
The TRIPs Agreement and the Pharmaceutical Industry: The Indian Experience

Atsuko Kamiike and Takahiro Sato

Abstract

The Patent Act of 1970 and DPCO have not only brought about the development of the Indian pharmaceutical industry but have also contributed to improvement of health and welfare in India. However, since the mid-1990s, the Indian pharmaceutical industry has faced new challenges on account of the WTO-TRIPS Agreement. It was assumed that introduction of pharmaceutical product patents would have a negative impact on the Indian pharmaceutical industry by hampering its growth. The industry can no longer manufacture by reverse engineering or export drugs whose product patents are in effect. However, contrary to expectations, the Indian pharmaceutical industry has been growing in the post-TRIPS period. On the other hand, there are still concerns that the new patent act might reduce generic drug supplies and lower access to medicines in India. Ensuring access to medicines at affordable prices is one of the most important tasks of the Indian government. Taking into consideration that India is the major supplier of affordable generic drugs, the issue of access to medicines is crucial not only for India but also for other poor developing countries. Thus, the Indian government should seek an appropriate balance between the development of the Indian pharmaceutical industry and the improvement of public health. In other words, the government should balance intellectual property protection with access to medicines

1 Introduction

The Indian pharmaceutical industry has achieved self-sufficiency in pharmaceutical production and emerged as one of the largest drug exporters in the world. India is one of the major drug-producing countries. The industry has become one of the major drug exporters since the late-1980s and showed promise of its global competitiveness. The Indian pharmaceutical industry continues to expand its presence across the world.

This success has been attributed to the industry's ability to conduct R&D and to develop generic drugs that the industry acquired and improved under the weak patent protection regime of the Patent Act of 1970 during the period of the 1970s to 1990s. The Patent Act of 1970, which recognized process patents but not product patents, paved the way for the progression of indigenous R&D.

However, since the mid-1990s, the Indian pharmaceutical industry has faced new challenges on account of the World Trade Organization's Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement).

In March 2005, India completed the amendment of the Patent Act of 1970 to comply with the TRIPS Agreement. It introduced product patents for drugs, foods, and chemical products and the patent term was increased to twenty years. At the beginning, it was assumed that the amendment of the patent act to introduce product patents would have a negative impact on India. It would hamper the growth of the Indian pharmaceutical industry because under the product patent regime, the industry can no longer manufacture by reverse engineering or export drugs whose product patents are in effect. In addition, that the amendment would result in lowered access to medicines in India due to a sharp rise in drug prices caused by the introduction of pharmaceutical product patents was of concern.

India is one of the largest pharmaceutical exporters and a major supplier of affordable and quality generic drugs in the world. At the same time, India is also one of the poorest developing countries lacking a national health insurance system and suffering from tropical diseases such as malaria and dengue fever. Along with South Africa, India has the highest number of reported HIV carriers in the world. That is to say, India is a country whose public health is feared to deteriorate rapidly because of the sudden rise in drug prices. Given that India is a major supplier of affordable generic drugs, the issue of access to medicines is crucial not only for India but also for other poor developing countries. The time is right to examine the case of India in the present day when the relationship between TRIPS and public health is of major concern.

The rest of the study is organised as follows: Section 2 provides an overview of the Indian pharmaceutical industry. Section 3 describes the TRIPS Agreement and the amendment of the Patent Act of 1970. Section 4 presents the impacts of the TRIPS Agreement on the Indian pharmaceutical Industry. Section 5 describes the trend of productivity in the Indian pharmaceutical industry. Section 6 examines the issue of access to medicines. Section 7 offers some concluding remarks.

2 Overview of the Indian Pharmaceutical Industry

The Indian pharmaceutical industry has shown steady growth during the last three decades and has emerged as one of the leading global players in generics. India is one of the major drug-producing countries in the world, being the fourth-largest producer by volume and the thirteen-largest by value, with about a 20-22 percent share in global generic production.

The Indian pharmaceutical industry, which had little technological capability to manufacture drugs indigenously in the 1950s, achieved self-sufficiency in pharmaceutical production and emerged as one of the largest drug exporters in the world in the late 1980s.

Behind the development of the industry are the weak patent regime under the Patent Act of 1970 and the Drug Policy of 1978.

After Independence, the Indian government appointed two committees: the Tek Chand Patents Enquiry Committee (1948-50) and the Ayyangar Committee (1959) in order to improve accessibility and affordability of essential drugs in India. These committees recommended amending the Designs and Patents Act of 1911, which recognised product patents for

pharmaceuticals. The Designs and Patents Act of 1911 was replaced by the Patent Act of 1970.¹ The Patent Act of 1970 recognised only process patents, and reduced the patent period from sixteen years to seven years. Automatic licences of right could be issued three years after granting of the patent. The Act allowed Indian pharmaceutical companies to produce alternative processes for drugs that were not patented in India. During the period from the 1970s to the 1980s, Indian companies began to take up R&D work on their own. The weak intellectual property protection regime as envisaged in the Patent Act of 1970 was a turning point in the development of indigenous pharmaceutical R&D. The Act encouraged reverse engineering and the development of alternative processes for products patented in other countries.

The Drug Policy of 1978 was the first comprehensive drug policy enacted in India. The basic framework of the Policy remained largely valid even up until the 1990s. The basic objective of the Policy was to achieve self-sufficiency in the production of drugs. The Policy emphasised the role of R&D and technology, and enhanced the technological capabilities of the Indian pharmaceutical industry through providing R&D promotion measures. Several measures to guide and control foreign companies with a 75 percent share of the domestic market were implemented so as to be consistent with the basic objective of the Drug Policy of 1978 and promote the production of bulk drugs and intermediates.

The Patent Act of 1970 and the Drug Policy of 1978 paved the way for the progress of indigenous R&D. The ability to develop generic drugs was acquired and improved during the mid-1970s to 1990s. Besides, other industrial policy measures such as the Foreign Exchange Regulation Act of 1974 (FERA) and the Drug Price Control Order of 1970 (DPCO 1970), which were disincentives to foreign companies, also played important roles in the development of the industry.

The Indian pharmaceutical industry, which worked on the basis of reverse engineering and process innovation, achieved self-sufficiency in technology, and has been strengthening export orientation on the tide of economic liberalisation since the early 1980s. The industry started to show good promise of global competitiveness, and today continues to expand its presence worldwide. Trade surplus of pharmaceutical products has been increasing since 1987. In the late 1990s, India achieved favourable pharmaceutical trade balance all over the world (Figure 1-1). The industry has emerged as the seventeenth-largest drug exporter in the world and exports about 40 percent of its production. As Figure 1-2 shows, the domestic and export markets have been growing steadily. While the industry has been growing at an annual growth rate of 10 percent, exports have been growing at about 20 percent (Figure 1-2). Exports are the driving force behind the industry.

¹ Anitha Ramanna, "Policy Implications of India's Patent Reforms," *Economic and Political Weekly*, vol.37, no. 21(2002), pp. 2065-2075.

Figure 1-1: Export and import of pharmaceutical products (USD in millions)²

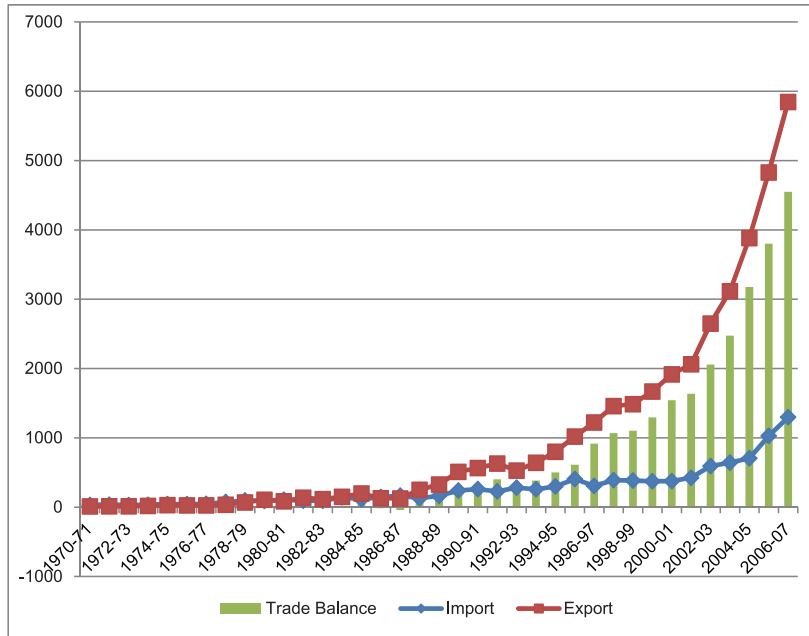
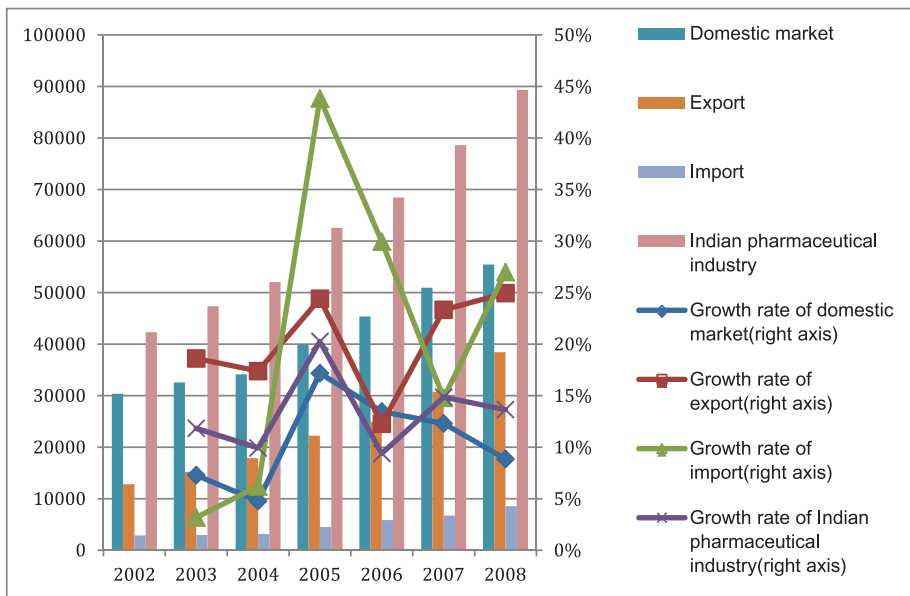


Figure 1-2: Pharmaceutical products markets (Rs. in crores)³



² Reserve Bank of India (RBI), *Handbook of Statistics on the Indian Economy 2008-2009* (2009); Pharmexcil, *Annual Report 2008-2009* (2009); Department of Pharmaceuticals, *Annual Report 2009-2010* (2010).

³ Department of Pharmaceuticals, *Annual Report 2009-2010* (2010).

3 TRIPS Agreement and India's Patent Regime

3.1 TRIPS Agreement and amendment of the Patent Act of 1970

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) set global minimum standards for the protection of intellectual property. The TRIPS Agreement deals not only with patents but also with other forms of intellectual property rights such as copyright, trademark, industrial designs, geographical indications, and confidential information. The TRIPS Agreement forced not only product patents for pharmaceuticals to be introduced but also twenty-year periods of patent protection at the least to be ensured. WTO members must comply with the obligations of the TRIPS Agreement. TRIPS compliance was postponed until 2005 for developing countries. Until the deadline for TRIPS compliance, India undertook three amendments in March 1999, June 2002, and March 2005. In March 2005, India completed the amendment of the Patent Act of 1970 to comply with the TRIPS Agreement.

The new patent act came into force on 4 April, 2005. It introduced product patents for drugs, foods, and chemical products and the patent term was increased to twenty years. The Indian patent regime has become fully TRIPS compliant. The amendment of the Act changed the institutional factors that had supported the growth of the Indian pharmaceutical industry.

3.2 TRIPS Agreement and data exclusivity

Another controversial TRIPS compliance issue in India is *data exclusivity*. In the case of pharmaceuticals, data exclusivity provides protection to the clinical data generated by innovator companies to prove the safety and efficacy of their products. Innovator companies are required to submit clinical test data relating to safety and efficacy to national regulatory authorities to obtain market approval for new drugs. Generic companies are not required to conduct their own clinical testing and submit their own test data to gain market approval. If a country does not grant data exclusivity rights, generic companies can refer to or use the data submitted by innovator companies when they apply for approval of their products.

Article 39(3) of the TRIPS Agreement requires WTO members to protect confidential information (undisclosed data) against unfair commercial use. Strictly speaking, the TRIPS Agreement does not refer to data exclusivity, nor does it refer to any period of data protection. The introduction of data exclusivity depends on the interpretation of Article 39(3) of the TRIPS Agreement because data protection regimes vary considerably among WTO members. The most difficult issue is whether government use of data submitted by innovator companies to determine bioequivalence of generic drugs is a commercial use or not.⁴

⁴ Vishva V. Ramlall, "The Pharmaceutical Industry in the Great White North and Land of the Rising Sun: A Comparison of Regulatory Data Protection in Canada and Japan," *IIP Bulletin* (2004), pp. 93-94.

India does not have any provisions related data exclusivity in the Drugs and Cosmetic Act, of 1940 and Rules, of 1945. In March 2003, the Indian government took an in-principle decision to provide data exclusivity for up to four years for toxicology, pharmacology, pharmacokinetic, and clinical trial data submitted by innovator companies.⁵ India continues to discuss the introduction of data exclusivity. However, this decision faced opposition from all sides in India.

In India, there are strong conflicts of opinion on data exclusivity between Indian companies and foreign companies. Indian companies insist that it would delay the launch of generic drugs and worsen access to cheaper medicines. They also insist that data exclusivity is not mandated by the TRIPS Agreement⁶. Foreign companies mention several benefits of introducing data exclusivity. These benefits include ensuring a higher degree of safety and efficacy of drugs, giving incentives to innovators, and expanding opportunities for outsourcing businesses in India. They also maintain that India has failed to comply with the TRIPS Agreement.⁷ The Indian pharmaceutical industry is not necessarily monolithic, however. Some Indian companies such as Piramal Healthcare, which is an R&D-oriented company and engaged in the contract research and manufacturing services (CRAMS) business, support the introduction of data exclusivity.⁸

And there are differences of opinion among different departments and ministries. The Ministry of Chemicals and Fertilizers and the Planning Commission support the introduction of data exclusivity because data exclusivity is important in attracting contract research to India.⁹ On the other hand, the Ministry of Commerce and Industry oppose the introduction. The Ministry insists that the TRIPS Agreement does not refer to data exclusivity and that the introduction of data exclusivity thus goes beyond the requirements of TRIPS.¹⁰

The Indian government set up several committees to discuss the introduction of data exclusivity. In 2007, a report of the Satwant Reddy Committee recommended five-year data exclusivity and several safeguarding measures so as to be compliant with the TRIPS Agreement.¹¹

A new emerging issue is arising as an aspect of a bilateral free trade agreement. In March 2011, under the negotiations of the India-EU Free Trade Agreement (FTA), the EU insisted on having an exclusive chapter on data exclusivity while Indian negotiators rejected this idea.¹² India said that it was against the inclusion of data exclusivity provision in any of its free trade agreements (FTAs) as it would hurt the interests of the domestic generic drugs industry.¹³

⁵ "India agrees to provide data exclusivity", *Express Pharma Pulse*, March 13, 2003.

⁶ Indian Pharmaceutical Alliance(IPA), *IPA Position Paper on Data Exclusivity*(2002); Indian Pharmaceutical Alliance(IPA), *IPA Position Paper on Data Protection* (2004).

⁷ Organisation of Pharmaceutical Producers of India (OPPI), *Pharmaceutical R&D and Data Exclusivity* (2003).

⁸ James Mathew and Gireesh Chandra Prasad, "India pharma majors back drug data exclusivity plan", *The Economic Times*, August 2, 2006.

⁹ P.T. Jyothi Datta, "No data exclusivity yet for pharma companies," *The Hindu Business Line*, June 15, 2006; Nithya Subramanian, "PMO working on pharma policy," *The Hindu Business Line*, July 11, 2005.

¹⁰ P.T. Jyothi Datta, "No data exclusivity yet for pharma companies," *The Hindu Business Line*, June 15, 2006.

¹¹ Department of Chemicals and Petrochemicals, Report on Steps to be Taken by Government of India in the Context of Data Protection Provisions of Article 39.3 of TRIPS Agreement (2007) [<http://chemicals.nic.in/DPBooklet.pdf>].

¹² "India will not provide data exclusivity: Anand Sharma," *Business Standard*, March 30, 2011.

¹³ "India against inclusion of data exclusivity in any FTA," *The Economic Times*, April 6, 2011.

4 Impact of the TRIPS Agreement on the Indian Pharmaceutical Industry

Fink argues that for developing countries, stronger intellectual property rights give rise to benefits in terms of increased trade, foreign direct investment, and technology transfer.¹⁴ However, these benefits mainly accrue to middle-income countries and the size of benefits depends on complementary policy reforms, notably improvements in other aspects of the investment climate. In this section, we examine the case of India, which is a low-income country.

The amendment of the Patent Act of 1970 changed the institutional factors that supported the growth of the Indian pharmaceutical industry. The Indian pharmaceutical industry has faced a number of new challenges on account of the TRIPS Agreement.

It was assumed that the amendment of the Patent Act to introduce product patents would have a negative impact on India. It would hamper the growth of the Indian pharmaceutical industry because it would no longer be able to manufacture by reverse engineering or export drugs whose product patents are in effect. However, contrary to expectations, as Figures 1-1 to 1-2 show, even in the post-TRIPS period, the industry has been growing rapidly.

In view of the TRIPS Agreement and impending changes to the Patent Act of 1970, the Indian pharmaceutical industry is pursuing a new business model. While Indian pharmaceutical companies are increasing their investment in R&D, they are increasing exports of generic drugs both to unregulated markets and regulated markets. The contract research and manufacturing services (CRAMS) business, which is a kind of outsourcing business, has been growing.

4.1 Increase in R&D investment

The TRIPS Agreement has not only increased the R&D expenditure of the Indian pharmaceutical industry but has also changed its R&D structure.

The pharmaceutical industry is a highly R&D-oriented sector. Under the pro-patent regime of the TRIPS Agreement, for pharmaceutical companies, sustainable growth depends on their continuous R&D for developing new drugs and new technologies.

Figures 4-1 and 4-2 show the trends in R&D expenditure in the Indian pharmaceutical industry in the post-TRIPS period. Since 2002, Indian companies have increased investment in R&D in order to overcome stiff competition in the global pharmaceutical market. Indian pharmaceutical companies are now becoming more R&D oriented.

While the Indian government lagged behind the private sector, it recognised the need to radically improve the policy framework of the pharmaceutical industry in view of TRIPS and impending changes to the Patent Act of 1970. At first, the government identified the pharmaceutical industry as one of the most important knowledge-based industries in which India had a comparative advantage.

¹⁴ Carsten Fink, *Intellectual Property and the WTO* (2004). [<http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/TRADE/0,,contentMDK:20508607~menuPK:169541~pagePK:148956~piPK:216618~theSitePK:239071~isCURL:Y,00.html>].

Figure 4-1: R&D expenditure in the Indian pharmaceutical industry¹⁵

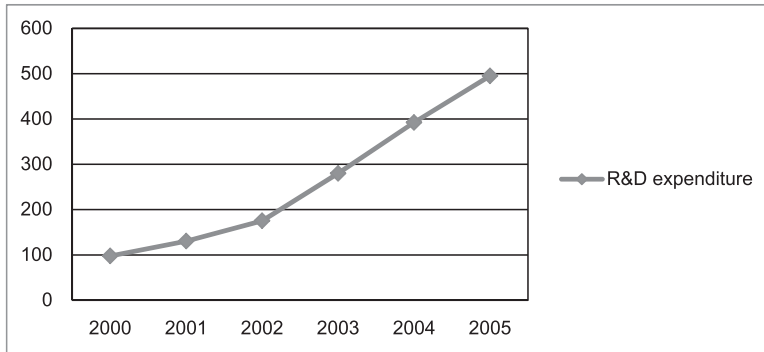
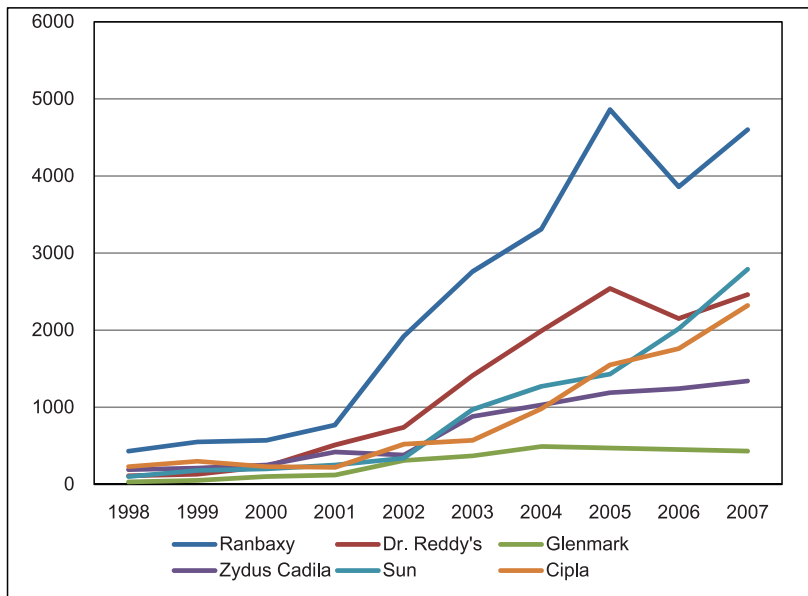


Figure 4-2: R&D expenditure in leading Indian pharmaceutical companies (Rs. in millions)¹⁶



In order to turn India into a global R&D hub, the government offered several R&D promotion measures to attract greater investment into the sector in order to update existing technologies and to bring into the country technologies that were not yet available. In 1999, the Government set up the Pharmaceutical Research and Development Committee (PRDC) to study and identify measures needed to strengthen the R&D base of the Indian pharmaceutical industry. The Committee recognized that priority must be given to initiating new drug development for diseases of relevance to the Indian population, while at the same time seizing opportunities to become a global player by introducing globally competitive products based on new molecules, new delivery systems, and so forth.

¹⁵ ASSOCHAM, *White Paper on Indian Pharma Industry Quest for Global Leadership* (2006).

¹⁶ Company's *Annual Report*, various years; Cygnus Business Consulting & Research, *Company Profile Top 200 Indian Pharma Companies* (Hyderabad: Cygnus Business Consulting & Research (2008).

Until the mid-1990s, R&D in the Indian pharmaceutical industry focused on R&D for the development of new processes for manufacturing drugs. Since that time, the new R&D focus has been on the following four aspects: (1) new drug delivery systems (NDDS); (2) R&D for generic products for the regulated market; (3) non-infringing processes; and (4) new drug development research (NDDR).

(1) Novel drug delivery systems (NDDS)

Indian companies are increasingly focusing on R&D for novel drug delivery systems (NDDS). NDDS is the most vigorous R&S area where most of the top Indian companies are increasing investment. Companies not engaged in NDDR such as Cipla have instead been involved in R&D for NDDS. Commercially, the most successful example is the NDDS developed by Ranbaxy for ciprofloxacin, whereby patients are required to take the drug once a day rather than the previous twice-a-day dosage. Ranbaxy licensed its once-a-day ciprofloxacin formulations to Bayer in 1999. Ranbaxy's R&D for NDDS is primarily focused on the oral segment. It is highly likely that they will continue to invest in R&D for NDDS in order to move up the value chain.

(2) R&D for generic products for the regulated market and non-infringing processes

Leading pharmaceutical companies in India have increased their R&D expenditures to develop generic products for the regulated market to satisfy quality and regulatory requirements for marketing off-patent drugs. Indian companies have also increased the development of non-infringing processes for filing drug master files (DMFs) and abbreviated new drug applications (ANDAs). Generic manufacturers cannot enter the market unless they develop non-infringing processes because the patent holder may hold patents for manufacturing processes even after the product patent has expired. Indian companies increased the number of DMF and ANDA filings particularly in the US.

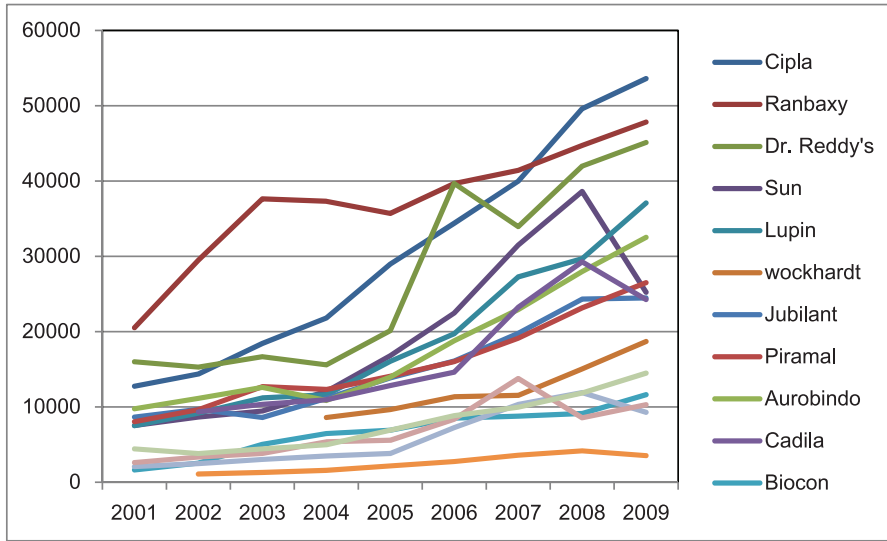
During the first quarter of 2011, Indian pharma companies filed 90 DMFs as compared to 75 and 91 DMFs respectively during first quarter of 2010 and 2009. The Indian pharma companies filed total 271 DMFs with US FDA during 2009 and 311 DMFs in 2010.¹⁷ In 2010, Indian pharmaceutical companies maintained their number-one position in the US generics market, bagging 33.17 percent or 139 of 419 original abbreviated new drug application (ANDA) approvals from the US Food and Drug Administration (USFDA).¹⁸

The increasing number of DMF and ANDA approvals is evidence that the Indian pharmaceutical industry has been expanding its presence in the regulated market. In the pre-TRIPS period, the Indian pharmaceutical industry focused on the Indian domestic market and unregulated market in East-Europe and Africa. The industry has been increasing its exports to the regulated

¹⁷ Sanjay Pingle, "Indian pharma firms filed 90 DMFs in Q1," *CPhl Online*, July 8, 2011 [<http://www.cphi-online.com/news/14729/Indian+Pharma+Firms+Filed+90+DMFs+in+Q1.html>].

¹⁸ P. B. Jayakumar, "Indian pharma remains top in US generics," *Business Standard*, January 3, 2011.

Figure 4-3: Sales of leading Indian pharmaceutical industry (Rs. in millions)¹⁹



market in developed countries such as the US and Europe. The regulated market is more lucrative than the domestic market and the unregulated market because drug prices in the regulated market are relatively high. In addition, with patents on many blockbuster drugs about to expire in five years from now, Indian pharmaceutical companies can manufacture drugs without infringement of product patents. This means that export opportunities for the Indian pharmaceutical industry will increase. As exports have been growing, sales of the Indian companies have been increasing dramatically (Figure 4-3). This is attributed to R&D for non-infringing processes.

(3) *New drug development research (NDDR)*

As supporters of TRIPS argued that the introduction of pharmaceutical product patents would encourage R&D for new drug development, Indian companies in the private sector began investing in R&D for new drug development research (NDDR) in the mid-1990s. Leading Indian pharmaceutical companies are all now engaged in R&D for new chemical entities (NCEs) and have set up their own research centre for NDDR. Indian companies have reported some successes in NDDR. A number of NCEs, which are at different stages of clinical trial, have been developed (Table 4-4).

However, none of the NCEs developed by Indian companies has yet been approved for marketing in any country. None of these companies is engaged in the entire process of drug development, lacking sufficient resources required to develop a drug and launch it into the market.

¹⁹ Company's *Annual Reports*, various years.

Table 4-4: New Chemical Entities (NCEs) Developed by Indian Companies²⁰

Company	Development Stage			
	Early Discovery/ Pre-Clinical	Clinical Trial		
		Phase I	Phase II	Phase III
Ranbaxy Laboratories	6	0	1	0
Dr. Reddy's Laboratories	1	1	0	1
Glenmark	6	2	3	0
Zydus Cadila	4	3	2	0
Piramal Healthcare	10	3	2	0
Lupin	4	1	4	1
Sun	3	0	1	0

The process of new drug development is classified into two stages: the pre-clinical stage and the clinical stage. At the pre-clinical stage, the objective of research is to develop a promising molecule using animal models. At the clinical stage, the molecule is tested on humans and developed for manufacturing and marketing. About 60 - 70 percent of expenditure for new drug development goes to funding clinical development.²¹

NDDR is not only time consuming, but huge costs are involved in discovering a molecule and eventually launching the product into the market. And the rate of failure is relatively high. Typically, out of ten thousand compounds synthesized, only about twenty reach the animal testing stage, of which only about ten compounds reach the clinical stage and maybe only one attains the approval of drug regulatory authorities. Moreover, only about three out of every ten drugs recover their R&D costs. The average length of time required is estimated to be between ten and eighteen years, with the clinical stage accounting for about half the total NDDR time.²² The cost of developing and launching a drug into the market is considered to be about US\$ 800 million in other countries²³. One of the largest R&D spenders in India, Dr. Reddy's Laboratories, spent only Rs. 55,841.027 million (about USD 133 million) in 2007.²⁴

Even though Indian pharmaceutical companies have increased their R&D spending, owing to their small size compared to large foreign pharmaceutical companies, most of them cannot afford the R&D costs associated with developing and launching a product because they are operating at the lower end of the value chain. Furthermore, since generic business has been facing severe competition both domestically and internationally in recent years, the Indian pharmaceutical industry is suffering downward pressure on margins.

For all of these financial and technological reasons, Indian companies adopted a strategy of developing new molecules and licensing them out to large foreign pharmaceutical companies in

²⁰ Compiled from company websites.

²¹ ICRA Limited, *The Indian Pharmaceutical Industry* (New Delhi: ICRA Limited, 1999), p. 16.

²² *Ibid.*, p. 16.

²³ Joseph A. Dimasi, Ronald W. Hansen and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Cost," *Journal of Health Economics* vol. 22(2003), pp. 151-185.

²⁴ Dr. Reddy's Laboratories Ltd, *Annual Report 2007-08*(2008).

the early stage of clinical development.

With accumulated experience in the area of NDDR, the technological level of Indian pharmaceutical companies has been steadily improving. The Indian pharmaceutical industry is certainly moving up the value chain.

4.2 Expansion of outsourcing business

The introduction of pharmaceutical product patents brings new business opportunities to the Indian pharmaceutical industry. In the 2000s, the pharmaceutical outsourcing business is increasing in India.

With the patents of many blockbuster drugs that generate more than 1 billion dollars in revenue each year drawing near their expiry dates and with increasing R&D costs, it is hard for foreign pharmaceutical companies to keep their bottom line. They have found recourse to outsourcing some of their research and manufacturing activities in order to save costs in the process.

In the past, foreign pharmaceutical companies tended to hesitate to manufacture new drugs in India because of the Patent Act of 1970, which did not recognise product patents on pharmaceutical products. Recently, however, foreign companies have been increasingly outsourcing the manufacture of their new drugs. The introduction of product patents by the amendment of the Patent Act of 1970 made it impossible for unlicensed Indian companies to manufacture patented drugs. The incentive for Indian companies to misappropriate the knowhow gained from contractors (foreign companies) was to be lowered. On the other hand, in terms of foreign companies, the amendment of the Patent Act of 1970 that introduces a product patent system in India lowered the risk of outsourcing to Indian companies

India has distinct advantages as an outsourcing destination. These advantages include excellent development and manufacturing skills, low R&D costs, low manufacturing costs (manufacturing costs in India are 40-50 percent lower as compared to Western countries), a large number of trained chemists and biologists, over eighty USFDA-approved plants (India has the highest number of USFDA-approved plants outside the US), abundant English-speaking skilled manpower, a large patient population providing a diverse pool for clinical trials for NCEs, and an IT industry.

Recently, the contract research and manufacturing services (CRAMS) business has been growing rapidly in India. CRAMS deals with manufacturing and research activities. Many Indian companies entered CRAMS, and the number of specialised CRAMS companies has increased. In the post-TRIPS period, India has become one of the most preferred outsourcing destinations for foreign pharmaceutical companies and is becoming a global manufacturing and R&D hub.

It can be said that the TRIPS Agreement has made the Indian pharmaceutical industry more R&D oriented and R&D intensive, pushing it up to the higher end of the value chain.

5 Productivity in the Indian Pharmaceutical Industry

Sato and Kamiike estimate the production function and total factor productivity (TFP) of the pharmaceutical industry in India in order to understand the drug policy and the industrial development described above.²⁵ It employs the growth accounting approach and the production function approach to estimate TFP growth and clarifies the characteristics of the Indian pharmaceutical industry. TFP is defined as a residual of economic growth that cannot be measured by an increase in factor inputs such as capital and labour. In other words, the residual of economic growth not explained by input growth can be interpreted as pure technological progress under certain conditions. The growth accounting approach measures TFP growth as a residual by subtracting the overall contribution of factor inputs from the growth rate of real value added. The production function approach clarifies the technical relationship between output and production factors. It can examine economies of scale, technological level, and substitutability between capital and labour. By using the production function approach, not only TFP but also other structural features of production like scale economies and non-neutral technological progress can be understood.

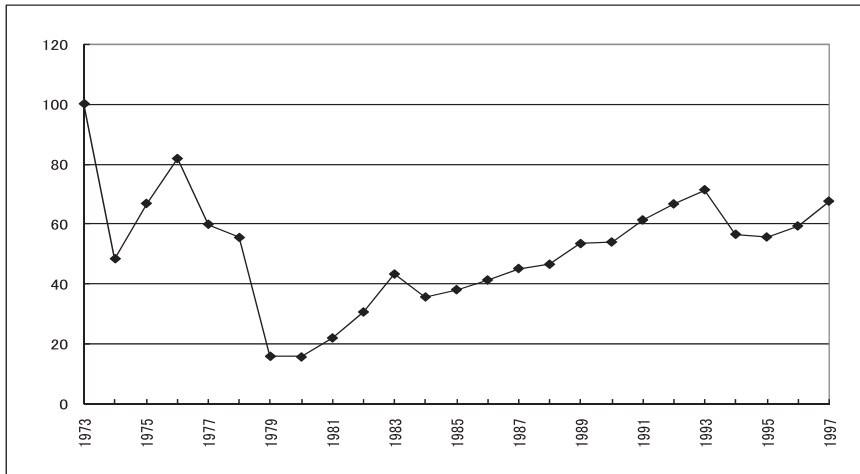
Sato and Kamiike use the Annual Survey of Industries (ASI), which is collected by the Central Statistical Organization of India, as the main data set. Empirical analysis is based on national- and state-level data for the period 1973 to 1997 in the case of the growth accounting approach and for the period 1984 to 1997 in the case of the production function approach.²⁶ The primary unit of enumeration in the survey is a factory in the case of manufacturing industries, and data are based on returns provided by factories. The ASI factory frame is classified into two sectors: the sample sector and the census sector. The sample sector consists of small plants employing 20 to 99 workers if not using electricity and 10 to 99 workers if using electricity. The census sector comprises relatively large plants. It covers all units having 100 or more workers and also some significant units that although having fewer than 100 workers, contribute significantly to the value of the manufacturing sector's output. While units in the census sector are approached for data collection on a complete enumeration basis every year, sample sector units are covered on the basis of well-designed sampling. The sector covered by the ASI is called the registered or organized sector. According to the National Account Statistics of India, the registered sector covers 65 percent of the total value added in the manufacturing sector in 1997.

As we have already described, it is noted that the period during the 1970s to the end of 1990s corresponds to the period of rapid progress of import substitution and then strengthening of export orientation in the Indian pharmaceutical industry. Estimated TFP obtained by the growth accounting approach is shown in Figure 5-1.

²⁵ Takahiro Sato and Atsuko Kamiike, "Total Factor Productivity in the Indian Pharmaceutical Industry," *Journal of Economics* vol. 106, no.2 (2005), pp.1-12 (in Japanese).

²⁶ Ibid.

Figure 5-1: Total factor productivity (TFP) from 1973 to 1997 (base year: 1973)²⁷



According to Figure 5-1, TFP fell from 1973 to 1979 and then increased slowly but steadily from the 1980s. It means that productivity improvement has been the driving force of the sustainable growth of the Indian pharmaceutical industry since 1980. In addition, the production function approach finds that firstly, there are economies of scale, secondly, the average annual growth rate of TFP is reaching about 7 to 10 percent, and thirdly, there is labour-saving technical progress.

Based on the estimation results, Sato and Kamiike summarize the development history of the pharmaceutical industry as follows²⁸:

(1) While Indian companies were protected and foreign companies were regulated by drug price controls, regulations on foreign share holdings, and anti-patent policy, TFP itself fell in the 1970s. This is because the growth of foreign companies, which were more efficient, had been suppressed by strengthening regulation and the growth of Indian companies was insufficient to recover the drop. At the same time, the oil crisis probably influenced the fall in TFP.

(2) Indian companies raising the share of the domestic market and improving the level of technology have been increasingly export-oriented since the early 1980s when economic liberalisation started. As the export markets and the domestic market expanded with a learning effect and an economies of scale effect, the international competitiveness of the Indian pharmaceutical industry improved.

(3) In addition, the Drug Policy of 1986 saw the enforcement of stricter regulations for foreign companies again and the deregulation of Indian companies. Then, economic reforms in 1991 significantly relaxed the regulations on foreign investment. During this period, the Indian pharmaceutical industry with international competitiveness in the field of generic drugs, which

²⁷ Takahiro Sato and Atsuko Kamiike, “Total Factor Productivity in the Indian Pharmaceutical Industry,” *Journal of Economics* vol. 106, no.2 (2005), p.6 (in Japanese).

²⁸ Ibid.

were easily imitated, competed with foreign companies. The Indian pharmaceutical industry, gradually accumulating R&D capabilities, achieved trade surplus all over the world in the late 1990s.

(4) Two important institutional developments can be emphasized. Firstly, the Drug Price Control Order (DPCO), which was introduced in 1970 with the aim of supplying drugs at affordable prices to the poor, gave the Indian pharmaceutical industry the incentive to export rather than sell to the domestic market because drugs could be sold at higher prices in overseas markets than in the domestic market. Secondly, good manufacturing practice (GMP) increased the reliability of Indian drugs in the world market. India decided to introduce GMP in the Drug Policy of 1986. GMP was laid down in Schedule M of the Rules and came into force in 1987. The introduction of GMP has contributed to the enhancement of trust in Indian products in the global market. In addition, complying with the GMP standards of US and Europe has increased exports to Western countries and has expanded opportunities for contract manufacturing. Generally speaking, the DPCO provides incentives towards export orientation and GMP gives an institutional basis for supporting the export orientation of the Indian pharmaceutical industry.

In summary, during the period from the 1970s to the late 1990s, the Indian pharmaceutical industry with economies of scale, technology, and learning effects on productivity has successfully shifted from import substitution to export orientation and from comparative disadvantage to comparative advantage.

Now, we measure the international competitiveness of India's pharmaceutical products by using revealed comparative advantages (RCA) and the trade specialization coefficient (TSC). Table 5-2 shows the RCA and TSC of pharmaceutical products in several countries during the period from 1985 to 2002.

India's RCA and TSC are the same as those of developed countries such as the UK and USA and are much higher than those of East Asian countries such as South Korea and Thailand. China produces a much higher volume of generic drugs than India. Pharmaceutical sales in China in 2003 reached 36 billion dollars.²⁹ This means more than seven times the sales of India in 2003. However, in 2002, RCA and TSC in India were much higher than in China. In 1985, India's RCA was slightly higher than China's and China's TSC was higher than India's. At that time, there was no difference between the two countries. However, enforcement of GMP in 1986 strengthened quality control and increased international confidence in Indian pharmaceutical products. Since 1985, India's RCA and TSC have remained much higher than China's. After China implemented GMP in 1992,³⁰ TSC improved, but RCA is below the level of 1985. From the comparison with China, India succeeded in import substitution of drugs, not only simply production increase, but also high international competitiveness at the same time.

²⁹ <http://www.china.com.cn/japanese/169980htm>.

³⁰ http://www.cjcci.biz/sansi_pdf_2004/2_3_2.htm.

Table 5-2: Revealed Comparative Advantages (RCA) and Trade Specialization Coefficient (TSC) in India and Other Countries³¹

	India		USA		UK		Japan		China		Korea		Thailand	
	RCA	TSC	RCA	TSC	RCA	TSC	RCA	TSC	RCA	TSC	RCA	TSC	RCA	TSC
1985	1.55	0.10	1.43	0.76	1.83	0.38	0.24	-0.53	1.25	0.49	0.14	-0.46	0.15	-0.84
1986	1.22	0.06	1.41	0.76	1.83	0.34	0.23	-0.53	1.19	0.37	0.17	-0.34	0.12	-0.82
1987	1.42	0.20	1.26	0.73	1.81	0.33	0.24	-0.56	1.14	0.19	0.14	-0.39	0.11	-0.83
1988	1.72	0.25	1.23	0.73	1.79	0.32	0.25	-0.56	0.95	0.09	0.12	-0.48	0.13	-0.75
1989	0.51	-0.34	1.02	0.70	2.03	0.33	0.27	-0.53	1.21	0.30	0.14	-0.41	0.10	-0.80
1990	2.30	0.39	0.97	0.67	1.88	0.34	0.28	-0.50	0.95	0.20	0.15	-0.44	0.11	-0.77
1991	2.27	0.43	0.93	0.65	1.88	0.33	0.29	-0.44	0.91	0.11	0.16	-0.44	0.10	-0.75
1992	1.57	0.25	0.92	0.63	1.93	0.30	0.30	-0.42	0.80	0.15	0.17	-0.40	0.13	-0.69
1993	1.51	0.33	0.88	0.60	2.09	0.32	0.28	-0.43	0.69	0.13	0.15	-0.45	0.24	-0.46
1994	1.55	0.33	0.84	0.60	1.98	0.29	0.27	-0.45	0.68	0.20	0.16	-0.44	0.13	-0.65
1995	1.61	0.28	0.79	0.59	2.18	0.31	0.29	-0.42	0.75	0.24	0.15	-0.45	0.16	-0.62
1996	1.65	0.40	0.80	0.59	2.08	0.28	0.31	-0.37	0.68	0.19	0.15	-0.47	0.13	-0.67
1997	1.78	0.39	0.78	0.59	2.10	0.29	0.30	-0.35	0.55	0.20	0.14	-0.43	0.12	-0.67
1998	1.59	0.38	0.80	0.57	1.95	0.28	0.28	-0.30	0.52	0.20	0.12	-0.31	0.10	-0.59
1999	1.54	0.44	0.86	0.55	2.00	0.21	0.31	-0.27	0.46	0.21	0.11	-0.39	0.09	-0.65
2000	1.56	0.49	0.98	0.57	2.28	0.21	0.33	-0.21	0.41	0.23	0.11	-0.41	0.10	-0.63
2001	1.37	0.49	0.97	0.57	2.07	0.18	0.31	-0.24	0.34	0.23	0.10	-0.48	0.08	-0.64
2002	1.30	0.45	0.90	0.56	2.00	0.19	0.26	-0.26	0.28	0.25	0.08	-0.52	0.04	-0.78

Note 1: The Indian figure in 1989 is regarded as an outlier.

Note 2: $RCA = [E(ij) / E(it)] / [E(nj) / E(nt)]$, where E is exports, i is the country index, j is the export goods index, n is all countries, and t is total export goods. If $RCA > 1$, it means that country i has comparative advantage in export goods j.

Note 3: $TSC = [E(ij) - M(ij)] / [E(ij) + M(ij)]$, where M is imports. If TSC is positive, it suggests that country i has international competitiveness in export goods j.

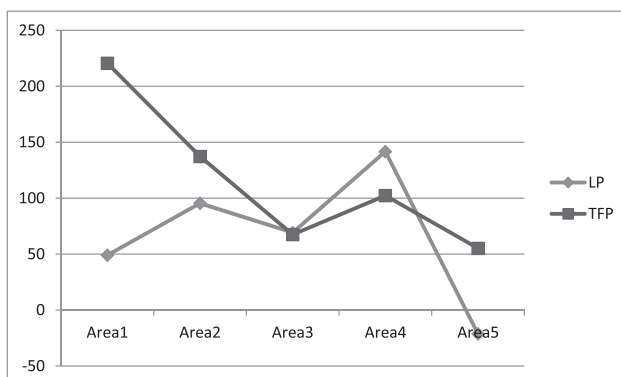
Kamiike, Sato, and Aggarwal estimate productivity growth in the Indian pharmaceutical industry across regions during the period from 2000-2001 to 2005-2006, using the unit-level panel database drawn from the ASI.³² It uses the most frequently applied measures of productivity such as labour productivity (LP) and TFP. Our empirical application is based only on census sector data because of our own empirical strategy. It finds that firstly, the production function of the Indian pharmaceutical industry has constant returns to scale, and secondly, the average annual growth rate of LP and TFP per year is more than 6 percent.

In fact, Figure 5-3 presents the growth rates of LP and TFP across five regions in the Indian pharmaceutical industry over the period from 2000 to 2005. It shows that both LP and TFP increased across all the regions over this period with LP in Area 5 (non-agglomerated area of the pharmaceutical industry) being the only exception. Nevertheless, productivity growth has been

³¹ Statics Canada, World Trade Analyzer.

³² Atsuko Kamiike, Takahiro Sato, and Aradhna Aggarwal, *Productivity Dynamics in the Indian Pharmaceutical Industry: Evidences from Plant-level Panel Data*, (Research Institute for Economics & Business Administration, Kobe University, RIEB Discussion Paper Series, DP2011-J01, 2011) (in Japanese).

Figure 5-3: Productivity growth rate across regions during 2000 to 2005 (percent)



Note: Area 1: New area: Himachal Pradesh and Uttarakhand.
 Area 2: Established area: Delhi, Haryana and Punjab.
 Area 3: Established area: Gujarat, Maharashtra, Goa, Dadra & Nagar Haveli, and Daman & Diu.
 Area 4: Established area: Andhra Pradesh, Karnataka, Tamil Nadu, and Pondicherry.
 The rest of the states are included in Area 5 as non-agglomerated areas.

particularly strong in agglomerated regions. Productivity grew more than 50 percent over this period, meaning that the average annual growth rate was more than 8 percent.

Kamiike, Sato, and Aggarwal confirm that the productivity of the Indian pharmaceutical industry has been improving even in the post-TRIPS period.³³ It can be said that in the Indian context, the introduction of pharmaceutical product patents is bringing new business opportunities to the Indian pharmaceutical industry. The recent new trends of the Indian pharmaceutical industry including R&D for non-infringing processes and CRAMS are considered important factors that have enhanced overall productivity, especially TFP in the agglomeration areas.

6 Issue of Access to Medicines

Fink argues that the stronger pharmaceutical patent rights required by TRIPS have raised concerns that greater pricing power by pharmaceutical companies will adversely affect access to medicines in poor countries. There is still a concern that the new patent act may affect access to medicines in India.³⁴

The Patent Act of 1970 eliminated the monopoly status enjoyed by foreign pharmaceutical companies and permitted unrestricted entry of drug manufacturers into the industry. Free entry of companies in the absence of product patent protection and competition among companies has resulted in competitive prices.³⁵

³³ *Ibid.*

³⁴ Carsten Fink, *Intellectual Property and the WTO* (2004) [<http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/TRADE/0,,contentMDK:20508607~menuPK:169541~pagePK:148956~piPK:216618~theSitePK:239071~isCURL:Y,00.html>].

³⁵ Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry—Patent Protection, TRIPS, and Developing Countries* (New Delhi: Oxford University Press, 2005), pp. 222-272.

India introduced the Drug Price Control Order in 1970. The DPCO, which fixes ceiling prices on drugs in India, contributes to keeping its drug prices the lowest in the world. The Patent Act of 1970 and the DPCO have not only brought about the development of the Indian pharmaceutical industry but have also contributed to improved access to medicines in India. However, Chaudhuri argues that the absence of product patents has played a more important role in controlling prices than the DPCO.³⁶ In the pre-TRIPS period, Indian companies would develop processes for these drugs and put them on the market, forcing the price to fall. However, this is impossible in the post-TRIPS period.³⁷

In 2005, India introduced product patents for drugs to comply with its obligations under the TRIPS Agreement.

In addition to the introduction of product patents, the DPCO has been gradually deregulated since its introduction in India. The number of bulk drugs under price controls gradually declined from 347 in 1987 to 163 in 1994 to 74 in 1995. The prices of new patented drugs are not regulated by the National Pharmaceutical Pricing Authority (NPPA).

Furthermore, the liberalisation of FDI regulation in the pharmaceutical sector in 2002 that allows FDI up to 100 percent under the automatic route accelerated the advance of foreign companies into India, and several Indian companies were taken over by foreign companies (Figure 6-1). After the recent takeovers, three of ten companies ranked by domestic sales are foreign companies. Foreign companies' share in the domestic market has already risen from 15 percent to 25 percent. That is to say, the Indian domestic market is becoming a more oligopolistic market than before. The Indian government, with its concerns about the rise in drug prices, established an inter-ministerial committee to review India's FDI norms in the pharmaceutical sector.³⁸

Table 6-1: Indian Companies Taken Over by Foreign Companies³⁹

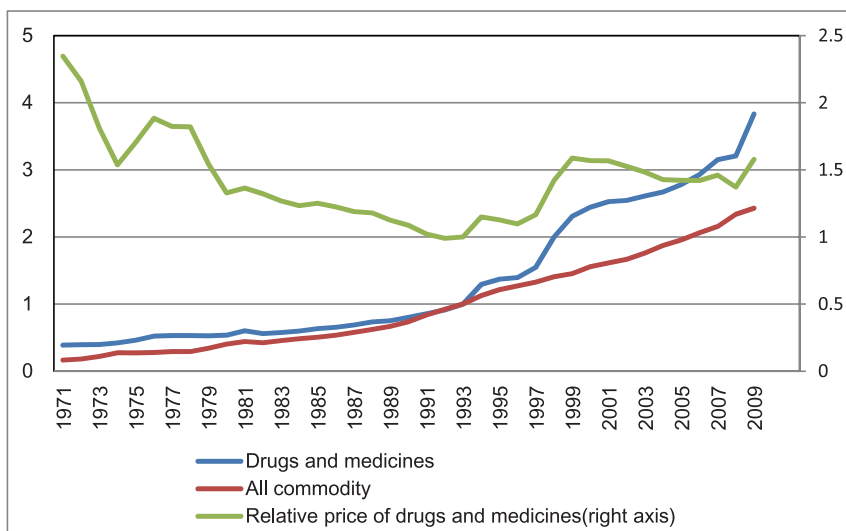
Year	Indian Companies	Foreign Companies	Takeover Amount (USD in millions)
Aug 2006	Matrix Laboratories	Mylan (US)	736
April 2008	Dabur Pharma	Fresenius Kabi (Singapore)	219
June 2008	Ranbaxy	Daiichi Sankyo (Japan)	4600
July 2008	Shanta Biotech	Sanofi Aventis (France)	783
Dec 2009	Orchid Chemicals	Hospira (US)	400
May 2010	Piramal Healthcare	Abbot Laboratories	3720

³⁶ *Ibid.*, p. 310.

³⁷ *Ibid.*, p. 311.

³⁸ Deepshikha Sikarwar and Khomba Singh, "Minister's panel look into FDI in pharma sector," *The Economic Times*, April 21, 2011.

³⁹ Company's press releases.

Figure 6-2: Trends in the whole price index of drugs⁴⁰

Lanjouw and Fink argue that patents generate considerably higher prices for protected drugs than for generic drugs.⁴¹ As Figure 6-2 shows, the relative price of drugs and medicines declined continuously from 1971 to 1992. The fall in relative price is due to the price control under the DPCO and the weak patent protection regime under the Patent Act of 1970. The whole sales price index of drugs and medicines has been rising sharply in the post-TRIPS period. The relative price has been rising gradually as well.

The TRIPS Agreement allows countries substantial flexibility toward protecting public health. India has taken measures to protect public health and ensure access to medicines. India disallowed the patents of new forms of known substances without clear enhancement of efficacy. Section 3(d) of the Patent Act has a list of areas that are not patentable in India. Section 3(d) defines what is not patentable. Section 3(d) states that the mere discovery of a new form of an old drug does not make it an invention.

Section 3(d): mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere new use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

⁴⁰ Reserve Bank of India (RBI), *Handbook of Monetary Statistics of India*, 2006; Reserve Bank of India (RBI), *Handbook of Statistics on the Indian Economy 2008-2009* (2009).

⁴¹ Jean O.Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of Poor and Suffering?"* (NBER Working Paper no. 6366. 1998); Carsten Fink., "Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry," *Journal of Industry, Competition and Trade* vol. 1, no.1 (2001), pp. 101-121.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Section 3(d) clearly says that a small change in the drug molecule by way of production of a derivative does not become equal to an invention.

Section 3(d) prohibits *evergreening*, which is the practice of foreign pharmaceutical companies to extend their patent terms by making small, trivial changes to existing medicines and thereby preventing entry of generic drugs.

Novartis AG, a Swiss pharmaceutical company, challenged Section 3(d). In January 2006, a patent application for the anti-cancer drug Glivec (imatinib mesylate) filed by Novartis AG was rejected by the Intellectual Property Appellate Board (IPAB) because it failed to satisfy the efficacy requirements of Section(3). And then, Novartis applied to the Madras High Court challenging the decision of the patent office.⁴² That is to say, Novartis challenged the legal validity of Section 3(d). In 2007, the Madras High Court rejected Novartis' challenge to Section 3(d) and held that it had no jurisdiction to determine the issue of TRIPS compatibility. Novartis has filed a special leave petition with the Supreme Court challenging the rejection of the Glivec patent.⁴³

Foreign pharmaceutical companies have been complaining that Section 3 (d) is not compatible with the TRIPS Agreement. Section 3(d) has been an obstacle to many inventions eligible for patent registration.

It can be said that Section 3(d) is a proactive measure to prevent the practice of evergreening.

7 Concluding Remarks

The Patent Act of 1970 and the DPCO have not only boosted the development of the Indian pharmaceutical industry but have also contributed to improving health and welfare in India. However, since the mid-1990s, the Indian pharmaceutical industry has faced new challenges on account of the WTO-TRIPS Agreement.

It was considered that introducing pharmaceutical product patents would have a negative influence on the Indian pharmaceutical industry because it would hamper its growth. The industry can no longer manufacture by reverse engineering or export drugs whose product patents are in effect. However, against expectations, the Indian pharmaceutical industry has been growing the post-TRIPS period and its productivity is improving even in post-TRIPS period. It can be said that the introduction of pharmaceutical product patents has given rise to business opportunities for the Indian pharmaceutical industry and is promoting the growth of the industry.

⁴² "HC suspects hearings in Novartis' Glivec case," *The Economic Times*, August 10, 2007.

⁴³ "Novartis moves SC in Glivec patent case," *The Economic Times*, August 29, 2009.

On the other hand, there are still concerns that the new patent act might reduce generic drug supplies and deteriorate access to medicines in India. Ensuring access to medicines at affordable prices is one of the most important tasks for the Indian government. Taking into consideration that India is a major supplier of affordable generic drugs, the issue of access to medicines is an essential one not only for India but for other poor developing countries, too.

However, innovation is important for sustaining economic growth and development. Intellectual property is an important factor in promoting innovation. It should be noted that if the issue of access to medicines is abused in order to protect vested interests, it may retard innovation.

Thus, the Indian government should seek an appropriate balance between the development of the Indian pharmaceutical industry and the improvement of public health. In other words, the government should balance intellectual property protection with access to medicines. It will, however, be difficult to succeed in both.