The Efficiency and Productivity of Indian Pharmaceutical Companies

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A Firm-Level Analysis

By

Aas Mohammad

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ABBREVIATIONS

ANDA	Abbreviated New Drug Application
ANNs	Artificial Neural Networks
APIs	Active Pharmaceutical Ingredients
ASI	Annual Survey of Industries
BCC	Banker, Charnes and Cooper
BCPL	Bengal Chemicals and Pharmaceuticals Limited
BIL	Bengal Immunity Limited
CAGR	Compound Annual Growth Rate
CCR	Charnes, Cooper and Rhodes
CDRI	Central Drug Research Institute
CMIE	Centre for Monitoring Indian Economy
CPI	Consumer Price Index
CRAMS	Contract Research and Manufacturing Services
CRS	Constant Returns to Scale
DEA	Data Envelopment Analysis
DGCIS	Directorate General of Commercial Intelligence and Statistics
DMF	Drug Master Files
DMU	Decision-Making Units
DPCO	Drug Price Control Order
DRS	Decreasing Returns to Scale
EC	Efficiency Change
EMRs	Exclusive Marketing Rights
EPS	Earning Per Share
EVA	Economic Value Added
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FERA	Foreign Exchange Regulation Act
FICCI	Federation of Indian Chambers of Commerce and Industry
FIPB	Foreign Investment Promotion Board
GMP	Good Manufacturing Practices
GOI	Government of India
HAL	Hindustan Antibiotics Ltd
HMI	Hicks-Moorsteen Index
ICMR	Indian Council of Medical Research

IDPL	Indian Drugs and Pharmaceuticals Limited
IID	Identically and Independently Distributed
IO	Industrial Organization
IPI	Indian Pharmaceutical Industry
IPR	Intellectual Property Right
IRS	Increasing Returns to Scale
LP	Linear Programming
M&A	Mergers and Acquisitions
MEP	Measure of Efficiency Proportion
MES	Minimum Efficient Scale
ML	Maximum Likelihood
MNC	Multinational Companies
MNE	Multinational Enterprises
MPI	Malmquist Productivity Index
MVA	Market Value Added
NCEs	New Chemical Entities
NDP	New Drug Policy
NLEM	National List of Essential Medicines
NPPA	National Pharmaceutical Pricing Authority
NSS	National Sample Survey
OPPI	Organization of Pharmaceutical Producers of India
PSU	Public Sector Units
R&D	Research and Development
RBI	Reserve Bank of India
SE	Scale Efficiency
SFA	Stochastic Frontier Analysis
SSPI	Small Scale Pharmaceutical Industry
SSPL	Smith Stanistreet Pharmaceuticals Limited
SVF	Sales Volume of Firms
TC	Technical Change
TE	Technical Efficiency
TFP	Total Factor Productivity
TRIPS	Trade-Related Aspects of Intellectual Property Rights
VRS	Variable Returns to Scale
WACC	Weighted Average Cost of Capital
WHO	World Health Organization
WTO	World Trade Organization

CHAPTER I

INTRODUCTION

1.1 Background of the study

Being healthy is a foundation for economic development and essential for a good quality of life. Better health has boosted rates of economic growth and overall development worldwide through improving productivity and thereby enhancing human capital. Therefore, health has been defined both as a cause and effect of economic development. The pharmaceutical industry plays a major role in healthcare with the help of well-trained and motivated health professionals, medical innovations, and, in particular, by improving access to medicines. Therefore, the pharmaceutical industry is specifically recognized in the UN Millennium Development Goals as an actor that can contribute to economic development. Furthermore, the pharmaceutical industry can play critical roles not only in improving access to medicines and quality care for citizens of developing countries but also in expanding their economic opportunities. While the major focus of the healthcare industry is to provide access to health services and quality medicines to the public, it also provides significant socio-economic benefits to society by expanding economic opportunities through the creation of jobs, supply chains, training and shaping public policy. The industry also plays an important role in technological innovation, which may reduce the costs of economic activity in the economy.

There are expectations that the pharmaceutical industry should contribute more to economic development through their activities and indirectly through improvements to healthcare infrastructure and capacity building. These activities, though longer-term in nature, can lead to a large-scale economic impact in developing countries. This reflects the complex role of companies in healthcare, as well as the special obligation inherent in a sector whose products and services are needed by people when they are at their most vulnerable. The main contributors in the healthcare sector, particularly in the pharmaceutical industry, are branded as drug manufacturers, generic drug manufacturers, firms developing biopharmaceutical products,

non-prescription drug manufacturers, and firms undertaking contract research. Besides these, there are also enablers of the industry such as universities, hospitals and research centers that play a role in R&D activities.

1.2 An overview of the Indian pharmaceutical industry

The Indian pharmaceutical industry is one of the largest and most highly developed science-based industries in the world's developing countries. Today, the industry is the fourth largest pharmaceutical producer in the world after the USA, Japan, and Germany, with around an 8% share of global production in terms of volume, and ranks 13th in terms of value, constituting around 1.5% of the world's total value. The size of the Indian pharmaceutical market reached US$ 22.86 billion in March 2010, of which the share of export was around 40% (around US$ 9.25 billion), and it was expected to grow by 14.1% per year in 2011-12 and 19% in 2013 (AR 2011-12). The total value of the output of the Indian pharmaceutical sector grew more than tenfold from Rs. 5,700 crores in 1991 to Rs. 61,219 crores in 2006 and Rs. 104,209 crores in 2010. The Indian pharmaceutical industry is growing very rapidly with an increasing international presence and has emerged as a technologically dynamic manufacturing industry in recent years (Kumar and Pradhan, 2003). The industry has succeeded in achieving a significant scale and level of technological capability for manufacturing modern drug cost-effectively to emerge as a major world force in the pharmaceutical product sector. 70% of India's domestic bulk drugs requirement (the active pharmaceutical ingredients) and almost 100% of formulations (the end products) are being procured from the Indian pharmaceutical industry (Pradhan, 2006). In addition to fulfilling the needs of domestic demand, the industry is also focusing on contract manufacturing, contract research, clinical trials, R&D activities, and direct exports to developing as well as developed nations. As a result, the industry today possesses the largest number of US Food and Drug Administration (FDA) approved manufacturing facilities outside the USA.

The main activities of the Indian pharmaceutical industry can broadly be classified as the production of bulk drugs and formulations. The bulk drug business is essentially a commodity business, whereas the formulation business is primarily a market-driven and brand-oriented business. Domestic firms are engaged in producing both bulk drugs as well as formulations, whereas multinational companies (MNCs) have continued to focus only on the formulations business. India is known today for producing high-quality generic medicines that are sold globally. Furthermore, India is

known to be one of the fastest growing pharmaceutical markets in the world. The following factors have fuelled the growth of drug production and the pharmaceutical market in India:

(i) Rapidly growing population of over a billion people;
(ii) Fast growing Indian economy with increasing incomes;
(iii) Changing disease profile and a huge patient base;
(iv) Improvements in healthcare infrastructure and the penetration of health insurance;
(v) Enhancing technological base;
(vi) Increasing expenditure on R&D;
(vii) Low manufacturing costs;
(viii) Adoption of patented products;
(ix) Patent expiries and aging populations in the US, Europe, and Japan.

Apart from the above factors, various policies and laws have been introduced by the Government of India such as the Drugs and Cosmetics Act (1940), Drugs Policy (1986), the Indian Patents Act (1970), the Drug Price Control Order (1995), Pharmaceutical Policy (2002), the Indian Patents (Amendment) Act (2005), etc. which have played a major role in the growth of the Indian pharmaceutical industry to consolidate its position in a competitive environment. The soft patent regime before 2005 provided opportunities for this industry to witness significant growth, particularly in generic drug production and exports. During this time, the industry prepared itself to surge ahead in the competitive global environment by adopting strategies such as increasing R&D activities, patent filings, inorganic growth strategies, contract manufacturing and research, co-marketing and co-licensing arrangements, and the diversification of markets.

At present, India has become one of the leading global players in the pharmaceutical sector with vast opportunities for both the domestic and foreign markets. The Indian pharmaceutical industry is entering an era in which it is not only going to play a crucial role in providing generic medicines to the world but will also become a global hub for R&D activities, which may be in the area of new drug discovery or different stages of clinical trials. The industry is preparing itself to face the challenges of the new patent regime and increasing competition from low-cost manufacturing and R&D destinations like China. Such challenges are helping the industry to modify its business strategies and thereby retain its competitive position in the pharmaceutical world. Many Indian

pharmaceutical companies have adopted the strategy of inorganic growth through mergers and acquisitions (M&A). Such activities enhance the strength of two entities to get market access, new technologies and new products. The Indian pharmaceutical industry has also been increasing R&D-related outlays significantly in recent years. Another noticeable trend which has been observed in the industry in the recent past is that it has emerged as an attractive destination for sourcing contract research, particularly clinical trials, and also contract manufacturing by many large firms from the developed countries. A well-developed manufacturing base, low-cost R&D and a large pool of skilled labourers are some of the factors which have contributed a lot to the growth of the Indian pharmaceutical industry in these business segments.

The size of the Indian pharmaceutical industry in 2005 reached the level of around 10,000 units, of which around 300 were large and medium pharmaceutical firms including both domestic companies and MNCs (GOI, 2009). It was not only the number of units that increased, but the profitability of the sector also showed a steady rise which acted as an incentive for increasing their investment in R&D-related activities. Domestic firms dominated the Indian market with more than 70% of the market share. High process R&D and low manufacturing costs helped the domestic firms to perform well in the export markets. The Indian pharmaceutical industry has also performed well in terms of exports. Pharmaceuticals are one of the top export items from India, accounting for more than 4% of India's total exports in 2006-07. Exports, which constitute around 40% of the industry's total production, have grown at a compound annual growth rate (CAGR) of 14% in the last decade. Exports have also played an important role in accelerating the growth of the indigenous pharmaceutical firms.

India exports its pharmaceutical products to more than 65 countries around the world. Major export markets include highly regulated markets such as the USA, Germany, the UK and Canada. Europe is the biggest export destination for Indian pharmaceuticals, accounting for more than 30% of the total exports, followed by America (25%). Indian firms have a cost advantage that facilitates the production of drugs at a much lower cost compared to other developed countries. From 2003-04 to 2007-08, the pharmaceutical industry of India was identified as one of the main drivers of the high export-led growth of India (GOI, 2008) and an employment generator possessing enormous positive externalities (GOI, 2009). Since the GOI recognized the product patent in the drugs after 2005, MNCs have started showing renewed interest in the Indian market. Lower production

costs in India are another reason for attracting MNCs and Foreign Direct Investment (FDI) inflows into the pharmaceutical sector. According to the Economic Survey (2006-07), the pharmaceutical industry accounts for about 2.91% of the total FDI into the country. The FDI in the pharmaceutical sector is estimated to have reached US$ 172 million, thereby showing a compound annual growth rate of about 62.6%. The drugs and pharmaceutical sector ranks 8th in India's top 10 FDI attracting sectors.

Some of the big Indian MNCs like Dr. Reddy's Lab, Cipla Ltd, Torrent Pharmaceuticals Ltd, Cadila Pharmaceuticals Ltd, Ind-Swift Laboratories Ltd, Ranbaxy Laboratories Ltd, etc. have created awareness about the Indian market's prospects in the international pharmaceutical market. Approvals, given by the Foods and Drugs Administration (FDA) and applied for with an Abbreviated New Drug Application (ANDA) and a Drug Master File (DMF), have also played an important role in making India a cost-effective and high-quality product manufacturer in the world. Also, the changes that have taken place concerning the patent laws, in terms of the change from a process patent to a product patent, have helped the Indian pharmaceutical industry in reducing the risk of loss of intellectual property. At present, tremendous progress has been seen in the pharmaceutical industry in relation to infrastructure development, technology-based creation, increasing expenditure on R&D-related activities and the manufacture of a wide range of products. Demand from the export market has been growing rapidly due to the capability of the Indian players to produce cost-effective drugs with world-class manufacturing facilities. The bulk drugs of all major therapeutic groups requiring complicated manufacturing processes are now being produced in India.

1.3 Structure of the Indian pharmaceutical industry

The Indian pharmaceutical industry consists of large, medium, and small enterprises and is one of the world's most price-competitive industries. According to the Organization of Pharmaceutical Producers of India (OPPI) in figures cited by Kallumal and Bugalya (2012), it is also one of the most highly fragmented industries in the world having around 10,000 manufacturing units in its organized and unorganized sectors. Kallumal and Bugalya go on to say that there are around 250 to 300 players in the organized sector, accounting for less than 5%, whereas 95% of the units of the industry are in the unorganized sector. As stated in their study "Trends in India's Trade in Pharmaceutical Sector: Some Insights", most of the

firms in the unorganized sector are small and medium enterprises, and the contribution of this segment is estimated to be around 35% of the industry's total turnover. The organized sector of this industry has played a very important role in promoting and sustaining development in this field and accounts for around 60 to 70% of the products in the market, with the top 10 firms representing 30%. Approximately 75% of India's demand for medicines is fulfilled by local production.

The Indian pharmaceutical industry consists of manufacturers of bulk drugs and of formulations. Bulk drugs are the active pharmaceutical ingredients (APIs) which are used as the raw materials for manufacturing the formulations, which are the end products in the form of tablets, capsules, syrups, etc. According to 2005 estimates, the ratio of the production of formulations and bulk drugs in the Indian pharmaceutical industry is in the order of 3:1 (OPPI). In the case of formulations, India has become self-sufficient; around 85% of the formulations produced in the country are sold in the domestic market, though some life-saving, new-generation-technology-barrier formulations are still being imported from other nations. In the case of bulk drugs, India was the world's third largest API manufacturing industry, valued at nearly $2 billion, in 2005. Currently, India's drug industry produces more than 400 different APIs and is among the world's top five API producers, accounting for approximately 6.5% of the world's API production (van Arnum, 2007). At present, drug prices in India are amongst the lowest in the world. India has now become a source of relatively good quality and cheap medicines for the rest of the world, which indicates a healthy growth of the Indian pharmaceutical industry.

1.4 Changing patterns in the Indian pharmaceutical industry since independence

During the last four decades, the Indian pharmaceutical industry has transformed itself from being almost non-existent in the 1970s to being a prominent provider of pharmaceutical products in the world today. At the time of the country's independence in 1947, the Indian pharmaceutical market was dominated by Western MNCs that controlled between 80 and 90% of the market, primarily through importing most of the bulk drugs from their parent companies abroad and selling the formulations in India at unaffordable prices. During this period, the patent regime was based on the Indian Patents and Designs Act 1911, which recognized both the product and the process patent regimes. This Act worked as a major entry barrier for domestic firms seeking to enter the pharmaceutical manufacturing

sector because most of the drug and pharmaceutical patents in India during that time were held by foreign MNCs. As a result, the Indian pharmaceutical market remained import-dependent until the government of India initiated a change in its policy stance towards this industry with the objective of achieving self-reliance in the healthcare sector through domestic production.

In 1972, the government of India relaxed its patent law and allowed indigenous companies to reverse engineer patented drugs and produce them using a different process that was not covered under the patent. The government discouraged the entry of MNCs into the market by imposing a restriction on foreign equity of up to 40% to encourage the domestic industry. The Act contributed to a significant reduction of the MNCs' share in the total formulation production in the country and proved to be instrumental in the growth of indigenous pharmaceutical production. The number of domestic firms engaged in pharmaceutical production increased considerably and formed a strong manufacturing base to fulfill the domestic requirements for bulk drugs and formulations. During the 1990s economic reforms were introduced which substantially relaxed the barriers to business and trade and induced new firms to enter the pharmaceutical industry. Up to 100% FDI was also permitted for manufacturing drugs and pharmaceuticals.

In 1995, another change took place in the Indian pharmaceutical industry with the establishment of the World Trade Organisation (WTO), under which India became a signatory of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, according to which it was supposed to introduce the product patent regime by 2005 (Exim, 2007). In the year 2005, India introduced the product patent and replaced the old process patent regime with the new patent regime. The Patent Amendment Act 2005, passed by Parliament in its budget session of 2005, brought the Indian Patent Act into full conformity with the intellectual property system in all respects. Under the new product patent regime, Indian firms were unable to copy and sell the patented drugs. Therefore, no patented drug that was launched after 1st January 2005 could be copied and sold. After the implementation of the product patent regime in India, a number of domestic firms started setting up their own R&D units as they realized the importance of R&D-related activities (Jha, 2007). The focus of the pharmaceutical firms has come to be governed by the size of their operations, with large firms emphasizing the discovery and development of new drugs; medium firms stressing the production of generics; and small firms opting for contract manufacturing (Rao, 2007). Thus, the

product patent regime has created a competitive environment in the Indian pharmaceutical industry.

1.5 Problem statement

The Indian pharmaceutical industry is going through a phase of transition due to policy changes. Under the process patent regime of 1970, the industry flourished with the supportive policies of the Government of India that were in force for more than three decades. This situation has, however, changed in the recent past with the TRIPS agreement in 1995, and subsequently again in 2005, thereby paving the way for product patenting. The various changes in the policies related to the trade and entry of multinational companies in the Indian pharmaceutical industry started during the early 1970s. However, the pace of growth of this industry showed a remarkable upswing only after 1991, and it also showed another major jump after the introduction of the product patent regime in 2005. While these changes have intensified the competition in the pharmaceutical sector from foreign multinational enterprises, it has also provided new opportunities for Indian pharmaceutical firms. In order to compete effectively with foreign MNCs, Indian firms need to change their age-old strategies. The new emphasis of the domestic firms should be on R&D-related activities in order to come out with new products or processes, to shift their operational bases in the global market, to integrate with the raw-material industry and to reduce transaction costs at different stages of manufacturing.

Taking into consideration all these significant policy changes, which are expected to have important implications for the operating performance of the pharmaceutical industry, it has become imperative to analyze the performance of the Indian pharmaceutical industry during recent years and to find out the factors responsible for the variations in the industry's efficiency and productivity levels. It is also important to examine whether only a handful of firms in the liberalized regime have performed better in maximizing their output while many others have lagged behind. This can be studied by undertaking an efficiency and productivity analysis because efficiency plays a crucial role in dictating the survival and growth of companies in various segments of the industry, particularly at a time when the industry is witnessing a dynamic structural transformation owing to external changes. It is also important to focus on the efficiency and productivity changes between various groups such as indigenous companies and MNCs, big firms and small firms, firms with and without R&D expenditure, and firms targeting the international market over a

period covering both process and product patent regimes, as well as to examine the overall relative performance of all firms in the Indian pharmaceutical industry.

1.6 Objectives and hypotheses of the study

1.6.1 Objectives

The study aims to evaluate the performance of Indian pharmaceutical companies by examining the levels of technical efficiency and total factor productivity (TFP) of individual firms from the industry using unit-level data from the Prowess Database of the Centre for Monitoring Indian Economy (CMIE) for the period 1997-2011 which cover both the period of the process and product patent regimes. This permits us to examine how the levels of productivity and efficiency of the Indian pharmaceutical industry have changed over the years.

The specific objectives of the study are as follows:

(i) To present a brief background of the pharmaceutical industry in India since its independence and examine the implications of the process patent regime and the product patent regime.
(ii) To examine the levels of efficiency of the pharmaceutical firms in India and discuss the determinants of efficiency.
(iii) To analyze the relative performances of the Indian pharmaceutical industry under the process patent regime and the product patent regime, and undertake a comparison of efficiency gains across different groups of firms.
(iv) To examine the productivity change and its various components for Indian pharmaceutical companies in the period 2001-2011.
(v) To estimate the technical efficiency of Indian pharmaceutical firms from 1997 to 2011 using the parametric Stochastic Frontier Analysis (SFA) and non-parametric Data Envelopment Analysis (DEA) techniques.

1.6.2 Hypotheses

In this study, the following hypotheses are formulated:

(i) The MNCs are relatively more efficient than the indigenous firms.

(ii) The firms with R&D-related outlays are technically more efficient compared to the firms without any R&D-related outlays.
(iii) The big firms are more efficient compared to the small firms' group.
(iv) The firms producing both bulk drugs and formulations are technically more efficient compared to the firms producing only bulk drugs or only formulations.
(v) The high export intensive firms are more efficient compared to the low export intensive firms.
(vi) The technical efficiency of the firms is not time invariant, especially in the post-TRIPS agreement and post-product patent regime periods.

1.7 Scope and limitations of the study

The present study covers both the post-reform and post-TRIPS agreement periods, i.e**.** 1997-2011. Data on the various inputs and outputs for estimating the efficiency and productivity of the Indian pharmaceutical industry have been compiled from the Prowess Database published by the Centre for Monitoring Indian Economy. Both the parametric Stochastic Frontier Analysis (SFA) and the non-parametric Data Envelopment Analysis (DEA) techniques have been used to estimate technical efficiency. The Malmquist and Hicks-Moorsteen indices have been utilized for calculating the productivity of the Indian pharmaceutical firms. In the SFA, four measures of outputs – total sales, foreign exchange earnings, profit after tax and total assets – have been used. Raw materials, wages and salaries of labourers, marketing and advertising costs and capital have been used as inputs. In the SFA, technical efficiency scores have been presented for different combinations of outputs and inputs. The firms have also been divided into different groups, namely, indigenous companies, MNCs, big firms, small firms, firms producing both bulk drugs and formulations, companies producing only formulations or only bulk drugs, firms with and without expenditure on R&D, high export intensive companies and low export intensive companies, based on their size, origin, product varieties, R&D expenditure and export performance.

To estimate technical efficiency using the DEA, two alternative combinations of inputs and outputs have been used; however, we have presented only one combination because of space constraints and the combinations having more or less similar trends. The inputs considered are raw materials, labour, power and fuel, marketing and advertising costs,

capital and net fixed assets. The outputs considered are total sales, foreign exchange earnings, profit after tax and total assets. The technical efficiency under constant returns to scale (CRS), variable returns to scale (VRS), and scale efficiency has been estimated for both different groups of firms and the entire industry as a whole, i.e. all the firms together. To calculate the total factor productivity of the firms utilizing the various productivity indices mentioned above, the study has used total sales, foreign exchange earnings, profit after tax and total assets as output variables. The input variables are raw materials, labour, power and fuel, marketing and advertising costs, net fixed assets, and capital.

The main limitation of the study is that only technical efficiency measures have been calculated; other measures of efficiency such as allocative, cost or profit efficiencies have not been estimated because of the non-availability of consistent price data. For the calculation of total factor productivity, data has only been taken for the period from 2001 to 2011 because not enough observations were available from 1997 onwards to make the panel balanced.

1.8 Organization of the book

The present study is organized into six chapters. The first chapter has given the introductory background, objectives, hypotheses and limitations of the study. The second chapter discusses the evolution and growth of the Indian pharmaceutical industry. The third chapter deals with the analysis of technical efficiency using the DEA technique. The fourth chapter analyzes technical efficiency using the SFA approach. The fifth chapter presents the productivity analysis of the Indian pharmaceutical industry using the Malmquist Index and the Hicks-Moorsteen Index. This is followed by the conclusion and policy suggestions in the last chapter.

CHAPTER II

EVOLUTION AND GROWTH OF THE INDIAN PHARMACEUTICAL INDUSTRY

2.1 Introduction

The pharmaceutical industry in India is nearly a century-old phenomenon, though the traditional systems of Ayurveda, Unani, and Siddha medicines have been in practice for many centuries. The modern pharmaceutical industry in India is basically a British import. In 1935 they set up a teaching institution in Calcutta for the purpose of training their medical practitioners. They used to ship the raw material from India to the UK and return the final products for the physicians' use. The domestic production of pharmaceutical products in India started in 1901 with the establishment of the first Indian-owned drug factory, the Bengal Chemical and Pharmaceutical Works in Calcutta, due to the pioneering efforts of Acharya P. C. Ray. During this time, many British medical scientists came to India to study the tropical infectious diseases which were spreading through their armies. They established several pharmaceutical research institutes like the King Institute of Preventive Medicine and Research in Madras (1904); the Haffkine Institute in Bombay (1904); the Central Research Institute in Kasauli (1905) and the Pasteur Institute in Coonoor (1907). However, these units faced several challenges like competition from foreign companies and a lack of government support. Up to the beginning of World War II, the UK continued to exploit India and kept it as its exclusive preserve for launching its pharmaceutical products in the Indian market. A few domestic enterprises had started up but could not make any significant impact on the Indian drug market. It is only from World War II onwards that the domestic firms started producing conventional medicines like serums and vaccines. The shortage of imported drugs in war time resulted in the foundation of a number of small companies that produced tablets and made other formulations.

The government was focusing on achieving self-sufficiency in the healthcare sector in a systematic way by investing in the pharmaceutical

industry through importing pharmaceutical products, although the government did not discourage foreign firms from competing in the Indian market. More foreign firms started marketing their products in the Indian drugs market, and some of them started importing raw materials in bulk and producing tablets, capsules, syrups and other formulations. The indigenous firms also began producing formulations like tonics, cough syrups and protein foods. The Drugs Act of 1940 was enacted, and rules were laid down in 1945 and 1948 authorizing the individual states to implement the drug standards control. The Central Drugs Laboratory (1950) was set up as the appellate authority for drug standards control, and the Central Drug Research Institute (1952) was established to stimulate research and development activities in this field.

At the time of the country's independence, the Indian pharmaceutical industry was dominated by foreign MNCs that controlled approximately 90% of the Indian market through importation. During this period, the patent regime was based on the Indian Patents and Designs Act 1911, which recognized both the product as well as the process patents. Most of the drug and pharmaceutical patents in India were held by foreign MNCs. They were importing most bulk drugs (active pharmaceutical ingredients) for their parent companies and selling the formulations (the final products) in India at unaffordable prices. The drug prices in India during this period were among the highest in the world. Therefore, several public drug manufacturing units like Indian Drugs and Pharmaceuticals Limited (IDPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL), Bengal Immunity Limited (BIL), and Smith Stanistreet Pharmaceuticals Limited (SSPL) were set up. Despite all these efforts, the Indian pharmaceutical industry was still in its infancy and remained import-dependent through the 1960s until the government started the policies aimed at achieving self-sufficiency through domestic production.

Experts blamed the existing IPR (intellectual property rights) regime for this continuous dependence on external supply. The existing IPR regime was inherited from the colonial era; in fact, the 1856 Act was consolidated into the Design and Patent Act 1911, incorporating both the process and product patents. The term of protection for these patents was 16 years, and could be further extended for another ten years if the patentee believed that he had not been remunerated for his innovation (Lalitha, 2002). The Patent Enquiry Committee (1948-1950) specified that "the Indian patent system has failed in its main purpose, namely to stimulate inventions among the Indians and to encourage the development and exploitation of new

inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public" (Government of India, 1949, cited by Ramana, 2002). Therefore, it recommended amendments to the existing IPR regime and the establishment of a new, more flexible institutional arrangement, which could encourage the development of the domestic industry and ensure self-sufficiency in the healthcare sector and reduce the price of medicines to make them affordable for the people of India.

The decade of the 1970s was a turning point for the Indian pharmaceutical industry. In 1970, the Government of India introduced some policy changes regarding the patent laws. A new Patent Act was introduced which recognized only the process patent and not the product patent. This Act became effective from 20th April 1972 onwards, allowing Indian companies to reverse engineer the patented drugs and manufacture them using a different process that was not under the patent. Moreover, the protection term of the patent was also reduced to only seven years. The entry of foreign MNCs was also discouraged by restricting foreign equity to 40%. The licensing policy was also biased towards indigenous firms and companies with less foreign equity. In addition, along with the industrial policy measures, the Drug Price Control Order (DPCO) was also established in 1970 to enhance people's access to quality drugs. There was very few incentives for MNCs to introduce new products in India. These policy measures taken by the GOI provided a conducive environment to lay the foundations of a strong manufacturing base for bulk drugs and formulations and accelerate growth in the Indian pharmaceutical industry. All these steps were taken deliberately to develop and encourage the domestic healthcare industry in producing cheap and affordable drugs. As a result, the Indian pharmaceutical industry not only met domestic requirements but also started exporting bulk drugs as well as formulations to the international market.

In 1995, when the World Trade Organisation (WTO) came into being, India, one of its founder members, automatically became a signatory of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and was compelled to reintroduce a product patent regime by 2005 (EXIM, 2007). Accordingly, in the year 2005, the Government of India reintroduced the product patent regime and the 35-year old process patent regime was modified and replaced with the more rigorous patent regime. It required a patent to be provided to products as well, and the TRIPS agreement's coverage was extended to food, drugs, and medicines, which had earlier been exempted from patent protection. The term of the patent

protection was extended to twenty years compared to the seven years which was provided by the Act of 1970. Thus, with the introduction of the product patent regime, the importance of research and development activities for the Indian pharmaceutical industry increased, with many firms setting up their own R&D units (Jha, 2007), and collaborating with research laboratories (FICCI, 2005). Since the GOI recognized the product patent in drugs after 2005, MNCs have started to show a renewed interest in the Indian market and are making a comeback, attracted by India's traditional strengths in contract manufacturing as an outsourcing location for research and development activities, particularly for clinical trials and other services. Lower production cost in India is another reason for attracting MNCs and Foreign Direct Investment (FDI) inflows into the pharmaceutical sector. All these policy changes, starting from the 1990s, were the start of a new chapter in the Indian pharmaceutical sector where free imports, foreign investment, and technological superiority determined the structure of the industry. Today, the Indian pharmaceutical industry has achieved a significant scale and level of technological capability for manufacturing new drugs cost-effectively to emerge as a major force in the world of pharmaceutical products.

2.2. Evolution of the Indian pharmaceutical industry

The evolution of the Indian pharmaceutical industry can be classified into the following three phases; each phase is characterized by different policy regimes and the industry's response to those policies:

(1) First phase (until the 1970s)
(2) Second phase (1970 to 1995)
(3) Third phase (1995 onwards)

2.2.1. First phase (until the 1970s)

During this phase, the Indian pharmaceutical industry was very small, not only regarding the number of firms but also in terms of the volume of production. The Indian pharmaceutical market was dominated by foreign firms and was dependent on imports. During this period, the patent regime was based on the Indian Patents and Designs Act 1911, which was in favour of the foreign MNCs because it recognized both product and process patents, and around 99% of patents in the pharmaceutical sector were held by these companies. As a result, this act was a major hindrance for Indian firms in manufacturing pharmaceutical products and needed to be relaxed in order to promote and encourage the domestic industry and

local production in the country. During this time, MNCs were taking advantage of the existing patent regime and exploiting the Indian drug market by selling their products at a very high price. In order to overcome the problem of high drug prices and the lower technical base of the domestic companies, the Government of India set up some public sector drug manufacturing units with technical support from countries like Russia which played a significant role in producing critical drugs at relatively low prices for the domestic market. MNCs were also encouraged to set up their manufacturing bases in India to strengthen the domestic industry.

2.2.2. Second phase (1970 to 1995)

The decade of the 1970s witnessed many policy changes made by the Government of India towards the pharmaceutical industry regarding the patent regime to enhance the manufacturing base in the country. In the year 1970, the Government of India introduced a new Patent Act, which recognized patents only on the process and not the product. According to this Act, drugs patented in other countries could be manufactured in India with a different process. Thus, the act encouraged reverse engineering and the development of alternative processes for products manufactured in other countries. The statutory term of a patent's protection was shortened to seven years. The Drug Price Control Order was also established in 1970 to make essential medicines accessible and affordable to the Indian populace. In the year 1973, the Foreign Exchange Regulation Act (FERA) was introduced to regulate the foreign MNCs in India by restricting the level of foreign equity holdings in a company to no more than 40%. However, foreign pharmaceutical firms that were involved in manufacturing bulk drugs with advanced technology were allowed to have more than 40% foreign equity under FERA. In the year 1978, the Government of India announced its Drug Policy which played an important role in reducing the MNCs' dominance in the domestic pharmaceutical market. The Drug Policy of 1978 was the first comprehensive drug policy enacted in India with the objective of achieving self-sufficiency in the healthcare sector by promoting the development of the domestic pharmaceutical industry. The policy was more concerned about the importance of R&D and technology and improved the technological capabilities of the industry by providing promotional measures for R&D. The policy further strengthened the regulation of foreign firms with foreign equity levels of above 40% (Government of India, 1982: II, 24-25). All these policy changes discouraged MNCs from introducing new products in India, and the share of MNCs in the total formulation production in the country also came

down significantly. On the other hand, these measures accelerated the growth of indigenous companies. According to the Organization of Pharmaceutical Producers of India, the size of the industry in terms of the number of domestic firms engaged in pharmaceutical production increased over the period from 2,200 units in 1969-70 to nearly 24,000 in 1995-95. Domestic firms also expanded their production capacity during this period. The production of bulk drugs increased from Rs. 18 crores in 1965-66 to Rs. 1,518 crores in 1994-95. The production of formulations increased from Rs. 150 crores to Rs. 7,935 crores during the same period. The growth in the manufacturing of formulations was more compared to the bulk drugs produced because of the large-scale production of generics by indigenous firms. By 1991, domestic firms accounted for around 70% of the bulk drugs and 80% of the formulations produced in the country.

Indian drug manufacturers started exporting to many developed as well as developing countries with the help of low costs and increased production capacity. Since 1990, there has been a substantial growth in the export of pharmaceutical products, in particular for formulations. Since then, India has maintained a positive balance in the pharmaceutical trade. The export of pharmaceuticals has increased from 2% of India's total exports in 1984-85 to more than 3% in 1995-96. The low-priced export of generics from India has played a crucial role in making the Indian pharmaceutical industry more and more export-oriented. There has been a substantial growth in the share of exports as a percentage of total pharmaceutical production, increasing from 3.22% in 1980-81 to 23.97% in 1994-95.

2.2.3. Third phase (1995 onwards)

The year 1995 was crucial in the history of the Indian pharmaceutical industry because it was in this year that the World Trade Organisation (WTO) came into effect and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement was one of those negotiated under the WTO. The TRIPS agreement reintroduced the product patent regime in many countries, including India. However, developing nations were given a ten year transition period to make their patent policies TRIPS compliant. In 2005, India introduced the product patent regime and became fully TRIPS compliant. The period after 1995, i.e. the post-TRIPS period, witnessed the strongest performance of the Indian pharmaceutical industry. The industry not only performed well in terms of production but also turned into a net foreign exchange earner during this period. Furthermore, due to the WTO's initiatives, tariff and non-tariff measures affecting world trade were also introduced that proved to be very helpful

for the Indian pharmaceutical industry to undertake activities such as clinical research, new drug development, etc.

The size of the pharmaceutical industry increased not only in terms of the number of firms, but the profitability of the sector and production levels have also gone up during this phase. The introduction of the product patent regime in 2005 brought new business opportunities to Indian pharmaceutical companies. During the 2000s, the pharmaceutical outsourcing business increased in India. Earlier, under the process patent regime, foreign pharmaceutical companies used to hesitate to manufacture new drugs in India because of the Patent Act of 1970, which did not recognize product patents on pharmaceutical products. However, today they are increasingly outsourcing manufacturing, drug discovery operations and clinical trials to India. In addition, the contract research and manufacturing services (CRAMS) business has also grown rapidly in India. Many Indian companies have entered into the CRAMS business, and the number of specialized CRAMS companies has also increased.

2.3. Growth and major changes in the Indian pharmaceutical industry since independence

Since independence, the growth pattern of the Indian pharmaceutical industry has been phenomenal, despite the fact that this sector is the most regulated and controlled among all business segments. It has been a glowing success with the support of excellent performances in many areas including quality human resources, a favourable policy environment, intellectual property rights (IPR) laws, national scientific and technological development, cost-effective manufacturing, proactive responses to domestic and global business opportunities, institutional infrastructure, etc.

However, after the introduction of the WTO and the TRIPS agreement, the Indian pharmaceutical industry has had to face several new challenges. The reintroduction of the product patent regime was one of the challenges it faced in order to meet its TRIPS obligations. Under this policy regime, Indian pharmaceutical firms are no longer allowed to exercise the reverse engineering process, which was one of the major reasons for the growth of the industry from 1970. In addition, economic reforms and the liberalization process decreased the tariffs and other trade barriers to a considerable extent, thus making the imports cheaper in many countries. Under such an environment, Indian firms are required to be much more innovative and explore overseas markets in order to remain globally competitive. Accordingly, to face all these challenges, the Indian pharmaceutical