The dynamics of pharmaceutical patenting in India: Evidence from USPTO data

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Abstract

This article analyses the impact of the implementation of the 'Agreement on Trade-Related Aspects of Intellectual Property Rights' (TRIPS) on various segments of the Indian pharmaceutical industry. In particular, it focuses on the conditions under which a strong patent system can create benefits for a developing country's pharmaceutical industry. The theoretical analysis suggests that the greater the technological capabilities of the Indian pharmaceutical industry the greater are its chances to benefit from the introduction of stronger intellectual property rights (IPRs). The evidence presented paints a generally positive picture of the state of the Indian pharmaceutical industry, with the existence of strong and growing technological competencies that can be used as a platform for further expansion. These conclusions are dependent on India's worldwide success in the industry and cannot be automatically applied to other developing countries, especially if their pharmaceutical industry is not strong at the moment of the transition to a stronger IPR regime.

Bibliographic Information

This Post-Print is the version of the article accepted for publication.
Published online 6 September 2007 in Taylor & Francis Online (www.tandfonline.com/).
Simonetti, Roberto; Archambault, Éric; Côté, Grégoire; Kale, Dinar. (2007). The Dynamics of Pharmaceutical Patenting in India: Evidence from USPTO Data. *Technology Analysis & Strategic Management*. 19(5), 625–642
 DOI: 10.1080/09537320701521382

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Introduction

The Indian pharmaceutical industry achieved considerable success in recent years under its old 1970 patent law, under which firms were not granted patents on final products, but rather on the process used to manufacture them. This meant that companies could produce medicines patented by international firms using a different process and sell them profitably at a low price. However, the new Indian patent law, which came into effect in 2005, enables firms to patent new products developed after 1995. This means that Indian companies will not be able to produce drugs based on products patented by other firms and will have to find new business models. The change in the Indian patent law is a direct effect of the implementation of the TRIPS agreement signed in 1994 after years of pressure mainly from the US government and industry, which saw pharmaceutical 'markets lost to successful imitators'.[1]

While large global pharmaceutical firms from industrialized countries stand to gain from the implementation of the 'Agreement on Trade-Related Aspects of Intellectual Property Rights' (TRIPs) as their revenues from exploitation of their intellectual property rights (IPRs) are shielded from imitators, the impact of this important institutional change on firms and consumers from developing countries is less clear. In fact, the impact of the new patent law will differ across the various segments of the pharmaceutical industry. Firms from developing countries that specialize in generics markets will lose domestic production opportunities for those drugs still protected by patents. However, new opportunities might arise for low-cost producers of generics drugs within the booming global generics industry as important patents expire soon and health services in industrialized countries take steps to reduce costs. Cost pressures in the large global pharmaceutical companies are also stimulating the growth of international outsourcing of contract research and manufacturing services (CRAMS) and clinical trials, with some developing countries standing to gain from this trend.[2]

Much of the impact of the new patent regime will take place in the drug industry segment protected by patent rights. Already much has been written on the possible consequences of the changes in patent law, especially about their impact on availability of drugs for the poor[3] and, from an industrial policy perspective, on whether stronger patent rights will be an advantage or disadvantage for the domestic pharmaceutical industry of developing countries.

This article contributes to the existing industrial policy debate by analysing the possible impact of implementation of the TRIPs agreement on the Indian pharmaceutical industry. The important related issue regarding the impact of these institutional changes on the price and availability of drugs for the poor, is not addressed here. In particular, the article focuses on the conditions under which a strong patent system can create benefits for a developing country's pharmaceutical industry.

Building on standard economic theory of industrial production and on existing empirical studies of similar regime changes in the past, the next section argues that transition to a stronger regime of patent rights can either boost the innovative capabilities of pharmaceutical firms in the developing country so that they can become global players, or relegate them to low value-added segments of the industry. The dynamic outcome is likely to depend on the strength of existing scientific and technological capabilities of the national pharmaceutical industry at the time of the regime change and the potential for further accumulation of the technological capabilities necessary to close the gap with industry global leaders.

After outlining the theoretical foundations of the argument, the article analyses the profile of innovative activities in India in the pharmaceutical field and their evolution over time using data on various indicators of inventive activity, with a particular focus on patents granted by the US Patent and Trademarks Office (USPTO). Patents are one of the most popular indicators of innovative activities and have been often used to measure the level of technological capabilities of countries, industries and firms in various technological fields.[4]

The conclusions assess to what extent existing technological capabilities of the Indian pharmaceutical industry and its firms' capacity to learn can enable some national companies to become global players.

The economic impact of the introduction of the patent system

This section develops the argument that the impact of the introduction of a stronger patent regime on the domestic pharmaceutical industry of a developing country can have different effects depending on the strength of the scientific and technological capabilities of the domestic industrial system at the time of regime transition. It starts by analysing the impact of the introduction of the patent system using a standard economic model of production, and then reviews the experience of Italy and Japan, that introduced product patents in the past.

Insights from the standard economic theory of production

The idea that the impact of the introduction of a tighter patent regime in a developing country can have very different outcomes on its industrial development has already been analysed by Scherer andWeisburst.[4] Using a standard textbook economic model of production that compares an industry under competitive and monopolistic market structures, they show that, in comparison with the case of perfect competition, the introduction of a monopoly through patent protection leads to a restriction in the quantity produced and an increase in price. As a consequence, the consumer surplus generated by the market decreases, that is, consumers can afford fewer drugs at higher prices and are worse off for two reasons: consumers who can still afford drugs have to pay more for them, perhaps consuming less of them, and consumers who cannot afford the drugs anymore are left without them.[5] A part of the consumer wealth (surplus) that is lost is appropriated by monopolistic firms in the form of monopoly profits, while another part is lost because of the inefficient market outcome under monopoly conditions.

Without the introduction of patents, developing countries that have the technological capabilities can copy existing drugs and produce them domestically at competitive prices. From a static perspective, this generates two advantages for the people in the developing countries through lower prices and increased production of drugs. First, the part of consumer welfare that is appropriated by foreign monopolists in the presence of the patent system is transferred back to consumers in the developing country. Second, the deadweight loss of welfare due to the inefficiency of monopoly, which is the fact that some consumers – usually the poorest – end up not buying drugs, does not take place because the market is competitive. It is therefore clear that, from a static perspective, consumers and firms in developing countries are better off without a tight regime of IPRs.

The usual argument in favour of patents, however, is based on a dynamic perspective. It states that without patent protection firms will underinvest in R&D and therefore will not produce new technology. In the long run, the loss due to the lack of technological progress far outstrips the short run loss due to the temporary monopoly introduced by the patent system.

Nonetheless, Scherer and Weisburst argue that the usual dynamic advantages that the patent system offers might not apply to developing countries, where local consumers cannot spend much individually or collectively compared to consumers in industrialized countries, so they do not contribute significantly to the profits of major foreign firms that invest in R&D. This, in turn, means that those firms will make their decisions about R&D investments without taking into consideration the choices of consumers in developing countries, and the lack of profits from developing countries is not likely to be responsible for discouraging the development of new drugs.

To sum up, it is likely that the patent system does not provide significant dynamic advantages to developing countries while it still generates all the problems arising from the establishment of monopolies in the economy.

There are, however, two possible scenarios in which the patent system can create benefits for the developing country's pharmaceutical industry: either when national firms are competent enough to compete with foreign multinationals through the introduction of new products and processes, possibly on a global scale; or when the technological capabilities in the home country are so strong that foreign multinationals find it profitable to establish important R&D facilities in the developing country. Given that firms in the developing country are likely to have a deep domestic base, both scenarios require a strong domestic innovative performance in the developing country. Without a strong domestic innovation performance, local firms cannot compete in the high value added industry segments that require innovation for success and are relegated to the low value added stages of the value chain. Moreover, foreign multinationals do not have incentives to locate knowledge intensive R&D activities in the developing country with a loss of opportunities for the accumulation of scientific and technological capabilities in the developing country.

The experience of Italy and Japan

In the 1970s Italy and Japan underwent the same transition that India is currently experiencing. Following pressure from large pharmaceuticals firms, Italy changed its law in 1978 to allow pharmaceutical products to be included in the patent system. The decision was ratified by parliament in 1982. Scherer reports that before the change in law Italy had become a world leader in generic drugs and exported to many nations. Within a decade after the introduction of product patents, however, Italy became a net importer of generic drugs and world leadership was taken by India, whose pharmaceutical industry had flourished after the abolition of product patents in 1970.[6]

Scherer and Weisburst[7] report that the increase in R&D expenditure expected in Italian pharmaceutical companies after the introduction of product patents did not materialize even though the number of patents granted in the US increased. The authors explain the increase of US patents by Italian inventors as a by-product of the fact that pharmaceutical firms had to set up legal offices as a consequence of the introduction of product patents. They conclude that increase in the propensity to patent (i.e. patents per unit of R&D) did not reflect an increase in the underlying innovative capabilities of Italian firms.

A possible culprit of the Italian pharmaceutical industry's failure to shift from an imitative to an innovative strategy after the change in the patent regime is the presence of tight price controls for drugs in the period of patent regime change, which 'overwhelmed the stimulative incentive of drug product patent introduction'.[8]

Japan also experienced a change in patent law in 1976 with the introduction of product patents. Aoki and Saiki[9] found that the regime change did not lead to an increase in market concentration partly because of the entry of foreign multinationals, which was facilitated by the liberalization of capital flows. As the theory suggests, R&D expenditure grew although in the 1980s the level of R&D intensity in the industry was still below that of other industrialized countries. Catching up in R&D intensity was completed in the 1990s.

The increase in R&D led to a shift in behaviour in the industry, which saw the innovative activities of firms changing from adaptation to innovation and to an increase in the quality of new technology introduced by Japanese firms. The number of patents increased only slightly after 1976 but, more significantly, there was a large shift from process to product patents, an increase in the citations received per patent, and an improvement in the technological trade balance due to the increase in the number of new licenses exported and their unit value. Japanese firms grew significantly and the largest have become significant global players with subsidiaries all over the world.

The authors conclude that the change in patent regime contributed significantly to the development of the pharmaceutical industry in Japan. The incentives offered by the new patent regime pushed Japanese pharmaceutical firms to innovate more and better, as the increase in quality indicators show. Aoki and Saiki are careful to qualify their conclusions by pointing out that the benefits of the new patent system were achieved mainly in the field of industrial policy rather than in health policy. However, they also claim that there were no significant negative effects on the Japanese health system because of its structure, which included tight price control on drugs.

The importance of domestic technological capabilities

The contrast between the cases of Italy and Japan reinforces the notion that the impact of the transition from a soft to a tight patent regime can be very different depending on the existing scientific and technological capabilities in the industry. Italian firms did not step up their R&D efforts to make a successful transition from an imitative to an innovative strategy, while Japanese firms undertook a substantial effort in learning activities.

The Japanese experience also casts some doubts on the impact of price controls on drugs, an issue hotly debated in India at the time of writing. While Scherer and Weisburst partly explain the decline of the Italian industry with the existence of price controls, the case of Japan shows that a successful transition can happen when drugs prices are regulated and not only left to market forces.

The implication of this analysis for India's prospect is that the greater the scientific and technological capabilities of the Indian pharmaceutical industry the greater are its chances to benefit from the introduction of stronger IPRs. For this reason the next sections look in depth at the state of India's scientific and technological performance in pharmaceutical technologies.

Before we proceed, however, it is worth clarifying that the question of the strength of India's capabilities in pharmaceutical science and technology should not be analysed in a 'black and white' fashion, but rather appreciate the shades of grey that empirical evidence usually produces. As the beginning of the article stated, the introduction of product patents will have different impacts on the various segments of the Indian pharmaceutical industry and some of the opportunities and threats facing India are fairly independent of the existence of product patents.

For example, Scherer and Weisburst's emphasis on the importance of R&D in the innovation process applies to the high end segments of the industry, such as the production of new chemical entities (NCEs), but less to other expanding areas, such as CRAMS, which in India 'was estimated at $532 million with contract manufacturing accounting for nearly 84 percent of the total'.[10] The pharmaceutical CRAMS markets are rapidly growing in India and will be an important source of growth especially for Indian companies that choose not to embark on the potentially rewarding but very risky innovative business of producing NCEs. In fact, the existence of strong IPRs might even act as an incentive for foreign MNCs to choose Indian companies as partners for CRAMS because their patents will be less likely to be infringed.

In addition, from a dynamic perspective, it is possible to envisage that successful expansion of CRAMS and other segments requiring significant technological competencies, such as clinical trials, might boost the accumulation of technological knowledge and the absorptive capacity of the Indian pharmaceutical industry, therefore leading to a future shift of companies to the high end segment of the industry in which R&D plays the key role in the innovation process. This gradual upward shift in the technological activities of firms from developing countries is a pattern already observed in other studies and should inform the interpretation of the results of the empirical analysis.

Indian performance in pharmaceutical technology

This section analyses the innovative performance of the Indian pharmaceutical industry using a variety of technological indicators and evidence from existing studies. It starts by studying the pattern of R&D expenditures in the industry, which are the main source of innovation in high end segments of the industry, such as the discovery of NCEs.

Research and Development

The analysis of R&D expenditures of domestic Indian firms has to distinguish between firms of Indian nationality and the subsidiaries of foreign MNCs. While many expect at least some Indian firms to raise their R&D intensity, that is R&D expenditure per unit of turnover, foreign owned firms can either transfer more R&D to their Indian subsidiaries because of the greater protection offered by the new patent law, or use the increased protection to exploit their existing patents produced in their home countries R&D centres.

Chaudhuri has noted that far from increasing investment in R&D in the local economy, the stronger patent regime is leading foreign multinationals to rely on the stronger protection by the law to exploit the IPRs they have already generated abroad:

> Three foreign multinationals started R&D for new drug development when India did not provide patent protection. These have been stopped. After TRIPS, except AstraZeneca none of the multinationals is involved in R&D for new drugs.[11]

The behaviour of the subsidiaries of foreign multinationals might partially explain the dip in R&D intensity observed in Figure 1 just after 2000.

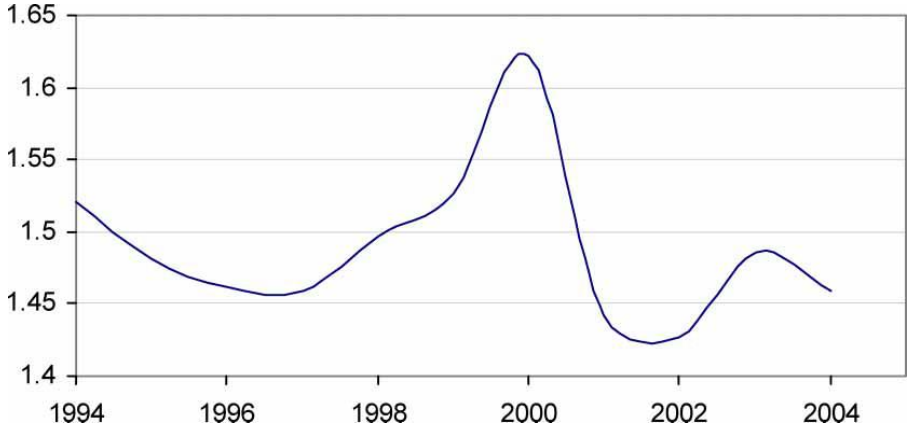

Figure 1. R&D intensity of Indian pharmaceutical companies, 1994–2004.
(Source: OPPI, 2004)

This effect of the introduction of stronger IPRs is confirmed by other studies, which suggest that MNCs will use the greater protection to extract rents from existing IPRs generated abroad.[12] Other recent studies, however, are more positive and quote instances of MNCs relocating R&D activities 'in India to reap the benefits offered by the sub-continent such as rich talent pool, which is available at low cost compared to the Western countries'.[13]

On the positive side, Chaudhuri not only notes that in recent years Indian companies increased their R&D investment for new drug development but also that India already has a good record of innovation in the industry in terms of new processes and new molecules, and the level of process innovation displayed by Indian companies in recent years is not trivial. Indeed, inventing around product patents that are usually protected by related process patents precisely to make imitation more difficult and costly, requires considerable competence.[14]

Sustaining and further building on existing competencies to compete in the global market requires a sustained set of investments from Indian firms, of which R&D expenditure is an important, though not unique, component. The extent to which Indian firms will focus on R&D is uncertain. In recent years the major national players have focused on a strategy of international expansion through mergers and acquisitions, and alliances with foreign companies. Although complementary to R&D, these activities are in competition for funds dedicated to investment activities, which also include setting up legal offices to support IPRs management and marketing expenditures. Indeed, industry analysts identify low R&D expenditure, on average around 4% of sales vs 10–20% of global firms, as one of the outstanding issues facing the industry.[15]

Industry-wide figures, however, hide a picture that is varied. On one hand, it is true that many Indian players are far from the R&D intensity of global companies and are mainly competing either in generics markets or in the provision of CRAMS in partnership with foreign firms. On the other hand, some leading Indian firms are gradually improving their R&D efforts and some are even spending more than 10% of their turnover in R&D, as Table 1 shows.

Table 1. R&D intensity of the major Indian pharmaceuticals firms (R&D expenditure as a percentage of turnover)

Company	2003–2004 (%)	2002–2003 (%)	Change
Dr Reddy's Lab.	13.0	9.9	3.1
Ranbaxy Lab.	7.3	6.5	0.8
Nicholas Piramal	4.3	1.8	2.5
Lupin	3.9	3.5	0.4
Orchid Chemicals	5.6	5.1	0.4
Cadila Healthcare	7.5	3.7	3.8
Wockhardt	7.9	6.2	1.7
Sun Pharma	10.2	7.5	2.7
Aurobindo Pharma	3.6	1.8	1.8
Biocon	10.0	4.5	5.5
Unichem Laboratories	2.2	2.7	-0.5
Divi's Lab.	2.5	2.8	-0.3
J B Chemicals	2.2	1.7	0.5
Shasun Chemicals	4.2	4.7	-0.5
Alembic	3.2	3.5	-0.3
Total	6.9	5.3	1.6

Source: PharmaBiz (2005)

Table 2. NCEs of leading Indian pharmaceutical firms

Firms	Patents filed for NCEs in 2003	Number of NCEs in the pipeline in 2006		
		Total	Phase III	Phase II
DRL	8	9	1	2
Ranbaxy	6	10		2
Wockhardt	3	6		1
Glenmark	2	6		2
NPIL	1	3		2

Sources: Company Annual Reports (2003), India Brand Equity Foundation (2007), *Pharma Focus Asia (*2007).

R&D expenditure of the leading companies in the industry also keeps increasing at high growth rates: ASSOCHAM reports that in 2005–2006 'the R&D expenditure of 50 major companies totalled USD495.19 million growing at a rate of 26% over the previous year'. More importantly, much R&D has shifted its emphasis from process innovation to product innovation towards discovery of NCEs.[16] Indeed, Table 2 shows that there are leading Indian firms that have started to build a significant pipeline of NCEs, with some products already at Phase II and even III of the approval process.

Given the high rate of failure of NCEs, it is still to be seen how many Indian firms will successfully become established in the NCEs segment of the industry, but the figures are encouraging.

India's Strength in Biotechnology

Positive news about India's scientific and technological capabilities in pharmaceuticals comes from research carried out at the Joint Centre for Bioethics of the University of Toronto, on the development of biotechnology, which offers exciting opportunities for the pharmaceutical industry. Thorsteinsdóttir et al.,[17] show that indicators of scientific output in biotechnology, such as papers published and citations received, have increased significantly in seven developing countries, including India, although their level is still far from that of the major industrialized countries.

Similar findings are reached by Quach et al.,[18] in their analysis of US patent data in biotechnology classes. Within the same seven industrializing countries, India ranks second after South Korea for number of biotechnology patents in the USA with a strong specialization in health biotechnology. They also find that most of the patents (around two thirds) are owned by Indian organizations rather than Indian subsidiaries of foreign multinationals. However, the most important role in biotechnology patenting is played by public research centres rather than private Indian companies. This suggests that in spite of the size and strength of the industry, India's private pharmaceutical sector might not yet be ready to compete in the global market through the production of IPRs.

Indian Patent Profile in Pharmaceuticals: Description of the Data Used

The following sections of the article use patent bibliographic information from the US Patent and Trademark Office (USPTO) to sketch a picture of the technological capabilities of the Indian pharmaceutical industry. Patents have long been used for this purpose, and US patents provide a good indicator of inventive activity at the international level because of the importance of the USA as a world market.

While patents do not capture the full range of innovative activities, especially those imitative and incremental activities that go on in developing countries, they are a suitable indicator to capture the extent to which the players in the Indian industry measure up against the international competition at the technological frontier.

Patents are classified following the practice of the Patent Technology Monitoring Branch (PTMB) of USPTO.[19] A patent is assigned to a country depending on the country of residence of the first-named inventor listed on the patent grant.[20] Pharmaceutical patents are defined as those whose primary US Patent Class (USPC) are either 424 or 514, both named 'Drug, bio-affecting and body treating compositions'.[21] Finally, only utility patents are included in the analysis, excluding plant and design patents.[22]

In order to put India's performance in context, we compare it to the other six countries used by Thorsteinsdóttir et al.,[23] and Quach et al.,[24] namely Brazil, China, Cuba, Egypt, South Africa and South Korea, and to the G7 countries.

Trends in Indian US Patenting in Pharmaceuticals

We start by outlining the trend in Indian patenting over time. Figure 2 shows the total number of Indian patents in the US over time, while Figure 3 shows only Indian patents in pharmaceuticals. The similar shape of the figures show that the growth in pharmaceutical patenting, which took off in the 1990s, is a phenomenon common to all Indian patenting.

Figure 4 also illustrates how the share of pharmaceutical patents on all Indian utility patents oscillates around 20% without showing a significant positive or negative trend.

Interestingly, these charts show a dip in the number of patents in the run up to 2005 with a pick up after this date. Perhaps this reflects the existence of uncertainty in the patenting strategies of Indian inventors in the run up to the implementation of TRIPS.

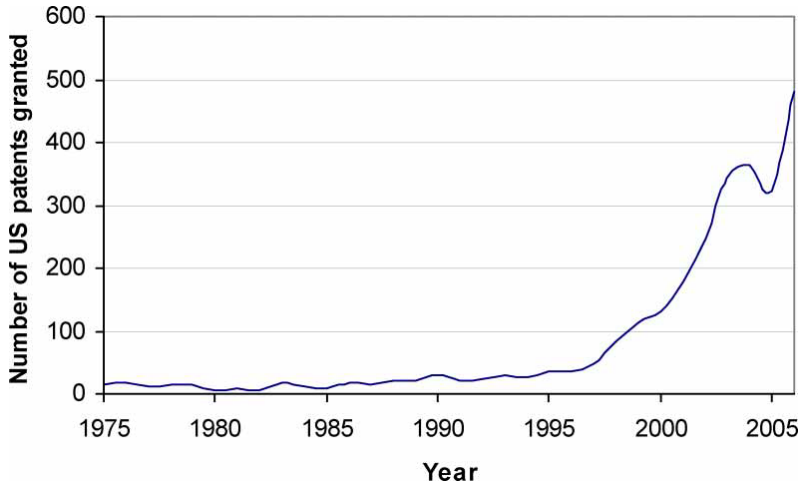

Figure 2. Patenting by Indian inventors in the USA over time: all utility patents.
(*Source:* Authors' calculations on USPTO data, database Patents BIB 2007)

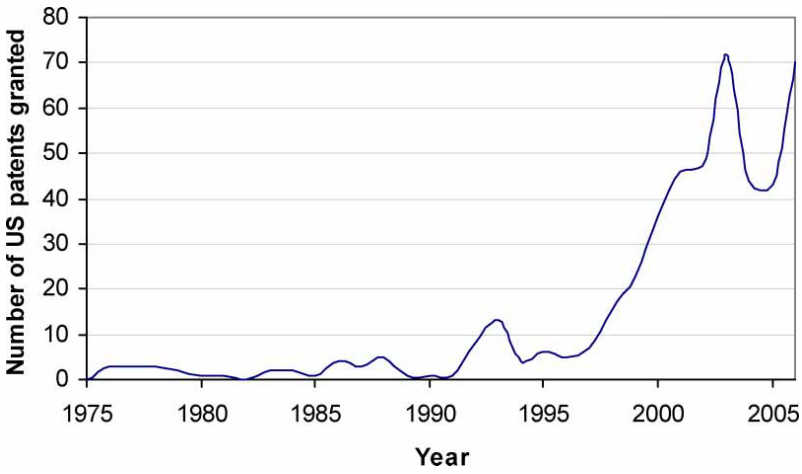

Figure 3. Patenting by Indian inventors in the USA over time: pharmaceutical patents.
(*Source:* Authors' calculations on USPTO data, database Patents BIB 2007)

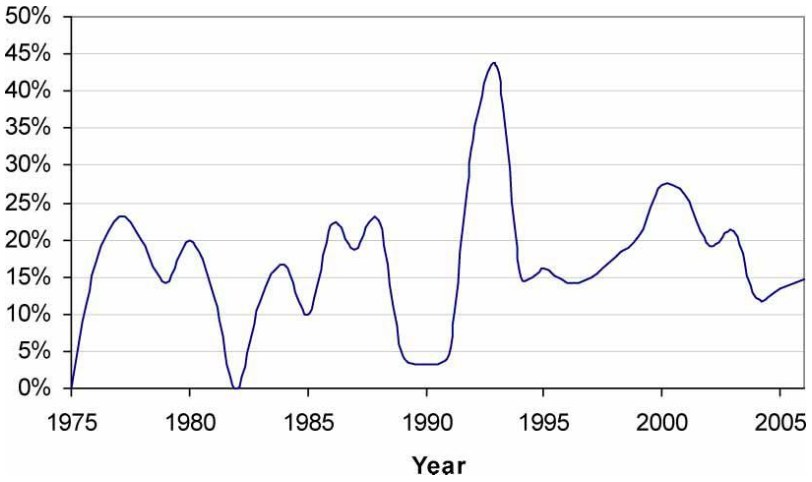

Figure 4. US patents by Indian inventors: share of pharmaceuticals over all Indian patents. (*Source:* Authors' calculations on USPTO data, database Patents BIB 2007)

Finally, we look at how the Indian profile of specialization in pharmaceutical patenting has changed over time. We use the widely adopted index of Revealed Technological Advantage (RTA), which gives an instant picture of the relative importance of a technological field in a country in comparison with the importance of the field in the rest of the world.[25] The index is the ratio between the share of patents in a technology field in a country and the share of patents in the same technology field for the whole world. The formula is:

$$RTA_{ij} = (P_{ij}/P_{it})/(P_{wj}/P_{wt})$$

where P_{ij} is the number of patents in country i (in our case India) in technology j (in our case pharmaceuticals), P_{it} is the total number of Indian patents, P_{wj} is the total number of pharmaceutical patents in the world and P_{wt} is the total number of patents in the world.

The RTA index has value zero when a country has not got any patent in the technological field analysed. A RTA value between zero and 1 shows a negative relative specialization for the country in the technology analysed while a value greater than one indicates a positive specialization.

Table 3. Indian technological specialization in pharmaceutical US patents (specialization index (RTA) in four periods)

Period	RTA
1991–1994	2.77
1995–1998	0.90
1999–2002	1.95
2003–2006	9.38

Source: Elaborations on USPTO data.

Table 3 reports the RTA in pharmaceuticals for India in four 4-year periods, from 1991–1994 to 2003–2006. The index is higher than one in all periods apart from the 1995–1998 period, when it is close to one (0.90). These results indicate that India has a positive relative specialization in

pharmaceuticals. This is an expected result given the strength of the Indian pharmaceutical industry, but still significant because strength in generics, which is mainly based on reverse engineering and imitation, does not necessarily reflect a strength in patenting, which implies the presence of inventive activity.

A more significant result is the fact that the RTA shows a huge leap forward in the last period, 2003–2006. This suggests that the changes brought about by TRIPS in the Indian patent system have greatly boosted US patenting by Indian inventors in pharmaceuticals. A positive interpretation of this result is that Indian pharmaceutical organizations, which are responsible for the bulk of patenting by Indian inventors, have started upgrading their technological activities. A more sober explanation is that the change in Indian patent regime has made it necessary for Indian organizations, especially in the pharmaceutical industry, to set up legal offices that are more likely to convert existing research output into patents not only in India but also abroad.

In order to see whether the increase in the RTA represent greater technological capabilities for the Indian pharmaceutical industry it is necessary to put this result in context. This is what the next two sections do by respectively comparing India to other countries and by investigating the quality of Indian patents.

Indian Patent Profile in Pharmaceuticals: Cross-country Comparisons

This section looks at how India fares in comparison with other countries in pharmaceutical US patenting. The top part of Table 4 illustrates the innovative performance of the G7 countries while the bottom part contains the figures for seven industrializing countries.

Table 4. Number of pharmaceutical US patents for selected countries

Country	1991–1994	1995–1998	1999–2002	2003–2006
USA	7,591	12,291	16,604	12,575
Canada	255	532	827	650
Japan	2,018	2,188	2,501	1,629
UK	928	1,166	1,569	1,056
Germany	1,193	1,431	2,041	1,479
France	810	1,222	1,604	1,025
Italy	381	434	491	316
Brazil	5	7	10	27
China	8	27	57	87
Cuba	0	3	13	4
Egypt	1	1	3	3
India	26	33	153	229
South Africa	9	18	21	13
South Korea	33	95	183	219

Source: Elaborations on USPTO data.

The comparison between the top and bottom sections of the table clearly illustrates how much catching up the industrializing countries still have to do, including South Korea, already an OECD member. The table also highlights India's good performance within the group of industrializing countries, especially in the last period when it even overtakes South Korea in the number of pharmaceutical patents. India is quickly catching up with Italy, but its real target should be countries like Germany, Japan and the UK that lead the industry with the USA, rather than Italy in which the industry has declined as we saw from the above discussion of the work by Scherer and Weisburst.[26]

The data for the USA should be interpreted with caution since it is the country in which the patents are granted. This means that its number of patents is artificially inflated by the presence of patents, mainly filed by individuals, with little economic value.[27]

So although the trend is positive and India is getting closer to the G7 countries, there is still much more work to do to close the gap with the world technological leaders.

Figure 5 offers a comparison of the profiles of specialization in pharmaceuticals of the seven industrializing countries already examined above.

The increase in specialization in pharmaceuticals in the last period, which we observed in the previous section for India, is a fairly generalized phenomenon in this group of countries, possibly because of the growing influence of TRIPS regulations in the various countries. Brazil and China, in particular, show a significant increase of specialization in the last period just like India. Cuba has also a very high specialization in pharmaceuticals but its very high values are partly a result of the small overall number of US patents granted to Cuban inventors.

Period	RTA
1991-1994	2.77
1995-1998	0.90
1999-2002	1.95
2003-2006	9.38

Figure 5. Technological specialization in pharmaceuticals in selected countries: RTA indices in four periods.
(*Source:* Authors' calculations on USPTO data, database Patents 2007)

India and Cuba show the highest specialization in pharmaceuticals in the group. This is consistent with the results by Quach et al.,[28] which found a strong health orientation in the biotechnology patents of these two countries. The third highest RTA belongs to Egypt, which however was the least specialized in health biotechnology in the Quach's study. It must be noted however, that the results for Egypt should be treated with much caution because of the extremely low number of patents granted to Egyptian inventors.

The Quality of Indian Patents: Analysis of Patent Citations

While patent counts are a widely used measure of technological activities, patents can vary substantially in quality.[29] This section uses two indicators of patent quality in order to provide a more complete picture of Indian performance in pharmaceutical patenting.

One common indicator of patent quality is the number of citations that each patent receives from successive patents.[30] Patents that are highly cited by following patents have a greater impact on subsequent innovation and therefore can be considered of higher quality. A problem with the use

of patent citations, however, is that very recent patents tend to have few or no citations just because they have not had time to be cited. For this reason, we have used a corrected number of cited patents, that is, only patents cited in the three calendar years immediately after they were granted.

Figure 6 illustrates the patent citations indicators relative to Indian inventors in pharmaceuticals over time from 1985 to 2003. The two indicators used are the number of patents cited within 3 years and the total number of citations received within 3 years, so the citations of patents granted in 2003 occur in the years 2004–2006.

The graphs show that in the late 1990s and early 2000s the performance of Indian pharmaceutical patents has improved significantly both in terms of overall number of citations received and number of patents cited. However, in very recent years there has been a slight setback.

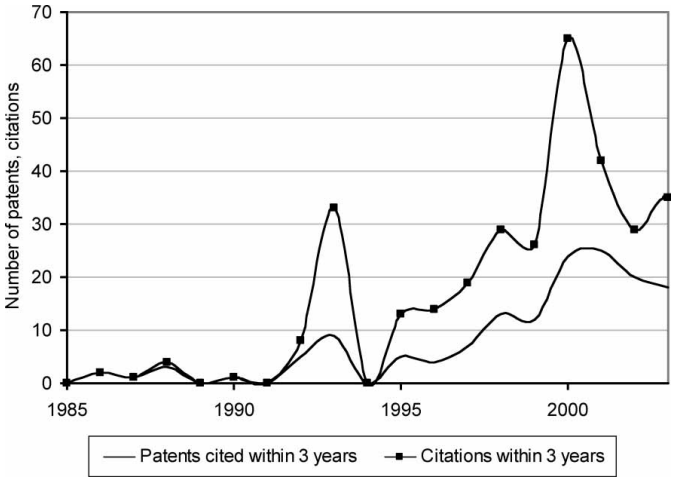

Figure 6. The quality of Indian pharmaceutical US patents over time. Number of patents cited and number of patent citations.
(*Source:* Science-Metrix calculations on USPTO data)

The main reason for the setback in the early 2000s is the decline in the number of Indian pharmaceutical patents in 2003 and 2004 that is apparent in Figures 1 and 2 above. Since Indian inventors are more likely to cite other Indian inventors (or even themselves) a decline in the number of Indian patents in 2003 and 2004 automatically generates a drop in the number of citations in the previous three years, which is what appears in the graph. The resurgence of Indian US patenting in 2005 and 2006 is already generating a reverse in the trend of citations in more recent years, with the number of citations already showing renewed growth in 2003.

The Quality of Indian Patents: Specialization in Fast-growing Patent Classes

Another way of controlling for the different importance of the patents included in the analysis is to look inside the US Patent Classes and disaggregate the results by subclasses. The two US Patent Classes that define pharmaceuticals in this paper, 424 and 514, are subdivided into more than 1000 detailed subclasses (up to nine digits). Some of those subclasses are new and fast-growing fields rich in technological opportunities while others represent older technologies that are likely to be replaced by innovative products and processes.[31]

In order to identify the subclasses with high technological opportunities, we have calculated the rates of growth of all pharmaceutical subclasses between the periods 1991–1995 and 2001–2005. Then we have identified 100 subclasses with the highest growth rates between the two periods. Those top 100 and the new subclasses (those with no patents in 1991–1995) are defined as 'fast-growing' in the analysis that follows.

Table 5 shows the percentage of patents in the fast-growing subclasses for the periods 2001–2003 and 2004–2006 for 10 countries. Brazil, Cuba, Egypt and South Africa were excluded because of the very low number of patents in fast-growing fields.

The table shows that the three industrializing countries outperform all of the G7 countries with the exception of Canada. A likely explanation of this result is that the three newly industrializing countries are concentrating their efforts in the up-and-coming fields of pharmaceutical technology, such as biotechnology, while countries with established research trajectories are locked into – or at least find it more difficult to move out of – more mature technological fields.

Table 5. Percentage of pharmaceutical US patents in fast-growing pharmaceutical subclasses

	2001–2003 (%)	2004–2006 (%)
USA	19	21
Canada	24	27
Japan	10	14
UK	13	15
Germany	14	15
France	13	14
Italy	9	15
China	20	24
India	23	21
South Korea	14	26

Source: Elaborations on USPTO data.

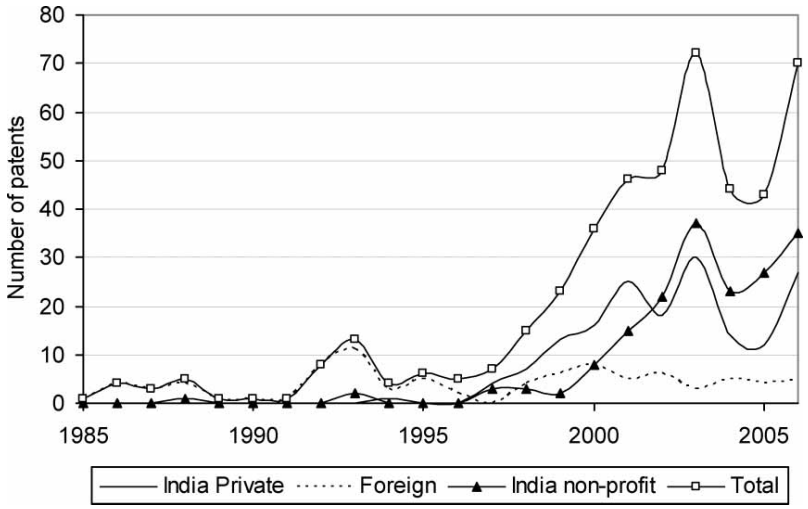

Figure 7. The assignees of Indian pharmaceutical US patents over time.
(*Source:* Authors' calculations on USPTO data, database Patents BIB 2007)

Who is Patenting: Analysis of the Patent Assignees

The final part of the analysis explores the trends in the institutional affiliation of Indian inventors by breaking down the number of patents granted to Indian inventors by the type of their institution, that is, the assignee of the patent (the owner of the IPR). The patents have been classified into three groups of assignees: Indian private, that is Indian companies, Indian public organizations, which include government laboratories and universities, and foreign assignees, which mainly represent foreign firms but also include foreign universities. Very few patents are not assigned and they have not been included in the graph.

The results are illustrated in Figure 7. The figure clearly shows that the growth in Indian US patenting is all due to patents granted to Indian institutions, either private or public. As also the analysis of biotechnology patents reported above showed, Figure 7 confirms that public research organizations are still playing a crucial role in India's generation of new technology also in pharmaceuticals. However, patenting is also rising significantly in private firms.

Conclusions

The article has explored the issue of the conditions under which a strong patent system can create benefits for a developing country's pharmaceutical industry. Using standard economic theory of production and previous empirical studies of patent regime changes in the past, this paper has argued that the transition to a stronger regime of patent rights, such as the implementation of the TRIPS agreement in India in 2005, can either boost the innovative capabilities of pharmaceutical firms in the developing country as more firms move to the high end segment of the industry and become global leaders or relegate them to low value-added segments of the industry. The outcome depends on the technological capabilities of the industry at the time of the change of the IPR regime. From this theoretical perspective, the paper has analysed the technological activities of Indian firms using various indicators of innovative activity mainly based on US patent statistics.

Patents only capture some aspects of inventive activities as much accumulation of technology occurs through other channels, such as learning-by-doing, reverse engineering or formal R&D to mention a few, but patents are particularly useful to study pharmaceutical technology because of the nature of the innovation process in this industry.[32]

The analysis of the US patenting activities of Indian inventors has painted an encouraging picture of the innovative activities of the Indian pharmaceutical industry. We observe a sharp increase in the number of pharmaceutical US patents granted to Indian inventors and a recent impressive increase in Indian specialization in pharmaceutical technology. There was a drop in the number of pharmaceutical US patents in 2003 and 2004, possibly related to uncertainty about the introduction of the new patent system in 2005, but the trend has been substantially reversed in 2005 and 2006.

India's performance looks positive when it is compared to other industrializing countries such as China, South Korea, Brazil and South Africa, both in terms of number of patents and profile of specialization in pharmaceuticals. Previous studies have also shown that India is fairly strong in health-related biotechnology, a key technology for the future of the pharmaceutical industry.

Unsurprisingly, the data also point to some areas where there is still work to do. The volume of Indian US patents, for example, is still well below that of the key G7 countries, whose firms are key players in the global pharmaceutical industry. Reports from the business press and the R&D

data available show that the bulk of Indian firms should do more to catch up with the level of R&D investment of the world industry leaders. With these levels of R&D intensity it is likely that most Indian firms will be confined to the generics and CRAMS markets. This is not necessarily all bad as these areas, especially CRAMS, have substantial growth potential in the future and might offer substantial opportunities for further accumulation of technological capabilities. Already Indian firms are engaging in alliances with global industry leaders and more are likely to follow, with India tipped to become a global R&D hub by some industry analysts.[33]

On the positive side, it is necessary to highlight the fact that some leading Indian firms are moving towards the high end of the industry by increasing substantially their R&D intensity (Table 2), US patents (Figure 7) and showing a significant pipeline of NCEs with some molecules already at phase II and even III of the approval process.

The picture looks still positive but more mixed when we look at the quality of Indian patents. On one hand, the number of US patent citations received by Indian pharmaceutical patents shows a strong positive trend from 1995, and Indian specialization in fast-growing pharmaceutical subclasses is higher than that of most G7 countries. On the other hand, there is a recent decline in the number of Indian patents cited and citations received in the early 2000s, although the upward trend in the number of citations received has started growing again in 2003. Moreover, this decline is probably mainly as a result of the drop in the number of Indian US patents in pharmaceuticals in 2003 and 2004, which might be related to uncertainty on the coming changes in the Indian patent system.

A possible cause for concern is that the percentage of Indian patents in fast-growing subclasses has dropped in the last period (2004–2006) and India has been overtaken by the both China and South Korea. This might indicate that Indian companies could do better by focussing their innovative activities on areas that offer more technological opportunities. Future research on the detailed analysis of the fast-growing classes in pharmaceuticals might be able to identify the fast-growing areas and shed more light on this issue.

Summing up, the evidence reviewed paints a generally positive picture of the state of the Indian pharmaceutical industry, with the existence of strong and growing technological competencies that can be used as a platform for further expansion. Although it is early days, it also looks as if the early impact of the new patent law on the industry has been fairly positive in encouraging at least some Indian firms to boost their innovative activities and efforts to catch up with the world leaders in terms of R&D, patents, global presence and NCEs. There are some concerns about the low average level of R&D spending in the bulk of the industry, which will focus mainly on generics markets, but the growth of international outsourcing in CRAMS and clinical trials will offer opportunities for economic growth and further learning that will contribute to the industry's future capabilities.

The evidence suggests that India's existing strength in pharmaceuticals before the transition to a strong IPR regime is helping its industry to reap some of the benefits of the new patent law. However, it is difficult to generalize these conclusions for the majority of developing countries that are going to strengthen patent protection. India's 35 years of weak IPR regime has been beneficial for its import substitution strategy, which is ultimately paying off. Countries that approach the transition to a stronger patent system will probably not be in as good a position as India is and this

probably means that the reward from the exploitation of product patents will go to foreign players with a negative net outcome for the local development of a successful pharmaceutical industry.

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21. It is also possible to attribute patents to a country in two other ways. One is to assign a patent to a country when any of the inventors listed on the patent are resident in a country. This, however, generates double counting and creates problems with the interpretation of the specialization indices used in the analysis. The other way is to assign a fraction of a patent to the country of each inventor.
22. The definition of pharmaceutical patents used by the PTMB falls between that used by Scherer and Weisburst, who only used class 514, and the USPC-SIC concordance, which includes other classes in addition to 424 and 514.
23. Utility patents are the general category of patents in the USA and account for most US patents. Other types of patents include design, plant and reissued patents. A utility patent is a patent issued for inventions that perform useful functions.
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