholars of FDI have examined whether and to what degree IP rights influence the willingness of MNCs to locate their FDI in particular countries. To be sure, strong IP rights are not sufficient incentives for MNCs to invest in a particular country – if they were, as one scholar has observed, "recent FDI flows to developing economies would have gone mainly to sub-Saharan Africa and Eastern Europe."[27] At the same time, as the same scholar also put it, "The movement toward much stronger global IPRs is consistent with processes of economic globalization … through the reduction of barriers to trade, investment, and technology flows. In this world, knowledge creation and its adaptation to product designs and production techniques are increasingly essential for competitiveness and growth." [28]

Given that innovations are the largest single force responsible for changes in rates of growth and productivity in developed as well as developing nations, how critical are IP protections to the spread of those innovations through FDI?[29] It may seem obvious that rates of innovation would recede if the innovations developed by one person or company could be copied and reproduced without limit or compensation by any other company in any country. Yet, serious questions have been raised about the benefits of respecting traditional IP rights, including appeals to the World Intellectual Property Organization (WIPO) arguing that those rights impair economic progress in developing nations.[30] In this view, IP rights could be said to limit the spillovers from FDI, by preventing native companies from appropriating for their own gains the technologies and/or products introduced through the FDI.

The relationship between innovation and intellectual-property rights is well-established in modern economics. In part, this link follows directly from the basic theory of markets. The development of most modern economic innovations, especially in technology areas, generally requires highly-skilled people and sophisticated equipment and business organizations; and the use of all that labor and capital is costly. The only reason that a business bears the costs and labor costs to develop something new, forgoing more immediate and certain returns from using its labor and capital in other ways, is a prospect of larger returns in the future.[31] The rest of the explanation lies in the nature of ideas. The ideas that animate economic innovations are what economists call "non-rival goods," which means that unlike physical goods such as a particular piece of equipment or land, the same idea can be used by many different people at the same time, and can be easily duplicated. Because a company cannot physically possess an idea as it can land or equipment, the idea's use by its developer does not preclude others from using it at the

[26] Hermes and Lensink (2003); Durham (2003); Alfaro et al. (2003). An efficient financial market can enable local entrepreneurs to secure financial backing and use lessons learned from FDI to start their own businesses or expand existing ones.
[27] Maskus (2000).
[28] *Ibid.*
[29] This discussion is adapted from its treatment by the author (Robert Shapiro) in Shapiro and Hassett. (2005).
[30] Group of Friends of Development (2005).
[31] For a literature review of the connections between innovation and IP protections, see Kanwar and Evenson (2001).

same time.[32] As a result, the returns from innovations require legal protections for the new ideas that animate them.

Economists have explored many aspects of this issue as they affect flows of FDI. A clear consensus has emerged in this literature, for instance, that the costs to a developing nation of ignoring the intellectual property rights of foreign companies exceed any benefits. In one line of inquiry, researchers examined whether innovating firms are sensitive to IP rights only in the place where they develop their innovations, or whether the strength of their patents in other countries also matters. The economic logic linking the development of new technologies and strong IP rights in foreign markets is clear: The prospect of a larger market for an innovator to earn returns directly stimulates R&D by expanding the potential customer base and so raising the potential rate of return on the R&D. In this regard, one recent study found that strong IP protections in developing nations directly stimulate the pace of innovation in more advanced economies.[33]

Critics of traditional IP protections claim that regardless of these effects, innovations benefit primarily those who develop them, and not people in developing countries. This is an important issue, since FDI depends on the receptivity of developing nations. However, as the literature review above attests, FDI tends to improve the growth and productivity gains of developing countries that accept FDI. Moreover, other analysts have found that developing economies benefit from respecting IP rights at least as much as advanced economies. One major study, for example, examined data for 95 countries from 1960 to 1988 and found that IP rights had a significant effect on growth in all cases, with the greatest effects occurring in both the high-income countries where the innovations were developed and those low-income countries where strong patent protections encouraged FDI involving innovations.[34] These results are confirmed by another study conducted in 2004 which examined 80 countries over four time periods covering 1975 to 1994.[35] The authors found that strong IP protections stimulated growth in countries with high *per capita* incomes and *even greater gains* in countries with low *per capita* incomes, by encouraging FDI and imports from advanced countries.[36]

Whether these technology transfers occur by export or FDI depends on the product and the market, with IP rights playing significant roles in both cases. The existence of strong IP rights in a developing country encourages exports of new technologies to that country by protecting the exporter from local imitations and increasing the size of the exporter's potential market, and several studies have found that countries with relatively stronger IP rights attract relatively more imports.[37] Foreign direct investment is likely to replace exports when the products are relatively R&D-intensive and the market is large, and when the costs of conducting

[32] In economic terms, ideas are considered to be "partially non-excludable goods:" An innovator acting as a private agent cannot prevent others from using his idea, in contrast to someone who owns a piece of land or a factory who can prevent others from using it by hiring security guards.
[33] Diwan and Rodrik (1991).
[34] Gould and Gruben (1996). M.A. Thompson and F. W. Rushing (1996) found these effects only when a country had achieved a certain level of GDP.
[35] Falvey et. al, (2004).
[36] *Ibid.* The researchers could not establish the same link for middle-income countries: The positive effects of patents on growth, from imports and FDI, were offset by negative effects associated with discouraging domestic imitators and slowing the pace of diffusion of new knowledge.
[37] Maskus and Penubarti (1999); Smith (2002).

the trade and transporting the goods are high and the costs of establishing new plants are low.[38] It is not surprising, for example, that FDI of technologies that are complex and easily imitated increases as IP rights are strengthened. The result, as documented in another analysis, is that the quality of technologies transferred to developing countries generally rises as those countries strengthen IP rights.[39]

More generally, researchers have established that technology transfers to a developing market increase as it strengthens patent rights,[40] and that every one-percent increase in the degree of patent protection in a developing country expands the stock of U.S. investment in that country by 0.45 percent.[41] The issue for FDI that transfers new technologies and products is ultimately the same as any other investment: Will it raise the firm's expected profits so that it can earn a higher return on its protected knowledge-based assets through FDI than in any other way?

The evidence also shows that countries with weak intellectual property rights receive relatively less FDI, and the investments they attract are technologically less sophisticated.[42] One recent study found that in countries with weak IP rights, foreign multinationals tend to focus on developing distribution channels for their products – compared to countries markets with stronger IP protections, where multinational focus more on transferring their production technologies and manufacturing.[43] More broadly, a survey of 100 U.S.-based multinational firms found significant reluctance among them to do business in India, Brazil, Argentina and Indonesia, all countries cited repeatedly by the Office of the U.S. Trade Representative for failing to respect and protect the IP rights of American companies and citizens.[44] More than 80 percent of the pharmaceutical companies included in the survey reported that they would not conduct any joint ventures or transfer or license their technologies in India, despite that country's huge market.[45]

A number of researchers have also found that countries that do not aggressively respect IP rights have a more difficult time achieving economic growth through technology transfers. One study looked at how reforms in IP rights in 16 countries over the period 1982 to 1999 affected technology transfers by U.S. multinational firms to their foreign affiliates.[46] The research showed that royalty payments to parent companies for the use or sale of technologies transferred to their affiliates increased at times of the reforms, as did R&D carried out by the affiliates as a complement to the technology imports from their parent companies.[47] The researchers concluded that, "U.S. multinationals respond to changes in IPR (IP rights) regimes abroad by increasing technology transfers to reforming countries."[48] These dynamics also

[38] Maskus (2000).
[39] Vishwasrao (1994).
[40] Taylor (2004).
[41] Maskus (1994).
[42] Lee and Mansfield (1996).
[43] Smarzynska, B. K. (2002).
[44] Edwin Mansfield (1998).
[45] Similarly, among the machinery producers surveyed, 73 percent said that they would not license the production of their products in Brazil and 59 percent would not do so in India.
[46] Branstetter *et al*. (2005).
[47] The countries include Argentina, Brazil, China, Indonesia, Japan, South Korea, Mexico, the Philippines, Spain, Taiwan, Thailand, and Turkey.
[48] Branstetter, *et. al*. (2005).

inform a World Bank study which found that during the same period of IP reform, the share of global trade comprised of knowledge-intensive or high technology products rose sharply.[49]

There is also substantial evidence that multinational firms often shift some of their R&D activity to developing countries which respect intellectual property rights, creating additional positive feedback effects in those countries. Once a MNC locates intellectually intensive activities in a country, those activities can have positive effects on other domestic businesses. For example, one study analyzed investment decisions by firms in a large number of countries and found that as a country's IP protections increase, firms there focus more on developing new intangible assets – new ideas – with a significant, positive effect on their growth.[50] These findings establish a clear causal chain and virtuous circle. Countries that respect IP rights encourage foreign MNCs to transfer their state-of-the-art technologies to those countries. Once that country's businesses and citizens become familiar with the new technologies, some domestic firms both adopt them and increase the rate at which they develop their own intellectual property. These developments lead to higher growth by domestic firms, which make the country an even more attractive locale for further FDI.

The importance of IP rights in encouraging FDI varies by sector.[51] FDI in lower-technology industries, such as textiles and apparel, electronic assembly, distribution, and hotels, is more sensitive to input costs and market potential than to the strength of IP protection. MNCs weighing FDI commitment for production of goods that are costly to imitate also may place less importance on IP rights. However, firms considering FDI for high-technology products that are relatively easy to copy – for example, pharmaceuticals, food additives and software – are most concerned about local IP rights.

Respect for the IP rights of foreign companies can benefit a developing nation in another important way: If multinational firms can expect to have their patents respected in certain countries, they may be more likely to invest in research that would be especially beneficial to those countries. One recent study, for example, found that research into anti-malaria treatments by pharmaceutical firms increased following improvements in IP protections in countries subject to malaria outbreaks.[52] These data suggest that greater respect for IP rights may be a matter of life and death in many developing countries.

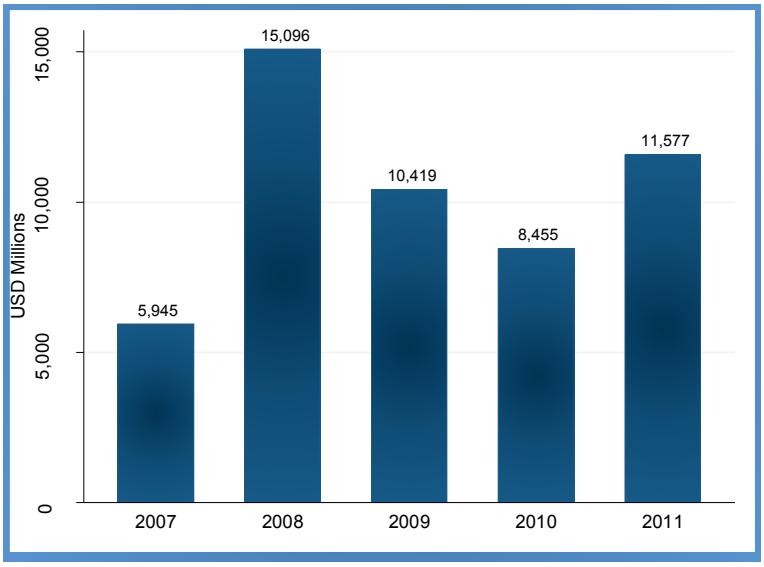
III. The Impact of Intellectual Property Rights on the Distribution of Pharmaceutical Industry FDI

As noted earlier, extensive research has linked the locations of certain types of foreign direct investment to the strength of intellectual property rights in those locations. This link should be manifest in the FDI of the pharmaceutical industry, given the large cost of developing most pharmaceutical treatments, the fact that their composition is usually a matter of public knowledge, and the relatively low cost of reproducing such treatments. Here, we examine the extent to which actual flows of pharmaceutical FDI reflect the depth and extent of IP rights.

[49] Fink and Braga (1999).
[50] Claessens and Laeven (2002).
[51] Maskus and Penubarti (1995).
[52] Lanjouw and Cockburn (2000).

While there are few public sources of reliable data on industry-specific FDI flows by country, we can estimate those flows for the pharmaceutical industry using data from the Organization for Economic Development and Cooperation (OECD) and the United Nations (UN). We start with the OECD's "International Direct Investment Statistics," which show that FDI by pharmaceutical companies headquartered in OECD countries averaged $10.3 billion per-year from 2007 to 2011, ranging from $5.9 billion in 2007 to $15.1 billion in 2008. (Figure 1).

Figure 1. Outward Foreign Direct Investment Flows in Pharmaceuticals, 2007-2011[53]

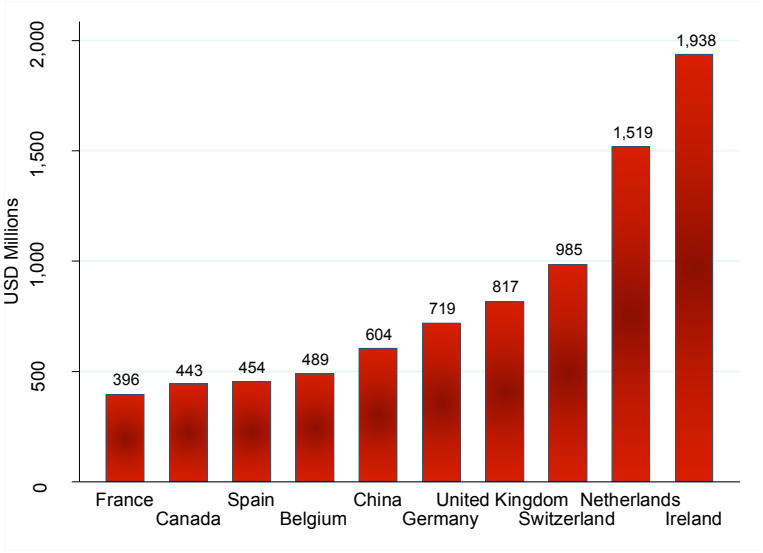


To estimate worldwide pharmaceutical FDI flows, we turn next to data from the United Nations Conference on Trade and Development (UNCTAD), which show that OECD countries accounted for about 53 percent of global FDI over the same years. Based on these data and the OECD data on pharmaceutical FDI by OECD countries, we estimate that global FDI flows in the pharmaceutical industry averaged $19.43 billion annually over the years 2007 to 2011.

Next, we determine where pharmaceutical FDI is located. UNCTAD does not provide detailed country-specific information on industry-specific FDI. However, the United Nations International Trade Centre (UNITC) issues country-specific data on outflows and inflows of FDI across broad industries; and those industries include "chemicals," which include pharmaceuticals as well as commodity chemicals. For example, UNITC data show that chemical industry firms in the United States undertook FDI averaging $11.7 billion over the four years from 2009 to 2012. The largest share of these FDI flows in chemicals went to the low-tax countries of Ireland and the Netherlands, followed by Switzerland, the United Kingdom, and Germany. (Figure 2, below) The nine largest recipients of U.S. chemical industry FDI accounted for an average of $8.4 billion in FDI flows per-year, 72 percent of all FDI by the industry; and 94 percent of that total went to countries with strong IP protections. Among the large recipients, only China, with an average of $604 million in annual U.S. chemical industry FDI, has IP protections that are significantly less strict than the other large and more advanced recipients.

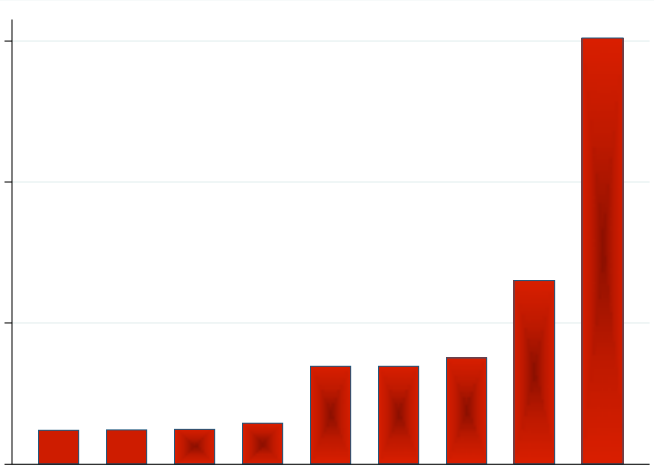
[53] OECD (2013).

Figure 2. U.S. FDI Flows in Chemicals and Chemical Products, Nine Largest Nation-Recipients, Average for 2009-2012 (US $ millions)[54]



The UNITC data also show that China was the only major Asian recipient of U.S. FDI in the chemicals sector. Japan, at number two, received annual FDI in this area averaging $261 million, followed by Thailand with $151 million in annual average U.S. FDI flows in chemicals. (Figure 3, below) India, at just $58 million in average annual U.S. FDI in chemicals, received less than 0.5 percent of the $11.7 billion of these flows.

Figure 3. Annual Average of U.S. FDI, in Chemicals, 2009-2012 (US $Millions)[55]



[54] United Nations International Trade Centre (2013).
[55] *Op. Cit.*

As noted earlier, many factors other than IP enforcement influence where firms locate their FDI, including market size, political institutions, and openness to trade and investment. To test how IP protections in particular affect FDI flows, we draw on the Ginarte-Park (G-P) index of patent rights, a measure developed by the World Bank and American University that rates countries on five measures of patent protection. An analysis of G-P Index results shows a fairly strong correlation between a nation's measure by this index and its total FDI flows over 2008 to 2012. Controlling for GDP, we found that each unit increase in the index – equal to about one standard deviation, or the difference between IP rights in Turkey compared to the United States – is associated with a 28.7 percent increase in FDI flows. (Figure 4, below) Each point in the figure represents a country based on its index value and FDI inflows.

Figure 4. Protection of Intellectual Property Rights and Inward FDI Flows, 2008-2012, By Nation[56]

We should expect to find a stronger relationship between IP protections and U.S. FDI by chemical industry companies, compared to all FDI flows. Pharmaceutical producers account for the bulk of this FDI, and they should be more sensitive to IP protections than producers in some other sectors where sunk costs of development are lower, and the difficulty and cost of reproducing the product is greater. To test this proposition, we perform the same analysis using the data on U.S. FDI in the chemicals sector. As expected, we found a stronger positive relationship between U.S. FDI flows in chemicals and chemical products and IP rights by nation, over the years 2009 to 2012: Across countries that received FDI from U.S. chemical industry companies over those years, each unit increase in the IP rights index was associated with a 46.5 percent increase in those U.S. FDI flows, after controlling for GDP. (Figure 5, below)

[56] Park (2001). UNCTAD (2013).

Figure 5. Protection of Intellectual Property Rights and Inward Flows of U.S. FDI in Chemicals and Chemical Products, 2009-2012, By Nation[57]

This measure shows that India has considerable room for improving its level of protection for intellectual property rights. In 2010, India received a score of 3.76 out of 5 on the Ginarte-Park index, trailing China (4.21) but scoring better than Brazil (3.43) and Russia (3.68). India also lags far behind the 4.38 average for all OECD countries and the 4.88 score for the United States, which ranks number one by this measure.

IV. Intellectual Property Protections in India

Intellectual property rights in India have evolved or passed through several distinct stages. The first phase covered the period before India gained its independence from Great Britain in 1947, during which India followed British IP laws, including those covering the patenting of pharmaceutical products. In this period, most Indian drug patents were granted to foreign firms, and foreign firms dominated India's pharmaceutical industry in 1947, with only limited participation by native Indian firms.[58]

This regime continued until 1970, when the Indian government drastically revised the country's IP laws as part of a new push to promote and expand domestic manufacturing. By western standards, these moves sharply narrowed IP rights and protections. To promote more indigenous production of pharmaceutical products, for example, the Indian Patent Act of 1970 limited the existing rights of patent holders in India in several important ways. First, the law ended entirely the patenting of pharmaceutical products and permitted patents only for the processes used to produce those products. Second, a firm could patent only one process for producing a particular pharmaceutical product, so no firm could achieve an effective monopoly for a particular treatment by patenting all possible ways of producing the treatment. Third, the term of patent protection for a pharmaceutical process was limited to the lesser of five years from

[57] *Op. cit.*
[58] Mueller (2007).

the grant of the patent or seven years from the initial filing of the patent application. Fourth, the Act introduced broad "compulsory licensing" provisions, under which a patent was deemed to be a "license of right" three years after its grant. From that time until a patent expired, anyone could use the patented process by paying a royalty. These new rules effectively ended patenting for foreign pharmaceutical products in India, and created the conditions for a thriving industry in generic production of those products. Indian generic versions of global brands such as Lipitor, Pfizer's top selling cholesterol drug, and Eli Lilly's popular anti-depressant, Prozac, were manufactured and sold in India within two years of their introduction in the United States.

This patenting regime continued until 1995, when India became a founding member of the World Trade Organization (WTO) and accepted in principle the rules of the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS). In practice, India has continued to provide patent protections for pharmaceutical products which fall far short of those guaranteed in the United States and other OECD nations. Under the terms of its WTO membership, India was granted a 10-year transition period to implement the pharmaceutical patent protections stipulated under TRIPS.[59] During this transition period, India agreed to provide a "mailbox facility" for applicants to file patent applications, provide those applicants a filing date, and extend exclusive marketing rights for certain mailbox applications filed during the transition period.[60] India enacted the Patents Acts of 1999 to comply with these requirements, after the United States filed a complaint with the WTO alleging India's non-compliance, and the WTO ruled against India.[61]

In 2002, India amended the 1999 patent law to provide a 20-year term of protection for all pharmaceutical patents, as mandated by TRIPS, starting at the conclusion of the transition period in 2005. In that year, however, India enacted new provisions for the compulsory licensing of patented pharmaceuticals in India, as well as other restrictions on IP rights. Under these provisions, Indian pharmaceutical producers can apply for a license to produce the patented treatments of other companies three years after the patent was granted, when the "reasonable requirements of the public" regarding the treatment have not been satisfied, or the treatment is not available at a reasonable price, or it is not "produced" in India.[62] The amendments also provide for the immediate issuance of a compulsory license to address a "public health emergency" or when the applicant intends to export the patented treatment to other countries with insufficient manufacturing capacity to address their public health concerns.[63] These provisions, still in place, account for much of India's low ranking on indexes of IP rights.

Indian authorities also have sought and secured additional exceptions and qualifying provisions to western patent laws and practices. For example, the United States, the European Union (EU) and western pharmaceutical firms interpret TRIPS as requiring certain years of "data exclusivity." Under this requirement, the data submitted by a patent applicant, once accepted by the patent authority, cannot be used to approve a generic form of the same treatment for some specified period — five years as in the United States or 10 years in EU. India, however, has adopted a "calibrated approach" that seeks to balance TRIPS requirements for data exclusivity

[59] TRIPS, Article 65.4.
[60] TRIPS, Arts. 70.8(a) and 70.9.
[61] WTO (1998).
[62] India Patents Act 2005, 84.
[63] India Patents Act 2005, 92-A.

against India's "national interest" in enhancing access to patented treatments by promoting the domestic generics industry. Under this approach, pharmaceutical data receive minimal protection for an unspecified transition period, and only after that period can the patenting producer claim five years of data exclusivity. In addition, all derivatives of known substances are considered non-patentable unless the applicant can show that the derivative is significantly more efficacious than the original substance. Under this controversial provision, Indian courts denied a patent to the treatment Glivac, which Novartis has patented in all western countries.

In summary, while India claims to comply with the requirements of the WTO and TRIPS, many foreign pharmaceutical producers view the country as an unfriendly environment and market for their patented products and FDI. Novartis has said publically that it located its new research institute in Singapore instead of India out of concerns about patent protection, and invested in a research institute in Shanghai because China is more committed than India to improving its IP rights and protections. More generally, a survey by Ernst and Young and the *Economist Magazine* found that more than 62 percent of multinational pharmaceutical companies consider threats to their intellectual property the most serious risk associated with doing business in India.[64] Similarly, a PriceWaterhouse Coopers study reported that 60 percent of multinationals operating in Asia cited law IP protections as the most important reason to consider leaving the region, and more than 50 percent cited unfair competition from generic brands in violation of IP rights as a major deterrent to foreign direct investments there.[65]

V. Foreign Direct Investment in India, 1991-2012

Next, we examine flows of FDI into India since 1991, when the Indian government first liberalized the economy following a serious balance of payments crisis. This initial liberalization brought substantial changes to the country's pharmaceutical industry, including an end to public monopolies for the production of certain drugs and requirements that bulk drug production adhere to certain ratios. The New Delhi government also reduced the number of drugs subject to state price controls from 347 in 1970 to 74 in 1995. Finally, the government sharply reduced its regulation of FDI in pharmaceuticals: In addition to easing approval requirements and limits on foreign equity holdings in the sector, the program removed most export requirements, technology transfer clauses, and employment and training requirements for pharmaceutical producers. Today, India has an automatic approval process for foreign pharmaceutical firms operating in the country and permits them to fully own Indian pharmaceutical companies.[66]

These measures did not bring about sharp increases in FDI for the pharmaceutical industry in India. Our analysis of those FDI flows draws on data from the annual reports of the Department of Industrial Policy and Promotion of the Ministry of Commerce and Industry, which provide monthly and annual data on FDI flows in and out of India,[67] These reports show the sectors with the largest FDI inflows and their cumulative FDI since the 2000s.[68]

[64] Shared Expertise Forums (2005).
[65] PriceWaterhouse Coopers (2007).
[66] Husain (2011).
[67] Department of Industry Policy and Promotion, FDI statistics (various years).
[68] The annual reports did not include data for sectors for 1991, which we secured directly from the Department.

Table 1, below, presents the data on total FDI to India and FDI in the "Drugs and Pharmaceutical Sector" covering the years from 1991 to 2012. These data measure FDI flows from April 1st of one year to March 31st of the next year. The data on FDI in pharmaceuticals include total equity flows, less reinvested earnings and portfolio investments, which provides the best measure of capital inflows for physical investments. The original data are presented in both rupees and dollars, to ensure that exchange rate fluctuations do not obscure any underlying trends. The data on FDI in drugs and pharmaceuticals, as a share of all FDI, are based on dollar values, but the results using rupees were nearly identical.

Table 1: FDI and FDI in Pharmaceuticals in India, 1991-2013

Year	Total FDI (Rupees Crore)	Total FDI (US $ million)	Pharmaceutical FDI (Rupees Crore)	Pharmaceutical FDI (US $ million)	Pharmaceutical FDI as a Share of All FDI
1991-92	409	167	11.33	4.63	2.77%
1992-93	1,094	394	9.6	3.46	0.88%
1993-94	2,018	656	155.3	50.47	7.70%
1994-95	4,312	1,373	31.71	10.1	0.74%
1995-96	6,916	2,037	176.92	52.1	2.56%
1996-97	9,654	2,751	172.03	49.03	1.78%
1997-98	13,548	3,739	118.55	32.72	0.88%
1998-99	12,343	3,066	103.98	25.83	0.84%
1999-00	10,311	2,409	220.32	51.47	2.14%
2000-01	10,368	2,463	160.29	35.94	1.46%
2001-02	18,486	4,065	355.56	77.94	1.92%
2002-03	13,711	2,705	191.58	40.07	1.48%
2003-04	11,789	2,188	500.99	108.91	4.98%
2004-05	14,653	3,219	1,348.83	293.36	9.11%
2005-06	24,613	5,540	759.7	172.44	3.11%
2006-07	70,630	12,492	1,012.84	224.2	1.79%
2007-08	98,664	24,575	1,351.68	340.35	1.38%
2008-09	123,025	31,396	20,614.14	4,246.76	13.53%
2009-10	123,120	25,834	1,006.29	213.08	0.82%
2010-11	88,520	21,383	961.09	209.38	0.98%
2011-12	165,146	35,121	14,605.03	3,232.28	9.20%
2012-13	121,907	22,423	6,011.49	1,123.46	5.01%

Several trends in these data almost certainly reflect the IP-related policy changes associated with India's membership in the WHO and its adoption of TRIPS requirements. In the early years of liberalization and before India joined the WTO, 1991-to-1995, FDI flows in drugs and pharmaceuticals averaged a modest $17.2 million per-year and totaled just $68.7 million, with $50.5 million of that total occurring in 1993-1994. With India's entry into the WTO in 1995, FDI increased substantially: From 1995 to 2005, over the course of India's 10-year transition to TRIPS requirements, these FDI inflows averaged $73.7 million annually, an increase of more than four-fold compared to 1991-1995. Furthermore, over the seven years since India adopted the TRIPS requirements, 2005-2006 to 2012-2013, FDI in the drugs and pharmaceutical sector averaged $1,220.2 million annually and totaled $9,762.0 million.

These large increases in FDI inflows to the drugs and pharmaceutical sector clearly coincide with changes in IP rights and protections in India, with the significant increases in 2003-2004 and 2004-2005 anticipating the changes coming in 2005 with the end of the transition to TRIPS requirements. FDI in drugs and pharmaceuticals as a share of all FDI also appear to reflect India's decision to adopt the TRIPS standards. From 1991 to 2003, FDI in the sector represented an annual average of 2.1 percent of all FDI inflows to India. From 2003 to 2013, the sector's share of all Indian FDI inflows more than doubled, to an annual average of 5.0 percent. As a result, the average annual growth rate of drug and pharmaceutical FDI increased from 21.6 percent for the period from 1991 to 2003, to 29.6 percent for the period since 2003. India's agreement to comply with WTO rules and regulations, and especially to accept the IP standards of TRIPS, have clearly been important factors driving drug and pharmaceutical FDI to India.

The FDI in India's drugs and pharmaceuticals sector since 2005, however, has occurred in an environment in which multinationals have become increasingly uncertain about the extent of India's commitment to WTO TRIPS regulation. While it is difficult to precisely estimate the impact of this uncertainty on FDI flows, we can observe how foreign investors reacted to anticipated and actual changes in India's IP regime. The data show clearly, for example, that FDI to the drugs and pharmaceutical sector increased sharply starting in 2003, in anticipation of the end of the transition period to WHO-TRIPS standards: From 2003 to 2004, FDI flows increased 171 percent, rising from $40 million to $108.9 million; and from 2004 to 2005, those flows jumped another 169 percent. (Table 1, above) However, following several legal controversies over patent protections in 2005, FDI flows to the sector declined from $293.4 million in 2005 to $172.4 million in 2006.

Since that time, FDI inflows in this sector have moved up and down with foreign investors' concerns about a series of Indian patent rulings against multinational pharmaceutical companies and India's general compliance with WTO-TRIPS. For example, these foreign investments in India jumped more than 11-fold in 2008-2009, and then fell even more sharply in 2009-2010 and remained depressed in 2010-2011 while the Indian Pharmaceutical Alliance challenged 81 patents granted by India's patent office since 2005. The same pattern was repeated with large increases in FDI in 2011-2012, followed by another steep drop in 2012-2013. One-third of those patent challenges involved the top three multinational drug producers (Pfizer, Novartis AG and Eli Lilly and Company).[69] In addition, the Indian government is this period recommended compulsory licensing for a number of patents held by foreign companies, such as Bristol-Myers Squibbs anti-cancer drug Sprycel, and rejected a number of patent applications by the same producers, such as Roche's application for the anti-breast cancer drug Herpetin.

The evidence shows that while India's acceptance of the WTO-TRIPS rules and regulations has encouraged FDI in pharmaceuticals, uncertainties about the depth and extent of that acceptance have held back greater FDI. This is also suggested by data on mergers and acquisitions, strategies that can provide foreign firms with a way to claim some of the IP-related benefits of a domestic firm. Foreign-based companies did not undertake significant mergers or acquisitions of Indian pharmaceutical firms until India accepted the WPO-TRIPS requirements for IP. Since those requirements came into force in 2005, however, foreign companies have taken over at least seven large Indian pharmaceutical firms: In 2006, U.S.-based Mylan

[69] Unnikrishnan (2010).

purchased Matrix Labs; in 2008, the Dabur Pharma was bought by Singapore-based Fresenius, Kabi purchased Dabur Pharma, and Japan's Diachii Sankyo took over Ranbaxy; in 2009, Sanofi Aventis of France bought Shantha Biotech, and the US-based Hospira took over Orchid Chemicals; and in 2010, Piramal Healthcare was purchased by the U.S. firm Abbot Laboratories.

Projecting Future FDI in India's Pharmaceutical Sector

Projecting the future path of these FDI flows is challenging, since the contradictions and conflicts between India's formal international commitments on IP and its administration of patent law have bred continuing uncertainty. We will use the following methodology to place upper and lower bounds on our estimates of the future growth of pharmaceutical FDI flows to India. We construct a lower bound based on the historical data: Over the period preceding India's acceptance of TRIPS, from 1991 to 2003, these flows grew at an average annual rate of 22 percent. The upper bound is more difficult to construct, since it should represent the FDI which could flow into the pharmaceutical industry if India improved its administration and enforcement of IP rights. Since 2003, Indian FDI in pharmaceuticals has increased at an average annual rate of 30 percent, a rate which incorporates the uncertainties that foreign investors have faced in this period even under TRIPS. If we focus on the period from 2002 to 2006, when investors simply anticipated the switch to a TRIPS-based regime, these FDI flows grew at an average annual rate of 63 percent.

We also can estimate an upper bound to these future flows by drawing on indices of IP rights and protections by country. For example, the Ginarte-Park (G-P) index ranks countries on the strength of their IP protections, especially their patent protections.[70] The G-P index is the un-weighted sum of five separate scores for 1) coverage (inventions that are patentable); 2) membership in international treaties; 3) duration of IP protection; 4) enforcement mechanisms; and 5) limitations or restrictions (for example, compulsory licensing when a government deems that a patented invention has not been exploited sufficiently). In the most recent G-P index (2010), India scored 3.76 out of a possible 5.00. India's G-P score has improved sharply since 1960, when it scored 1.03 out of 5.00, with most of the improvements occurring since India signed on to the WTO in 1995. Relative to the other BRIC countries, India scored higher than Brazil (3.43) and Russia (3.68), and lower than China (4.21). For additional reference, the United States scored 4.88 in 2010. Another index, the GIPC Index published by the Global Intellectual Property Center of the U.S. Chamber of Commerce, ranks the IP regimes of various countries based on 1) patent protections; 2) copyright and trademark protections; 3) enforcement; and 4) membership and ratification of international treaties.[71] In 2012, India ranked eleventh out of 11 countries, with a GIPC score of 6.24 out of a possible 25.00.

We can use these indexes to estimate FDI flows into India's pharmaceutical sector if its average value were closer to the averages for China or the United States, once we establish the relationship between a country's score and its FDI flows. The OECD studied that relationship using the Ginarte-Park Index and found that a 1 percent change in a country's IP rights enforcement, as measured by the G-P Index, was associated with a 2.8 percent increase in its FDI flows. Following this finding, for India to raise its G-P patent rights index score to the level of

[70] Park (2008).
[71] US Chamber of Commerce (2012).

China or the United States, it would have to upgrade its IP regime by 12 percent and 30 percent, respectively.[72] Based on the OECD study, a 12 percent improvement in India's G-P index score should lead to a 33 percent increase in IP rights-sensitive FDI, and a 30 percent improvement should produce an 83 percent increase in this FDI. In short, India could substantially increase its FDI flows in pharmaceuticals and other patented product industries by upgrading its IP regime to the level of China or, optimally, to the level of the United States.

We adopt these two levels as the lower (33 percent) and upper (83 percent) bounds of average annual growth of future FDI flows to India's pharmaceutical sector, if India took steps to upgrade its IP regime. However, we cannot create a meaningful baseline for measuring how much additional FDI one could expect under the lower and upper bounds of improvement, using a simple arithmetic average, because FDI flows to India in pharmaceuticals have been so volatile, year to year. (Table 1, above) To smooth out this volatility, we use five-year averages covering the entire period, from 1992-1993 to 2009-2013, with an average annual growth rate of 28.9 percent. This analysis suggests that compared to its current path, India could increase FDI into its pharmaceutical sector over the rest of this decade (2013-2020) by more than $4.2 billion or 17.0 percent by adopting an IP regime equivalent to China, and expand this FDI by $143.2 billion or nearly five-fold by applying the strict enforcement of IP rights seen in the United States. (Table 2, below)

Table 2: Estimated FDI in Drugs and Pharmaceuticals to India with Current IP Rights, and with Moderate to Strong Improvements in those Rights ($ millions)

Years	Current Growth (28.9% annual growth	Moderate Improvement: 33% annual growth	Strong Improvement: 83% annual growth
2013-2014	$1,448	$1,494	$2,056
2014-2015	$1,867	$1,987	$3,762
2015-2016	$2,406	$2,643	$6,885
2016-2017	$3,102	$3,515	$12,600
2017-2018	$3,998	$4,675	$23,058
2018-2019	$5,153	$6,218	$42,195
2019-2020	$6,642	$8,270	$77,217
Total	**$24,616**	**$28,802**	**$167,773**

VI. The Availability of Patented Pharmaceuticals In India

India's limitations on the IP rights of patented pharmaceuticals developed by foreign firms have had significant effects on related flows of FDI, including FDI devoted to pharmaceutical R&D. These lower levels of FDI in this area, in turn, have limited the availability of new patented treatments in India. As a result, India's current IP regime affects the health of many Indians. These effects can be seen in the availability of patented treatments for conditions which are important drivers of mortality rates among Indians, especially the availability of newly-developed drugs. As we will see, the health-related costs of India's current

[72] Moving from a score of 3.76 to 4.21 or 4.88 represents a 12 percent or 30 percent change in the index.

IP regime also can be evaluated by estimating the benefits which could be derived from reforming that regime.

India's Health Profile

The World Health Organization (WHO) estimates that India accounts for 21 percent of the worldwide burden of disease.[73] WHO's country health profile for India shows, for example, that maternal, infant and childhood mortality rates are all higher in India than in the other BRIC countries. The leading causes of deaths among infants and children under age five, in descending order, are pneumonia, premature birth, diarrhea, birth asphyxia, other neonatal and congenital illnesses, injuries, measles, HIV/AIDS, and malaria.[74] While the nation has made advances in addressing many communicable diseases, including major progress in eradicating polio, rapid changes in the lifestyles of tens of millions of Indians have increased the incidence of many serious non-communicable diseases, including cardiovascular and cerebrovascular diseases, metabolic diseases, cancers, and mental illnesses. WHO's most recent accounting show that more than half of all deaths in India are attributable to non-communicable diseases. Table 3, below, lists major causes of death among Indians in 2008.

Table 3. Major Causes of Mortality, India, 2008[75]

Disease	2008	Percent of Total
All Communicable Diseases	**3,673,600**	**37.1%**
Tuberculosis	279,700	2.8%
HIV/AIDS	184,900	1.9%
Diarrheal Diseases	1,086,100	11.0%
Respiratory Infections	680,200	6.9%
Childhood cluster Diseases	222,000	2.2%
Maternal Conditions	62,800	0.6%
Perinatal Conditions	727,00	7.4%
All Non-Communicable Diseases	**5,241,400**	**53.0%**
Respiratory diseases	1,090,800	11.0%
Digestive Diseases	243,600	2.5%
Diabetes	176,700	1.8%
Neuropsychiatric conditions	142,400	1.4%
Cardiovascular Diseases	233,100	2.4%
Other	**979,700**	**9.9%**
Total Deaths	**9,894,700**	**100.0%**

Trends in Patenting of New Drugs and Pharmaceuticals in India

Greater access by Indians to the latest treatments for the leading causes of death almost certainly would produce substantial economic and social benefits. The Indian Patent Office reports that the number of Indian patents for new pharmaceuticals has trended upward since the late 1990s, averaging 807 new patents per-year over the 2006-to-2011 period compared to an

[73] WHO (2012A).
[74] WHO (2012).
[75] WHO (2013).

average of 340 patents annually for 2001-to-2006 and 256 per year for 1997-to-2001. (Table 4, below) However, pharmaceutical patents have increased at a slower rate than patents in other areas, so they account for a shrinking share of all patents. From 1997 to 2005, drugs represented an average of 16.4 percent of all patents issued each year; since 2005, that share has fallen to 8.8 percent, or by nearly half. This decline reflects both India's shift from process-based to product-based patents, and the reluctance of many foreign-based pharmaceutical firms to make their most advanced treatments available in India.[76]

Table 4: Patents Granted in India for Pharmaceutical Products, 1997-2011[77]

Year	Total Patent Grants	Drug Patent Grants	Drug Patents as a Share of All Patents
1997-1998	1,844	291	15.8%
1998-1999	1,800	150	8.3%
1999-2000	1,881	307	16.3%
2000-2001	1,318	276	20.9%
2001-2002	1,591	320	20.1%
2002-2003	1,379	312	22.6%
2003-2004	2,469	419	17.0%
2004-2005	1,911	192	10.1%
2005-2006	4,320	457	10.6%
2006-2007	7,539	798	10.6%
2007-2008	15,316	905	5.9%
2008-2009	16,061	1,207	7.5%
2009-2010	6,168	530	8.6%
2010-2011	7,509	596	7.9%

Foreign pharmaceutical producers continue to provide the vast majority of new treatments used in India. While indigenous Indian production accounts for 95 percent of the drugs used in India, foreign-based firms dominate patent grants in new pharmaceuticals and drugs. The Indian IPO issued 3,488 pharmaceutical patents from April 2005 through March 2010, for example, and more than 3,000 of those patents were granted to foreign–based firms.[78] Similarly, foreign-based firms were awarded 771 of the 1001 patents granted for new pharmaceuticals and drugs from April 2010 through March 2013.

The R&D conducted by foreign pharmaceutical firms active in India is highly concentrated in areas which coincide with the major health concerns of developed countries.[79] Almost 96 percent of all research activities undertaken by these firms from 1999 to 2009 focused on non-communicable diseases, including cardiovascular diseases, cancers, diabetes and metabolic diseases. Communicable diseases, including such major burdens for India as malaria and tuberculosis, were subjects of less than 2 percent of their R&D projects, while parasitic

[76] Under the old rules, a firm could claim a patent by slightly modifying the way a molecule is synthesized, so several generic firms could hold separate patents for producing the same drug.
[77] Office of the Controller General of Patents, Designs, Trade Marks and Geographic Indication, (2011).
[78] Unnikrishnan (2013).
[79] Abrol *et al*. (2011).

diseases also common in India, such as leprosy, diarrhea and leishmaniasis, accounted for 2.5 percent of the projects.

These data contain certain positive trends. Since India's formal transition to TRIPS in 2005, these firms have devoted more R&D to communicable and parasitic diseases. Further, of 186 clinical trials undertaken in India from 2007 to 2009 by both foreign and domestic firms, 11 involved treatments for communicable and parasitic conditions.[80] Since TRIPs, both domestic and foreign firms have intensified their commitments to R&D. R&D investments as a percentage of domestic firms' sales, their "R&D intensity," increased from less than 3 percent in 2003 to 5.35 percent in 2006 and averaged 4.91 percent from 2005 to 2010. (Table 5, below) Similarly, the R&D intensity of foreign-based firms in the Indian market increased from 0.71 percent in 2003 to 4.01 percent in 2010, averaging 2.90 percent from 2005 to 2010. Their increased R&D in India is also evident in their FDI, which increased from an average of $42 million per-year from 1995 to 2003, to $800 million per-year for 2004-2010. Even setting aside 2009, a year with unusually large FDI, their average annual investments in India increased from $42 million in the first period to $225 million in the second period. Yet, there also is cause for some concern that these activities could decline in the future. For example, Hoechest recently reduced its R&D investments in India, and Ciba-Geigy closed its large R&D center in India.

Table 5: R&D Intensity in Indian Pharmaceutical Sector, 1995-2010[81]

Years	R&D Intensity Domestic Companies	R&D Intensity Foreign Companies	FDI ($ million)
1995	1.34	0.77	$10.10
1996	1.71	0.91	$52.10
1997	1.55	0.95	$49.03
1998	1.43	0.88	$32.72
1999	1.56	0.70	$25.83
2000	1.56	0.66	$51.47
2001	2.30	0.72	$35.94
2002	2.64	0.65	$77.94
2003	2.93	0.71	$40.07
2004	3.81	1.10	$108.91
2005	4.98	1.63	$293.36
2006	5.35	2.39	$172.44
2007	5.01	2.67	$224.20
2008	4.78	2.86	$340.35
2009	4.89	3.84	$4,246.76
2010	4.50	4.01	$213.08

Pharmaceutical R&D and FDI in India

We further analyzed these data on R&D and FDI and found a correlation between R&D intensity and FDI by foreign pharmaceutical firms in India of 0.50. The analysis shows that an

[80] *Op.cit*.
[81] Bulk Drug Manufacturer's Association of India (2011).

increase in FDI is followed on average by an increase in R&D investments, with an elasticity of 0.44 with respect to FDI. Applying these results to our earlier projections of FDI for 2014-2020 (Table 2, above), we can estimate how much pharmaceutical R&D in India should increase, if India were to attract more FDI by improving its IP protections.

If India adopted an IP regime as strict as China's, and pharmaceutical FDI grew 33 percent annually, pharmaceutical R&D in India should grow 13 percent per-year. Similarly, if India's IP enforcement were as strict as the United States, and FDI grew 83 percent annually, related R&D would grow 33 percent per-year. Table 6, below, presents our estimates of future FDI and R&D by foreign pharmaceutical firms in India, if India adopted IP protections at the same level as China or the United States.[82]

Table 6: Projected FDI and R&D by Foreign Drug Producers in India, 2014-2020, If India Upgraded its IP Protections to the Level of China or the United States ($ millions)

Year	FDI under China's IP Regime	FDI under the U.S. IP Regime	R&D under China's IP Regime	R&D under the U.S. IP Regime	Increase in R&D under China's IP Regime	Increase in R&D under the U.S. IP Regime
2014	$1,494.2	$2,055.9	$645.4	$759.6	$74.3	$188.5
2015	$1,987.3	$3,762.4	$729.3	$1,010.3	$83.9	$250.7
2016	$2,643.1	$6,885.1	$824.1	$1,343.6	$94.8	$333.4
2017	$3,515.3	$12,599.8	$931.2	$1,787.1	$107.1	$443.4
2018	$4,675.4	$23,057.5	$1,052.3	$2,376.8	$121.1	$589.7
2019	$6,218.3	$42,195.3	$1,189.1	$3161.1	$136.8	$784.3
2020	$8,270.3	$77,217.4	$1,343.6	$4,204.2	$154.6	$1,043.2
Total	**$28,803.9**	**$167,773.4**	**$6,715.0**	**$14,642.7**	**$772.6**	**$3,633.2**

Upgrading India's IP protections to the level of China, therefore, would increase pharmaceutical R&D by foreign firms in India by an estimated $773 million over the next seven years, and providing IP protections at the level of the United States would expand that R&D by more than $3.6 billion over that period. If the enhanced R&D were targeted to the diseases that impose large burdens on India, which thus far have received scant R&D investment by Western drug producers, we could see substantial improvements in the health of the Indian people.

In addition, greater R&D by foreign firms in India would also benefit Indian pharmaceutical companies. The Standing Committee on Commerce noted in a 2013 report to the Indian parliament that very few Indian drug companies focus on developing new chemical entities, and their breakthroughs are rare. Innovation by Indian pharmaceutical companies has been limited largely to process chemistry and reverse engineering capabilities, leaving them dependent on foreign manufacturers for drug discovery. Those domestic firms intent on

[82] R&D historical data are available only through 2010, so we constructed an estimate of baseline R&D in 2013 by applying the 0.44 elasticity of R&D to FDI to the percentage change in FDI from 2010 to 2013. Using these estimates, we project baseline R&D expenditures in 2013 of $571.12 million. FDI increased 427 percent from 2010 to 2013 ($213.1 million to $1,123.5 million), so the percentage increase in R&D expenditures=4.27*0.44=1.88. Hence, the total increase in R&D = 1.88*197.86 + 197.86 = $571.12.

developing new products often also depend on foreign pharmaceutical producers. For example, a number of Indian pharmaceutical firms use a strategy called "out-licensing," in which they take the lead in the pre-clinical stages of development and hand off the rest of the process to a foreign company that gains the right to market the compound in particular markets. Using this out-licensing model, DRL has worked with Novartis on an anti-diabetic compound DRF 4158, Ranbaxy entered into a deal with Bayer for Cipro NDDS and RBx 2258, and Glenmark out-licensed compounds for the treatment of asthma with Forest of North America and Tejin of Japan.[83] An increase in R&D investment by foreign pharmaceutical companies operating in India, therefore, could support more of such joint development projects and expand the innovative activities of Indian drug companies.

VII. The Economic Benefits of Providing Strict IP Protections for Pharmaceuticals Produced by Foreign and Domestic Companies

Many researchers have analyzed the links between a nation's economy and the health of its people, in India and elsewhere. For example, a study by the Water and Sanitation program of the World Bank (2010) found that preventable illnesses caused by poor sanitation reduced India's GDP by 6.4 percent in 2006-2007.[84] Diseases that can be caused by poor sanitation – diarrhea, malaria, acute lower respiratory infections, measles, intestinal worms, and so on – are more likely to affect children and poor households, increasing the likelihood of premature death. The authors estimated that these diseases cost India more than $29 billion per-year simply due to premature mortality, another $4.8 billion in productivity losses, $4.7 billion more in unnecessary health care costs, as well as additional costs from work absenteeism and reduced tourism. Similarly, a 2006 study by WHO explored the economic impact for India of chronic conditions such as heart disease, stroke and diabetes.[85] The researchers found that these conditions reduced India's national income by some $9 billion in 2005, and the losses increased over time. Over the decade from 2005 to 2015, these costs are projected to total some $230 billion, equal to losses of 1.7 percent of GDP in 2005 and 5.04 percent of GDP in 2015.

Another World Bank study from 2010 analyzed the economic gains likely to accrue to India if it somehow eliminated all non-communicable diseases, including cardiovascular diseases, cancers, diabetes, stroke and asthma: The authors estimated that the gains would have increased the country's GDP in 2004 by between 5 percent and 10 percent.[86] Another recent analysis projected the economic costs to India of five major non-communicable diseases (cardiovascular disease, cancers, chronic respiratory diseases, diabetes, and mental illness) over an 18-year period (2012-2030).[87] The authors found that the undiscounted costs of these illnesses for India could total as much as $6.2 trillion over this period.[88]

These studies all point to the large economic benefits which India could secure – equivalent to 6 percent or more of the country's GDP – by investing in better and more

[83] Abrol *et al* (July 2011).
[84] World Bank (2010); Abegunde and Stanciole (2006); Mahal *et a*l (2010).
[85] WHO (2006).
[86] Mahal *et al*. (2010).
[87] Bloom *et al.* (2013).
[88] *Ibid.*

accessible treatments for the diseases that impose the largest burdens on India. With current GDP of $1.874 trillion, these analyses suggest that substantial improvements in health outcomes could raise India's GDP by some $110.5 billion per-year, a 6 percent increase. Moreover, this estimate may be quite conservative, since it covers only a handful of conditions, and because the economic benefits should accumulate over time.

The Economic Benefits Associated with IP Protections for Pharmaceuticals

There is no doubt that India would derive significant benefits from providing strict IP protections for pharmaceuticals, beginning with the increases in FDI and R&D by foreign pharmaceutical companies. Next, we will estimate some of the economic benefits associated with health improvements which could be traced to those increases in FDI and R&D in India.

This analysis begins with a 2013 accounting of the total economic costs associated with non-communicable diseases (NCDs), including accidents, in India in 2004.[89] In that year, NCDs resulted in the deaths of 4.8 million Indians, or 59.4 percent of all deaths; and 24 percent of those deaths involved individuals of prime working age (35-to-64 years old). These economic costs have three aspects, starting with the direct medical costs. In that regard, the National Sample Survey Organization reports that Indians in 2004 undertook nearly 2.5 billion outpatient visits and 30.6 million hospital stays, and 40 percent of the hospital stays and 35 percent of the out-patient visits involved NCDs. The study estimated those costs for NCDs at 400.31 billion Rupees, or $9.2 billion at 2004 exchange rates. (Table 7, below)

Illnesses and accidents involve other costs as well. In most cases, for example, medical care for Indians involves government subsidies for the medical expenditures. The 2013 study estimates that the subsidies for cases of non-communicable diseases cost the Indian government and taxpayers 111.7 billion rupees in 2004, or an additional $2.2 billion (Table 7, below). Finally, illnesses and accidents also impose indirect economic costs, when patients and sometimes their care givers are unable to work or at least unable to work full-time. The author of the study estimated those indirect economic costs for NCDs in 2004 at between 1,094 billion rupees and 1,113 billion rupees in 2004, or some $23 billion.

All told, the study found that non-communicable diseases in India imposed costs totaling about $34.5 billion in 2004. Its author also used his 2004 model to estimate costs of medical care, government subsidies and foregone income associated with non-communicable diseases in 2012: He calculated that NCDs cost India some $52 billion to $64 billion in 2012, or between 2.8 percent and 3.5 percent of the country's 2012 GDP of $1,842 billion.[90]

[89] Singh (2013).
[90] World Bank (2013).

Table 7: Economic Costs of Non-Communicable Diseases: Medical Care, Government Subsidies and Foregone Income, 2004 (Rupees billions)[91]

Disease	Medical Costs	Subsidies	Foregone Income	Total Costs
Heart Disease	58.18	23.92	144.0-158.0	226.1-240.1
Hypertension	44.0	6.62	199.0	249.62
Other Respiratory	30.64	7.80	87.0-92.0	125.4-130.4
Asthma	31.54	5.72	102.0-107.0	139.3-144.3
Joints and Pain	41.94	10.42	175.0	227.4
Kidney and Urinary	41.75	8.39	44.0-46.0	94.1-96.1
Neurological	28.97	7.98	61.0-62.0	98.0-99.0
Psychiatric	6.87	1.47	20.0-21.0	28.3-29.3
Diabetes	36.43	4.29	163.0	203.7
Cancers	26.38	13.38	64.0-79.0	103.8-118.8
Accidents	53.62	21.19	22.0-27.0	96.8-101.8

Given these large costs, reducing their incidence and/or severity should provide substantial economic savings, as well as human benefits. As noted earlier, innovative foreign pharmaceutical firms often forgo the Indian market for their most advanced treatments, or delay their introduction, out of concerns that India's IP regime will not prevent domestic generic producers from reverse-engineering the new product and selling the generic versions in both India and third-country markets. Under IP protections comparable to those in place in China or the United States, therefore, foreign pharmaceutical companies would launch new products in India more often and sooner.

Several studies have examined the benefits associated with the use of new pharmaceutical products as compared to older-vintage generic treatments. One study, for example, found that the costs of hospitalization and other non-drug medical expenditures declined when newer drugs replaced older drugs.[92] Another analysis used data on new drug launches in 52 countries over the period 1982 to 2000 and found that launches of new chemical entities accounted for almost 40 percent of the increase in longevity observed in those countries from 1986 to 2000, increases averaging 3 weeks per-year or almost 10 months in total.[93] The same study also found that delays in the launches of new treatments tended to reduce longevity.

To estimate the economic benefits of greater use of new pharmaceuticals in India, at least with regard to no-communicable diseases, we first examine the relationship between IP protections and new product launches in India. To establish this relationship, we analyze the correlation between the availability of new patented products in India and India's score on the Ginarte-Park IP index. Between 1995 and 2010, this score increased from 1.03 to 3.76, an improvement of 265 percent. Over roughly the same period, 1998 to 2011, annual patents grants for new pharmaceuticals in India increased from 291 to 596, a 105 percent increase. Based on these data and India's IP index scores, we find that the elasticity of changes in the availability of new patented treatments to improvements in IP rights in India is 0.39. The positive relationship between these two terms confirms that if India improves its IP regime, the availability of new

[91] *Ibid.*
[92] Lichtenberg (2002).
[93] Lichtenberg (2003.

patented pharmaceuticals will increase. The precise finding of 0.39, however, can only provide a reasonable approximation of how the availability of new treatments in India would change under a strict IP regime. Given the limited data, the new availability of patented products can only approximate new drug launches. In addition, the new Indian patents counted in this analysis include a modest number granted to domestic Indian pharmaceutical firms, as well as the great majority granted to foreign pharmaceutical firms in India.

Next, we examine the relationship between the availability of new pharmaceuticals and the survival rates from non-communicable diseases in India. The WHO country profile for India includes data on average life expectancy for each age cohort. We focus here on the increases in life expectancy from 1990 to 2011 for Indians age 30 to 64 years old. (Table 8, below) Over this period, for example, the average longevity of Indians in their forties increased approximately 4 percent, or nearly 1.2 years. Combining these data with the percentage increases in newly-available patented pharmaceuticals, we can say that the 105 percent increase in availability of patented treatments during this period was closely associated with a 4 percent increase in average life span.

Table 8: Life Expectancy at Ages 30 to 64, Indians of both Genders, 1900 and 2011

Age Cohort	Expected Years to Live		Increase, 1990-2011	Percentage Increase
	1990	2011		
30-34	40.19	41.66	1.47 years	3.66%
35-39	35.86	37.19	1.33 years	3.71%
40-44	31.58	32.81	1.23 years	3.89%
45-49	27.37	28.50	1.13 years	4.13%
50-54	23.34	24.33	0.99 years	4.24%
55-59	19.57	20.40	0.83 years	4.24%
60-64	16.24	16.68	0.44 years	2.71%

Based on this analysis, we begin to estimate the value of the health improvements associated with a strict IP regime for India. We found that India's 265 percent increase in the IP index led to a 105 percent increase in the availability of newly patented pharmaceuticals in India, and that these increases in the availability of patented treatments led to a nearly 4 percent increase in the average life span of Indians. India's score on the IP index would have to increase an additional 12 percent to reach China's score. Based on the relationships just described here, we estimate that a 12 percent improvement in IP rights in India would lead to a 5 percent increase in the availability of newly patented drugs; and that such increased access to new pharmaceuticals should lead to an four-week increase in the average life expectancy of working age Indians. Similarly, India's score on the IP index would have to increase an additional 30 percent to reach the score of the United States. We estimate that a 30 percent improvement in IP rights in India would lead to a 12 percent increase in the availability of newly patented treatments, and that such enhanced access to new pharmaceuticals should lead to an increase in the average life expectancy of working age Indians of ten weeks.

It is not possible to value precisely these increases in average lifespan associated with a stricter IP regime, but we can provide a reasonable approximation of the long-term economic value of everyone, on average, living longer. The long-term economic benefit of India adopting

an IP regime as strict as China should be roughly equal to the average income of Indians over one month, multiplied by the total working population in their working years. Similarly, the long term economic benefit of adopting IP protections as strict as the United States should be approximately equal to the average income of Indians over 2.5 months, times the total working population age 30 to 64.

To estimate the economic value of these longevity changes, in productivity and income gains, we used average wage data from the Annual Survey of Industries (ASI).[94] The average wage in 2010-2011, the latest year available, was 67,464 rupees. ASI also reports that from 2001-2002 to 2010-2011, wages grew at an average annual rate of 6.7 percent. Applying this growth rate since 2010-2011, we estimate that the average wage in 2012-2013 was 76,900 rupees, or an average weekly wage of 1,479 rupees. Next, we estimate the share of India's population age 30 to 64 that is working: The total population of that age is reported to be 434,285,350,[95] with a labor force participation rate of 57.7 percent,[96] or an employed population of 250,582,647 persons in the age group. Based on the 2012-2013 average wage, Indians age 30 to 64 generate economic value of some 370.61 billion rupees per-week, or $8.1 billion weekly. Therefore, we estimate the long-term economic value of extending the productive lifespan of working age Indians by four weeks, by adopting IP protections comparable to China, at 1,482.44 billion rupees, or $32.23 billion. Similarly, increasing by 10 weeks the average, productive life of working Indians age 30 to 64, associated with India adopting IP protections comparable to the United States, should produce an estimated, long-term economic value of 3,706.1 billion rupees or $80.6 billion. These values are provided in Table 9, below.

Table 9: Long-Term Economic Value of the Longer Life Expectancy Associated with Stricter IP Protections and Increased Access to Newly-Patented Treatments

Improvement in India's IP Regime	Increase in Newly Patented Treatments	Additional Life Expectancy	Long-Term Economic Value
12 percent (China)	5 percent	4 weeks	$32.2 billion
30 percent (U.S.)	12 percent	10 weeks	$80.6 billion

We can also estimate a range for the annual savings which greater access to newly patented treatment could generate based on lower medical costs, smaller government subsidies, and less foregone income. In principle, we could model these savings, given sufficient historic and current data. As those data are not available, however, we approach these issues in a more general way. For guidance, we turn to a 2002 landmark study which analyzed a range of economic benefits and savings arising from the introduction of new drugs.[97] Using data from the Medical Expenditure Panel Survey for the United States in the years 1996, 1997 and 1998, the study found that the introduction of new drugs led to higher drug and drug-related expenditures that averaged $18 per-case across medical conditions. Those additional costs were more than offset by reduced spending on hospitalizations, doctor visits and other non-drug expenditures, averaging together $129 per-case across conditions. Therefore, the introduction of a new pharmaceutical produced average net savings of $111 per-case. Based on average per-case

[94] Government of India (2013). "Annual Survey of Industry." Note that some service industries are covered as well.
[95] Government of India (2013-A).
[96] Index Mundi (2113).
[97] Lichtenberg (2002).

medical costs of $816, including all drug and non-drug expenditures, the introduction of a new pharmaceutical reduced associated medical costs by 13.6 percent. A similar analysis limited to the U.S. Medicare population found average savings of about 12 percent.

These results are derived from data reflecting U.S. health care arrangements and medical conditions. American healthcare arrangements and practices are much more advanced – and much more costly – and medical care is much more broadly available in the United States. Yet, Indian medical care involves broadly similar hospitals, clinics and doctor visits, and many generally similar procedures. So, it seems reasonable to speculate that the percentage savings in medical costs from greater access to newly patented pharmaceuticals in India would be similar to the percentage savings in the United States – and perhaps even greater. One reason that these cost savings could be greater is that India currently has access to many fewer newly patented drugs than the United States did in the late 1990s, so increases should have larger economic benefits.

Here, we will merely estimate the savings, if the introduction of newly patented pharmaceuticals in India leads to overall savings in medical care costs of 10 percent, 20 percent or 30 percent. (Table 10, below) While we present these estimates as across-the-board cost savings for our range of values, the actual cost reductions could be weighted more towards a decline in direct medical costs such as hospitalizations, doctor visits, procedures and supplies, or more towards greater reductions in foregone income as patients recover more quickly.

Table 10: Potential Cost Savings from Greater Access to Newly Patented Drugs ($ billions)

Potential Percentage Savings	Baseline Costs	Total Savings	Savings in Direct Medical Costs	Savings in Government Subsidies	Savings from Less Lost Income
10 percent	$52 - $64	$5.2 - $6.4	$1.39 - $1.71	$0.33 - $0.41	$3.47 - $4.27
20 percent	$52 - $64	$10.4 – $12.8	$2.78 – $3.42	$0.66 – $0.81	$6.94 – $8.54
30 percent	$52 - $64	$15.6 - $19.2	$4.16 - $5.12	$0.99 - $1.22	$10.4 - $12.8

By this broad accounting, the total annual cost savings from introducing more newly patented pharmaceuticals could range from $5.2 billion to $12.8 billion, and even as great as $19.2 billion per-year. These annual savings would represent between 0.28 percent and 0.68 percent of India's GDP, and perhaps as much as 1.02 percent of GDP. Moreover, these cost savings are based only on the incidence and costs of non-communicable diseases and accidents. The WHO reports that non-communicable diseases and accidents account for 62.9 percent of all deaths in India, with communicable diseases accounting for the remaining 37.1 percent. If the cost savings from increasing access to newly patented treatments for non-communicable diseases and accidents are comparable to the savings from increasing such access to new pharmaceuticals for communicable diseases, the additional annual cost savings would range from $3.1 billion to $7.6 billion, and even as great as $11.3 billion. All told, therefore, the annual cost savings from increasing access to newly-patented pharmaceuticals would range from an estimated $8.3 billion to $20.4 billion, and even as great as $30.5 billion. These annual savings would represent the equivalent of between 0.04 percent and 1.09 percent of India's GDP, and perhaps as much as 1.63 percent of GDP. Finally, these savings would come on top of the long-term economic benefits derived from longer life expectancy, which we estimated earlier at between $32.2 billion and $86.0 billion.

VIII. The Pharmaceutical Industry's Contributions to India's GDP and Incomes

In addition to the economic benefits associated with longer life expectancy and cost savings in direct medical costs, government subsidies and foregone income, the expansion of India's drugs and pharmaceutical sector from increased FDI in that sector would also generate broad macroeconomic benefits. To assess these benefits, we begin with the contribution of pharmaceutical FDI to India's GDP. These data are provided in Table 11, below, for the years 1991-2012.[98]

Table 11: Contribution of Pharmaceutical FDI to India's GDP, 1991-2012

Year	GDP (US $ millions)	Pharmaceutical FDI (US $ millions)	Pharmaceutical FDI as a Share of GDP
1991	$274,842	$4.63	0.002%
1992	$293,262	$3.46	0.001%
1993	$284,194	$50.47	0.018%
1994	$333,014	$10.1	0.003%
1995	$366,600	$52.1	0.014%
1996	$399,787	$49.03	0.012%
1997	$423,160	$32.72	0.008%
1998	$428,741	$25.83	0.006%
1999	$464,344	$51.47	0.011%
2000	$474,692	$35.94	0.008%
2001	$492,379	$77.94	0.016%
2002	$522,798	$40.07	0.008%
2003	$617,573	$108.91	0.018%
2004	$721,585	$293.36	0.041%
2005	$834,217	$172.44	0.021%
2006	$949,117	$224.2	0.024%
2007	$1,238,700	$340.35	0.027%
2008	$1,224,097	$4,246.76	0.347%
2009	$1,365,373	$213.08	0.016%
2010	$1,710,917	$209.38	0.012%
2011	$1,872,845	$3,232.28	0.173%
2012	$1,841,717	$1,123.46	0.061%

These data show, as expected, that the contribution of pharmaceutical FDI to India's GDP has generally been greater since India adopted the TRIPS standards: Over the nine years, 2004 to 2012, those FDI flows were equal to 0.08 percent of GDP on an average annual basis, compared to 0.01 percent for the 13 years 1991 to 2003. Nonetheless, FDI flows in the pharmaceutical industry remain very modest. Another measure is the net value-added of India's pharmaceutical sector as a share of GDP, a relevant measure because most FDI in this sector are

[98] World Bank Development Indicators database (2012). By some estimates, patented drugs accounted for 9.6% of total demand which is expected to reach 13.3% by 2014.

mergers and acquisitions, not "greenfield" investments. Put another way, what matters here for GDP is not only the flow of new foreign capital but also the contribution of the existing stock of capital.[99] These data show that the sector's contribution to GDP was generally stable from 2001 to 2011. (Table 12, below) These data confirm that there is large potential for India to increase its FDI inflows in pharmaceuticals, and for the sector to contribute a larger share of GDP.

Table 12: Contribution of the Pharmaceuticals Sector to India's GDP, 2001-2011[100]

Year	Sector's Net Value Added ($ million)	GDP ($ million)	Sector's Net Value Added As a Share of GDP
2001-2002	$6,391	$492,379	1.30%
2002-2003	$6,927	$522,798	1.32%
2003-2004	$7,785	$617,573	1.26%
2004-2005	$9,295	$721,585	1.29%
2005-2006	$11,031	$834,217	1.32%
2006-2007	$11,807	$949,117	1.24%
2007-2008	$15,527	$1,238,700	1.25%
2008-2009	$15,527	$1,224,097	1.31%
2009-2010	$16,012	$1,365,373	1.36%
2010-2011	$18,536	$1,492,379	1.26%

Capital Investment and Employment

We should expect that greater FDI in this sector would expand Indian employment, and the data show that employment in the sector has increased with capital investment. (Table 9, below) The data do not allow us to distinguish between employment at India's foreign versus domestic pharmaceutical firms, and the additional capital investment could be domestic or foreign. However, the potential employment gains from foreign investments are greater than those from domestic investment, because the domestic investments come from the pool of investment for all sectors in India, while the foreign investments come from the pool of capital available for investment in all countries.

To estimate the impact on employment and incomes from grater FDI in pharmaceuticals, we collected data from the Annual Survey of Industries (multiple reports) on total employment and total invested capital in the pharmaceuticals and chemicals sector of Indian manufacturing. These data are expressed in lakhs of rupees, and we did not convert them to US dollars, since we are looking for a correlation between physical capital investment in the sector and employment in the sector. (Table 9, below) In technical terms, the correlation between changes in capital investment and changes in employment is approximately 0.9 with an estimated elasticity of 0.34.

[99] These value-added data come from the Annual Survey of Industries database, the principal source of industrial statistics in India.

[100] Government of India, "Annual Survey of Industries" (2013). Changes in the industrial classification occurred over this period. In the NIC-98 classification, pharmaceuticals were absorbed into the broader chemicals industry group. In the NIC-2008 reclassifications, pharmaceuticals were classified as a separate 2-digit industry. To make the data comparable, we include other chemical industries when calculating value added in the years 2008 and later.

This means that a one percent increase in invested capital in this industry leads to a 0.34 percent increase in its employment. We also collected data on total wages and salaries in the industry, and those data show that increases in capital investment are followed by higher average wages and salaries as well as higher employment.

From 2001 to 2011, invested capital in India's pharmaceutical sector grew from 11,226,653 to 25,788,228 rupees lakh, or 129.7 percent. (Table13, below) Over the same period, employment in the sector grew by 338,911, or 44.5 percent. Finally, the average wage of those pharmaceutical workers, based on total employment and total wages, increased by 29,862 rupees, or 70.5 percent.

Table 13: Employment, Invested Capital, and Wages in India's Pharmaceutical Industry 2001-2011[101]

Year	Invested Capital (Rupees Lakhs)	Total Persons Employed	Total Wages (Rupees Lakhs)	Average Wage (Rupees)
2001-2002	11,226,653	761,244	322,239	42,331
2002-2003	10,727,608	755,113	317,359	42,028
2003-2004	11,151,487	740,441	320,829	43,329
2004-2005	11,487,184	784,907	349,582	44,538
2005-2006	14,580,229	825,435	377,083	45,683
2006-2007	16,292,375	877,083	424,533	48,403
2007-2008	17,367,578	892,944	471,355	52,787
2008-2009	21,627,600	960,136	557,129	58,026
2009-2010	22,697,284	1,003,372	626,126	62,402
2010-2011	25,788,228	1,100,155	794,239	72,193

The Employment and Wage Benefits of Stricter IP Rights and Enforcement in Pharmaceuticals

This analysis enables us to estimate the direct employment and wages benefits that should follow if India adopted a stricter approach to IP rights and enforcement. Earlier, we estimated the additional FDI that would flow to India's drugs and pharmaceutical sector if the country adopted IP protections comparable to those in China and the United States. To estimate the employment and income gains associated with such stricter protections, we first establish the share of total capital investment in the sector derived from FDI. Those data are presented in Table 14, below.

[101] *Ibid.*

Table 14: FDI as a Share of Total Invested Capital in India's Pharmaceutical Sector, 2001-2011

Year	Pharmaceutical FDI (Rupees lakhs)	Total Invested Capital (Rupees lakhs)	FDI's Share of Total Invested Capital
2001-2002	35,556	11,226,653	0.32%
2002-2003	19,158	10,727,608	0.18%
2003-2004	50,099	11,151,487	0.45%
2004-2005	134,883	11,487,184	1.17%
2005-2006	75,970	14,580,229	0.52%
2006-2007	101,284	16,292,375	0.62%
2007-2008	135,168	17,367,578	0.78%
2008-2009	2,061,414	21,627,600	9.53%
2009-2010	100,629	22,697,284	0.44%
2010-2011	96,109	25,788,228	0.37%

These data show that on an annual basis, FDI accounted for about 1.44 percent of total invested capital in India's pharmaceutical sector over the 10 years from 2001 to 2011. Earlier, we calculated that pharmaceutical FDI flows to India should grow at an annual rate of 33 percent if India adopted IP protections at the level of China, and at an annual rate of 83 percent if India adopted the strict IP regime of the United States. In the first case (China-level IP protections), the acceleration in FDI would expand total invested capital by 0.5 percent per-year; in the second case (U.S.-level protections), it would result in a 1.2 percent annual increase in total capital investment.

To estimate total invested capital for the years 2012-2020, we start by applying the historic 9.7 average annual growth of the capital to the data for 2010-2011, which gives us a value of 28,284,704 rupees lakh for 2011-2012. To project total invested capital under an IP regime comparable to China, we apply an average annual growth rate of 10.2 percent – the 9.7 percent historic growth, plus the additional 0.5 percent growth from the higher FDI in response to the stricter IP protections – to the 2011-2012 base. Similarly, to project total invested capital under an IP regime comparable to the United States, we apply an average growth rate of 10.9 percent (historic growth, plus additional 1.2 percent growth from the higher FDI in response to the much stricter IP protections).

To estimate the employment associated with the additional invested capital, we use the 0.34 elasticity of employment with respect to invested capital which we derived earlier. First we apply this value to employment for 2010-2011, and estimate employment for 2011-2012 of 1,136,711. We then apply the 0.34 elasticity to this base for future years, and estimate that the increases in pharmaceutical FDI and total invested capital under an IP regime comparable to China would lead to average annual employment gains of 0.17 percent per year (0.50 x 0.34 = 0.17) in 2012-2020. Similarly, the increases in FDI and total invested capital in India's pharmaceutical sector under an IP regime as strict as the United States would lead to average annual employment gains of 0.41 percent (1.2 x 0.34 = 0.41) for the years 2012-2020.

Finally, to estimate the average wage for those employed in the expanding sector for the years 2012-2020, we start by dividing the total wages paid to workers by the total number of persons employed over the entire period. This gives us a baseline average wage of 51,172 rupees. Next, we then apply the historic average annual growth rate of wages of 6.1 percent to estimate the new average wages for the years 2012-2020. Finally, we convert these wages to U.S. dollars at an exchange rate of 46 rupees to a dollar, the average exchange rate in 2010-2011.

The Results in Additional Employment and Higher Wages

We find that if India provided IP protections comparable to those currently provided by China, the total invested capital in the Indian pharmaceutical sector would increase from 28,284,704 rupees lakh in 2011-2012 to 61,432,079 rupees lakh in 2019-2020, or 117.2 percent. (Table 15A, below) Of this increase, 1,627,955 rupees lakh or about 5 percent can be attributed to stronger IP protections. Total employment in the industry over the same period would grow from 1,136,711 jobs to 1,597,626 jobs, an increase of 460,915 positions or 40.5 percent. Of this increase, 18,027 jobs or 4 percent is attributed to the stronger IP protections. Finally, the average wage in the sector would increase from 76,605 Rupees ($1,665.33) to 123,123 Rupees ($2,676.59), an increase of 46,518 Rupees or 60.7 percent.

Table 15A: Increases in Pharmaceutical Sector Employment and Incomes If India Adopted the IP Protections of China, 2011-2020

Year	Total Invested Capital (Rupees Lakhs)	Total Employment	Average Wage (Rupees)	Average Wage (U.S. $)
2011-2012	28,284,704	1,136,711	76,605	$1,665.33
2012-2013	31,164,279	1,186,119	81,286	$1,767.09
2013-2014	34,337,014	1,237,675	86,254	$1,875.09
2014-2015	37,832,756	1,291,471	91,525	$1,989.67
2015-2016	41,684,388	1,347,605	97,118	$2,111.26
2016-2017	45,928,142	1,406,180	103,053	$2,240.28
2017-2018	50,603,939	1,467,300	109,350	$2,377.17
2018-2019	55,755,764	1,531,077	116,033	$2,522.46
2019-2020	61,432,079	1,597,626	123,123	$2,676.59

We further find that if India provided IP protections comparable to the United States, the total invested capital in the Indian pharmaceutical sector would increase from 28,284,704 rupees lakh in 2011-2012 to 64,624,720 rupees lakh in 2019-2020, or 128.5 percent. (Table 15B, below) Of this increase, 4,007,840 rupees lakh or 11.0 percent can be attributed to stronger IP protections. Total employment in the industry over the same period would grow from 1,136,711 jobs to 1,627,261 jobs, an increase of 490,550 positions or 43.2 percent. Of this increase, 43,851 jobs or 8.9 percent is attributed to the stronger IP protections. Finally, the average wage in the sector would increase from 76,605 Rupees ($1,665.33) to 123,123 Rupees ($2,676.59), an increase of 46,518 Rupees or 60.7 percent.

Table 15B: Increases in Pharmaceutical Sector Employment and Incomes If India Adopted the IP Protections of the United States, 2011-2020

Year	Total Invested Capital (Rupees Lakhs)	Total Employment	Average Wage (Rupees)	Average Wage (U.S. $)
2011-2012	28,284,704	1,136,711	76,605	$1,665.33
2012-2013	31,362,272	1,188,847	81,286	$1,767.09
2013-2014	34,774,700	1,243,374	86,254	$1,875.09
2014-2015	38,558,424	1,300,403	91,525	$1,989.67
2015-2016	42,753,843	1,360,046	97,118	$2,111.26
2016-2017	47,405,751	1,422,426	103,053	$2,240.28
2017-2018	52,563,819	1,487,666	109,350	$2,377.17
2018-2019	58,283,120	1,555,899	116,033	$2,522.46
2019-2020	64,624,720	1,627,261	123,123	$2,676.59

IX. The Impact on FDI of Stricter IP Protections for Other Industries in India

India's weak enforcement of IP rights affects major sectors of the nation's economy. The U.S. Chamber of Commerce released a report in July 2013 describing India as an "International Outlier on IP" in terms of policy, regulation and the judiciary.[102] Similarly, the most recent index of IP rights from the Global Intellectual Property Center (GIPC), released in December 2012, ranks India last among the BRIC countries on virtually every indicator. While India's formal acceptance of TRIPS elevated its score on the Ginarte-Parks Patent Rights Index, the country remains substantially behind China, Taiwan, Singapore and many other Asian nations. And the Office of the United States Trade Representative (USTR) consistently includes India on its "Special 301 Report Priority Watch List" of countries notable for IP infringements, citing a weak legal framework and enforcement of IP rights, long backlogs in granting patents, the recent compulsory licensing decisions, and absence of protections to prevent unfair commercial use.

Since patent rights are important in many industries, stricter IP enforcement in India should encourage higher FDI flows across many sectors of the Indian economy. To gauge the potential dimensions of such an effect, we first will review the distribution of FDI inflows for selected industries, as reported by the Ministry of Commerce in a July 2013 report.[103] These data (Table 16, below) present the cumulative FDI flows from 2000 to July 2013 for the services sector, four manufacturing industries, and the drugs and pharmaceutical industry. We selected these industries based on the availability of data on their FDI flows, employment and output, which we apply later.

[102] US Chamber of Commerce (July 2013).
[103] Ministry of Commerce of India (July 2013).

Table 12: Cumulative FDI Flow to Selected Industries of the Indian Economy, 2000-2013[104]

Sector	Cumulative FDI ($ million)	Share of All FDI	Sector's Share of GDP
Services	$38,255	19%	56.5%
Manufacturing – Selected Industries			
Drugs and Pharmaceuticals	$11,320	6%	1.7%
Computer Software & Hardware	$11,906	6%	5.0%
Chemicals (other than fertilizers)	$9,235	5%	3.0%
Automobile Industry	$8,932	4%	7.0%
Metallurgical Industries	$7,697	4%	2.5%

Since many of the industries attracting substantial FDI are relatively large,[105] promoting greater FDI could have substantial effects on India's GDP and employment. For example, India's services sector – including such industries as banking, insurance, outsourcing, R&D, courier and technology testing – contributes almost 60 percent of the country's GDP. FDI in these areas has declined for a number of reasons, including government regulations capping the maximum investments that foreign companies can undertake, as well as the weak IP regime.[106]

To assess how improvements in IP rights and enforcement could affect FDI in these industries, and how greater FDI would affect total capital investment, output and employment, we return to the comparisons of India to China and the United States. Some of these industries, however, have historically grown much more slowly than the pharmaceutical sector. Therefore, instead of assuming that an industry's FDI would grow at a 33 percent annual rate under an IP regime comparable to China, and at an 83 percent rate under IP rights and enforcement comparable to the United States, we assume here that a stronger IP system would promote FDI inflows of 20 percent to 40 percent over 2012-2013 levels. Using these assumptions and data on FDI by sector from the 2013 annual report of the Department of Industrial Policy and Promotion (DIPP) of the Government of India, we can estimate FDI flows for these industries under a stricter IP regime. (Table 17, below)

We estimate that if India adopted IP protections that resulted in 20 percent annual growth in FDI, FDI would increase by nearly $1 billion per-year in services and by $755 million per-year across four manufacturing industries. If those IP protections resulted in 40 percent annual growth in FDI, FDI would increase by nearly $2 billion per-year in services and by $1.5 billion per-year across the four manufacturing industries.

[104] There are inconsistencies in India's reporting of the services sector, which may include construction and hotels and tourism. Unlike industry definitions in the United States, the Indian government's definition of its "Chemicals" industry does not include drugs and pharmaceuticals, as well as fertilizers.

[105] These data have been obtained from the ASI website, as well as the economic survey.

[106] For example, the government only recently raised the cap on foreign investment in in basic and cellular services companies from 74 percent to 100 percent; but only 49 percent of such an investment is automatically allowed while the rest must be approved by the Foreign Investment Promotion Board. Similarly, the cap on FDI in Indian insurance companies is 49 percent.

Table 17: Projected Annual FDI Flows Assuming 20 Percent and 40 Percent Increases in FDI From Improved IP Rights and Enforcement, Selected Industries (US $ million)

Sector and Industries	FDI 2012-2013	FDI with 20 Percent Annual Growth	FDI with 40 Percent Annual Growth
Services	**$4,833**	**$5,800**	**$6,766**
Manufacturing – Selected Industries			
Compute Software & Hardware	$486	$583	$680
Chemicals (other than fertilizers)	$292	$350	$409
Automobile Industry	$1,537	$1,844	$2,152
Metallurgical Industries	$1,466	$1,759	$2,052
Total, Selected Manufacturing Sectors	**$3,781**	**$4,536**	**$5,293**

The Indian government does not publish data on total capital investment for the services sector, and therefore we cannot examine how changes in total capital investment have affected the sector's employment. Instead, we will use FDI as a rough proxy for total capital investment and analyze how percentage changes in the FDI flows to these industries and sector since 2000 have affected their employment and output. Using data on FDI flows in 2000-2001 and 2010-2011 from the Department of Industrial Policy and Promotion and a 2010 report by the National Council of Applied Economic Research, we see that FDI to the services sector (including construction) and the metallurgical industry increased sharply over this period. (Table 18, below) FDI to the chemicals industry (which does not include pharmaceuticals and excludes fertilizers) increased substantially, and FDI inflows to the computer software and hardware industry and the automobile industry grew more modestly.

Table 18: FDI Inflows by Sector, 2000-2011 (US $ millions)

Sector and Industries	2000-2001	2010-2011	Percentage Change
Services, including Construction	$43.3	$8,357.0	19,200%
Manufacturing – Selected Industries			
Computer Software & Hardware	$194.0	$796.0	310%
Chemicals (other than fertilizers)	$125.2	$4,041.0	3,128%
Automobile Industry	$283.3	$923.0	226%
Metallurgical Industries	$15.3	$1,786.0	11,573%

To properly analyze how these percentage changes in FDI affected output and employment, we need output and employment data for each industry and sector. These data are available from the Indian government's Annual Survey of Industries for some industries, but not others. In addition, the government revised its industry classification system during the last decade, and disaggregated data at the three-digit industry level are unavailable for many industries. Therefore, we use the output and employment data from the 2012-2013 Economic Survey of India, which simply divided the economy into services and manufacturing.[107] (Table 19, below) Manufacturing includes power and construction as well as traditional manufacturing;

[107] Government of India, Economic Survey, Tables 1.3 and 1.3a (2013).

and services includes trade, hotels and restaurants, transport, storage and telecommunications, finance, insurance and real estate and community, social and personal services.

Table 19: FDI, Output and Employment, Services and Manufacturing, 2001-2011

Sector	FDI 2000-2001, $ million	FDI 2010-2011, ($ million)	Output 2001-2002, Rupees crore	Output 2010-2011, Rupees crore	Employment 2001-2002	Employment 2010-2011
Services	$214.9	$11,347.0	1,261,159	2,829,380	2,481,000	4,803,000
Manufacturing	$730.4	$9,198.0	585,971	1,284,941	980,000	1,720,000

With these data, we can calculate the response or elasticity of employment and output to changes in FDI.[108] We find that in the services sector, the elasticities of both output and employment to changes in FDI capital were 0.02; in manufacturing, the elasticity of output to changes in FDI capital was 0.10, and the elasticity of employment to FDI capital was 0.07.

Now we can apply these elasticities to the services sector and the four manufacturing industries presented earlier with their FDI inflows (Table 14, above). For example, the elasticity of FDI with respect to employment in manufacturing is 0.07, so if FDI under a stricter IP regime (as the proxy for invested capital under a stricter IP regime) grows 20 percent annually across manufacturing industries, those increases should produce 1.4 percent annual gains in employment in those manufacturing industries (0.07 x 0.20 = 0.014). The impact on output and employment is much greater in manufacturing than services.

This analysis suggests that if India adopted stricter IP rights and enforcement that result in 20 percent annual growth in FDI across the services sector and the four selected manufacturing industries, output in services would increase by 1,031,300 rupees lakh per-year, and output across the four manufacturing industries would increase by 1,832,853 rupees lakh. (Table 20A, below) Among the four manufacturing industries, chemicals and automobiles would experience the greatest gains, followed by metallurgical industries and computer software and hardware. Under an even stricter IP regime that results in 40 percent annual FDI growth, services output would increase by 2,061,600 rupees lakh, and the annual output of the four manufacturing industries would increase by 3,665,706 rupees lakh.

Applying an exchange rate of 46 Rupee = $1, IP reforms that result in 20 percent annual growth in FDI would add some $2.24 billion to annual service sector output, and $3.99 billion to the annual output of the four manufacturing sectors. We further estimate that IP reforms which result in 40 percent annual growth in FDI would lead to an increase in the output of Indian service industries of nearly $4.5 billion per-year, and increase the output of the four selected manufacturing sectors by nearly $8.0 billion.

[108] Again, these elasticities are proxies for the response of output and employment to changes in total invested capital.

Table 20A: Projected Annual Output Gains with Higher FDI Flows, Services Sector and Selected Manufacturing Industries, Rupees Lakh

Sector	Output, 2012	20% Annual FDI Growth		40% Annual FDI Growth	
		Percent Change	Additional Output /Year	Percent Change	Additional Output /Year
Services	257,816,500	0.4%	1,031,300	0.8%	2,061,600
Manufacturing (selected industries)	91,642,649	2.0%	1,832,853	4.0%	3,665,706
Computer Software & Hardware	10,872,089	2.0%	217,442	4.0%	434,884
Chemicals	35,229,032	2.0%	704,581	4.0%	1,409,162
Automobiles	30,044,070	2.0%	600,881	4.0%	1,201,762
Metallurgical Industries	15,497,458	2.0%	309,949	4.0%	619,898

Similarly, if India adopted stricter IP rights and enforcement that results in 20 percent annual growth in FDI across the services sector and the four selected manufacturing industries, employment in services would increase by 19,900 jobs per-year, and employment across the four manufacturing industries would increase by 31,452 jobs annually. (Table 20B, below) Among the four manufacturing industries, the automobile and metallurgical industries would see the greatest job gains, followed by chemicals and computer software and hardware. Under an even stricter IP regime that results in 40 percent annual FDI growth, services employment would increase by 39,800 jobs per-year and the employment gains in the four manufacturing industries would increase by 62,904 jobs annually.

Table 20B: Projected Annual Employment Gains with Higher FDI Flows, Services Sector and Selected Manufacturing Industries

Sector	Employment 2012	20% Annual FDI Growth		40% Annual FDI Growth	
		Percent Change	Additional Jobs/Year	Percent Change	Additional Jobs/Year
Services	4,975,000	0.4%	19,900	0.8%	39,800
Manufacturing (selected industries)	2,241,438	1.4%	31,452	2.8%	62,904
Computer Software & Hardware	229,208	1.4%	3,209	2.8%	6,418
Chemicals	630,017	1.4%	8,802	2.8%	17,604
Automobiles	715,550	1.4%	10,108	2.8%	20,216
Metallurgical Industries	666,663	1.4%	9,333	2.8%	18,666

IX. Conclusions

In a global economy with relatively free flows of investment and trade, among and between advanced and developing nations, all parties benefit from the strict enforcement of intellectual property rights. A strong IP rights regime encourages innovative companies to transfer new technologies and business methods to their subsidiaries in developing countries, through large foreign direct investments; and those investments spur the modernization process in those countries, generating new gains in productivity, growth, and employment.

For many years, India declined to enforce the traditional IP rights of foreign companies and, in turn, received little FDI. Those FDI flows increased when India joined the WTO in 1995

and transitioned to TRIPS standards in 2005. Yet, in the crucial pharmaceutical sector as well as other industries, India's enforcement of IP rights through its courts and regulatory bodies remains haphazard and uncertain.

Our research and analysis have established that if India moves to a stronger IP regime, with rights and protections comparable to China or even the United States, it will generate very large benefits for the Indian economy and people. FDI flows to India's pharmaceutical sector would increase sharply, as would its research and development activities. These increases in pharmaceutical FDI and R&D would expand the sector's output and employment. India's access to the world's most advanced pharmaceuticals also would increase, improving the health of Indians. In particular, average life expectancy would rise, creating large long-term economic gains, while the costs of health care and the government subsidies that support it would ease. Nor is the pharmaceutical industry unique in these respects: A stronger IP regime would also expand FDI, output and employment in much of India's service sector and manufacturing industries.

India has the opportunity to become a global center for pharmaceutical development and production; and more generally, it has the ability to attract FDI on the scale of its neighbor and competitor, China. If India is to approach such goals, and perhaps even achieve them, its government will have to embrace serious reforms that will strengthen the intellectual property rights of foreign companies in India.

References

Abegunde, Dele & Anderson Stanciole (2006). "An estimation of the economic impact of chronic non-communicable diseases in selected countries." WHO. http://www.who.int/chp/working_paper_growth%20model29may.pdf.

Abrol, Dinesh, Pramod Prajapati & Nidhi Singh (2011). "Globalization of the Indian Pharmaceutical Industry: Implications for Innovation." *International Journal of Institutions and Economics*, Vol. 3, No. 2, July 2011, pp. 327-365. http://ijie.um.edu.my/RePEc/umk/journl/v3i2/Fulltext8.pdf.

Aitken, Brian & Harrison, Ann (1999). "Do Domestic Firms Benefit from Direct Foreign Investment?" World Bank. http://siteresources.worldbank.org/INTTRADERESEARCH/Resources/544824-1282767179859/Venezuela.pdf.

Alfaro, Laura, Chanda, A., Kalemli-Ozcan, S., & Sayek S. (2000). "FDI and Economic Growth: The Role of Local Financial Markets." Harvard Business School. Working Paper 01-083.

Alfaro, Laura, Chanda, A., Kalemli-Ozcan, S., & Sayek, S. (2003). "FDI Spillovers, Financial Markets, and Economic Development." IMF Working Paper, pp. 1-33, September 2003. http://ssrn.com/abstract=880280.

Balasubramanyam, V.N., Salisu, M., & Sapsford, D. "Foreign Direct Investment and Growth: New Hypotheses and Evidence," Working Papers ec7/96, Department of Economics, University of Lancaster.

Bhadoria, Vikas, Bhajanka, A., Chakraborty, K., & Mitra, P. (2012). "India Pharma 2020: Propelling Access and Acceptance, Realizing True Potential." McKinsey & Co. 2012. http://online.wsj.com/public/resources/documents/McKinseyPharma2020ExecutiveSummary.pdf.

Blomström, Magnus, Globerman, S., & Kokko, A. (2000). "The Determinants of Host Country Spillovers from Foreign Direct Investment," CEPR Discussion Papers No. 2350.

Blomström, Magnus (1986). "Foreign Investment and Productive Efficiency: The Case of Mexico." *The Journal of Industrial Economics.* Vol. 35, No. 1 (Sep., 1986), pp. 97-110.

Blomstrom, Magnus, Kokko, A., & Zejan, M. (1995). "Host Country Competition and Technology Transfer by Multinationals," NBER Working Papers 4131, National Bureau of Economic Research, Inc. 1995.

Bloom, David E., Cafiero, E., McGovern, M., Prettner, K., Stanciole, A., Weiss, J., Bakkila, S., & Rosenberg, L. (2013). "The Economic Impact of Non-Communicable Disease in China and India: Estimates, Projections, and Comparisons." National Bureau of Economic Research. Working Paper No. 19335. August 2013. http://www.nber.org/papers/w19335.

Branstetter, Lee, Fisman, R., & Fritz Foley, C. (2005). "Do Stronger Intellectual Property Rights Increase International Technology Transfer?" National Bureau of Economic Research, Working Paper No. 11516, July 2005.

Bulk Drug Manufacturer's Association of India (2011). "Statistics." http://www.bdmai.org/statistics.php#Exports%20Composition%20of%20Pharmaceutical%20Industry.

Carkovic, Maria & Levine, Ross (2002). "Does Foreign Direct Investment Accelerate Economic Growth?" University of Minnesota Department of Finance Working Paper. June 2002. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=314924.

Cepeda, Ricardo H. Cavazos, Lippoldt, D. C., & Senft, J. (2010). "Policy Complements to the Strengthening of IPRS in Developing Countries." OECD. Trade Policy Working Paper No. 104, Sept 14 2010. http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=TAD/TC/WP%282010%2912/FINAL&doclanguage=en.

Claessens, Stijn & Laeven, Luc (2002). "Financial Development, Property Rights, and Growth." The World Bank, Policy Research Working Paper Series 2924, 2002.

Diwan, Ishac & Rodrik, Dani (1991). "Patents, Appropriate Technology and North-South Trade." *Journal of International Economics*, Vol. 29, No. 1, 1991.

Duggan, Mark & Aparajita Goyal (2012). "Pharmaceutical Patents and Prices: A Preliminary Empirical Assessment Using Data from India." World Bank Policy Research Working Paper No. 6063. May 1, 2012. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2054361&download=yes.

Durham, J. Benson (2003). "Foreign Portfolio Investment, Foreign Bank Lending, and Economic Growth." Federal Reserve Board International Finance Discussion Paper No. 757. July 2003. http://ssrn.com/abstract=382063.

Falvey, Rod, Greenaway, D., & Foster, N. (2004). "Intellectual Property Rights and Economic Growth." Internationalisation of Economic Policy Research Paper, No. 2004/12. http://ssrn.com/abstract=715982.

Fink, Carsten & Carlos A. Primo Braga (1999). "How Stronger Protection of Intellectual Property Rights Affects International Trade Flows." The World Bank, Policy Research Working Paper Series 2051, 1999.

Germidis, Dimitri A. (1977). "Transfer of Technologies by Multinational Corporations." OECD, Proceedings of the Development Centre of the Organisation for Economic Cooperation and Development.

Goldberg, Pinelopi Koujianou (2009). "Intellectual Property Rights Protection in Developing Countries: The Case for Pharmaceuticals." December 2009. http://www.econ.yale.edu/~pg87/Goldberg_Marshall.pdf.

Gould, D.M. & William C. Gruben (1996). "The Role of Intellectual Property Rights in Economic Growth." *Journal of Development Economics,"* Vol. 48, No. 2, 1996.

Government of India, Department of Industry Policy and Promotion, Ministry of Commerce & Industry, FDI Statistics. Various years. http://dipp.nic.in/English/Publications/FDI_Statistics/FDI_Statistics.aspx.

Government of India, Office of the Controller General of Patents, Designs, Trade Marks and Geographic Indication, (2011). "Annual Report 2010-2011." http://ipindia.gov.in/cgpdtm/AnnualReport_English_2010_2011.pdf.

Government of India, "Annual Survey of Industries." (2013). Ministry of Statistics and Programme Implementation. http://mospi.nic.in/Mospi_New/upload/asi/ASI_main.htm?status=1&menu_id=88.

Government of India, Ministry of Commerce (July 2013). "Fact Sheet on Foreign Direct Investment (FDI) III, April, 2000 – July 2013." http://www.dipp.nic.in/English/Publications/FDI_Statistics/2013/india_FDI_July2013.pdf.

Government of India, Economic Survey, Statistical Index, http://indiabudget.nic.in/es2012-13/estat1.pdf.

Government of India, Ministry of Statistics and Programme Implementation (2013). "Annual Survey of Industries." http://mospi.nic.in/Mospi_New/upload/asi/ASI_main.htm?status=1&menu_id=88.

Government of India, Ministry of Home Affairs (2013A). "Primary Census Abstract Data." http://www.censusindia.gov.in/2011census/population_enumeration.aspx.

Graham, Edward & Wada, Erika (2001). "Foreign Direct Investment in China: Effects on Growth and Economic Performance," in forthcoming book, *Source of development*.

Haddad, Mona & Ann Harrison (1993). "Are There Positive Spillovers from Direct Foreign Investment? Evidence from Panel Data for Morocco." *Journal of Development Economics*, Vol. 42 (1), pp. 51-74.

Hermes, Niels & Robert Lensink (2004). "Does Aid Work? New Evidence from Recent Empirical Studies." May 2004. http://ssrn.com/abstract=893020.

Husain, Shahbaaz (2011). "Foreign Direct Investment in Indian Pharmaceutical Industry." Competition Commission of India. 2011. http://cci.gov.in/images/media/ResearchReports/shahbaazInternreportdec2011.pdf.

Index Mundi (2013). "Labor Participation Rate." http://www.indexmundi.com/facts/india/labor-participation-rate.

Iihan Ozturk (2007). "Foreign Direct Investment - Growth Nexus: A Review of the Recent Literature." *International Journal of Applied Econometrics and Quantitative Studies,* Vol. 4, No. 2, 2007.

India Brand Equity Foundation (2013). "India Pharmaceutical Industry." August 2013. http://www.ibef.org/industry/pharmaceutical-india.aspx.

India Patents Act 2005, 84.

India Patents Act 2005, 92-A.

Kanwar, Sunil & Evenson, R. (2001). "Does Intellectual Property Protection Spur Technological Change?" Yale University, Economic Growth Center Discussion Paper No. 831, June 2001.

Kinoshita, Yuko &Campos, N. F. (2003). "Why Does FDI Go Where it Goes? New Evidence from the Transition Economies." William Davidson Institute Working Paper No. 573. June 2003. http://ssrn.com/abstract=414540.

Kokko, Ari. (1994). "Technology, Market Characteristics, and Spillovers." *Journal of Development Economics*, Vol. 43, 279-293.

Lall, Sanjaya (2000). "FDI and Development: Policy and Research Issues in the Emerging Context." Queen Elizabeth House Working Paper Series, Working Paper Number 43. Oxford University. June 2000.

Lanjouw, Jean O. & Iain Cockburn (2000). "Do Patents Matter?: Empirical Evidence after GATT." National Bureau of Economic Research Working Paper No. 7495, January 2000.

Lee, Jeong-Yeon & Edwin Mansfield (1996). "Intellectual Property Protection and U.S. Foreign Direct Investment." *Review of Economics and Statistics,* Vol. 78, 1996.

Lichtenberg, Frank (2002). "Benefits and Costs of Newer Drugs: An Update." NBER Working Paper No. 8996. June 2002. http://www.nber.org/papers/w8996

Lichtenberg. Frank (2003). "The impact of new drug launches on longevity: evidence from longitudinal disease-level data from 52 countries, 1982-2001." NBER Working Paper No. 9754. (June 2003). http://www.nber.org/papers/w9754.

Mahal, Ajay, Anup K. & Engelgau, M. (2010). "The Economic Implications of Non-Communicable Disease for India." HNP Discussion Paper, World Bank. January 2010. http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/EconomicImplicationsofNCDforIndia.pdf.

Mansfield, Edwin (2001). "*Intellectual Property Protection, Foreign Direct Investment and Technology Transfer."* International Finance Corporation, Discussion Paper. 2001.

Mansfield, Edwin, & Romeo, A. (1980). "Technology transfer to overseas subsidiaries by U.S. based firms." *Quarterly Journal of Economics*. Vol. 95, pp. 737-750. 1980.

Maskus, Keith E. (1994). "The International Regulation of Intellectual Property." *Weltwirtschftliches Archive*.

Maskus, Keith E. (2000). "Intellectual Property Rights and Foreign Direct Investment." Centre for International Economic Studies. Working Paper No. 22. May 2000.

Maskus, Keith & Penubarti, M. (1999). "How Trade-Related Are Intellectual Property Rights?" *Journal of International Economics*, Vol. 39.

Mueller, Janice M. (2007). "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation." University of Pittsburgh Law Review, Vol. 68, No. 3, 2007. http://ssrn.com/abstract=923538.

Nunnenkamp, Peter & Spatz, Julius (2003). "Foreign Direct Investment and Economic Growth in Developing Countries: How Relevant Are Host-Country and Industry Characteristics?" Kiel Working Paper No. 1176. July 2003. http://ssrn.com/abstract=425260.

OECD, "International Direct Investment Statistics, http://www.oecd.org/statistics/

Park, Walter G. (2001). "R&D, Spillovers, and Intellectual Property Rights." December 2001. http://nw08.american.edu/~wgp/RD%20Spillovers%20IPRs.pdf.

Park, Walter G. (2008). "International patent protection: 1960-2005." *Research Policy.* January 2008. http://www.american.edu/cas/faculty/wgpark/upload/IPP-Research-Policy-May-2008-3.pdf.

PricewaterhouseCoppers (2010). "India Pharma, Inc.: Capitalising on India's Growth Potential." http://www.pwc.in/assets/pdfs/pharma/PwC-CII-pharma-Summit-Report-22Nov.pdf.

Shapiro, Robert J. & Kevin A. Hassett (2005). "The Economic Value of Intellectual Property." Sonecon, Washington, DC. http://www.sonecon.com/docs/studies/IntellectualPropertyReport-October2005.pdf.

Singh, Mohini (2013). "Economic Impact of NCDs in India: A discussion paper." http://zunia.org/post/economic-impact-of-ncds-in-india-a-discussion-paper.

Smarzynska, B. K. (2002). "Composition of Foreign Direct Investment and Protection of Intellectual Property Rights: Evidence from Transition Economies." The World Bank, Policy Research Working Paper No. 2786, 2002.

Smith, Pamela J. D. (2002). "Patent Rights and Trade: Analysis of Biological Products, Medicinals and Botanicals, and Pharmaceuticals." *American Journal of Agricultural Economics,* Vol. 84, pp. 495-512, 2002. http://ssrn.com/abstract=312053.

Smith, Pamela (1999). "Are Weak Patent Rights a Barrier to U.S. Exports?" *Journal of International Economics*, Vol. 48, No. 1, 1999.

Sjöholm, Fredrik, (1999). "Do Foreign Contacts Enable Firms to Become Exporters?" Working Paper Series in Economics and Finance 326, Stockholm School of Economics.

Taylor, M. Scott (2004). "Trips, Trade and Growth." *International Economic Review*, Vol. 35, 2004.

Unnikrishnan, C.H. (2010). "Pfizer, Novartis and Eli Lilly got bulk of contentious patents." *Wall Street Journal*. April 6, 2010. http://www.livemint.com/Companies/NBolnLPZltophVmhUrxwrO/Pfizer-Novartis-and-Eli-Lilly-got-bulk-of-contentious-paten.html**.**

Unnikrishnan, C.H. (2013). "Despite their criticism of India's strict IP regime, foreign pharma won 77% of all patents in last three years." *MEDCity News.* September 16, 2013. http://medcitynews.com/2013/09/despite-their-criticism-of-indias-strict-ip-regime-foreign-pharma-won-77-of-all-patents-in-last-three-years/

U.S. Chamber of Commerce (2012). "Measuring Momentum: GIPC International IP Index, First Edition." December 2012. http://www.theglobalipcenter.com/wp-content/uploads/2013/01/020119_GIPCIndex_final1.pdfhttp://www.theglobalipcenter.com/wp-content/uploads/2013/01/020119_GIPCIndex_final1.pdf.

U.S. Chamber of Commerce (2013). "India: International Outlier on IP: A Review of India's Relationship with Intellectual Property Rights and Its Economic Consequences." Global Intellectual Property Center. July 2013. http://www.theglobalipcenter.com/wp-content/uploads/2013/07/India_Outlier_FIN.pdf.

Usha Nair-Reichert & Weinhold, Diana (2000). "Causality Tests for Cross-Country Panels: New Look at FDI and Economic Growth in Developing Countries." *Oxford Bulletin of Economics and Statistics*, Vol. 2, pp. 153-172. 2000. http://www.ciber.gatech.edu/papers/workingpaper/1999/99_00-12.pdf.

Vishwasrao, Sharmila (1994). "Intellectual Property Rights and the Mode of Technology Transfer." *Journal of Development Economics,* Vol. 44, No. 2, 1994.

Wai-MunHar, Kai-Lin Teo & Kar-Mun Yee (2008). "FDI and Economic Growth Relationship: An Empirical Study on Malaysia." *International Business Research*, Vol. 1, No. 2, pp. 11-18, April 2008.

Wang, Miao (2001). "Manufacturing FDI and Economic Growth: Evidence from Asian Economies." http://dx.doi.org/10.2139/ssrn.440440.

World Bank (2010). "The Economic Impacts of Inadequate Sanitation in India: Inadequate Sanitation Costs India Rs. 2.4 Trillion (US$53.8 Billion)." http://www.wsp.org/sites/wsp.org/files/publications/wsp-esi-india.pdf.

World Bank (2013). Data: India. http://data.worldbank.org/country/india.

World Health Organization. (2012). "India: Health Profile." http://www.who.int/gho/countries/ind.pdf.

World Health Organization (2012A). "Country Cooperation Strategy at a glance, India." http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_ind_en.pdf.

World Health Organization (2013). "Disease and Injury Country Estimates." http://www.who.int/healthinfo/global_burden_disease/estimates_country/en/index.html.

World Trade Organization, TRIPS, Arts. 70.8(a) and 70.9.

About the Authors

Robert J. Shapiro is the chairman of Sonecon, LLC, a private firm that advises U.S. and foreign businesses, governments and non-profit organizations on market and political conditions, especially affecting economic policy and security matters. Dr. Shapiro has advised, among others, U.S. President Bill Clinton, British Prime Ministers Tony Blair and Gordon Brown, U.S. Vice President Albert Gore, Treasury Secretaries Timothy Geithner and Robert Rubin, and then U.S. Senators Hillary Clinton and Barack Obama. He and Sonecon also have advised many private firms, including Amgen, AT&T, Exxon-Mobil, Gilead Sciences, Google, Nordstjernan of Sweden, and Fujitsu of Japan, as well as non-profit entities such as the American Public Transportation Association, PhRMA, and the U.S. Chamber of Commerce. Dr. Shapiro is also an advisor to the International Monetary Fund, a Senior Fellow of Center on Business and Public Policy at the Georgetown University McDonough School of Business, director of the NDN Center on Globalization, and chair of the U.S. Climate Task Force. From 1997 to 2001, he was Under Secretary of Commerce for Economic Affairs. Prior to that, he was co-founder and Vice President of the Progressive Policy Institute. Dr. Shapiro also served as the principal economic advisor to Bill Clinton in his 1991-1992 presidential campaign, senior economic advisor to Albert Gore, Jr. in 2000 and John Kerry in 2004, and Legislative Director for Senator Daniel P. Moynihan. In 2008 and 2012, he advised the campaigns and presidential transitions of Barack Obama. He has been a Fellow of Harvard University, the Brookings Institution, and the National Bureau of Economic Research. Dr. Shapiro holds a Ph.D. and M.A. from Harvard University, a M.Sc. from the London School of Economics, and an A.B. from the University of Chicago.

Aparna Mathur is a Resident Scholar at the American Enterprise Institute, where she focuses on health care and health care policy, taxation, finance and technology issues. Dr. Mathur also is a noted scholar in international finance and econometrics, and an affiliate analyst for Sonecon, LLC. She has been a consultant to the World Bank, a researcher at the Tata Energy Research Institute, and an instructor in economics at the University of Maryland and Georgetown University. Dr. Mathur holds a Ph.D. and M.A. from the University of Maryland, as well as degrees from Hindu College and the Delhi School of Economics of Delhi University.