

The TRIPs Agreement and Pharmaceutical Industry: The Indian Experience

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Abstract

The Patent Act of 1970 and DPCO not only have brought the development of the Indian pharmaceutical industry but also have 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. The introduction of pharmaceutical product patent was supposed to have negative impacts on the Indian pharmaceutical industry. It would hamper the growth of the Indian pharmaceutical industry. The industry can no longer manufacture by reverse engineering and export drugs that product patents are effective. However, contrary to the expectations, the Indian pharmaceutical industry has been growing post-TRIPS period. On the other hand, there are still concerns that the new patent act might reduce generic drug supplies and decline the access to medicines in India. It is one of the most important tasks for the Indian government to ensure access to medicines at affordable prices. 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 appropriate balance between the development of the Indian pharmaceutical industry and the improvement of public health. In other word, the government should balance intellectual property protection with access to medicines.

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1. Introduction

The Indian pharmaceutical industry has achieved self-efficiency in pharmaceutical production and emerged as one of the largest drug exporters in the world. India is one of the major drugs producing countries. The industry has emerged as one of the major drug exporters since the late-1980s and showed a 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 abilities to conduct R&D and to develop generic drugs which the industry acquired and improved under 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 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 TRIPS Agreement. It introduced product patents for drugs, food and chemical products and the patent term was increased to 20 years. At the beginning, the amendment of the patent act to introduce product patent was supposed to have negative impacts 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 and export drugs that product patents are effective. In addition, it was concerned that the amendment would result in the decline of the access to medicines in India due to sharp rise of drug prices caused by the introduction of pharmaceutical product patents.

India is one of the largest pharmaceutical exporters and the major supplier of affordable and quality generic drugs in the world. At the same time, India is also one of the poorest developing countries which lack national health insurance system and suffer 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 that it is feared that public health will deteriorate rapidly because of sudden rise of drug prices. Given 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. It is well timed to examine the case of India at the present day when the relationship between TRIPS and public health are questioned sharply.

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 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 Indian Pharmaceutical Industry

The Indian pharmaceutical industry has shown steady growth during 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 20-22% share in global generic production.

The Indian pharmaceutical industry, which had little technological capabilities to

manufacture drugs indigenously in the 1950s, has achieved self-sufficiency in pharmaceutical production and emerged as one of the largest drug exporter 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, 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 (Ramanna 2002). The Patent Act of 1970 recognised only process patents, and reduced a patent period from sixteen years to seven years. Automatic licenses of right could be issued three years after the granting of the patent. The Act allowed Indian pharmaceutical companies to produce alternative process for drug 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 process for products patented in other countries.

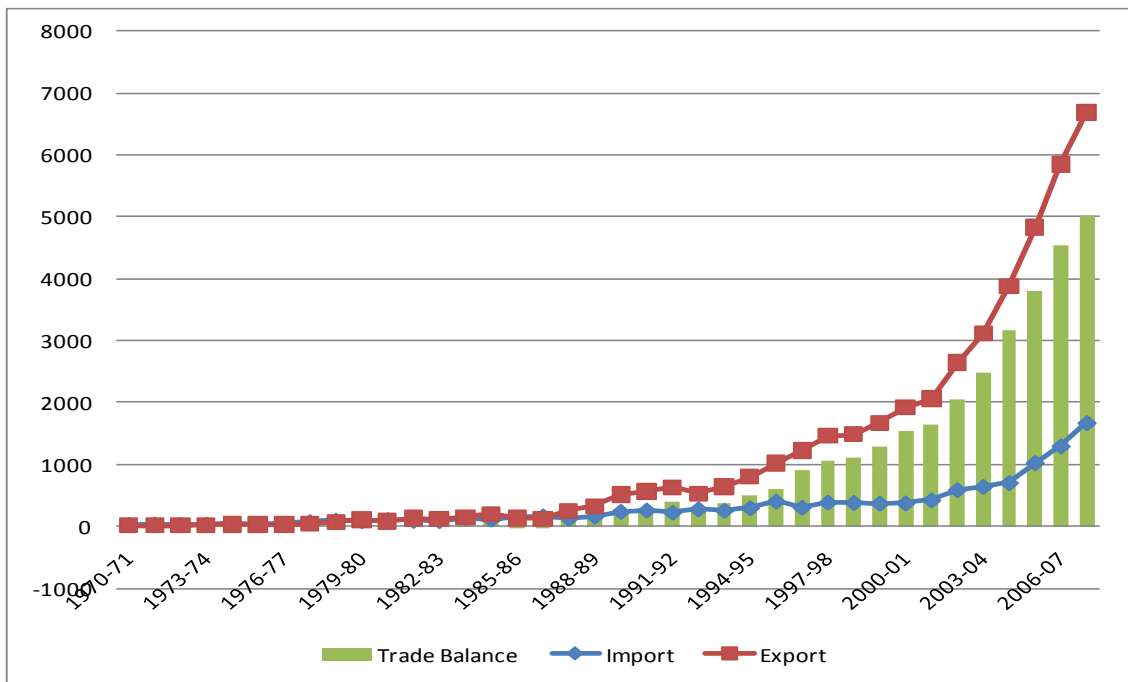
The Drug Policy of 1978 was the first comprehensive drug policy enacted in India. The basic framework of the Policy remained largely valid even up until the 1990s. The basic objective of the Policy was to achieve self-sufficiency in the production of drugs. The Policy emphasised the role of R&D and technology, 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 75% share of the domestic market were implemented to be consistent with the basic objective of the Drug Policy of 1978 and promote to produce bulk drugs and intermediates.

The Patent Act of 1970 and the Drug Policy of 1978 paved the way for 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 (DPCO1970) which were disincentives for foreign companies also played important roles to the development of the industry.

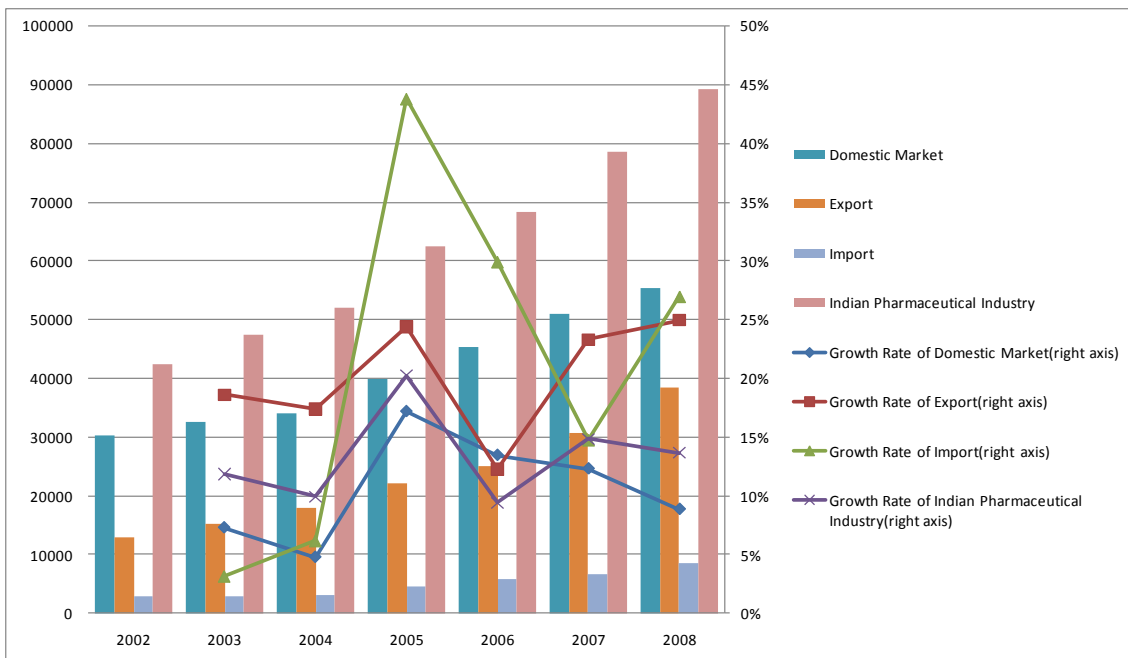
Indian pharmaceutical industry that worked on the basis of reverse engineering and process innovation achieved self-sufficiency in technology, and has been strengthening export orientation in the tide of economic liberalisation since the early 1980s. The industry started to show good promise of global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

Table/Figure 1-1: Export and import of the pharmaceutical products (USD in millions)



Source: RBI (2009), Pharmexcil (2009), Department of Pharmaceuticals (2010).

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



Source: Department of Pharmaceuticals (2010).

3. TRIPS agreement and India’s Patent Regime

3-1. The TRIPS Agreement and The 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. 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. TRIPS Agreement forced not only to introduce product patents for pharmaceuticals but also to ensure the 20year-periods of patent protection at the least. The WTO members must comply with the obligations of TRIPS agreement. TRIPS compliance was postponed until 2005 for developing countries. Until the deadline of TRIPS compliance, India carried out 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 TRIPS Agreement.

The new patent act came into force on April 4, 2005. It introduced product patents for drug, food and chemical products and the patent term was increased to 20 years. The Indian patent regime has become fully TRIPS compliant. The amendment of The Act changed the institutional factors which 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 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 get market approval for new drug. Generic companies are not required to conduct their own clinical test and submit their own test data to get market approval. If a country does not grant the data exclusivity rights, generic

companies can refer or use the data submitted by innovator companies when they apply for approval of their products.

Article of 39(3) of TRIPS agreement requires WTO members to protect confidential information (undisclosed data) against unfair commercial use. Strictly speaking, 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 TRIPS agreement because data protection regime varies considerably among WTO members. The most difficult issue is whether the government use of data submitted by innovator companies to determine bioequivalence of generic drugs is a commercial use or not (Ramlall 2004: 93-94).

India does not have any provisions related data exclusivity in the Drugs and Cosmetic Act, 1940 and Rules, 1945. In March 2003, the Indian government took an in-principle decision to provide data exclusivity up to four years on toxicology, pharmacology, pharmacokinetic and clinical trial data submitted by innovator companies¹. India continues to discuss about 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 insisted that it would delay the launch of generic drugs and decline the access to cheaper medicines. They also insisted that data exclusivity is not mandated by TRIPS agreement (IPA 2002; 2004). Foreign companies mentioned several benefits of introduction of data exclusivity. These benefits include: to ensure higher degree of safety and efficacy of drugs, to give the incentives to innovator, and to expand the opportunity of outsourcing business in India. They also insisted that India failed to comply with TRIPS agreement (OPPI 2003). Indian pharmaceutical industry was not necessarily monolithic. Some Indian companies such as Piramal Healthcare which is R&D oriented company and engaged in contract research and manufacturing services (CRAMS) business supported to the

¹ “India agrees to provide data exclusivity,” *Express Pharma Pulse*, 13 March 2003.

introduction of data exclusivity².

And there were differences of opinion among different departments and ministries. Ministry of Chemicals and Fertilizers and Planning Commission supported the introduction of data exclusivity because the data exclusivity is important to attract contract research in India³. On the other hand, Ministry of Commerce and Industry opposed the introduction. The Ministry insisted that TRIPS agreement does not refer to data exclusivity, and thus the introduction of data exclusivity go beyond the requirements of TRIPS⁴.

The Indian government set up several committees to discuss on the introduction of data exclusivity. In 2007, the report of Satwant Reddy Committee recommended five year data exclusivity and several safe guarding measures to be compliant with TRIPS agreement (Department of Chemicals and Petrochemicals 2007).

The new emerging issue is imposed as a part of bilateral free trade agreement. In March 2011, under negotiation of the India-EU Free Trade Agreement (FTA), the EU had been insistent on having an exclusive chapter on data exclusivity while the Indian negotiators have been denying giving any relaxation on this⁵.

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 industry⁶.

² “India Pharma majors back drug data exclusivity plan,” *The Economic Times*, 2 August, 2006.

³ “No data exclusivity yet for pharma companies,” *The Hindu Business Line*, 15 June, 2006,
“PMO working on pharma policy,” *The Hindu Business Line*, 11 July, 2005.

⁴ “No data exclusivity yet for pharma companies,” *The Hindu Business Line*, 15 June, 2006.

⁵ “India will not provide data exclusivity,” *rediff Business*, 30 March, 2011,
<http://www.rediff.com/business/report/india-will-not-provide-data-exclusivity-sharma/20110330.htm>

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

4. The Impact of TRIPS agreement on Indian Pharmaceutical Industry

Fink (2004) argues that for developing countries, stronger intellectual property rights bring about benefits in terms of increased trade, foreign direct investment and technology transfer. 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 shall examine the case of India which is a low income country.

The amendment of The Patent Act of 1970 changed the institutional factors which 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.

The amendment of the patent act to introduce product patent was supposed to have negative impacts on India. It would hamper the growth of the Indian pharmaceutical industry because the industry no longer to manufacture by reverse engineering and export drugs that product patents are effective. However, contrary to the expectations, as Figures 1-1 to 1-2 show, even in the post-TRIPS period, the industry has been growing rapidly.

In view of TRIPS agreement and impending changes to the Patent Act of 1970, Indian pharmaceutical industry pursues new business model. While Indian pharmaceutical companies are increasing their investment on R&D, they are increasing exports of generic drugs both to unregulated market and regulated market. Contract Research and Manufacturing Services (CRAMS) business which is a kind of outsourcing business has been growing.

4-1. Increase of R&D Investment

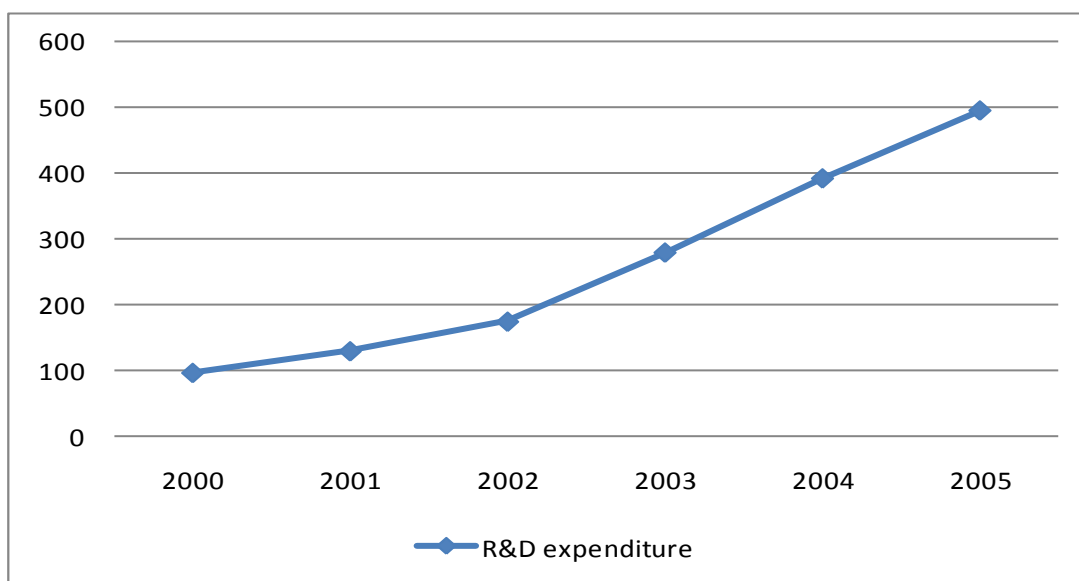
TRIPS agreement not only has increased R&D expenditures of the Indian

pharmaceutical industry but also has changed the R&D structure of the industry.

The pharmaceutical industry is a highly R&D-oriented sector. Under the Pro-patent regime under TRIPS agreement, for pharmaceutical companies, sustainable growth depends on their continuous R&D for developing new drugs and new technology.

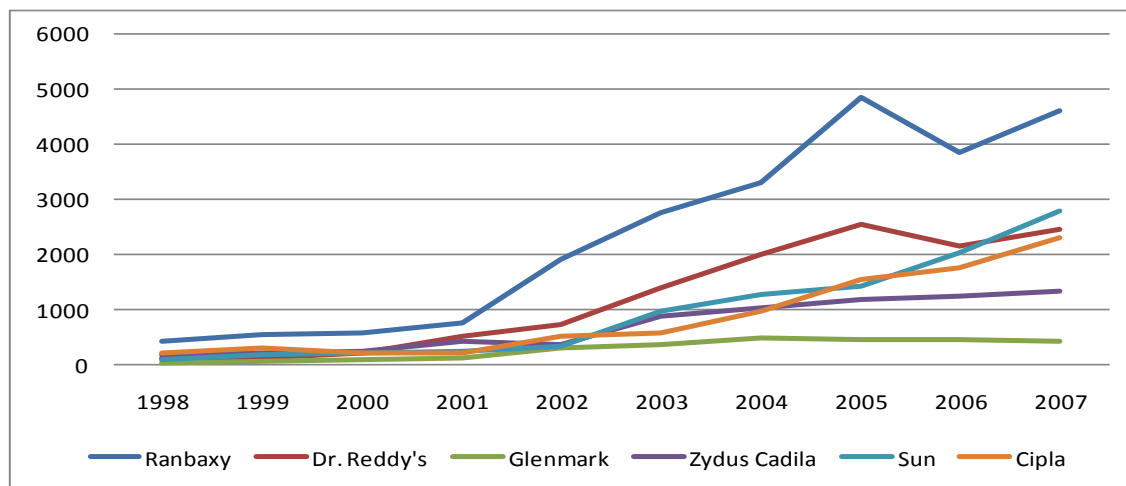
Figure/Table 4-1 and 4-2 show the trends in R&D expenditure in the Indian pharmaceutical industry in the post-TRIPS period. Since 2002, Indian companies have increased investment in R&D in order to overcome stiff competition in the global pharmaceutical market. The Indian pharmaceutical companies is turning to be more R&D oriented.

Figure/Table 4-1: R&D expenditure in Indian pharmaceutical industry



Source: ASSOCHAM (2006).

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



Source: Company's *Annual Report*, various years, Cygnus Business Consulting & Research (2008).

While the India government lagged behind private sector, it recognised the need for radically improving the policy framework for 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.

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 the 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 the 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.

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

(1) New Drug Delivery Systems (NDDS)

Indian companies are increasingly focusing on R&D for Novel Drug Delivery System (NDDS). NDDS is the most vigorous R&S area where most of the top Indian companies are increasing investment. Companies which are 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 Ranbax for ciprofloxacin, whereby patients are required to take the drug once a day rather than the previous twice-a-day dosage. Ranbax licensed its once-a-day ciprofloxacin formulations to Bayer in 1999. Ranbax'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.

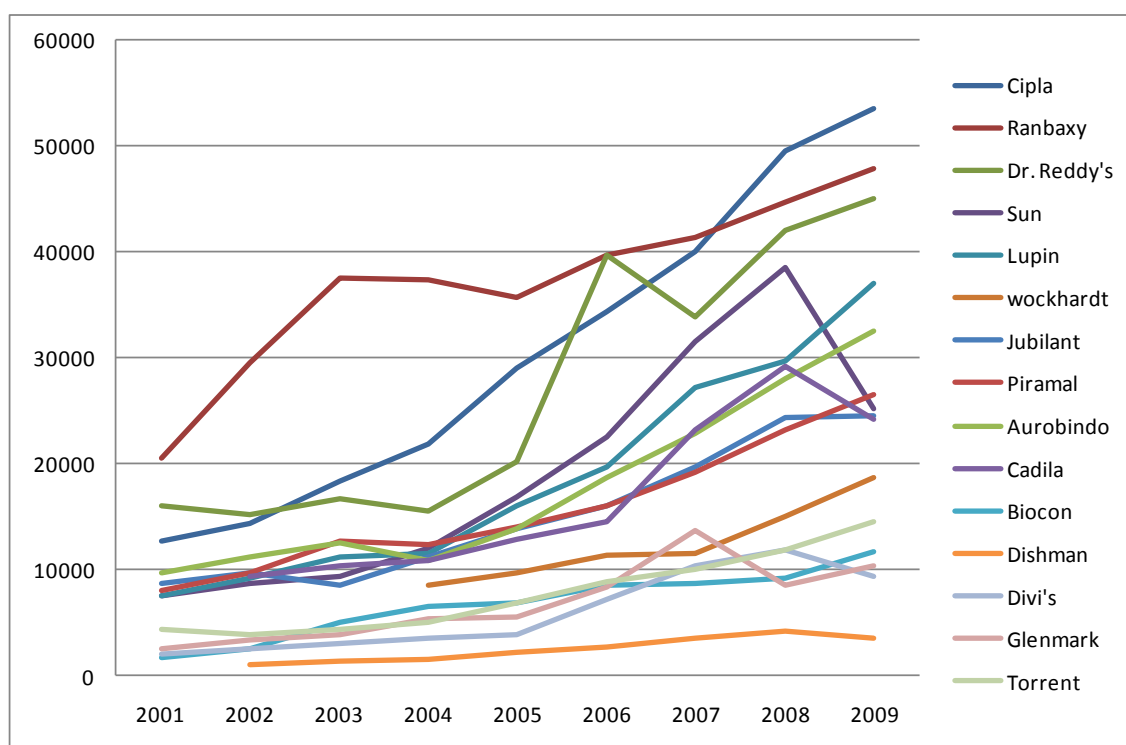
(2) R&D for generic products for the regulated market and non-infringing processes

The leading pharmaceutical companies in India have increased their R&D expenditures for development of generic products for the regulated market to satisfy quality and regulatory requirements for marketing off-patented drugs. Indian companies also have increased the development of non-infringing processes for filling Drug Master Filings (DMFs) and Abbreviated New Drug Applications (ANDAs). Generic manufacturers cannot enter the market unless it develops a non-infringing process because the patent

holder may have patents for manufacturing processes even after the product patent has expired. Indian companies increased the number of DMFs and ANDAs filings particularly in US.

During the first quarter of 2011, Indian pharmaceutical companies filed 90 and total 271 DMFs with US FDA during 2009 and 311 DMFs in 2010⁷. In 2010, Indian pharmaceutical companies maintained their number one position in the US generics market, by bagging 33.17 per cent or 139 of 419 original Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA)⁸.

Table/Figure4-3: Sales of the leading Indian pharmaceutical industry (Rs. in millions).



Source: *Company's Annual Reports*, various years.

⁷ “Indian Pharma Firms Filed 90 DMFs in Q1,” *CPhI Online*, 08 July, 2011, <http://www.cphi-online.com/news/14729/Indian+Pharma+Firms+Filed+90+DMFs+in+Q1.html>.

⁸ “Indian pharma remains top in US generics,” *Business Standard*, 3 January, 2011.

The increasing number of DMFs and ANDAs approvals is the evidence that the Indian pharmaceutical industry has been expanding the presence of the regulated market. In pre-TRIPS period, the Indian pharmaceutical industry focused on Indian domestic market and unregulated market in East-Europe and Africa. The industry has been increasing the export to the regulated market in the developed countries such as U.S. and Europe. The regulated markets are more lucrative than the domestic market and the unregulated market because the drug prices in the regulated market are relatively high. In addition, with patents on many blockbuster drugs which about to expire in five years from now, Indian pharmaceutical companies can manufacture drugs without infringement of product patent. This means that export opportunity for the Indian pharmaceutical industry will increase. As export has been growing, sales of the Indian companies has been increasing dramatically (Table/Figure4-3). This is attributed to R&D for non-infringing process.

(3) New Drug Development Research (NDDR)

As supporters of TRIPS argued that the introduction of pharmaceutical product patent encouraged 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. The leading Indian pharmaceutical companies are all now engaged in R&D for NCEs and have set up their own research centre for NDDR. Indian companies have reported some successes in NDDR. A number of new chemical entities (NCEs) have been developed which are at different stages of clinical trials (Figure/Table4-2).

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.

Figure/Table 4-2: New Chemical Entities (NCEs) developed by Indian companies

| 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 |

Source: Compiled from company websites.

The process of new drug development is classified into two stages: the pre-clinical stage and 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 in humans and developed for manufacturing and marketing. About 40% of expenditure of new drug development goes to funding clinical development (ICRA 1999).

NDDR is not only time consuming, but huge costs are involved in discovering a molecule and eventually launching the product into market. And the rate of failure is relatively high. Typically, out of 10,000 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 (ICRA 1999). The average length of time required is estimated at between ten and eighteen years, with the clinical stage accounting for about half the total NDDR time (ICRA 1999). The cost of developing and launching a drug into the market is considered to be about

US\$ 800 million in other countries (DiMasi et al. 2003). One of the largest R&D spenders in India, Dr. Reddy's Laboratories, spent only Rs. 5,5841.027 million (about USD 133 million) in 2007 (Dr. Reddy's Laboratories Ltd. 2008).

Even though Indian pharmaceutical companies have increased their R&D spending, owing to their small size compared to the 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 the large foreign pharmaceutical companies in the early stage of clinical development.

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

4-2. Expanding of Outsourcing Business

The introduction of pharmaceutical product patent brings new business opportunity to the Indian pharmaceutical industry. In 2000s, Pharmaceutical outsourcing business has been increasing in India.

With many blockbuster drugs which generate more than 1 billion dollars of revenue each year getting off-patented and with increasing R&D costs, it is hard for the 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 tend to hesitate to manufacture new drugs in India because of the Patent Act of 1970, which did not recognised product patent on pharmaceutical products. Recently, however, foreign companies have been increasing to outsource manufacturing of their new drugs. The introduction of product patent by the amendment of the Patent Act of 1970 made it impossible for Indian companies not licensed to manufacturing patented drugs. The incentive of 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 product patent 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 cost, low manufacturing cost (manufacturing cost in India is 40-50 per cent lower as compared to western countries), a large number of trained chemists and biologist, over 80 USFDA approved plants (India has the highest number of USFDA approved plants outside the US), abundant English speaking skilled manpower, large patient population providing a diverse pool for clinical trials for NCEs, and IT industry.

Recently, Contract Research and Manufacturing Services (CRAMS) business has been growing rapidly in India. CRAMS deals with manufacturing and research activities. Many Indian companies entered into CRAMS, and the number of the specialised CRAMS companies has increased. In post-TRIPS period, India is 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 TRIPS agreement has made the Indian pharmaceutical industry more R&D oriented and R&D intensified, pushing it up in the higher end of value chain.

5. Productivity in the Indian Pharmaceutical Industry

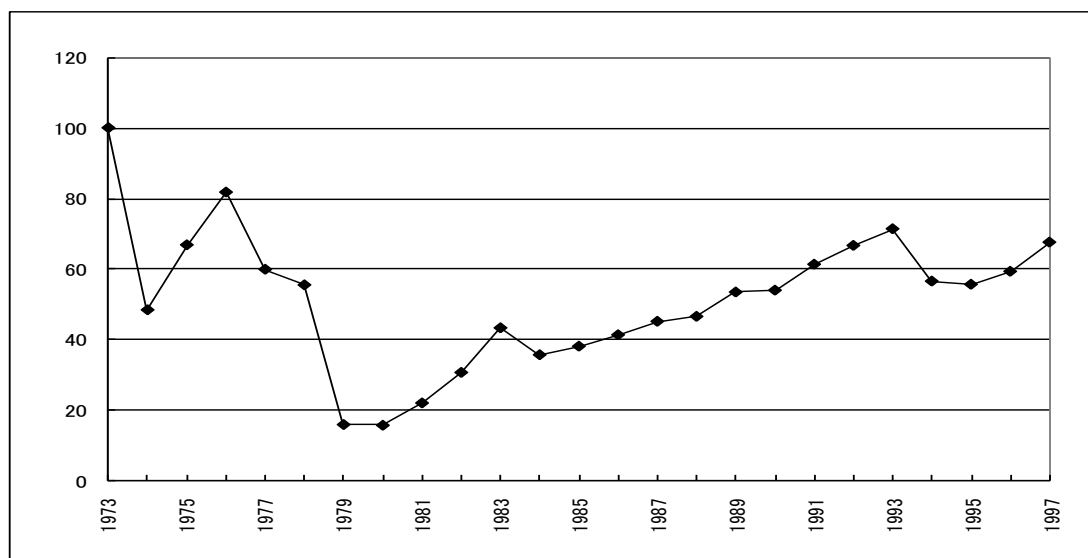
Sato and Kamiike (2005) estimate the production function and total factor productivity (TFP) of pharmaceutical industry in India in order to understand the drug policy and the industrial development as described above. It employs the growth accounting approach and the production function approach for estimation of the TFP growth and clarifies the characteristics of the Indian pharmaceutical industry. TFP is defined as the residual of economic growth which cannot be measured by an increase in factor inputs such as capital and labour. In other words, the residual of economic growth which is not explained by input growth can be interpreted as pure technological progress under some conditions. Growth accounting approach is to measure TFP Growth as a residual by subtracting the overall contribution of factor inputs from growth rate of real value added. The production function approach is to clarify the technical relationship between output and production factors. It can examine the 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 obtained.

Sato and Kamiike (2005) use Annual Industry Survey (ASI) as a main data set, which is collected by the Central Statistical Organization of India. The empirical analysis is based on national and state level data for the period 1973 to 1997 in the case of growth account approach and for the period 1984 to 1997 in the case of the production

function approach. 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 2 sectors: the census sector and the sample 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 which although having less than 100 workers, contribute significantly to the value of manufacturing sector's output. While the 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 a well designed sampling. The sector which the ASI covers is called as registered or organized sector. According to the National Account Statistics of India, registered sector covers 65 percent of the total value added in manufacturing sector in 1997.

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

Table/Figure 5-1: Total Factor Productivity (TFP) from 1973 to 1997 (base year: 1973)



Source: Sato and Kamiike (2005).

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

Based on the estimation results, Sato and Kamiike (2005) summarize the development history of the pharmaceutical industry as follows:

(1) While Indian companies were protected and foreign companies were regulated by drug price controls, regulations on foreigner's share holdings, and anti-patent policy, TFP itself had fallen in the 1970s. This is because the growth of foreign companies which were more efficient had been suppressed by the strengthening regulation and the growth of Indian companies did not have enough to recover the drop. At the same time, the oil crisis might affect the fall of the TFP.

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

(3) In addition, the Drug Policy of 1986 made stricter regulations for foreign companies again and the deregulation of Indian companies. Then, economic reforms in 1991 made significant relaxation of the regulations on foreign investment. During this period, Indian pharmaceutical industry with international competitiveness in the field of generic drugs which were easily imitated has competed with foreign companies. The India pharmaceutical industries gradually accumulating in R & D capabilities has achieved trade surplus for 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 aim to supply drugs at affordable price for the poor gave the Indian pharmaceutical industry the incentive for exporting rather than selling to domestic market because drugs was able to be sold at higher price in overseas market than in domestic market. Secondly, Good Manufacturing Practice (GMP) increased the reliability of Indian drugs in the world market. India decided to introduce Good Manufacturing Practice (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 the enhancement of trust of Indian products in the global market. In addition, to comply with GMP standard of U.S. and Europe has increased export to western countries, and has expanded the opportunity for contract manufacturing. Generally speaking, DPCO provides the incentives to export-orientation and GMP gives an institutional basis for supporting the

export-orientation in 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 successfully has shifted from import substitution to export-orientation and from comparative disadvantage to comparative advantage.

Now, we measure the international competitiveness of the India's pharmaceutical products by using Revealed Comparative Advantages (RCA) and Trade Specialization Coefficient (TSC). Table/Figure5-1 shows the RCA and TCR of pharmaceutical products in several counties during the period from 1985 to 2002.

Table/Figure5-1: Revealed Comparative Advantages (RCA) and Trade Specialization Coefficient (TSC) in India and other countries

| | 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 |

Source: Statics Canada, World Trade Analyzer.

Note 1: Indian figure in 1989 is regard as outlier.

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

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

India's RCA and TSC is the same as developed countries such as UK and USA and much higher than East Asian countries such as South Korea and Thailand. China produces generic drug much more than India. Pharmaceutical sales in China in 2003 reached 36 billion dollar⁹. It means more than seven times sales of India in 2003. However, in 2002, RCA and TSC in India are much higher than in China. In 1985,

⁹ <http://www.china.com.cn/japanese/169980htm>

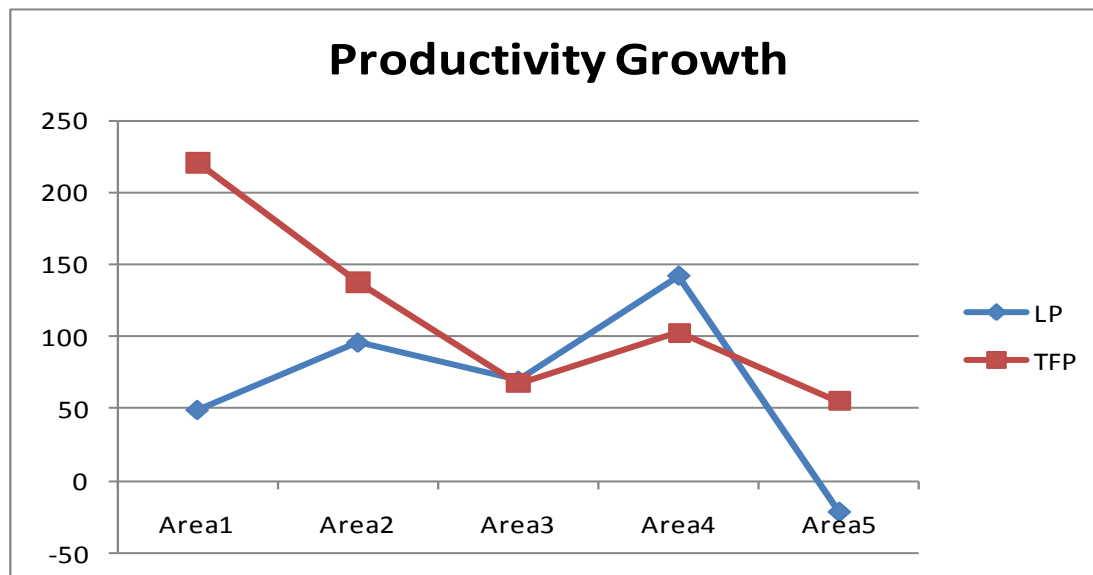
India's RCA is slightly higher than China's one and China's TSC is higher than India one. At that time, there was no difference in the two countries. However, enforcement of GMP in 1986 strengthened quality control and increased international confidence in Indian pharmaceutical products. Since 1985, India's RCA and TSC has remained much higher than China's ones. After China implemented GMP in 1992¹⁰, 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 increase production, but also achieved high international competitiveness at the same time.

Kamiike, Sato and Aggarwal (2011) estimates productivity growth in the Indian pharmaceutical industry across the regions during the period from 2000-01 to 2005-06, using the unit-level panel database drawn from the ASI. It uses the most frequently applied measures of productivity such as labour productivity (LP) and TFP. Our empirical application is based only on the census sector data due to the 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 was more than 6 percent.

In fact, Table/Figure 5-3 presents growth rates of LP and TFP across five regions in Indian pharmaceutical industry over the period from 2000 to 2005. It shows that both LP and TFP have increased across all the regions over this period with LP in Area 5 (non agglomerated area of pharmaceutical industry) being the only exception. Nevertheless, productivity growth has been particularly strong in agglomerated regions. The productivity grew over 50 percent over this period, meaning the average annual growth rate was more than 6 percent.

¹⁰ http://www.cjcci.biz/sansi_pdf_2004/2_3_2.htm

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



Note: Area 1: new and dynamic area: Himachal Pradesh and Uttarakhand. Area 2: established and least dynamic area: Delhi, Haryana and Punjab. Area 3: established and most dynamic area: Gujarat, Maharashtra, Goa, Dadra & Nagar Haveli, and Daman & Diu. Area 4: established old and somewhat dynamic area: Andhra Pradesh, Karnataka, Tamil Nadu, and Pondicherry. The rest of the states included in Area 5 as non agglomerated areas.

Kamiike, Sato and Aggarwal (2011) confirms that the productivity of the Indian pharmaceutical industry has been improving even in post-TRIPS period. It can be said that in the Indian context, the introduction of pharmaceutical product patent brings new business opportunity to the Indian pharmaceutical industry. Recent new trends of the Indian pharmaceutical industry including R&D for non-infringing processes and CRAMS are considered as important factors which enhanced overall productivity, especially TFP in the agglomeration areas.

6. Issue of Access to Medicines

Fink (2004) argues that stronger pharmaceutical patent rights required by TRIPS have raised concerns that greater pricing power by pharmaceutical companies would adversely affect access to medicines in poor countries. There is still a concern that the new patent act may affect the access to medicines in India.

The Patent Act of 1970 eliminated the monopoly status enjoyed by the foreign pharmaceutical companies and permitted unrestricted entry of drug manufacturers in to the industry. Free entry of companies in the absence of product patent protection and competition among the companies has resulted in competitive prices. (Chaudhuri 2005).

India introduced the Drug Price Control Order in 1970. The DPCO which fix ceiling prices on drugs in India contributes to keep drug price the lowest in the world. The Patent Act of 1970 and DPCO not only have brought the development of the Indian pharmaceutical industry but also have contributed to improvement of access to medicines in India. However, Chaudhuri (2005) argues that the absence of product patent has played a more important role in controlling prices than DPCO. In pre-TRIPS period, the Indian companies would develop process for these drugs and put them in the market, forcing the price to fall. However, this is impossible in the post- TRIPS period (Chaudhuri 2005).

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

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

Furthermore, the liberalisation of FDI regulation in pharmaceutical sector in 2002 that allows FDI up to 100% under the automatic route accelerated the advance of foreign companies into India, and several Indian companies were taken over by foreign companies (Table/Figure 6-1). After the recent takeover, three of ten companies ranked by domestic sales are foreign companies. Foreign company’s share in the domestic market has already risen from 15% to 25%. That is to say, the Indian domestic market is turning into more oligopolistic market than before. The Indian government with concerns about the rise of drug price established an inter-ministral committee to review India's FDI norms in the pharmaceutical sector¹¹.

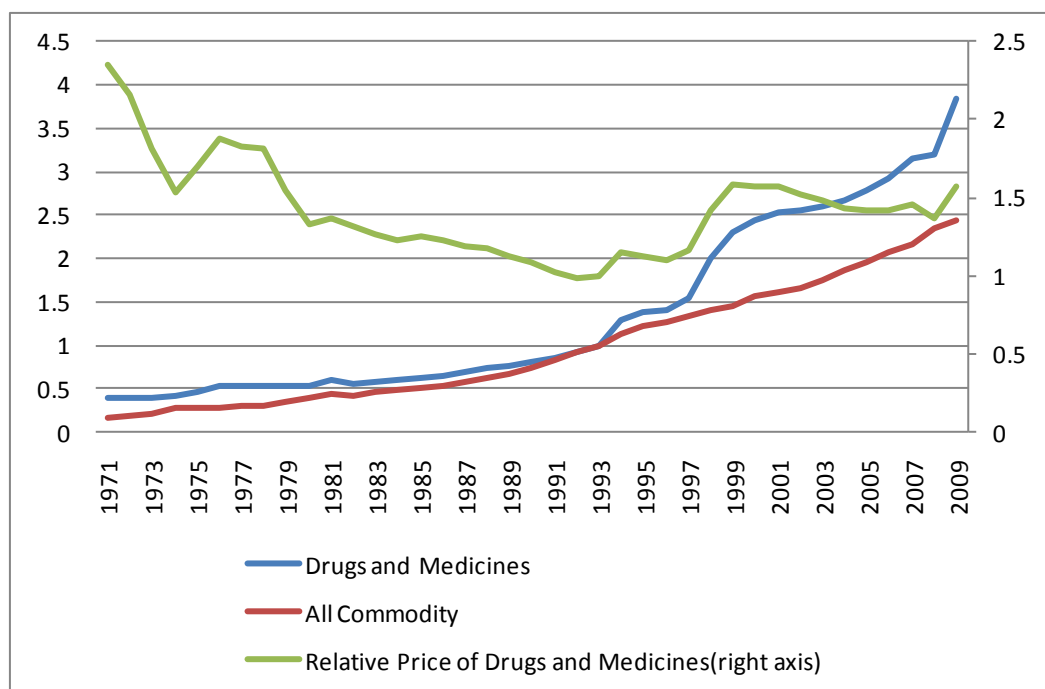
Table/Figure 6-1: Indian companies taken over by foreign companies

| Year | Indian companies | Foreign companies | Takeover Amount (USD in millions) |
|-------------|---------------------|----------------------------|--------------------------------------|
| August 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 |

Source: Company's Press Releases.

¹¹ “Minister’s panel look into FDI in pharma sector,” *The Economic Times*, 21 April, 2011.

Table/Figure 6-2: Trends of whole price index of drugs



Source: RBI (2006, 2009)

Lanjouw (1998) and Fink (2001) argue that Patents generate considerably higher prices for protected drugs than for generic drugs. As Table/Figure6-2 shows, the relative price of drugs and medicines was declining from 1971 to 1992 continuously. The fall of relative price is due to the price control under 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.

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 patenting of new forms of known substances without clear enhancement of efficacy. Section 3(d) of the patent act has list of area which are not patentable in India. Section 3(d) defines what is not patentable. Section 3(d) gives out 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.

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, Swiss pharmaceutical company challenged Section 3(d). In January 2006, the patent application for the anti-cancer drug Glivec (imatinib mesylate) which was filed by Novartis AG was rejected by the Intellectual Property Appellate Board (IPAB) because it failed to satisfy the efficacy requirements under Section(3). And then, Novartis applied to the Madras High Court challenging the decision of the patent office¹². 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 denial of Glivec patent¹³.

Foreign pharmaceutical companies have been criticizing that Section 3 (d) is not compatible with TRIPS Agreement. Section 3(d) has been obstacle for many inventions which are eligible for registering patent.

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

¹² “HC suspects hearings in Novartis’ Glivec case,” *The Economic Times*, 10 August, 2007.

¹³ “Novartis moves SC in Glivec patent case,” *The Economic Times*, 29 August, 2009.

7. Concluding Remarks

The Patent Act of 1970 and DPCO not only have brought the development of the Indian pharmaceutical industry but also have 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.

The introduction of pharmaceutical product patent was supposed to have negative impacts on the Indian pharmaceutical industry. It would hamper the growth of the Indian pharmaceutical industry. The industry can no longer manufacture by reverse engineering and export drugs that product patents are effective.. However, contrary to the expectations, the Indian pharmaceutical industry has been growing post-TRIPS period. The productivity of the Indian pharmaceutical industry has been improving even in post-TRIPS period. It can be said that the introduction of pharmaceutical product patent brings new business opportunity to the Indian pharmaceutical industry and promotes growth of the industry.

On the other hand, there are still concerns that the new patent act might reduce generic drug supplies and decline the access to medicines in India. It is one of the most important tasks for the Indian government to ensure access to medicines at affordable prices. 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.

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

Thus, the Indian government should seek appropriate balance between the development of the Indian pharmaceutical industry and the improvement of public health. In other word, the government should balance intellectual property protection with access to medicines. However, it is hard to be successful at both.

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