The Emergence of New R&D Paradigms in the Indian Pharmaceutical Industry: Post TRIPS Period

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Received 23 April 2011, revised 1 June 2011

India, being a signatory of WTO agreements, has moved from no or partial patent protection to full fledged patent protection. This represents a radical break from the past in which developing countries typically had only weak levels of patent protection. In this context, this research examines the steps involved in development of R&D capabilities in the Indian pharmaceutical firms as a response to strengthening of patent law. This paper analyses the post-TRIPS behaviour of domestic pharmaceutical firms in India with respect to R&D intensification, development of new molecules and enhanced DMF filings. The study establishes that firms in the post WTO era have increased their R&D efforts tremendously and are moving towards the development of advance level process and product R&D capabilities. Such firms have also opted for vigorous DMF filings abroad reflecting qualitative modifications and adjustments in its R&D capabilities in the production of exportables.

Keywords: TRIPS, innovation, NCE, DMF

The drivers of globalization are bringing in ‘competency destroying changes’¹ for firms in different industries. The established firms need restructuring of existing competencies to avoid the failure in the face of such changes.² New regulatory environment or radical innovations are the changes which make existing competencies redundant.³ New environments and realities are forcing countries and firms to reconfigure their competencies to survive and succeed in fast changing business environments. Rapid technological growth and industrial development in the East Asian economies viz., Korea, Japan, Singapore, Hong Kong, Thailand, Malaysia, Indonesia and China have been widely acknowledged in the literature. There seems to be a general consensus that the success of these economies owes a lot, in general, to their ability to imitate, absorb, assimilate and replicate foreign innovation facilitated by national level technology and industrial policies.⁴ The Indian government has regularly taken many initiatives to encourage public, private as well as foreign investments in pharmaceutical R&D with an ultimate aim to make drugs available to the masses at affordable prices. The most significant initiative, however, was the non-recognition of pharmaceutical product patents. In the 1970s, India introduced complex laws and policies to regulate the domestic pharmaceutical industry particularly, to counteract monopoly abuses by foreign multinationals, and to jumpstart the local production. The 1970s Patents Act propelled Indian firms on the reverse engineering path and spurred the growth of highly inward looking pharmaceutical firms with the industry focusing on the domestic market. The ‘imitative’ follower trajectory differed greatly from the technological trajectories followed by the firms in the US and Europe. From an Indian perspective, lack of intellectual property rights (IPR) laid the foundation for a strong domestic industry in the initial formative years and later, gradual liberalization in 1990s enhanced competition and concern for quality and innovation.⁴

Over the past few years, however, there have been a number of changes in the policy framework. The Indian Patent Act of 1970 that governed the IPR regime during the last three decades has undergone important changes. The Patents (Amendment) Act, 1999 amended the Patents Act, 1970 with retrospective effect from 1 January 1995. The Act was amended again in May 2002 and finally a full-fledged product patent regime was introduced in India from 1 January 2005 through a presidential decree which was endorsed by parliament in March 2005.

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The firms that developed knowledge and capabilities in reverse engineering based R&D in the past have had to reorient themselves for R&D based innovation to survive and compete in a regulated and open market. For firms that have given little attention to research and innovation in the past, this transition is very difficult. Indian firms have responded to these changes in novel and complex ways. Using empirical evidence from firm level investigations, this paper shows how Indian firms have evolved from reverse engineering setups operating under the process patent regime to technologically advanced and sophisticated organizations capable of catering to diverse markets in the product patent regime.

**Objectives and Hypothesis of the Study**

The paper aims to examine the changes in R&D behaviour of Indian pharmaceutical firms and the modalities explaining such change. The hypothesis drawn from this objective is:

1. The R&D of Indian Pharma as a percentage to net sales has increased for the period 1996-2008:
   - The R&D capabilities have been scrutinized in terms of firms’ enhanced innovativeness through the development of New Chemical Entities (NCEs) and increase in Drug Master Files (DMFs) with United States Food and Drug Administration (USFDA). Thus, the following set of hypothesis can be drawn:

2. Increase in the development of NCEs indicates innovativeness of Indian Pharma
3. Increase in DMFs are positively linked with R&D capabilities of Indian Pharma

**Methodology**

The study has been carried out by analysing the economic behaviour of 20 pharmaceutical companies that cover around 50 per cent of pharmaceutical sector in two patent periods over 39 years i.e., from 1970 to 1994 and 1995 to 2009. The companies included in the study are Cipla, Ranbaxy, Glenmark, Dr Reddy’s, Lupin, Piramal Healthcare, Wokhardt, Aurobindo, Torrent, Indswift, Orchid, Alembic, IPCA, Unichem, Glenmark, JB Chemicals, Medicasp, Divi, Zandu and Cadila Healthcare. The terms ‘research’ and ‘development’ in this study are not restricted to technology alone, but cover other business and management processes as well. The R&D intensification of companies in the post WTO phase has been studied in terms of R&D as a percentage to net sales for the period 1996-2009. The innovativeness of Indian pharmaceutical companies has been scrutinized in terms of enhanced production of NCEs by employing the Product and Process R&D Classification Model. Since USA is the largest export destination for Indian pharmaceuticals (around 1/4th of total pharmaceutical exports), the rise in DMFs with US FDA that reflect the R&D capability and bulk drug export intensity of Indian Pharma has been studied.

**Genesis of The Patents Act, 1970**

At the time of independence in 1947, India’s pharmaceutical market was dominated by western MNCs that controlled a larger share of the market primarily through importation. Approximately 99 per cent of all pharmaceutical products protected by patents in India at the time were held by foreign companies and domestic Indian drug prices were among the highest in the world. In contrast to 62 per cent of market share in the early 1950s, the market share of indigenous sector declined to 32 per cent by 1970 (ref. 8). As a result, due to lack of competition, drug prices in India were very high. Besides, in the 1970s, India was dependent on imports for many of the essential bulk drugs. The import dependence constricted consumption in a country deficient in foreign exchange and inhibited the growth of industry.

The Indian pharmaceutical market remained import-dependent through the 1960s until the government initiated policies stressing self-reliance through local production. To facilitate an independent supply of pharmaceutical products in the domestic market, the Government of India founded 5 state-owned pharmaceutical companies. To end the dominance of foreign drug companies, the Indian government enacted a series of policies designed to foster self-sufficiency in the production of basic drugs. The Government of India introduced the Patents Act, 1970 which came into force in 1972 wherein it followed a policy of positive discrimination towards indigenous companies.

The Act of 1970 practically eliminated the monopoly status which MNCs had enjoyed until then. An MNC inventing/discovering a new drug could, at best, patent the process of manufacturing it provided it was new. Unlike in the previous patent regime, it could not patent all the processes known to it even if these were new. For a particular drug, only one method or process—the best known to the applicant could be patented.
The spirit of this policy regime of the 1970s was reinforced by Drug Policy, 1978 with its three-fold objective of self reliance in pharmaceutical technology, self sufficiency in drug production and easy and cheap availability of drugs. This in a sense summarizes the policy framework adopted in the 1970s with a clear emphasis on import substitution and self-reliance in the production of bulk drugs as well as formulations and in creating indigenous technological capability of process development (bulk).  

Post 1970 Scenario

Structural Change and Production Growth

Complete elimination of product patent protection and also the provision that only one process could be patented by an applicant, brought about significant changes in the Indian pharmaceutical industry (IPI). The indigenous firms were quick to respond to the favourable provisions in the Act of 1970 which brought in a renaissance. More units larger in size and capacity, set up in the 1970s and 1980s started producing drugs, which were primarily imported till then. Technical institutes that were set up in the early 1950s and 1960s had created technical and engineering skills, which could easily adapt the technology developed elsewhere proved to be very advantageous for the industry. By 1972, over 100 essential drugs covering a wide spectrum of therapeutic groups like antibiotics, sulpha drugs, anti leprotic drugs, analgesics, antipyretics, vitamins, tranquillizers, photochemical and various other pharmaceutical chemicals were produced in India from basic stages. 

After the changes in the patent law, large scale production of bulk drugs was started by the indigenous sector in the late 1970s, particularly in the 1980s. The development of the bulk drugs sector is actually the most important achievement of the pharmaceutical industry in India leading to a transformation of the industry. 

The result was that the MNCs lost their market domination. From around 60 per cent market share in the late 1970s, their share declined to 40 per cent by the early 1990s (Table 1).

The older firms such as Ranbaxy and Cipla saw dramatic growth essentially after the revision of the Patents Act. Their ranks in the domestic retail market were respectively 43rd and 56th in 1971, way behind the MNCs such as Glaxo, Pfizer, Hoechst, Lederle, Ciba, May & Baker, Abbott, Sandoz, Boots, Smith Kline and French which dominated the industry those days. Today, Cipla is the largest company and Ranbaxy, the 2nd largest company in the domestic market, and only one MNC (Glaxo Smith Kline) has sales comparable to them.

The favourable environment also attracted entry of a number of new firms. Among the top companies, Sun Pharmaceuticals, for example, was set up in 1983 and Dr Reddy’s Laboratories in 1984. A large number of specialized bulk drugs manufacturers, set up since the 1970s–particularly in the 1980s–contributed immensely to the transformation of the Indian pharmaceutical industry. The more prominent among them are Shasun (1976), Morepen Laboratories (1984), Aurobindo (1986), Neuland Laboratories (1986), Divi’s Laboratories (1990), Orchid Chemicals and Pharmaceuticals (1992), and Hetero (1993).

From over 2200 units in 1969-70, the size of Indian pharmaceutical industry has increased to nearly 24,000 in 1995-96. Many of them were small-scale units receiving incentives from the Government, such as reservation of drugs for exclusive production. Many of them commenced their operations specializing in generics production. 

Production of bulk drugs increased from Rs 900 million in 1974-5 to Rs 7300 million in 1990-91 and to Rs 15,180 million in 1994-95. Production of formulations increased from Rs 4000 million in 1974-5 to Rs 38,400 million in 1990-91 and to Rs 79,350 million in 1994-95. Exports also started increasing steadily. From a meager US$ 54.3 million in 1974-75, exports of drugs and pharmaceuticals increased to US$ 536.6 million in 1990-91 and to US$ 694.0 million in 1994-95. Till 1987-88, imports were larger than exports except for a few years. But with the steady growth in domestic production and exports, the country has become a net exporter since 1988-89 (ref. 8).
Technology Process

During the last three decades of last century, the large private Indian pharmaceutical firms focused their efforts on reverse engineering oriented process R&D, and activity was limited to applying known knowledge, or to making small adjustments in the contents. A few public laboratories under the Council of Scientific and Industrial Research (CSIR) also operated in pharmaceutical R&D, specifically imitative process R&D. There had been widespread reverse engineering for non-infringing processes. This is not to suggest that infringing process development (simple imitation) did not take place. Indeed, the industry acquired substantial technological capability of process development through reverse engineering, both infringing processes for off-patented molecules and non-infringing processes for patented molecules. This phenomenon has often been referred to as the process revolution in the Indian pharmaceutical sector. As a result, the bulk drug industry grew at a phenomenally high rate of 21 per cent and 11 per cent p.a. during the 1970s and 1980s, respectively. Along with process revolution, simple product development in conventional dosage forms which had already started in the post independence era, continued post 1970s. As a result, the formulation industry also registered impressive growth rates of 13 per cent and 10 per cent p.a. respectively, during the same periods. The impetus largely came from the massive expansion of bulk drugs due to the process revolution and the policies to deter captive consumption of bulk. Indeed there was a marked increase in R&D expenditure of the industry during this period: it stood at Rs 500 million in 1986 accounting for nearly 2 per cent of the industry’s sales turnover compared to less than 1 per cent prior to 1970. As an outcome of the policy framework, MNCs became reluctant to launch their new drugs in India. But that did not deprive the Indian patients from the latest drug discoveries. Indian firms introduced these new drugs in the market using non-infringing processes, perhaps with a time lag marginally exceeding the demand lag.

One of the most obvious indicators of success achieved by the Indian pharmaceutical industry in the period since the adoption of the Patents Act of 1970 has been shortening of the time lag between introduction of a drug in the global market by the inventor and marketing of the same drug in the Indian market. Indian firms have been able to progressively shorten the time lag between the introduction of a drug by the inventor and its introduction in the Indian market. The overall impact of this mix of policies was favourable for the industry.

TRIPS Agreement and Patent (Amendment) Act, 2005

The year 1995 recorded another milestone for the Indian pharmaceutical sector. The World Trade Organization (WTO) came into effect in 1995. One of the agreements negotiated under WTO was the Trade-Related Aspects of Intellectual Property Rights (TRIPS). India being a founder member of WTO, automatically became a signatory to the TRIPS Agreement.

TRIPS provided a three-stage frame for countries such as India which did not grant product patent rights in pharmaceuticals when TRIPS came into force on 1 January 1995:

(i) Introduction of a facility (mail box) from 1 January 1995 to receive and hold product patent applications in the fields of pharmaceuticals (and agricultural chemicals). Such applications were not to be processed for the grant of a patent until the end of 2004. But Exclusive Marketing Rights (EMRs) could be obtained for that application if a patent had been granted in some other WTO member country.

(ii) Compliance, from 1 January 2000, with other obligations of TRIPS, namely, those related to the rights of the patentee, term of patent protection, compulsory licensing, reversal of burden of proof and so on.

(iii) Introduction of full product patent protection in all fields including pharmaceuticals from 1 January 2005. All the product patent applications held in the mail box were also required to be taken up for examination from 1 January 2005.

Compliance with the TRIPS requirements took substantial time in India reflecting the significant opposition to TRIPS in India. To meet its TRIPS obligations, India amended its patent law on 22 March 2005, abolishing its ‘process’ patents law and reintroduced Western style ‘product’ patents for pharmaceuticals, food, and chemicals. This action effectively ended 36 years of protection for Indian pharmaceutical companies and stipulated that Indian companies selling copycat drugs must pay foreign patent holders a ‘reasonable’ royalty for copies sold in
the Indian market. The amendment made reverse engineering or copying of patented drugs illegal after 1 January 1995. The Act allowed for only two types of generic drugs in the Indian market: off-patent generic drugs and generic versions of drugs patented before 1995.

The Act encouraged significant numbers of foreign pharmaceutical companies to participate in the Indian market and, in 2005 foreign drug producers filed approximately 8,926 patent applications to cover their patented drugs sold as generics in the Indian market. Whereas, the Patents Act of 1970 had discouraged patenting activity in the country and the number of patents granted per year fell from 3,923 in 1970-71 (of which 629 were to Indian applicants, 3,294 to foreign applicants) to 1,019 in 1980-81 (349 Indian, 670 foreign).

Enhanced R&D Intensity

Changes in patent law under TRIPS obligation, preventing the reverse engineering of patented molecules forced Indian firms to enhance their R&D efforts and investments (Table 2). It was initiated by Dr Reddy’s Laboratories and Ranbaxy Laboratories. Since then many other companies have joined in. The twenty companies listed in Table 3 spent Rs 83.8 crores on R&D in 1996 and Rs 2192 crores in 2009. The R&D as a percentage of net sales was 2.62 per cent for the twenty companies in the year 1996 and rose to nearly 8.40 per cent in 2005 and was 6.5 per cent in the year 2009.

The R&D spend of the major Indian companies has grown at a compound annual growth rate (CAGR) of 38 per cent during the period 2000-01 to 2005-06 (ref. 18). The period after 2005-06 experienced a decrease in R&D in Indian pharmaceuticals reflecting the influence of global recession and in 2009, it has shown promising trend. A company wise trend more incisively reflects the development in the R&D pattern of Indian pharma. The R&D spending as a percentage to net sales for certain firms has matched international standards and in few instances has outpaced many foreign MNCs such as Glaxo Smithkline, Novartis, Sanofi, etc.

Five companies comprising Dr Reddy, Glenmark, Torrent, Ind Swift and Cadilla Healthcare have double digit R&D expenditure as a percentage to net sales intermittently; a fact, hitherto never recorded in the history of Indian pharmaceutical industry (Table 3).

Shift in the Production Paradigm: Production of NCEs

The shift from process patent to product patent regime led Indian firms to invest more in the development of NCEs, a fact never recorded before 1995. The following classification is based on Kale’s model of classification of process and product R&D.

Pharmaceutical R&D can be broadly classified into three types: (i) Development of NCEs; (ii) Modifications of existing NCEs (new chemical derivatives, new formulations, new combinations); and (iii) Development of new processes for manufacturing drugs (whether old or new).

In the pre-TRIPS scenario, R&D in the Indian pharmaceutical companies was primarily of the third type. The current research has shown that the Indian pharmaceutical industry is actively participating in the first two kinds of R&D post-WTO.

Traditionally, pharmaceutical R&D has two distinct phases; (i) product research and (ii) process development for production. In case of process R&D, the capabilities in reverse engineering, generics R&D and New Drug Delivery Systems (NDDS) are mapped as basic, intermediate and innovative. Reverse engineering involves copying the manufacturing process using indigenous sources of technology while generic R&D includes reverse engineering.
producing the product with non-infringing and innovative processes. NDDS involves development of technology to introduce a drug at diseased site in a novel way.

In case of product R&D analogue research, new target or new leads and original NCE research can be characterized as analogue, intermediate and advanced level capabilities. Analogue research involves modification of existing molecule which can provide better efficacy or reduce the side effects of existing molecules. The intermediate capability in product R&D represented by new target or new leads requires higher skills than analogue research. Finally, totally original research will involve putting up whole new hypothesis about the disease and its treatment. It will require in-depth knowledge about biological and chemical aspect of disease as well as skills in areas like target validation and lead optimization.

A large share of R&D investment continues to be in generic formulation development and API process research, but the scenario is rapidly changing and investment is also being deployed in cutting-edge New Drug Discovery Research (NDDR) by several Indian companies. Although, there is a lot to achieve in research, this emerging pattern truly signifies the onset of the IPR regime in India. At present, there are more than fifteen Indian companies which are involved in R&D for development of new drugs. Most of these companies have set up or are in the process of setting up new research centres with NDDR as a major objective. Ranbaxy, for example, has set up its new research centre at Gurgaon. It employed about 400 scientists and spent an amount of Rs 460.51 crore in 2007-08, the largest for R&D among Indian companies and total of Rs 2597.77 crore from 1996 to 2008 (ref. 20). The Table 3 shows the R&D in NCEs by Indian pharmaceutical companies.

![Table 3 – Company wise R&D as a percentage to net sales](image)

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<th>2008</th>
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Source: CMIE, Prowess database

Table 3 – Company wise R&D as a percentage to net sales

![Image](image)
research, medium sized and small sized firms have also invested in NCE research. Amongst the small sized firms investing in novel discovery research, Glenmark’s performance is exceptional. All companies covered in Table 4 have entered into drug discovery research only after 1995, the year India signed the TRIPS Agreement; no investment in drug discovery was observed prior to 1995 in India.

A DMF is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. For exporting bulk drugs to USA, Indian companies are required to file a DMF including detailed information on kind of equipment, location of the plant, description of production facility, process chemistry, raw material specifications, stability data, impurity profile, etc. Types of DMFs are as follows:

Type I: Manufacturing site, facilities, operating procedures, and personnel (no longer applicable)

Type II: Drug substance, drug substance intermediate and material used in their preparation, or drug product

Type III: Packaging material

Type IV: Excipient, colourant, flavour, essence, or material used in their preparation

Type V: FDA accepted reference information

The documentation to register drugs is extremely detailed and often very expensive. The review procedures of such documentation are very stringent and do not permit any low cost approach. The complete process details, site plans and all intricate details are demanded and have to be provided. The cost of filing a DMF can go up to US$ 200,000 depending on the product (the steps involved, the processes, the number of tests to be done, and so on).

The increase in DMF filing is the important barometer of rising R&D capabilities in India. India is rapidly emerging as a trusted outsourcing destination for not only generic drugs but also high-end, difficult to manufacture innovator/patented drugs. Indian companies have been at the forefront in leveraging the increased outsourcing demand for APIs/intermediates, as reflected in the aggressive DMF filing by Indian companies (Fig. 1).

India has the highest number of DMFs amongst all key competing economies. From 1998-2010, India had more than 2031 filings, 3 times higher than that of China. Other countries such as Italy, Spain, Mexico, Brazil, etc., are still way behind. The share of DMFs by Indian firms has increased considerably from 14 per cent in 2000 to 50 per cent in 2009.
While analysing performances of individual companies that form part of the sample, some interesting facts came to light. Dr Reddy is ranked first in US DMFs from India (390 Type II active US DMFs) and ranked number three in US DMFs globally. Ranbaxy (239), Aurobindo Pharma (145) and Cipla (115) are ranked second, third and fourth, respectively, revealing the export oriented research scenario in Indian pharmaceutical industry (Table 5).

To satisfy the US FDA’s regulatory requirements, dedicated plants for drug manufacture need to be set up at huge costs. The costs are much higher than that incurred in a plant following WHO GMP (good manufacturing practices) or that following the guidelines in EU countries. Certification is not a onetime process and requires maintenance of pre specified norms throughout. In other words, an US FDA norms compliant plant is six times the cost of an ordinary plant of the type most small Indian pharmaceutical companies have. The cost of such a plant for even a simple bulk drug may cost around US$ 3-5 million in India (excluding documentation and other costs incurred on exports). Most of the Indian companies which have set up such dedicated bulk drug facilities for the US market have invested at least US$ 10 million. To have a reasonably good portfolio of bulk drugs, the cost of plant and maintenance would be around US$ 20 million.

India has one of the largest numbers of FDA approved bulk drug plants in the world outside of USA. The Fig. 2 shows that there was no such production facility before 1985. The ten years spanning 1985 to 1995 saw coming up of only 11 such plants (only 1 by 1990), whereas the post WTO period (1998-2005) witnessed mushrooming of such facilities and number shot up to 119.

Conclusion
The findings in this study confirm that the pharmaceutical industry in India has been deeply affected by the two patent law regimes. The TRIPS Agreement represents an enormous challenge for pharmaceutical firms in developing countries, although in cases of certain Indian pharmaceutical firms, it has acted as a catalyst, accelerating their movement towards the innovative R&D. The results show that innovative Indian pharmaceutical firms have developed basic level of process R&D capabilities through imitative R&D and as a response to change in patent law these firms are moving
towards the development of advance level process and product R&D capabilities. The difference of knowledge base, organizational practices in imitative and innovative R&D implies that the processes and capabilities that served firm well in the past may not be relevant in new environment. Many capable Indian pharmaceutical companies have been quick to recognize these challenges and have gone for suitable measures like investing more resources into product and process development. In addition, Indian companies are responsible for most of the increase in patent filings in the US in the form of rising DMFs reflecting qualitative modifications and adjustments in R&D capabilities in the production of exportables.

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