TRIPs AND INNOVATION TRENDS IN THE INDIAN BIOPHARMACEUTICAL INDUSTRY
To many industry experts within and outside the Indian pharmaceutical industry, the recent changes to the Indian patent law is a watershed event this is likely to have long term implications on the competitiveness of the industry. Yet even after seven years from the event little is known about how the changes influenced the industry. Many domestic firms believe that the new patent law is likely to halt their aspirations to become a dominant generic player while many multinational firms believe that the new law will open up their firms to new market opportunities well beyond those in the developed world. In this report we paint a broad brush on how the most recent changes to the Indian patent law influenced firm strategies and the competitiveness of local players in the industry. Given the current sets of firm capabilities that Indian and foreign firms are armed with, we believe the new patent law is likely to result in both these categories of firms reconfiguring their strategies. Also, how firms adapt to the new reality will determine their performance in this new era. We present our broad findings and our conjecture on the long term implications of the new patent law on the Indian pharmaceutical industry.

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Shakthi Nagappan, BioAsia
The pace of innovation has been encouraging, and the success of several new pipeline products in the next five to six years will redefine discovery research by Indian pharma companies under the product patent regime—Dr. Rajesh Jain (Ph.D), Jt. Managing Director Panacea Biotec Ltd.
EXECUTIVE SUMMARY

When acceding to the Trade Related Aspects of Intellectual Property Rights or TRIPS for short, India committed to making radical changes to its intellectual property law especially patent law. This report attempts to understand how TRIPS influenced firm strategies. It also aims to foster discussion on the role patents play in the strategies and the development of capabilities of both Indian and foreign firms in the Indian pharmaceutical industry.

India acceded to the TRIPs accord in 1994. However the move to strengthen patents globally took place despite a lack of empirical consensus on how patents influence firm strategies, innovation and competition. In India, the TRIPS treaty was implemented at a time when many global players were eyeing India’s large market for drugs for accelerated growth. The domestic players has also accumulated substantial absorptive capacity to manufacture generic pharmaceutical drugs and distribute it both locally and overseas.

The 2005 changes to the patent law was not the first time India modified its patent law. The set of changes that were made in 1970 that made India’s patent law pro-access played a significant role in the development of the Indian pharmaceutical industry. On one hand, the TRIPS related changes to the patent law which made India’s patent law pro-innovation, was expected to provide incentives for innovation to firms in the bio-pharmaceutical industry.

On the other hand, given the experience of 1970, TRIPS was also expected to be a dampener to the Indian pharmaceutical industry and arrest its rapid growth. Did it happen?

Using manually collected data of Indian pharmaceutical patents and Indian pharmaceutical product market data, we paint a broad brush of the changes ushered in by TRIPS in the Indian pharmaceutical industry. We speculate some of the key drivers of growth in the post TRIPS era for both domestic and foreign firms alike.

This report aims to foster discussion on this pertinent debate as India stands poised at the crossroads of opportunity and uncertainty. Going forward intellectual property will shape capabilities and relationships for both multinationals as well as domestic stakeholders. A lot depends on the regulations, policies and research capabilities of firms in an intensely competitive and complex business environment.

In this article by exploiting roughly 40 years’ worth of Indian pharmaceutical and combining it with other data sources, we provide some clues about the transformation the industry is experiencing due to the new patent law along with the strategies that have enabled firms to succeed in this industry in the new environment.
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From its modest beginnings, the Indian pharmaceutical market, valued at an impressive US$12 billion in 2010, has grown to become one of the largest and fastest growing sectors in India. India’s unique process patent regime was credited for the rapid growth of the industry. In 1970, the Indian government disallowed patenting of New Chemical Entities (NCEs) and compounds (collectively referred to as product patents), which enabled firms to produce newly introduced medicines that were under patent protection elsewhere at a fraction of the cost. Yet, in 2005, after a 35-year process patent regime, India reintroduced product patents in order to conform to the World Trade Organization’s (WTO) mandate. This move was hugely controversial. With almost 90% of the industry specializing in generic drugs, many argued that the product patent regime would signal the death knell of the industry. Others argued that the large Indian pharmaceutical market would be a fertile ground for foreign discovery based pharmaceutical firms to enter and thrive in India.

Roughly 70% of India’s population lives in the rural areas, yet access to healthcare is about 10 times better in urban areas (rural — 0.36 beds per 100,000 people; urban — 36 beds per 100,000 people).

Thus, although rural markets represent a larger opportunity in principle, the reality is that infrastructure bottlenecks and the rampant availability of counterfeits pose serious challenges to penetrating rural markets.

The pharmaceutical industry in general has been characterized by two broad business models — discovery based and generics based.

While Indian firms have developed expertise such as the development of cost-effective processes and quality enhancement, marketing and distribution over a period of time, upstream capabilities such as R&D and drug discovery require extensive capital and human input where they are relatively less developed. On the other hand, given that a significant portion of their revenues globally come from new drugs, multinationals specialize in the drug discovery.
In part, the strong opinions on this subject are on account of India’s experience prior to 1970. Largely due to the fact that empirical evidence on the effects of product patents in a context such as India is sparse, little is known about how product patents affect firm strategies, competition and social welfare.

With the domestic market estimated to reach about US$49 billion, the potential that the Indian pharmaceutical market holds is unquestionable. However, who its dominant players will be, especially in the shadow of the new patent reforms, does not appear to be as clear cut.

Reverse engineering although not as complicated as new drug discovery, is not less complex. It requires sophisticated organic and biochemistry expertise.

Dr. G. V. J. A. Harshavardhan
Director: Viral Vaccines, Rotavirus Vaccine Development Project &
International Affairs
Bharat Biotech International Ltd
And seven years later, the debate still rages on...

There could easily be 70 to 80 million people who can afford expensive medicines, just as they go out and buy expensive cars, branded clothes and consumer goods... That is equal to the size of a UK or a Germany Pharmaceutical executive.
Competitive advantage is not just a function of how one plays the game; it is also a function of the assets that one has to play with and how these assets can be deployed and re-deployed in a changing market—Teece et al. (1997: 529)
Patent versus patient

*Evolution of India’s patent regime*
India, not unlike other countries, has been constantly struggling to balance granting incentives for innovation on the one hand with making drugs available to the needy on the other. Pre-independent India followed the British patent system and continued to do so even after independence. In spite of this, the vast market opportunity in the form of a large target population made India an attractive destination for many foreign firms. Prior to 1970, the Indian pharmaceutical market was dominated by western multinational corporations that controlled over 75% of the market, primarily through imported drugs. It was widely believed at that time in India that the patent regime was a major impediment to development of an indigenous drug industry.

After independence from sovereign rule, the independent government focused much of its efforts on achieving self-reliance through government sponsored investments in the pharmaceutical sector. In 1970, in order to make drugs affordable to the population at large, the Indian government enacted the new Patents Act and voided product patents for pharmaceuticals, food and chemical-based products. Under the 1970 Act, only a new method or process of manufacture could be patented and not the product itself, and that too only for a period of five to seven years. This meant that even a slight modification in the synthesis of a molecule was patentable, a provision that allowed several firms to produce essentially the same product through different processes, which ultimately led to the withdrawal of large multinationals. By 1980, the market share of multinationals fell to 50%, and continued to fall over the next decade. Indian pharmaceutical production, both formulation and bulk drugs, grew rapidly after the implementation of the new Act.

The Indian patent system (of the pre-Independence period) has failed in its main purpose, namely, to stimulate invention among Indians and to encourage development and exploitation of new inventions for industrial purpose in the country, so as to secure the benefits thereof to the largest section of the public.

-Patent Enquiry Committee, in 1950
This meant that even a slight modification in the synthesis of a molecule was patentable, a provision that allowed several firms to produce essentially the same product through different processes, which ultimately led to the withdrawal of large multinationals. By 1980, the market share of multinationals fell to 50%, and continued to fall over the next decade. Indian pharmaceutical production, both formulation and bulk drugs, grew rapidly after the implementation of the new Act.

_Ranjit Shahani, head of Novartis India_
The controversial provisions of the 2005 patent law

*Better or bitter pill?*
The year 1986 marked the launch of the Uruguay Round of international trade negotiations initiated by the WTO, which lasted for almost a decade.

The TRIPS agreement, one of the important results of the Uruguay Round, mandated strong patent protection, especially for pharmaceutical products, thereby allowing the patenting of NCEs, compounds and processes.

Bowing reluctantly to international pressure, the Indian government acceded to the WTO mandate and signed the TRIPS treaty in 1994. In doing so, it committed to reforming its patent law. Unlike the 1970 reforms, this time around, enacting a new patent law that conformed to the WTO’s mandate took several years, in part due to the opposition to the new Act within India. In 1995, when the Indian government attempted to amend its patent law to make it TRIPS compliant, the Bill was defeated in the Upper House.

Subsequently in 1999, when India’s plea to the Dispute Settlement Body of the WTO to be allowed to retain its 1970 patent law was defeated, notably by the United States and the European Union, the Indian government legislated a first set of amendments to its patent law. This amendment enabled India to comply with the Paris Convention Treaty (PCT), under which applications for international patents could be filed through the Indian Patent Office (IPO). Also, during the period between 1995 and 1999, the Indian government began accepting and processing applications pending the legislation of a new patent law through the grant of exclusive marketing rights.

The legislation that finally marked conformity with the TRIPS treaty was passed in late 2004 and came into effect on January 1, 2005. The 2005 Act, nonetheless included two very controversial provisions. One was the contentious Section 3(d) wherein patentability depends on proving efficacy (therapeutic). Further, compulsory licensing (Section 84) requires satisfying the “reasonable” requirements of the public and the availability of drugs at a reasonable price. However, the interpretation of these safeguards is still open to debate with its validity in the Indian courts yet to be tested comprehensively.
Patent reforms can affect the biopharmaceutical industry in two ways — by presenting barriers to imitation, thereby lowering performance (competition effect); or by stimulating licensing, thus enabling better performance (license effect).

Moreover the changes in the Indian pharmaceutical industry in the past have closely mirrored the evolving intellectual property regime changes in India. In the following sections we explore the resultant changes of the Indian pharmaceutical industry with the ‘new’ patent law.

Would the patent changes encourage multinationals to enter with ease?

Would Indian pharma innovate and adapt given the new challenges introduced with the patent changes?

Would domestic firms have the ability to utilise the existing assets or creating new ones to maintain their dominance?

Would the patent changes encourage foreign investment in R&D and transfer of technology?

Would the dominant position of Indian pharma be threatened?
The scenario post patent changes

*Exploring new frontiers*
Given that the enforcement of a stronger intellectual property regime has created considerable controversy, the likely effects on both domestic as well as foreign firms are of much interest to policy makers, participants, industry experts alike. While global players wait with bated breath to see if India will actually benefit from these patent changes in the long term, the policy makers and consumers wait to see how the new law would affect the domestic industry and access to essential drugs.

Here are some broad snapshots of how the new patent law has influenced innovation and competition.

**Patenting activity**

*Uptick in patenting activity*

As expected, changes in the patent law accelerated patenting activity (see Figure 1). From a mere 146 granted patent applications per year in the pre-TRIPS period (1962-94), this number increased to about 393 granted patent applications\(^1\) per year (1994-97) and further to about 882 granted patent applications per year pre-reform period (1998-2005). In the post-reform period (2005-2009), the number of granted patent applications per year stood at about 666 per year.

Thus, as expected, the introduction of stronger patent protection encouraged a surge in patenting activity, both by domestic and foreign firms.

*Increases by both Indian and domestic entities but greater increases among foreign entities*

Figure 2 shows the relative increases in patenting activity by entity type (foreign or Indian). In virtually every period, the number of granted patent applications per year was higher for both entities relative to the pre-TRIPS period. Notably, the increases were higher for foreign entities relative to domestic entities.

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\(^1\) Cumulative number of patents that were eventually granted and filed at Indian patent office divided by the number of assignees by year
As alluded to earlier, foreign entities are driven to increase patenting activity both by a greater incentive to innovate for Indian markets and to prevent imitation. Domestic entities are driven solely by a greater incentive to innovate.
The introduction of the product patents regime in 2005 has led pharma firms to shift their focus more towards R&D - Dr. Rajesh Jain (Ph.D), Jt. Managing Director Panacea Biotec Ltd

Patent filings by smaller entities

If increases in foreign patenting in India were merely driven by a few large foreign multinationals, then the concentration of patents among foreign entities should have increased post 1994 and should also be higher relative to the concentration of patents among Indian entities post 1994.

The fact that the concentration of patents was lower among foreign entities relative to Indian entities after 1994 suggests that the patent law amendments encouraged patenting by several small foreign firms.\textsuperscript{2}

\begin{table}[h]
\centering
\caption{Patent assignees}
\begin{tabular}{|c|c|c|c|c|c|}
\hline
\textbf{Period} & \textbf{Foreign assignees} & & \textbf{Domestic assignees} & & \\
 & \textbf{Granted patent application per year} & \textbf{Patents} & \textbf{Patents per assignee} & \textbf{Granted patent application per year} & \textbf{Patents} & \textbf{Patents per assignee} \\
\hline
1962-1994 & 136.75 & 4376 & 6.78 & 9.69 & 310 & 5.00 \\
2005 - 2009 & 630.20 & 3,151 & 3.02 & 35.80 & 179 & 2.03 \\
\hline
\end{tabular}
\end{table}

\textsuperscript{2} Higher concentration implies few firms hold lots of patents.
**Foreign entities are more R&D intensive**

Foreign entities hold both more process and product patents. This can be attributed, in part, to differences in R&D spending. Since, on average, foreign multinationals are larger, they also spend relatively more in R&D relative to domestic entities. This is reflected in the fact that foreign entities hold about eight times more process patents than Indian entities.

![Figure 3: Total granted process patents](image-url)
Foreign firms hold most of the product patents

While a small percentage of the Indian pharmaceutical industry has managed to ramp up its R&D capability to produce products for the market, a significant number of biopharmaceutical firms still find it challenging to transition to a new drug discovery. Hence it is not surprising that a predominant number of product patents are held by MNCs.
**Greater increase in product patent by foreign firms**

With foreign entities, the proportion of product patents increased from 0% in the pre-TRIPS period to 11% in the pre-PCT era, and further to 31% in the pre-reform era and 27% in the post-reform era. In the case of domestic entities, it increased from 0% in the pre-TRIPS to 6% in the pre-PCT era\(^3\), reaching 12% in the pre-reform era and 16% in the post-reform era.

**Indian entities exhibit better capabilities at process R&D than product R&D**

Foreign entities together held 15 times more product patents than domestic firms. However, foreign entities together held only eight times more process patents than domestic firms. The unique history of the Indian pharmaceutical industry, which led domestic firms to build their capabilities in process engineering, may explain why Indian entities are relatively better than their foreign counterparts in process R&D rather than product R&D.
Indian entities specialize in process

Overall around 89% of all granted patent applications were process patents with about 81% of all granted applications belonging to foreign assignees being process patents. 11% of all foreign assignees and 6% of all domestic assignees were product patent holders.

Table 2: Proportion of process patents

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<tr>
<th>Period</th>
<th>Foreign assignees</th>
<th>Domestic assignees</th>
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<tr>
<td>1962-1994</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>1994-1998</td>
<td>89%</td>
<td>94%</td>
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<tr>
<td>1999-2004</td>
<td>69%</td>
<td>88%</td>
</tr>
<tr>
<td>2005-2009</td>
<td>73%</td>
<td>84%</td>
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Licensing

The strength of patents also influences licensing. Stronger patents, in theory, should also increase licensing activity. The match between the technology of MNCs and the complementary capabilities of domestic firms should facilitate technology in-licensing by domestic firms and contracting out of manufacturing and distribution by MNEs. One of the stumbling blocks for firms entering new markets is their lack of reach into rural and poorly connected pockets. With generic drug manufacturing technology ably supported by government policies and undisturbed for many years, India developed a robust mechanism of manufacturing and distribution. Whereas Indian infrastructure is, at best, still developing, organizational structures and distribution networks are existing assets that foreign firms can tap into.

We now explore how both the quality and the nature of licensing deals changed with changes in the patent regime.

### Table 3- Licensing Deals of top 20 Indian firms

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<tbody>
<tr>
<td></td>
<td>Out</td>
<td>In</td>
<td>Deals per firm</td>
<td>Out</td>
</tr>
<tr>
<td>Top 5</td>
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<td>1</td>
<td>0.20</td>
<td>8</td>
</tr>
<tr>
<td>Top 10</td>
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<td>1</td>
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<td>10</td>
</tr>
<tr>
<td>Top 15</td>
<td>1</td>
<td>1</td>
<td>0.20</td>
<td>13</td>
</tr>
<tr>
<td>Top 20</td>
<td>1</td>
<td>1</td>
<td>0.20</td>
<td>13</td>
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**Uptick in licensing**

Among the top 20 domestic and foreign firms put together, the number of licensing deals per firm increased from 0.10 deals per firm in the pre-TRIPS era to 1.85 deals per firm in the pre-PCT era. The trend continued with the number of deals per firm increasing to 3.85 deals per firm in the pre-reform era to six deals in the post-reform era.
Patent law changes increased in-licensing more than out-licensing for Indian firms and out-licensing more than in-licensing for foreign firms

The number of in-license deals per Indian firm increased from 0.05 in the pre-TRIPS era to 0.65 in the pre-PCT era, to 1.5 in the pre-reform era to 2 in the post-reform era. The number of out-license deals per Indian firm increased from 0.05 in the pre-TRIPS era to 0.7 in the pre-PCT era, to 1.8 in the pre-reform era to 2.8 in the post-TRIPS era to 0.2 in the pre-PCT era, to 0.4 in the pre-reform era to 0.85 in post reform era.

The number of out-license deals per foreign firm did not increase by much — rising from 0 in the pre-TRIPS era to 0.2 in the pre-PCT era, to 0.25 in the pre-reform era to 0.35 in post-reform era.

Table 4: Licensing Deals of top 20 foreign firms

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<tbody>
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<td>Out</td>
<td>Deals per firm</td>
<td>In</td>
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<td>0</td>
<td>4</td>
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<tr>
<td>Top 10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
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<tr>
<td>Top 15</td>
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<td>0</td>
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<td>4</td>
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<tr>
<td>Top 20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
</tbody>
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R&D location

_Most patents held by foreign entities were for inventions outside India_

Of all patents held by foreign entities, only between 0.5% and 3.5% of the patents were for inventions exclusively by Indian inventors. This proportion marginally decreased with the patent law change from 3.5% in the pre-TRIPs era to 0.5% in the post-reform era, primarily due to an uptick in foreign patenting of inventions outside India.

_Very few collaborative patents_

Foreign entities seldom collaborated with Indian scientists. The proportion of collaborative patents (patents held by both an Indian and foreign inventor) was relatively small and did not change significantly with the change in patent law. On average, the proportion of collaborative patents held by foreign assignees varied between 0.3% and 0.4% and remained flat through the eras.

_The domestic industry, in view of the growing attractiveness of the Indian market for research based products, has begun working on new avenues of drug development and placing a greater focus on innovation- Dr. Rajesh Jain (Ph.D), Jt. Managing Director Panacea Biotec Ltd_
Many patents held by Indian entities invented outside India

Many patents held by Indian entities involved foreign scientists. About 20% of all patents held by Indian entities were exclusively for inventions made abroad, and about 19% of all patents held by Indian entities were for inventions made in collaboration with one or more foreign scientists. The patent law appears to have increased the proportion of patents held by Indian entities for inventions in India. In the post-reform era, about 80% of all patents held by Indian entities were for inventions made exclusively by Indian scientists. The number of collaborations appears to have reduced after the change in patent law, standing at just 3% in the post-reform period. Thus, the new patent law increased Indian invented patents held by Indian entities but did not affect the proportion of Indian invented patents held by foreign entities.

Table 5: Foreign assignee patents by inventor type

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<td>Collaboration</td>
<td>10</td>
<td>5</td>
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<td>9</td>
</tr>
<tr>
<td>%</td>
<td>0.3%</td>
<td>0.4%</td>
<td>0.3%</td>
<td>0.3%</td>
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<tr>
<td>Indian</td>
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<td>46</td>
<td>48</td>
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<tr>
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<td>3.5%</td>
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<tr>
<td>Total</td>
<td>3445</td>
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<td>3129</td>
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Contract research for new product development as well as contract manufacturing and technology licensing by MNCs through Indian pharma firms have emerged as new business models in recent years as a result of the changed patent regime- Panacea Biotech-Dr. Rajesh Jain (Ph.D), Jt. Managing Director Panacea Biotec Ltd

- Increase in patenting activity by both domestic and multinational firms
- The new regime, however, does not stimulate offshoring of R&D
- A negligent increase in collaborations, even in process technology
- Very few patents exclusively by Indian inventors, even in process technology
- A positive increase in licensing activity for both foreign and Indian firms
- License deals per firm are higher for an exporter relative to an Indian firm and lowest for top MNEs
- Increased in-licensing over out-licensing for Indian firms and out-licensing over in-licensing for foreign firms
- Superior domestic market performance by Indian firms and declining performance of foreign firms after patent law change
Performance

Superior domestic market performance by Indian firms and declining performance of foreign firms after patent law change

The number of Indian firms among the top five increased from two in the pre-TRIPS period to four in the post-reform period. Likewise, the number of Indian firms in the top 10 increased from two in the pre-TRIPS period to eight in the post-reform period. The number of Indian firms among the top 15 increased from four in the pre-TRIPS period to 11 in the post-reform period.

Domestic firms performance in domestic market (revenues)

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In this paper, we explored how the recently concluded patent reforms in India, which strengthened patents, influenced strategies and competition in the Indian pharmaceutical industry. We highlight the dual roles that patents can play in the technology strategies of firms. While on one hand stronger patents increases appropriability and consequently the incentives to innovate, on the other, it also encourages firms to specialize – to either to exclusively produce technology or manufacture and distribute. While most of the industry experts and policy makers expected patents to stimulate domestic innovation and foreign patenting its influences on licensing of technology knowhow or even manufacturing was largely unexpected. In essence, our preliminary analysis indicates that it is unlikely that the patent changes in 2005 will reverse the effects and gains that were ushered in by the patent law of 1970.

Thus in essence our analysis highlights that the effect of Intellectual Property Rights in an industry is idiosyncratic to and is contingent upon the underlying capabilities of firms in that industry. When capabilities are fragmented such that only a few firms can produce proprietary technology of their own, or only a sub-set of firms have market access, stronger patents may promote specialization. Consequently, the possibilities for licensing and the functioning of Markets For Technology (MFT) will likely preserve the dominance of industry players that already have established distribution channels and market access. With the Indian pharmaceutical industry, a preponderance of domestic firms that have market access but are still ramping up their R&D capability. Multinationals typically possess that capability but many of them especially the relatively newer entrants are still ramping up their distribution networks to cater to Indian markets. These appears to have increased incentives for specialization resulting in multinationals specializing as technology suppliers and domestic firms specializing in commercializing technology.

An obvious implication of our results is that for firms with significant downstream capability, stronger patents is not likely to be a threat, but rather beneficial, because with stronger patents such firms are just likely to have better access to cutting edge technology. For firm with ability to produce proprietary technology, stronger patents are likely to increase the number of options to monetize technology– by facilitating out licensing, firms can just out-license their technology to domestic firms rather than embedding the technology into a product.

That said, the jury is still out of what the long terms effects of stronger patents might be for the Indian pharmaceutical industry. Given that many provision of the law yet to be tested in the Indian courts, it is yet unclear whether patents truly confer property rights to the patent holder and how deviations between the letter of the law and is enforcement means to the industry. The near future will perhaps provide more insights on whether patents truly confer all rights on the innovation to its holder.
We wish to thank Mr. Rajeev Nannapenni, Vice-Chairman and Chief Executive Officer, Natco, Dr. Rajesh Jain (Ph.D) Jt. Managing Director, Panacea Biotec Ltd. for their insightful comments. We also thank Srikanth Velichaeti, ISB.
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