POST TRIPS PATENTING REGIME AND PHARMACEUTICAL INDUSTRY OF INDIA WITH REFERENCE TO NORTH WEST REGION: CHANGING PARADIGMS, PERSPECTIVES AND PRAGMATICS

Ph D. THESIS

Submitted

IN FULFILLMENT OF THE REQUIREMENTS
FOR THE AWARD OF THE DEGREE OF

DOCTOR OF PHILOSOPHY

BY

SUNITA MISHRA
(Reg. No 90610502)

SCHOOL OF MANAGEMENT AND SOCIAL SCIENCES

THAPAR UNIVERSITY, PATIALA-147004 (INDIA)

NOVEMBER, 2010

CERTIFICATE

Certified that the thesis entitled 'POST TRIPS PATENTING REGIME AND PHARMACEUTICAL INDUSTRY OF INDIA WITH REFERENCE TO NORTH WEST REGION: CHANGING PARADIGMS, PERSPECTIVES AND PRAGMATICS' which is being submitted by Ms. Sunita Mishra in fulfillment of the requirements for award of the Degree of Doctor of Philosophy in Management, Thapar University Patiala, is a record of candidate's own work, carried out by her under my supervision and guidance. The matter embodied in this thesis has not been submitted in part or full to any other University or Institute for the award of any degree.

Ravi Kiran

Dr (Ms) Ravi Kiran
Professor
School of Management & Social Sciences,
Thapar University,
Patiala

Place: Patiala
Date: 07-11-2010

ACKNOWLEDGEMENTS

It is a matter of great privilege to acknowledge the help and guidance which I received from several eminent sources.

I am profoundly indebted to my worthy supervisor, Dr (Ms) Ravi Kiran, Professor, School of Management & Social Sciences, Thapar University, Patiala, for her sustained guidance and continuous motivation in the accomplishment of my work. In fact, words can hardly convey the measure and abiding gratitude that I owe to my supervisor.

I am equally indebted to Sh. T.C.Kansal, General Secretary of Haryana Drug Manufacturers' Association since 1993 and General Secretary of North Zone of IDMA for providing me in depth knowledge of pharmaceutical industry which proved a boon for me in furnishing my work. I am grateful to Mr Rajiv, Owner of Mcdil Laboratory, who provided me the deep routed knowledge about the small scale pharmaceutical industry.

I deeply express my gratitude to Mr Tarsem Garg, Chancellor, M.M.University, Mullana, for providing all type of support from the university. I am equally indebted to Dr N.P.Mehta, Pro-Vice Chancellor, M.M.University, Mullana for motivating me at all levels to complete the research work .

I express my regards and gratitude to Dr Santha Kumari, Professor and Head, School of Management and Social Sciences, Thapar University, Patiala for providing keen interest, unfailing support, inspiration and ingenuous suggestions.

I deem it a pleasure to express my regards and gratitude to Dr Abhijit Mukherjee, Director, Thapar University, Patiala for providing the necessary facilities. I wish to convey my regards to Dr Susheel Mittal, Dean, Research and Sponsored Projects, Thapar University, Patiala for his constant help and guidance.

And lastly, on a very personal note, I wish to thank my husband, Rajiv, without whose cooperation, it would have been impossible for me to accomplish this task. I also extend my thanks to my daughters, Madhurima and Priyanka, who have shown great patience throughout my work.

Sunita Mishra

Sunita Mishra

Dated: November 7, 2010

C O N T E N T S

ABSTRACT

The Indian pharmaceutical industry initially, governed by the Patents Act of 1911, allowed the MNCs to take advantage and they patented heavily in the country and the indigenous firms were legally prevented from manufacturing most of the new drugs introduced by the transnational corporations (TNCs) during the life of the patent. The Patent Act of 1911, amended in 1970 provided protection for the processes of manufacturing the drug for seven years from the date of filing the application or for five years from the date of the grant of the patent. It was harshly criticized by the multinational companies operating in India at that time on the grounds that it would reduce the incentives for investments in that sector. A large number of indigenous and smaller enterprises entered the market and competed with existing firms. Over the years, it became a much more fragmented industry. The period 1970-95, generally known as the pre-TRIPS period, has been considered as a flourishing phase of the Indian pharmaceutical industry.

The scenario changed after world trade organization (WTO), 1995 and India, being a signatory member of WTO, adopted TRIPS. Under TRIPS, all countries have to provide for protection of product patents from January 1, 1995. Developing countries like India, which did not have a regime of product patents, could take advantage of a transition period of ten years until January 1, 2005. However, perceptions about IPRs in India also changed over time and a paradigm shift occurred in the industry and caused a marked shift in India's policy around 1998-99. Industry bodies and various groups changed their stand and now took a pro-patent view. Accordingly 'The Patent Act 1970' was amended and under the Patents (Amendment) Act, 2005 patents are to be granted both for products and processes for all the inventions in all fields of technology. As a result, reverse engineering possibilities, hitherto available to the pharmaceutical industry, will only be limited to those drugs that will go off-patent. The period 1995-2008 (i.e., the post-TRIPS period) is thus very important for the pharmaceutical industry of India. In the above backdrop, the present study examines the impact of TRIPS on the pharmaceutical industry of India in the the post-TRIPS period in terms of patents, R&D and exports.

The analyses have been done at the industry level, at the level of selected leading pharmaceutical companies and also for the sample survey of 100 firms selected from the north west region of India. The results of the industry level data depict that patents have increased in the pharmaceutical industry of India in the post-TRIPS period. Growth of R&D of the industry as a whole has been higher in the post-TRIPS period as compared to the pre-TRIPS period. Growth of exports is also higher in the post-TRIPS period as compared to the pre-TRIPS period. The results of the present study also show that patenting activities of the leading pharmaceutical companies have improved consistently. Not only the patent filing has increased, the patents granted have also increased in the post-TRIPS period. In the case of ANDA filings with USFDA and DMF filings, the situation has dramatically changed in the last few years. Now, besides Ranbaxy and DRL, other firms like Cipla and Sun Pharmaceuticals, Cadilla, Aurobindo and Glenmark are also increasing ANDA and DMF filings.

The firm level analyses of the north west region depict that the firms have reported a shift to better technology, an increase in in-house R&D, enhancement in the proportion of turnover spent on R&D, enlargement of the number of products introduced and augmented sales. The analyses also reflect that the firms in the north west region of India are preparing themselves for the change, they do not perceive Schedule M as a hasty decision and are not threatened by MRP based excise duty on the existing prices although the existing literature does not support it (Cygnus, 2006; Dey, 2007; Jaisankar, 2007; Jaikumar, 2008). These results have further been tested by the regression analysis. Overall results depict an improvement in patenting, R&D and exports in the post-TRIPS period.

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

Abbreviation	Full Form
ANDA	Abbreviated New Drug Application
ANOVA	Analysis of Variance
API	Active Pharmaceutical Ingredient
ASSOCHAM	Associated Chambers of Commerce and Industry of India
CII	Confederation of Indian Industry
CL	Compulsory Licensing
DMF	Drug Master File
DPCO	Drug Price Control Order
DSB	Dispute Settlement Body
EFZ	Excise Free Zone
EMR	Exclusive Marketing Rights
EPO	European Patent Office
FDI	Foreign Direct Investment
FICCI	Federation of Indian Chambers of Commerce and Industry
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practice
IDMA	Indian Drug Manufacturers' Association
IP	Intellectual property
IPR	Intellectual Property Right
LDC	Less developed country
MNE	Multinational enterprise
MNC	Multinational Corporation
MRP	Maximum retail price
NCE	New Chemical Entity
NDDS	Novel Drug Delivery System
NGO	Non Government Organization

Abbreviation	Full Form
PCT	Patent Cooperation Treaty
R&D	Research and Development
SSI	Small Scale Industry
TNC	Transnational corporation
TRIPS	Trade Related Intellectual Property Rights
USFDA	United States Food and Drug Administration
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

CHAPTER - I

INTRODUCTION

1.1 History of the Indian pharmaceutical industry

The Indian Pharmaceutical Industry is about 120 years old. Production of modern medicine by indigenous units started with the setting up of the Bengal Chemical and Pharmaceutical Works in Calcutta (1892), which was followed by the establishment of the Alembic Chemical Works in Baroda (1907) and the Bengal Immunity in 1919. At that point of time, the Patents Act of 1911 was in practice, which facilitated patenting all the known and possible processes of manufacturing a drug besides patenting the drug itself. Foreign multinational corporations (MNCs) were quick to take advantage of this provision. They consistently imported bulk drugs from their home countries and produced formulations in India, contending that locally available bulk drugs were not of the desired quality. They also patented heavily in the country (Kamath, 2002). The indigenous firms were legally prevented from manufacturing most of the new drugs introduced by the transnational corporations (TNCs) during the life of the patent secured by the latter, i.e., for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not been sufficiently remunerative to the patentee. The domestic firms were also forbidden from processing a patented drug into formulations or importing it.

As a result, at the time of independence, the industry was dominated by multinational corporations and the prevailing drug prices were among the highest in the world (Henderson, 1997). Between 1947-57, 99 percent of the 1704 drugs and pharmaceutical patents in India were held by foreign multinational enterprises (MNEs) which controlled 80 percent of the market (Dubey, 1999). To study patents and provide suggestions on the type of patent system that India should implement, two expert committees were established in independent India. The Patent Enquiry Committee (1948-50) reported that, “the Indian patent system has failed in its main purpose, namely to stimulate inventions among 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" (pp 12). The second committee, known as the Ayyangar Committee (1957-59), noted that foreign patentees were acquiring patents not "in the interests of the economy of the country granting the patent or with a view to manufacture there, but with the object of protecting an export market from competition from rival manufacturers particularly those in other parts of the world". Thus India "is deprived of getting, in many cases, goods at cheaper prices from alternative sources because of the patent protection granted in India" (Ramanna, 2003). These reports concluded that foreigners held 80-90 per cent of the patents in India and were exploiting the system to achieve monopolistic control of the market. The committees therefore suggested that a patent system which focused on access to resources at lower prices would be beneficial to India. The Patent Act of 1970 was based on the recommendations of these committees. The Act found support among domestic firms and various political parties in India.

1.2 The Patent Act 1970

The Patent Act of 1911 was amended in 1970, which came into force in 1972. The 1970 Patent Act provides protection for the processes of manufacturing the drug for seven years from the date of filing the application or for five years from the date of the grant of the patent. Under this Act only one process that was used in the actual manufacturing could be patented. The introduction of the Patent Act 1970 was perhaps the single most significant policy initiative taken by the government that laid the foundation of the modern pharmaceutical industry.

Meanwhile the drug price control order (DPCO) 1970, also acted as a disincentive to multinational corporations (MNCs) as it set a ceiling on the overall profits of the MNCs. Later, even when the DPCO reduced its coverage, threat of 'reverse-engineering' kept subsidiaries of MNCs operating in India away from introducing new products in the Indian market**.** These changes brought a revival to the pharmaceutical industry of India. More units larger in size and capacity were set up in the 1970s and 1980s and started producing drugs, which were primarily imported till then.

1.3 Growth of the Pharmaceutical Industry in the pre-TRIPS period (1970-95)

These policy interventions brought radical transformations in the Indian pharmaceutical industry. The policy changes removed entry barriers in the industry. A large number of smaller enterprises entered the market and competed with existing firms. Over the years, it became a much more fragmented industry. In 30 years there was a ten-fold increase in the number of firms producing pharmaceuticals (Kamath, 2002).

The production of drug formulations grew at an average annual rate of 14.4 percent between 1980-81 and 1992-93; the negative balance of trade in bulk drugs and drug formulations that prevailed throughout the 1970s and 1980s was turned into a trade surplus by 1990 (Fink, 2000).

The period 1970-1993 also saw a declining market share of TNCs in India. In 1970, Indian-owned firms held a share of only 10-20 percent of the total pharmacy market, TNCs accounted for the remaining 80-90 percent. By 1980, Indian firms and TNCs had an equal share of about 50 percent; by 1993, Indian firms had raised their share to 61 percent (Fink 2000). In 1996, of the top ten firms in pharmaceutical sales, six were Indian firms rather than the subsidiaries of foreign multinationals (Lanjouw,1998).

By 1991, Indian firms accounted for 70 percent of the bulk drugs and 80 percent of the formulations produced in the country. (Lanjouw,1998). Domestic firms produced about 350 of the 500 bulk drugs consumed in the country. Employment in the pharmaceutical sector was estimated to have reached almost half a million by 1995 (Lanjouw,1998). As a result of the implementation of this Act the number of patents granted per year fell by three quarters over the decade (1970-71 to 1980-81) from 3923 in 1970-71 (629 Indian applicants, 3294 Foreign applicants) down to 1019 in 1980-81 (349 Indians, 670 foreign) (Lanjouw,1998).

The period 1970-95, generally known as the pre-TRIPS period, was a flourishing phase of the Indian pharmaceutical industry.

1.4 WTO and TRIPS

The scenario changed when the World Trade Organization (WTO) was established in 1995 as a successor to the general agreement on tariffs and trade 1947 (GATT-1947). India was a founder member of the GATT-1947 and the WTO-1995. Being a signatory member of WTO, India had signed on to TRIPS.

1.4.1 World Trade Organization (WTO)

WTO is the principal international organization governing multilateral trade among members. The WTO administers the implementation of a set of agreements, which include the General Agreement on Tariffs and Trade, other agreements in the goods sector and, in addition, agreements in two other areas, i.e., trade in services and Trade-Related Intellectual Property Rights. The WTO agreements were negotiated on the basis of a 'single undertaking' which implies that membership to the organization obligates the acceptance of the results of the Uruguay round of multilateral trade negotiations without exception.

1.4.2 Trade-Related Intellectual Property Rights (TRIPS)

The agreement on Trade-Related Intellectual Property Rights (TRIPS) is an international treaty by the World Trade Organization (WTO), which sets down minimum standards for most form of intellectual property (IP) regulations within all member countries of the World Trade Organization.

1.4.3 Requirements of TRIPS Agreement

Under TRIPS, all countries have to provide for protection of product patents from January 1, 1995. Developing countries like India, which did not have a regime of product patents, could avail themselves of a transition period of ten years - until January 1, 2005, via Articles 65(2) and 65(4) of the TRIPS agreement, to affect the switch over. However, to take advantage of this transition period of ten years, some conditions were levied which have been elaborated in Articles 70(8) and 70(9) of the TRIPS Agreement.

1.4.3.1 Mailbox

Article 70(8) of the TRIPS Agreement required India to provide "a means" by which product patent applications could be filed from January 1, 1995. Such applications were to be examined only from the date of January 1, 2005; till then the applications would be kept in a "mailbox". The mailbox system mandates such a facility for the interim period or until the product-patent facility is introduced.

1.4.3.2 Exclusive Marketing Rights (EMRs)

According to article 70(9) of TRIPS, during the transitional period, EMR is to be granted for a period of five years from the date of obtaining marketing approval in that country or until a product patent is granted or rejected, whichever is shorter. It means that India should receive patent applications for pharmaceuticals and agro-chemicals from January 1, 1995 and that, exclusive marketing rights should be granted to an applicant, who applies for those rights.

The following criteria are to be fulfilled for granting EMR:

- A product patent has been granted in any WTO country.
- A patent application has been filed in any WTO country on or after January 1, 1995.
- Marketing approval has been obtained in that country.
- An application for a product patent should have been filed in India on or after January 1, 1995 under the mailbox facility under article 70(8).

Developed countries emphasized that TRIPS should be added to GATT because less developed countries (LDCs) were imitating the innovations of developed countries. LDCs, on the other hand, stressed that TRIPS should not be added to GATT because it will lead to an alarming increase in the prices of pharmaceuticals on one hand and will cause harm to high-tech infant industries on the other. Ultimately, TRIPS was added to the GATT treaty at the end of the Uruguay round of trade negotiation in 1994. Developed countries further stressed that establishing strong intellectual property rights would actually benefit the

developing countries by encouraging foreign direct investment (FDI), the transfer of technology gearing domestic research and development (R&D).

Domestically and internationally India resisted conforming to TRIPS and refused to comply with its provisions earlier. The reason was that The Indian Patent Act of 1970 had continued to govern the IPR regime in India over the last 30 years which was really a prosperous phase of the Indian pharmaceutical industry. That was the only reason that India did not revise its patent laws as required by TRIPS in spite of bilateral and multilateral pressure exerted by The United States of America to change its patent laws. (Ramanna, 2003) The simple reason was that to conform to TRIPS, India would have to revise one of the main aspects of its patent policy that only process and not product patents would be granted to pharmaceuticals and agro chemicals. Moreover at the internal level, industry groups also resisted any attempt to join international treaties that would lead to change in the existing policies. For example, IDMA (Indian Drug Manufacturers' Association), a major pharmaceutical lobby in India and FICCI (Federation of Indian Chambers of Commerce and Industry), the most influential representative of Indian industry at the time, were strong proponents of India's Patent Act, 1970(Ramanna, 2003).

1.5 Changing Paradigms, Perceptions and Pragmatics about IPR

However, perceptions about IPRs in India changed over time. It was only due to changing perspectives that a paradigm shift occurred in the industry and caused a marked shift in India's policy around 1998-99. Industry bodies and various groups changed their stand and now took a pro-patent view (Ramanna, 2003; Rangnekar, 2005). The CII (Confederation of Indian Industry), ASSOCHAM (Associated Chambers of Commerce and Industry of India) and even FICCI, the most influential representative of Indian industry, now started favouring intellectual property rights. For example, the CII took the position in its statements before the Gujral Committee (a committee established by the Indian parliament to solicit views and prepare a report on the impact of the WTO agreement on India) that India was not able to get relevant technology due to the absence of product patents. ASSOCHAM also took a pro-patent view before the Gujral Committee and stressed that India needed to strengthen its patent laws in

order to attract foreign direct investment (Ramanna, 2002; Ramanna, 2003; Rangnekar, 2005).

At this time, FICCI, the erstwhile strong proponent of India's Patent Act, 1970, also began openly to promote strengthening the patent laws. On the political front, political parties and industry groups had now started favouring intellectual property rights in the wake of economic reforms. The Bhartiya Janata Party after coming to power in 1998 abandoned its opposition to patent reform and adopted a pro-patent position. Even some domestic firms like Dr. Reddy's laboratories and Ranbaxy, who had prospered under the existing patent structure, now started visualizing significant avenues for profit from the new patent regime. Another domestic constituency promoting change emerged from top Indian research and scientific institutes, who had also felt that India could benefit from patents rather than publications only. As a result, a marked shift in India's policy occurred around 1998-99 (Ramanna, 2002; Ramanna, 2003; Rangnekar,2005). Accordingly 'The Patent Act 1970' was amended.

1.6 Amendments in The Patent Act 1970

Three amendments were made to the patent Act 1970 with a view to fulfilling India's obligation of the TRIPS requirements.

1.6.1 The Patents (Amendment) Act 1999

In compliance to the provisions of the transitional arrangement and protection of existing subject matter as per Articles 65 and 70 of TRIPS, India notified an amendment to the Patent Act 1970, by proposing and introducing exclusive marketing rights (EMRs) provisions on January 1, 1995. However, this notification failed to receive assent of the parliament and lapsed thereafter. Consequently, India was dragged to the dispute settlement body (DSB) by the United States and European Union. On receiving the adverse judgments from DSB, India successfully enacted the 1st amendment introducing the EMR provision retrospectively from January 1, 1995. A non-obstante clause was introduced through sub-section 2 of section 5 of the Patents Act 1970 and

the same was linked to the newly introduced chapter IVA, section 24 A to 24 F thereof. The criteria for qualifying for EMR as per chapter IVA have been as follows.

1. A patent application/specification with the claim for a patent for an invention covering an article or substance on the basis of appropriate tests conducted on or after January 1, 1995 is filed on the country where the invention has been claimed. The said country should have a convention- country status vis-à-vis India as on the date of filing.

2. Filing a patent application for a patentable invention in India (as above) for the method or process of manufacture of the invention relating to the identical article or substance and obtaining a grant of a process patent in India.

3. Granting an approval to sell or distribute the article or substance from the appropriate authority in India.

4. Applying for an EMR in India, attaching:

   (a) details of the product patent granted in convention country;
   (b) details of process patent granted in India;
   (c) details of marketing approval granted in India; and
   (d) copy of the product patent (mailbox) applications filed in India for an identical product for which process patent and marketing approval has been granted to the same applicant who has filed the same patent application.

1.6.2 The Patents (Amendment) Act, 2002

The Patents (2nd Amendment) Act, 2002 amended the definition for 'invention' as follows.

- Section 2(1) (j) defines 'invention' as a new product or process involving an inventive step and capable of industrial application.

Other features of The Patents (2nd Amendment) Act, 2002 are as follows.

- Micro-organisms were made patentable under Section 3 (j) of The Patents Act, 1970 from this amendment.
- The patent term has been extended to 20 years for all fields of inventions from the date of filing of application through the substitution of Section 53.
- The Patents (2nd Amendment) Act, 2002, deleted the provision 'license of right' from the compulsory license options, for TRIPS compliance.
- Reversal of burden of proof under Section 104-A has been inserted.
- The Patents (2nd Amendment) Act, 2002 incorporated the research exemption under Section 107-A.

1.6.3 The Patents (Amendment) Act, 2005

The Patents (Amendment) Act, 2005 seeks to complete India's full-scale compliance with the TRIPS agreement. The Act has the effect of invalidating section 5 of the Indian Patent Act 1970 which granted only process patents for food, medicines and other drug substances. Under the Patents (Amendment) Act, 2005 patents will be granted both for products and processes for all the inventions in all fields of technology. As a result, reverse engineering possibilities, hitherto available to the pharmaceutical industry, will be limited to those drugs that will go off-patent. The other implications for the pharmaceutical sector under this new patent system are as follows.

- The Act introduced Section 92 (A) of the Act which deals with compulsory licensing of pharmaceuticals for export purposes. This is meant to facilitate the Indian industry to continue supplying cheaper generic versions of patented drugs to those LDCs that do not have adequate domestic manufacturing capabilities.

- The Patent (Amendments) Act, 2005 has also omitted chapter IVA and sections 24A to 24F of the original Patent Act 1970, discontinuing EMR provisions (as the product patent regime has been made operational).

- The patent term will be twenty years from the date of the application under Article 33 of the TRIPS agreement (compared to the seven years term under the

1970 Act), which is applicable to all the member countries and thus rules out all the differences in the protection terms prevailing frequently in different countries.

- Patents will be granted irrespective of the fact whether the drugs were produced locally or imported from another country. Although the grant of the patent excludes unauthorized use, sale or manufacture of the patented item, yet there are clauses which provide manufacturing or other such rights of the patented item to a person other than the patent holder under Article 31.

- Under Article 34, the onus of proving on the legal complaint that the process used by another enterprise is totally different than the patented process would lie with the defendant and he will have to prove that he is not guilty of infringement. (In the 1970 Act, the responsibility was with the patent holder).

This is the broad framework which will guide the pharmaceutical industry of India in the WTO regime.

1.7 Pharmaceutical Industry in the Post-TRIPS Period (1995-2008)

The period 1995-2008 (i.e. the post-TRIPS period) saw the strongest performance of the Indian pharmaceutical industry on several fronts. TRIPS compliance of the intellectual property right regime has not reduced the innovation capacity of the domestic pharmaceutical industry which has visualized an increase in both research budget and patenting. The recent surge in patent applications in India in the post-1995 period has now received attention in policy analysis. It provides important data for evaluating the potential for domestic actors to adjust to the new patent regime. The number of patent applications filed in the Indian patent office had risen approximately 150 per cent in 1997-98 from 1993-94, crossing the 10,000 mark for the first time in 1997-98 (Ramanna, 2002). Even after that, the trend of patent filing in our country has been increasing tremendously. In 2008, a total of 35,218 patent applications were filed, 6040 from domestic and 29,178 from foreign applicants (WIPO, 2009). The number of patent applications filed in the Indian Patent Office has risen approximately 420 per cent in 2006 from 1995 (WIPO, 2009). In terms of the number of PCT international

applications (IAs) filed in 2008, India stood at 18th position. (PCT Yearly Review, 2008)

The pharmaceutical industry is also showing good performance in terms of exports. It is one of the top export items from India accounting for more than 4 percent of India's total exports in 2006-07. Exports, which constitute around 50 percent of the industry's total production, have grown at an annual growth rate of 14 percent in the last decade. Major export markets include highly regulated markets such as USA, Germany, UK and Canada. Europe is the biggest export destination for Indian pharmaceuticals accounting for more than 30 percent of the total exports, followed by the Americas region (25 percent). The players are changing their R&D strategy from 'reverse engineering' to 'patent driven'. R&D expenditure as a percentage of sales, which stood at around 2 percent in 1993-94, increased to around 5 percent in 2005-06(Occasional paper by Export-Import Bank of India, 2007).

It is only with an increase in R&D spending that Indian companies could file large number of drug master files(DMFs) and abbreviated new drug applications (ANDAs) with US FDA because filing of DMFs and submitting of ANDAs involve R&D efforts. Indian pharmaceutical companies started filing DMFs in the US around the 1980s, but until the late 1990s, only a few DMFs were filed. Since then the rate of filing has accelerated. Presently, Indian pharmaceutical companies are increasing the number of regulatory filings such as DMFs and ANDAs as these enable them to manufacture and market drugs in the regulated markets such as the United States and Europe.

In the above backdrop, the present study examines the impact of TRIPS on the pharmaceutical industry of India in the post-TRIPS period in terms of patents, R&D and exports at the industry level and at the level of the selected leading pharmaceutical companies. These companies are: i) Ranbaxy; ii) Dr. Reddy's Laboratory (DRL); iii) Sun Pharmaceutical Industries Limited; iv) Wockhardt Limited ; v) Cadilla Healthcare Limited; vi) Glenmark Pharmaceuticals Limited ;vii) Torrent Pharmaceuticals Limited; viii) Cipla; and ix) Aurobindo Pharma.

These companies have been selected on the basis of their sales and profitability ratios. These companies also figure in the list of top twenty key players in the Indian pharmaceutical industry in 2008, as given in a report jointly prepared by the India Brand Equity Foundation (IBEF) and Ernst & Young Pvt. Ltd.

The study also includes the impact of TRIPS at the firm level by taking a sample of one hundred firms selected from northwest India. This involves comparative analysis of patents, R&D and exports of small firms vis-à-vis medium and large firms.

1.8 Objectives of the Study

The broad objectives of the study are to study the post-TRIPS scenario in pharmaceutical industry of India by:

1) analysing the patenting activity in the pharmaceutical industry of India in the post-TRIPS period;
2) analysing the R&D in the pharmaceutical industry of India in the post-TRIPS period; and
3) analysing the exports in the post-TRIPS period in the Indian pharmaceutical industry.

1.9 Significance of the Study

The study would be unique in the approach trying to give an integrated and holistic view of pharmaceutical sectoral trends in the post-TRIPS period with reference to patents, R&D and exports. The study would help to portray a detailed picture of the Indian Pharmaceutical Industry as a result of TRIPS compliance.

The study shall build upon earlier studies done on this topic and contribute to the already done work, especially in the terms of data analysis and recommendations. The research work shall also serve as a reference document for all future researches in the similar subject or related areas. Thus, the study on this critical sector of Indian economy, i.e., the pharmaceutical sector would be quite relevant and significant not only for the industry but also for academic and government policy makers.

1.10 Organization of the Thesis

Chapter I – Introduction

This chapter gives a brief history of the pharmaceutical industry of India. While explaining the flourishing phase of the Pharmaceutical Industry in pre-TRIPS period, it tries to focus attention on the changing perceptions about IPRs that caused a paradigm shift in industry leading to the inclusion of TRIPS in the WTO agreement. This chapter defines the objectives of the study. It also includes the significance of the study. Finally, it introduces the organization of the thesis.

Chapter II - Review of Literature

This chapter presents results from different empirical studies done on the pharmaceutical industry of India. The review helps to know the direction of the research being done. It is only after going through these empirical studies that research gaps could be identified and emphasis could be focused on the right direction. This chapter also includes the need for the study.

Chapter III - Research Design and Methodology

In this chapter the methodology used for the study has been described. It discusses the selection of samples and survey areas and then methods of data collection. Further, this chapter explains the various tools and techniques used to analyze the data. Development of the hypotheses and research questions also come under the purview of this chapter.

Chapter IV – Results and Discussions

This chapter covers the study of the post-TRIPS patenting scenario of the pharmaceutical industry of India. At industry level, it has tried to depict the patenting scenario in the post-TRIPS period. The study uses the growth rates of R&D and exports in the pharmaceutical industry of India in the pre and post-TRIPS periods to see the impact of TRIPS on them. Then by taking some selected leading large scale pharmaceutical companies of India, the study again tries to analyse the patenting, R&D and export scenario in post-TRIPS period. The study has tried to analyse the performance of the pharmaceutical industry in

the post-TRIPS period**.** Then through a firm level analysis of one hundred firms from the north west region of India, the study attempts to find out whether the same results hold good for the sample firms surveyed. The data collected through questionnaire have also been analysed by factor analysis and multiple regression for in depth analysis of the impact of TRIPS on the Indian pharmaceutical sector.

Chapter V - Conclusions, Limitations and Further Study

This chapter includes the major findings of the study. It also covers testing of hypotheses. Based on these, the study presents a complete view of research. This chapter also covers the limitations of the study and finally suggests areas where future research can be undertaken.

CHAPTER – II

REVIEW OF LITERATURE

The advocates of a strict patent regime suggest that product patents will result in a metamorphosis of the industry. It would lead to an increase in the international technology transfer to India by encouraging foreign firms to relocate their R&D units into this country because of its sizable pool of low cost and technically skilled labour (Mashelkar, 2004). A few more studies have supported this view. However, the empirical results of a few other studies appear not to be supportive of this view.

Keeping this in mind, the present study classifies the literature review in two categories. Section 2.1 covers the studies supporting TRIPS in the Pharmaceutical Industry whereas section 2.2 covers the studies expressing concerns over strong adherence to TRIPS. Section 2.3 presents the gaps in research and section 2.4 emphasizes the need for the study. Section 2.5 covers the concluding remarks.

The literature review has been divided into two parts:

2.1 Studies supporting TRIPS in the pharmaceutical industry; and

2.2 Studies expressing concerns over strong adherence to TRIPS

2.1 Studies Supporting TRIPS in the Pharmaceutical Industry

Tancer(1999) found that when India liberalized her policy towards foreign investment in 1991, there was a positive response from capital exporting countries. Yet, the multinational pharmaceutical firms did not participate in this. The major reason underlying their decision was the absence of pharmaceutical product patents in India. Clearly, the intellectual property environment in a country affects the flow of foreign investment, particularly in those industries heavily dependent on intellectual property protection. India is unique among developing countries as she has a thriving Pharmaceutical Industry dedicated to providing healthcare at the lowest possible cost. India's growing pharmaceutical industry, however, is based on reverse engineering of existing drugs, not on innovative research. Following the TRIPS agreement, India is obligated to provide strong patent protection to the

Pharmaceutical Industry by 2005 and as such it may expect a positive response from capital exporting countries.

The study by Smith (2000) reveals what the companies were doing to prepare for 2005 and beyond. The study predicts that although the new patent regime has the potential to reward multinational corporations at the expense of Indian firms, even then, the local firms are likely to benefit from stricter laws. By evaluating the different strategies like technological strengthening, redefining new drug discovery and focus on export being adopted by the 12 large scale companies (4 MNCs and 8 Indian), the researcher predicts that Indian and MNCs both will figure prominently in the future of the pharmaceutical sector although in somewhat changed form. The 2005 law will vault some Indian pharmaceutical companies into globally prominent positions.

Gupta (2000) examines the trends in patenting by India in USA since WTO. The patenting activity from India has been analyzed in terms of pre- and post-WTO trends. As per the study, private sector firms in the area of drugs and pharmaceuticals have shown the maximum interest in post-WTO patenting activity in USA. The results clearly indicate that there is a greater effort by the Indian R&D organizations to obtain patents in USA since the WTO has been established.

Kamath (2002) cites that the 1970 Patent Act certainly helped the domestic companies to grow but it did not promote creativity. As a result, the industry in particular and the economy in general suffered dead-weight losses. In conclusion, he writes that forthcoming and continuing changes in the law required by TRIPS are in fact a blessing in disguise for an industry that is yet to receive its true creative potential. The researcher feels that such laws promote and reward creativity and should be welcomed rather than opposed.

Lalitha (2002) on the basis of the SWOT analysis brings out that the major strength of the industry is in process development nurtured by the Patent Act of 1970, which has helped the industry to grow and has also benefited the consumers. On the basis of this built-up capacity, in the WTO regime also, India could benefit by the

strategies of multinational corporations. But, simultaneously, efforts should also be geared towards improving the domestic research and development and increasing the FDI in R&D. Care needs to be exercised in processing the FDI cases, so that such investments do not result in increasing the FDI *per se*, but also contribute to improving technology. Most importantly, the Indian Pharmaceutical Industry needs to assure the common public that in the process of globalization and in the pursuit of new drug discovery, people's access to medicines and the interests of the consumers will not be adversely affected.

Ramanna (2003) explores that **e**xternal trade pressure was inadequate to ensure compliance to TRIPS. This is clear from the fact that from 1995-1998, India did not revise its patent laws as required by TRIPS. It was only the changing interest of industry groups by 1998-99 that were ultimately instrumental in forcing the government to implement full compliance to TRIPS and in evolving a pro-IPR constituency in India.

Kubo (2004) has examined the factors behind the observed patterns of R&D expenditure and patenting by Indian pharmaceutical companies after the signing of the TRIPS agreement in 1995. His study is based on a sample of 242 Indian domestic pharmaceutical firms over the period 1988-2002. The results show that R&D intensity and the patent to R&D ratio have increased after 1995. It also found that vertically integrated firms, i.e., the firms that produce both the bulk drugs and formulations, are filing the majority of product patent applications as well as a large share of process patents than firms specializing in bulk drugs only. This may be because the introduction of product patents had created the possibility of opportunistic behaviour between formulation manufacturers and bulk drug manufacturers.

The study by **Grace** (2004) reveals that the prospects of changing intellectual property in the Pharmaceutical Industry are extremely positive for the future of the Indian industry. The introduction of product patent law in India is already having an effect on the product and market strategies of Indian firms. With the introduction of product patents, Indian firms will have reduced revenue options from the sale of

drugs domestically, since generic copies of newer drugs will become illegal. However, to compensate for this revenue loss, Indian firms have already increased their emphasis on exporting to the more profitable regulated markets. There is also an increased focus on product innovation, with the most successful firms investing an increasing amount in R&D including in partnership with MNCs and with increasingly positive results. The study shows that one third of all FDA applications came from India in 2003 and this number is expected to be one half in 2004. MNCs have been interested in working with Indian firms, attracted by lower cost structure, estimated to be one-eighth in R&D compared to western firms.

Chadha (2005) has conducted a micro econometric study based on a sample of 65 Indian pharmaceutical companies. The results show that a stricter patent regime has stimulated patenting activity in the Indian Pharmaceutical Industry as the number of process patent applications has increased between1991-2004. The researcher opines that harmonization of patent laws world-wide coupled with the recent expiration of a number of blockbuster drugs has opened a window of opportunity for Indian pharmaceutical manufacturers who are known for their skill at producing generic versions of off- patent drugs at low costs.

The recent (third) amendment to the Patent Act, 1970 brings India into full compliance with its obligations under the TRIPS Agreement. This amendment was characterized by a relatively muted rhetoric and a remarkable level of shared consensus amongst campaigners and critics. Focusing largely on domestic compulsions, as opposed to the global, the study by **Rangnekar (2005)** explores whether the shared consensus sets too narrow an agenda for patent reform. The study suggests that the limits to implementing TRIPS are equally on account of ambivalence within the government with respect to intellectual property and the changing self-interest of sections of the Indian pharmaceutical industry. Thus, despite a favourable international climate in the area of intellectual property, the patent reform in India has been doubly constrained by the narrow agenda and domestic factors.

Chadha (2006) has pointed out that the export focus of Indian firms, propelled by the recognition of process patents in different countries, has made them penetrate a number of countries based on their low cost structure. They are now concentrating not only on off-patent drugs but also on undertaking contract research. The share of pharmaceutical exports in total Indian exports increased from 2.20 percent in 1992 to 3.56 percent in 2002. The Pharmaceutical Industry is in the transition phase and is ready to face new challenges that could bring major changes in its business environment. With stronger patent laws, contract research, joint ventures and clinical trials at a fraction of the cost in India as compared to developed countries, India seems to be the right choice for pharmaceutical FDI in the near future.

Dhar and Gopakumar (2006) analyse the likely impact that the change in the country's patent regime could have on the Indian generic pharmaceutical industry. Although Indian firms are yet to make a mark in the area of new drug discovery, the firms seem to be on course for major developments on this front, as is obvious by the sharp increase in their patenting activity. The analysis shows that the leading firms of the industry have been showing considerable dynamism during the period 1995-2004. Particularly noteworthy was the increase in the R&D spending of some of the leading firms, in particular, Ranbaxy and Dr Reddy's. As a result, R&D intensities of the firms have improved significantly. While the R&D intensity of Ranbaxy has improved from 4.6 in 1995 to .3 in 2004, for Dr Reddy's it has improved from 2.0 in 1995 to 12.3 in 2004. The R&D efforts of the leading Indian firms have borne considerable fruits as well, as market approvals in both the US and the UK, in particular, have increased in the past few years.

The study by **Pradhan (2006)** examines the impact of a stronger protection regime for intellectual property on the exports of a technologically imitative country, India. The results obtained from OLS estimation of the augmented gravity Model indicate that other things being equal, in the absence of patent rights (IPR=0) India would export about, on an average, $38,000 of pharmaceuticals whereas in the face of providing maximum patent protection (IPR=5) globally India's export more than doubled to about $82,000.To determine the extent of export increase for different levels of patent protection statistical simulation has been undertaken and results

obtained. The empirical analysis presented in the study suggests that even an imitative developing country's exports need not be negatively affected by the strengthening of the patent regime globally and, in fact, in the case of pharmaceuticals, India stands to benefit from market expansion effects.

Mani (2006) in his study undertakes a detailed mapping out of the sectoral system of innovation of India's pharmaceutical industry. The study highlights that the TRIPS compliance of the intellectual property right regime has not reduced the innovation capacity of the domestic Pharmaceutical Industry which has visualized an increase in both research budget and patenting. The R&D expenditure of the Indian Pharmaceutical Industry has increased from Rs.564.4 million in 1988-89 to Rs.3775.1 million in 1998-99. The number of pharmaceutical patents granted to Indian inventors was 56 during 1995-99, which increased to 246 during 2000-04. However, it has not made them work on R&D projects that may lead to the discovery of drugs for neglected diseases of the developing world. The researcher feels that this is an area where public policy support is still required.

The study by **Nauriyal (2006)** shows that the changed patenting regime will definitely have an impact on the business behaviour of pharmaceutical firms, both foreign and Indian. While the foreign firms would like to utilize the potential of the Indian market through out-sourcing alliances and competition, Indian firms may also prefer to follow a combination of the strategy 'Cooperate and Compete', just to take advantage of the increasing attractiveness of the global generic market. The study also shows that the focus of R&D is likely to be more on 'life style related diseases' than on 'tropical diseases'.

Chaturvedi and Chataway(2006) highlight that Indian firms are adapting themselves to the changing environment. R&D is recognized as the 'survival kit' in the post-TRIPS scenario. The researchers observe that Indian firms are investing in R&D not only for new drug discovery but also for developing capabilities to assimilate and exploit knowledge available externally. They are also positioning

themselves as a partner of choice for technology-savvy national and multinational firms.

The study by **Basant (2007**) explains that a higher pharmaceutical price in Pakistan vis-a-vis India has not been because of the differences in the intellectual property rights regime between the two countries. The reason behind it is that in India a weak patent regime was combined with policies to reduce market concentration, curb monopolies and encourage bulk drug production, initially through public sector investments. Moreover, the size of the Indian market could have lead to the development of indigenous process capabilities. Meanwhile, in Pakistan, the same patent policy has not been combined with policies adopted in India and since the market size is much smaller, it did not have the same effect.

Gupta (2007) opines that the Indian Pharmaceutical Industry has exciting opportunities in the post-TRIPS period. Indian companies are increasing their rates of DMF (Drug Master File) filings every quarter. Indian generic players are also increasing their participation in the advanced markets, particularly the US. Accordingly, ANDA (Abbreviated New Drug Application) filings with USFDA (United States Food and Drug Administration) are also increasing in the post-TRIPS period.

The study by **Rai (2008)** investigates emerging firm strategies of the Indian pharmaceutical companies to overcome the challenges posed by the new patent regime. By taking a sample of 94 pharmaceutical firms, the study analyses the strategic choices for Indian Pharmaceutical Industry in the post-TRIPS period. By explaining the competitive strategies adopted by different firms, the study also shows that Indian firms are fully geared to face the post-TRIPS scenario. Since the issue of affordability and accessibility to medicine to the poor is a closely linked issue, the study proposes to identify key growth drivers for the industry and offers policy suggestions to the government to create an enabling business environment for local industry.

Table 2.1: Major Themes of the Reviews Regarding Studies Supporting TRIPS in the Pharmaceutical Industry

Issue	Study	Contribution
Changing perceptions about TRIPS	Ramanna (2003)	Changing interest of industry groups by 1998-99, were ultimately instrumental in forcing the government to implement full compliance of TRIPS and in evolving a pro-IPR constituency in India.
	Rangneker (2005)	The transformed Indian Pharmaceutical Industry is itself looking for patent protection.
Flow of FDI	Tancer (1999)	TRIPS policies get positive response from capital exporting countries.
	Chadha (2006)	India is the right choice for pharmaceutical foreign direct investment in the near future.
Better opportunities for exports	Pradhan (2006)	India stands to benefit from market expansion effects.
Increase in R&D and R&D intensity	Kubo (2004)	R&D intensity and patent to R&D ratio has increased in India after 1995 for large pharmaceutical firms.
	Grace (2004)	Most successful firms investing an increasing amount in R&D including in partnership with MNCs, and with increasingly positive results.
	Dhar and Gopakumar (2006)	There has been an increase in the R&D spending of some of the leading firms, in particular, Ranbaxy and Dr Reddy's. As a result, R&D intensities of the firms have improved significantly.
	Gupta (2000)	After the establishment of WTO, there is a greater effort by the Indian R&D organizations to obtain patents in USA.
	Chaturvedi and Chataway (2006)	Indian firms are investing in R&D not only for new drug discovery but also for developing capabilities to assimilate and exploit knowledge available externally.
Stimulation of patenting activity	Chadha (2005)	Positive and significant impact of the introduction of stronger patents on patenting activity.
	Sunil (2006)	Domestic Pharmaceutical Industry has visualized an increase in both, research budget and patenting
	Gupta (2007)	DMF & ANDA filings with USFDA are increasing in post-TRIPS period.
Exciting opportunities in post-TRIPS period.	Smith (2000)	The 2005 law will vault some Indian pharmaceutical companies into globally prominent positions.
	Lalitha (2002)	Strengths should be utilized to benefit from opportunities.
	Nauriyal (2006)	Foreign and Indian pharmaceutical firms may prefer to follow a combination of the strategy 'Cooperate and Compete', just to take advantage of the increasing attractiveness of the global generic market

2.2 Studies Expressing Concerns over Strong Adherence to TRIPS

Lanjouw (1998) expresses concerns over adherence to strong IPRs. Although strong IPRs are important to multinational corporations in deciding where to locate R&D facilities, there does not seem to be any compelling reason for them to locate in India even after product patenting has been introduced. Although strong intellectual property rights may make the Indian environment more appealing to MNCs as a location for R&D, it is unlikely that it will make a dramatic difference in their choices. The simple reason is that although strong intellectual property rights are important to MNCs in deciding where to locate their R&D facilities, given the centralized nature of R&D and the fact that costs are not the paramount concern, there does not seem to be any compelling reason for them to locate their R&D facilities in India even after product patents are available.

Srinivasan (1999) has clearly shown that higher price has nothing to do with the effectiveness of the medicine and the patented drugs have the highest price. By comparing the Tender Rates and Retail Market Rates of 64 basic drugs in 1998-99, the researcher has shown that more than 80 percent of the medicines are overpriced. The same medicine produced by a multinational corporation is sold at different prices in different countries. He has proved it by comparing the prices of drugs marketed by Glaxo in India and Sri Lanka, where the results show that in Sri Lanka, the price increase ranged from 121 percent to 7100 percent. The researcher expresses the concern that globalization does not seem to discipline companies into selling at even reasonably comparable prices in neighbouring countries

Fink (2000) in a simulation study highlights some relevant variables that are likely to determine the impact of pharmaceutical patent protection on prices in India. The study clearly demonstrates that if future drug discoveries are mainly new varieties of already existing therapeutic treatments, the impact is likely to be relatively small. But if the newly discovered drugs are medicinal break-throughs, prices may be significantly above competitive levels and static welfare losses may be large. From the view point of transnational corporations, potential profits depend crucially on the overall price elasticity in the therapeutic group. If the demand is highly price-elastic

as one may expect in a low-income country with limited insurance coverage, TNCs profits are likely to be small. However, if one takes into account the possibility of future changes in the Indian health care system, viz., the opening of medical insurance provision to private competition, it may reduce the price sensitivity of demand and patent holders' profits could increase substantially.

Glasgow (2001) examines the role which antitrust law ought to play in assessing and enforcing potentially undesirable behaviour by drug companies. By citing various loopholes of the Hatch-Waxman Act 1984 through quoting empirical examples, the study examines the ways by which pharmaceutical companies attempt to lengthen the patent life of their brand-name drugs. By analysing the various practices employed by the large companies specializing in brand-name drugs the researcher expresses concern that intellectual property protection is not being used to provide an incentive for innovation. Rather, intellectual property rights are being used to gain and maintain an exclusive market share for the most profitable, not necessarily the most beneficial, drugs. He further adds that antitrust law, in addition to avenues such as legislative reforms, should properly step in to curtail those abuses of intellectual property rights that have clearly moved beyond their proper scope.

The study by **Adede (2001)** highlights that the debate has continued on the usefulness of TRIPS Agreement in relation to the developing countries and on the problems relating to its specific requirements which is the subject of debate within the WTO. The study points out that even after five years of the entry of the TRIPS agreement, arguments are still being made for or against its usefulness and acceptability to the developing countries. There is an assertion that TRIPS and patent protection may not be beneficial to developing countries and patents are obviously bad for poor countries. They are largely the preserve of western multinational companies, allowing them to establish monopolies, drive out local competition, divert research and development away from the needs of poor countries and force up the price of everything from seeds to software. In the process, patents prevent the poor people from getting lifesaving drugs, interfere with age-old farming practices and allow foreign "pirates" to raid local resources, such as medicinal plants, without getting permission or paying compensation.

The study by **Walker (2001)** addresses the environmental and developmental impacts of patent protection by focusing on the global agreement on trade related aspects of intellectual property rights (TRIPS). While the TRIPS agreement serves as an important step in harmonizing international intellectual property system, it currently fails to properly balance public and private interests especially the gap between the rich and the poor. The researcher contends that TRIPS fails to help build "innovative, ethical and sustainable societies".

Aggrawal and Saibaba (2001) predict that major changes can be expected in the Indian pharmaceuticals industry from 2005 due to the agreement on TRIPS, under which India will be required to introduce product patents for pharmaceutical products. By comparing the prices of the four largest-selling 'on-patent' drugs in India, in the UK and US, and in Pakistan, which, unlike India, have always recognised product patents, the researcher shows that the prices of these four drugs of mass consumption were 9.9 times higher in Pakistan, 17.5 times higher in the UK and 37.3 times higher in the US. Although the TRIPS agreement may also lead to increased research on diseases common in developing countries, these benefits can be obtained in alternative ways and without high costs. Thus, the TRIPS agreement is not in the national interest and should be renegotiated.

The study by **Lall and Albaladejo (2002)** is based on 87 countries for the year 1997-98, and classifies them into four groups. The researcher has calculated Technology Effort Index and Industrial Performance Index of these countries. The results show a positive correlation between IPRs, Industrial performance and technological efforts. The results indicate that stronger IPRs are probably beneficial for countries with high performance index. However, countries with low and very low performance index are unlikely to benefit from TRIPS. There does not, seem to be a case for applying stronger IPRs uniformly across the developing world. As the outcome is likely to be context specific, the economic considerations call for a differentiated approach to TRIPS according to levels of industrial and technological capabilities. The study reports that without more detailed investigation, it may be premature to draw any general conclusions about the net benefits for TRIPS.

The study by Zuniga and Combe (2002) focuses on the economic impact of patent protection of pharmaceuticals in the Mexican industry. The researchers have tried to make a brief evaluation of the static and dynamic effects of the introduction of patent protection for pharmaceuticals in Mexico and to compare them to those predicted by economic literature. Although the static effects have been limited since multinationals already controlled the private market before the reforms, dynamic gains are still far from being felt. Reinforcing patent protection will not automatically change the access and the ways to finance R&D projects. They suggest that other factors besides patent protection must be taken into account before expecting an increased R&D activity in the Mexican pharmaceutical sector

Lalitha (2002) has raised concerns regarding the drug policy (2002) which she feels is a hotchpotch of measures that do not address many problems typical to the Indian pharmaceutical industry. She feels it is one-sided echoing mostly the business interests and fails to reflect the health needs or the approaches to the health-related issues in the economy. She apprehends that it may affect the industry negatively in the long run.

The study by **Lanjouw (2002)** highlights that no doubt, globally available and well-defined patent rights could increase the benefits derived from greater public financing of research on pharmaceutical products for the developing world, but for major global diseases the justification for extending patents in poorer countries is less clear. The study considers standard intellectual property and regulatory mechanisms that could be used to differentiate protection, but it also concludes that all these have serious drawbacks. The new mechanism presented in the study is structured to avoid these problems. It would allow the implementation of a global patent regime that would be sensitive to the development level of countries and the characteristics of particular drug markets.

Kumar (2002) explores implications of the TRIPS regime for developing countries. He apprehends that the strengthening of the intellectual property rights regime is likely to affect the prices of a large number of important drugs adversely. The strengthening of the IPR regime may further limit the access to technology by

developing country enterprises. Moreover a number of local enterprises in developing countries may come under pressure to close down or form alliances with larger firms, resulting in a concentration of the industry. Further, the dependence on imports may increase. Introduction of product patents are likely to increase drug prices. The researcher emphasizes that it is by no means clear that strengthening of IPRs will increase inventive activity even in the developed world, especially for solving the problems and diseases faced by developing countries. A strengthened IPR regime may actually slow down the pace of technological development by stifling the flow of R&D spillovers that are important inputs in research.

The study by **Chaudhuri (2002)** examines whether the amendment to the Indian Patents Act, 1970 has benefitted the Indian Pharmaceutical Industry especially with the provisions available under the TRIPS agreement. The study looks at the exemption, exception and compulsory licensing provisions in pharmaceuticals. The researcher is of the view that while amending the Patents Act, 1970, India has not taken full advantage of the flexibilities which the TRIPS agreement provides. The most glaring failure relates to compulsory licensing. The wording of the general grounds for compulsory licences is not amenable to easy interpretation and is not operationally useful. The procedure is cumbrous and time consuming. It provides opportunities to the powerful patentees to manipulate the process by litigation to prevent others from getting such licences. If the bias in the Patents Act 1970, which did not grant product patents in pharmaceuticals, was in favour of the non-patentees, the bias in the amended Act is clearly in favour of the patentees.

The study by Lanaszka (2003) highlights that WTO rules on intellectual property rights are controversial because of the persistence of the asymmetry in the level of development and research capacities between the developed and the developing countries. It is, of course, true that exploitative business practices are possible only to the extent that monopoly positions are tolerated. However, many developing countries lack the necessary financial resources and have not yet developed appropriate competition rules to deal effectively with the challenges presented by the TRIPS agreement. The leading industrialized countries must pay attention to the social and economic needs of the developing countries for which a change of attitude

is necessary. It should begin with the idea of fairness as one of the principles governing the dialogue between the developed and the developing countries. Fairness entails sensitivity to the special needs of developing countries and one important dimension of this sensitivity is the recognition of the problems posed by human needs, such as health.

Pradhan's (2003) study focused on R&D activities of foreign and Indian firms. On the basis of a survey undertaken of R&D by the pharmaceutical industry, Pradhan confirms that the foreign firms are far behind domestic firms in terms of R&D intensity. The observed R&D intensity of domestic firms is 2.6 percent and is three and half times than that of foreign firms, which is 0.74 percent. The study confirms that foreign firms' R&D intensity was continually lying below sample average and appeared to be declining since 1997. Although with the implementation of TRIPS, the competitive pressure has worked efficiently in pushing Indian pharmaceutical firms into R&D activity, however its impact is likely to be limited to a few large and medium sized firms, as the large segment of small size firms lacks the huge resources that are required for product development.

According to a study by **Chaudhury, *et. al.* (2003)** as per the TRIPS agreement, WTO members are required to enforce product patents for pharmaceuticals, but the debate about the merits of this requirement has been extremely contentious. Many low income economies claim that patent protection for pharmaceuticals may result in substantially higher prices for medicines, with adverse consequences for the health and well-being of their citizens. On the other hand, research-based global pharmaceutical companies argue that prices are unlikely to rise significantly because most patented products have therapeutic substitutes. In this study, the researchers have tried to investigate the basis of these claims empirically. The results suggest that concerns about the potential adverse welfare effects of TRIPS may have some basis. The study estimates that in the presence of price regulation, the total annual welfare losses to the Indian economy from the withdrawal of the four domestic product groups in the fluoroquinolone sub-segment would be on the order of U.S. $305 million, about 50% of the sales of the entire systemic anti-bacterials segment in 2000. Of this amount, foregone profits of domestic producers constitute roughly $50

million. The overwhelming portion of the total welfare loss therefore derives from the loss of consumer welfare. In contrast, the profit gains to foreign producers in the presence of price regulation are estimated to be only around $19.6 million per year.

Aggarwal's (2004) study focused on export competitiveness, which is based on the analysis of primary survey. The researcher identifies the factors that determine the export competitiveness of firms in the Indian pharmaceutical industry. The findings suggest that the competitiveness of firms depends not only on firm specific advantages but also on government fiscal incentives. Among the firm specific factors own R&D efforts emerged as one of the prime factors influencing export competitiveness. Technology imports, on the other hand, did not play a significant export-enhancing role. The study also finds that the determinants of export competitiveness differ across firms of different size and ownership. High transaction and production costs are found to be major constraints faced by Indian exporters. The study draws useful policy implications like the role of government on export promotion, and brand promotion and marketing in foreign markets to strengthen the export competitiveness of the industry.

Abrol (2004) analyses the post-TRIPS behaviour of domestic and foreign pharmaceutical firms in India with respect to technology acquisition, knowledge transfer and domestic R&D. According to Abrol, the evidence available on the diffusion of knowledge contradicts the claim of TRIPS advocates that its adverse effect on prices of patented medicines would be adequately compensated by the benefits of technology transfer and domestic R&D. The researcher opines that due to the introduction of strong IPRs, pharmaceutical multinationals are now advantageously placed to control the knowledge diffusion and integrate the local capabilities of a country like India into their own myopic and narrowly benefiting innovation strategies. The researcher feels that the link between strong patent regimes and technology transfer is not easy to test. Moreover the route of contract manufacturing has only a limited use for the survival.

According to **Dhillon (2004**) the TRIPS agreement has brought about a new global regime for protecting intellectual property. Developing countries, however, may

benefit from this change, but only in the long run. In the short run, only the developed countries are likely to be the primary gainers. The introduction of global intellectual property rights into such areas as pharmaceuticals products, agricultural inputs, biotechnology, environment technology and electronic database has serious development consequences that merit careful consideration.

Sampath's (2005) study further endorses the view that Indian firms will face severe challenges to adapt to the emerging patent regime, while operating in an industrial and regulatory climate that still is not fully geared towards its needs in the light of tough international competition. The empirical study of 103 firms found a very high correlation between export intensity and R&D investments in the Indian pharmaceutical sector. Given that almost all Indian firms fully fund their own research activities through their profits, their concern is primarily on investing into drugs that assure them maximum return. It means emphasis will be given on R&D investment on global diseases only.

The study by **Raju (2005)** shows that though the TRIPS Agreement prescribes the maximum standards that will substantially increase the degree of harmonization of intellectual property, it does not provide a uniform law. Even the protection is on a universal scale leaving considerable room for national laws to define a number of important aspects. The idea of patenting itself was a creation of the industrialized countries for protecting their intellectual creations. The developing countries were always on the receiving end. In this study, the researcher examines the amendments in the Indian patent system as a consequence of TRIPS and Indian reaction to the same in substantial and procedural levels. The study also analyses the implications of the transitional period to suggest further options available to India and puts forward some suggestions to improve the patent regime in the country as a whole.

Chaudhuri (2005) has tried to examine whether the amendments, made in the Patent Act to comply with TRIPS, have taken advantage of the provisions and flexibilities, which have been promised in TRIPS, to strike a balance between the private rights of patentees and the socio-economic needs and objectives of society. According to him India has not been able to take full advantage of the compulsory licensing provisions.

The process is much more legalistic than TRIPS requires. It provides an opportunity to the powerful patentees to manipulate the process by litigation to prevent others to get such licenses. It is still possible to incorporate the necessary public health provisions in India's patent laws.

In her study, **Bhaduri (2006)** finds that much of the arguments favouring imposition of TRIPS in India are ill-founded and contradictory. She has tried to highlight some rhetorics about TRIPS, like a week IPR regime is seen as a threat by innovators, to compensate the innovator as the cost of R&D has gone up manifolds and India will not suffer much as majority of the drugs are off-patented and has compared them with realities. She has critically examined the veracity of these arguments by citing some empirical examples. In the end she concludes that extending monopoly rights up to 20 years can lead to a situation where the complacency effect of a monopolist, arising out of a secure market, could lead to a decline in R&D expenditure, because it will have no incentive to search for more efficient processes of the same product during the patent life. The consumers may, therefore, have to pay higher prices for inefficient processes of the novel drugs under the TRIPS, which is in sharp contrast with the stated objectives of the WTO.

According to **Reddy (2006),** the growth in R&D for larger pharmaceuticals, such as Ranbaxy, is greater than the growth for the general pharmaceutical sector. Larger pharmaceuticals have the resources to devote more investment for R&D and can afford to think about the future. Smaller pharmaceuticals do not have these resources and might not be able to survive in the market. In the future, it seems that there will be more market consolidation and large pharmaceuticals will continue to grow larger and take over the market as the larger pharmaceuticals have already begun to partner with MNCs and license out products to them.

A few studies have tried to highlight the problems being faced by small pharmaceutical units in post-TRIPS period.

The issues that have dragged down the shutters of small scale pharmaceutical units in the post-TRIPS period are: compliance to schedule M, excise duty on MRP instead of

ex-factory price, migration of drug manufacturing units to excise free zones. To comply with schedule M requirements, the minimum cost of upgrading one drug manufacturing firm was estimated to be over Rs 15 million. Since most of the SSI units lacked the needed financial muscle for this up-gradation, they had to shut down their operations. Moreover, the levy of excise duty on MRP with an abatement of 40 percent, that came into effect from January 7, 2005, had made the plight of business of those SSI units still miserable, who anyhow managed to upgrade their manufacturing facilities to schedule M standards. **[Cygnus, 2006]**

Pradhan (2007) also expresses doubts as to whether the signing of TRIPS will be beneficial for the small pharmaceutical firms in India. Since 1990s, the regulatory regime for small firms underwent dramatic changes with withdrawal of most of the favourable policies and implementation of regulations like a long-term product patent regime, withdrawal of exemption from price controls, implementation of good manufacturing practices, etc. These new policies have a number of implications for the survival and growth of small pharmaceutical firms. By collecting unit level data from Annual Survey of Industries for the year 2000-01, the researcher has tried to address the static differences between small and large pharmaceutical units in efficiency and other performance indicators.

According to **Chaudhuri (2007)** R&D expenditure has dramatically increased for a segment of the Indian Pharmaceutical Industry after TRIPS came into effect. Based on the R&D expenditure of 109 companies (out of which 28 were major R&D spenders), the results of his study show that R&D intensity of the major spenders has improved from 1.78 percent in 1992-93 to 8.79 percent in 2005-06. However if the outcome of R&D is focused, the study finds that even after TRIPS, India's proficiency continues to be in process development and in innovating new products they are yet to prove their competence as no new chemical entity has yet been developed. In the absence of TRIPS-compliant protection, the impact on R&D for developing country firms is unlikely to be negative because developed countries have such protection anyway and these countries have the largest markets for new drugs.

Jaisankar (2007), agrees that pharma small scale industries have been hit hard with the implementation of schedule M and setting up of excise free zones. He adds that schedule M was conceived on the lines of USFDA. Although schedule M was a good regulation, it was nevertheless a hasty decision on part of the government. It does have its benefits with quality improvements and other factors, but it should have been gradually phased in. It took the FDA nearly 15 years to implement the schedule in the US. This overnight implementation of schedule M is the biggest problem faced by SSIs in pharma.

Chawala (2007) has tried to highlight the problems which the units set up in excise free zones (EFZs) are facing. Such an influx of industry resulted in price escalations and huge premiums on the initial cost. Lack of adequate infrastructure, absence of proper construction machinery and manpower, coupled with the urgency of starting the units at the earliest resulted in a lot of difficulty being faced by these units. The researcher visualizes that producing in excise free zones is a great opportunity for established players only. The author apprehends that one third of the industry will either become unprofitable or go sick if one does not have strong fundamental knowledge and a strong pharma business background. This needs a very careful planning on the part of the government.

According to **Dey (2007)** the announcement of excise and income tax free zones in 2003 by the central government was no doubt a great opportunity for many small and medium scale industries, especially for contract manufacturers, however, the industry is divided and debating over excise free zones. Pharmaceutical firms present in excise-exempt states are now most concerned about how to protect their investments made in these zones and the tax benefits availed by them. They argue that if there is a change in the policy, the small scale industry based in excise free zones will have to bear the brunt. Whereas, the opposite lobby refuses to buy these arguments asserting that these states cannot be allowed to prosper at the cost of other states.

Jayakumar (2008) opines that more than half of the small-scale pharmaceutical units operational in India have either closed down or indefinitely suspended business activities in the last two years, having being struck by unfavourable government

policies and the inability to compete with big companies in the changed business environment. The good manufacturing practices norms forced them to invest heavily in modernization to comply with the rules. As a result, many manufacturers surviving on thin profit margins exited the business, instead of risking investments on borrowed capital. Even those units which migrated to the excise free zones hoping for contract manufacturing business from big units are in trouble due to over capacities created in the hill states.

Khader (2008) discusses the challenges faced by pharmaceuticals in prosecuting a patent application in the post-TRIPS patent regime in India. As section 3(d) of the Indian Patent Act 1970 has turned out to be a contentious issue, the present study analyses problems in prosecution of a PCT patent application and effect of exclusions to patentability and how they could be utilized to challenge a patent before grant and pre-grant opposition procedure.

The study by Nair (2008) explores that although patent rights often result in monopolistic pricing of drugs which make them unaffordable to large number of populations particularly from economically backward developing countries, nevertheless if interpreted and implemented properly, the provisions under TRIPS may not be a major impediments for making drugs even under patent protection available at an affordable price. His major concern however, is that no proper and simple modality is yet available for the developing and least developed countries for implementing an effective system for achieving the goals spelt out in the Doha declaration. This study is an attempt to understand the strategies adopted by one such affected country, Brazil. The researcher opines that whether the Brazilian model is tenable across the cross section of countries similarly affected is yet to be established.

The above review highlights that a lot of issues have emerged after the TRIPS agreement. A brief of these issues that have emerged from the review has been presented in Table 2.2

Table 2.2: Major Themes of Reviews Regarding Concerns over Strong Adherence to TRIPS in the Pharmaceutical Industry

Issue	Study	Contribution
Difficult to sustain the export dynamism	Chaudhury (2000)	Government preferred to adopt a stricter compulsory licensing regime than what is required under TRIPS.
Misuse of patents, i.e., patents just to increase prices and profits	Glassgow (2001)	Intellectual property rights are not being used to provide an incentive to innovation. Rather they are being used to gain and maintain an exclusive market share for the most profitable, not necessarily the most beneficial, drugs.
	Srinivasan (1999)	Globalization does not seem to discipline companies into selling at even reasonably comparable prices in neighboring countries
	Aggarwal and Saibaba (2001)	TRIPS agreement is not in the national interest and should be renegotiated.
	Chaudhuri (2005)	India has not been able to take full advantage of the compulsory licensing provisions.
	Nagesh (2002)	The strengthening of IPR regime is likely to affect the prices of a large number of important drugs adversely.
IPRs to establish monopolies	Adede (2001)	Patents are largely the preserve of western multinational companies, allowing them to establish monopolies and drive out local competition.
	Abrol (2004)	Due to the introduction of strong IPRs, pharmaceutical multinationals are now advantageously placed to control the knowledge diffusion and integrate the local capabilities of a country like India in to their own myopic and narrowly benefiting innovation strategies.
	Nair (2008)	No proper and simple modality is yet available for the developing and least developed countries for implementing an effective system for achieving the goals spelt out in the Doha declaration.
No guarantee of increase in R&D investment of developing countries	Pradhan (2003)	R&D activities of MNCs are mainly concentrated in the home country.
	Lanjouw (1998)	Even the strong IPRs may not compel MNCs to locate R&D facilities in India.
R&D investment on global diseases only	Sampath (2005)	Emphasis will be given on R&D investment on global diseases only because the study finds a very high correlation between export intensity and R&D investments in the Indian pharmaceutical sector.
	Lalitha (2002)	Drug policy 2002 is one-sided echoing mostly the business interests and fails to reflect the health needs or the approaches to the health-related issues in the economy.
Implications for the survival & growth of small pharmaceutical firms	Pradhan (2007)	The challenge for survival is quite formidable for small firms under the new regime. Some units may be closed.
	Jaisankar (2007)	The overnight implementation of schedule M is the biggest problem faced by SSIs in pharma.
Extending monopoly rights up to twenty years can lead to a	Bhaduri (2006)	Extending monopoly rights up to twenty years can lead to a decline in R&D expenditure. There will be no incentive to search for more efficient processes

decline in R&D expenditure		of the same product during the patent life.
A differentiated approach is needed	Lanaszka (2003)	A change of attitude is necessary. The idea of fairness as one of the principles should govern the dialogue between the developed and the developing countries
	Raju (2005)	The idea of patenting itself was a creation of the industrialized countries for protecting their intellectual creations. The developing countries were always on the receiving end.
	Lanjouw (2002)	Global patent regime is sensitive to the development level of the countries.
Patent protection will not automatically increase R&D	Zuniga and Combe (2002)	Reinforcing patent protection will not automatically change the access and the ways to finance R&D projects
Increase in R&D of only large & medium size firms	Reddy (2006)	Growth in R&D for larger pharmaceuticals is greater than the growth for the general pharmaceutical sector. Smaller pharmaceuticals do not have these resources and might not be able to survive in the market.
	Pradhan (2003)	Although the competitive pressure has worked effectively in pushing Indian pharmaceutical firms into R&D activity, however, this impact is likely to be limited to a few large and medium size firms. Large segment of small size firms lack the huge resources required for product development.
Increase in R&D has nothing to do with patent protection	Chaudhury (2007)	Even after TRIPS, what Indian companies have really demonstrated is the ability to develop generics for the regulated (and other) markets – an ability which they acquired and improved during the pre-TRIPS period.
Welfare loss to developing countries	Fink (2001)	Unless the new medicines are more efficient, there will be a decline in the health level of the people.
	Chaudhury *et.al.* (2003)	Concerns about the potential adverse welfare effects of TRIPS may have some basis.

2.3 Identifying Gaps in Research

After going through the literature, it is clear that although a lot of studies have been done on the Indian pharmaceutical industry in general and also on SWOT analysis, R&D investment, affordability of medicines, either independently or in relation with TRIPS context, the focus of these studies has been on one or two aspects and a comprehensive analysis has not been done. Moreover, very limited work has been attempted covering the trends in the pharmaceutical industry in northwest region. The present study intends to fill this gap.

The present work is a comprehensive one as it has tried to analyse the impact of TRIPS on the Indian pharmaceutical industry preferably from all sides, i.e., from the viewpoint

of the industry as a whole and from the viewpoint of selected leading large scale companies. Along with these, the present research also undertakes to study 100 firms operating in excise-free zones and non-excise free zones of the north west region by covering the size-wise as well as age-wise analysis. The study is an attempt to understand their patenting perspectives, their R&D strategies and their export orientation to see the impact of TRIPS on the pharmaceutical industry of India.

2.4 Need for the Study

In the globalized era there is a strong need for continuous research to analyse the impact of any international treaty signed by the government, as the impact may be different for different sections. Although some pioneer work has already been done by various researchers on the impact of TRIPS on the pharmaceutical industry of India, most of those research studies reflect the results at industry level and not enough research is available on firm level. Moreover, little literature is available which covers the large, medium and small scale pharmaceutical firms at firm level in north west region of India. Hence, the present study has been undertaken to cover all aspects of the pharmaceutical industry to present a comprehensive, integrated and holistic approach to the policy makers.

2.5 Theoretical Framework

The Indian pharmaceutical industry represents a successful high technology based industry, which has witnessed consistent growth over the last three decades (Ramani, 2002). Before 1970s the size of Indian Pharmaceutical Industry was small, both in terms of number of firms and volume of production. MNCs dominated the market, because the patent regime, based on The Indian Patents and Designs Act 1911, recognized both product and process patents. Due to monopoly status enjoyed by the MNCs, drug prices remained high during this period. In 1970, Government of India introduced a new Patent Act, which came into effect in 1972, recognizing only process patent and not product patent. The Act enabled Indian firms to use ‘reverse engineering process’, to manufacture drugs, without paying royalty to the original patent holder.

The scenario changed with the establishment of WTO as, being a signatory member, India had to sign TRIPS. The TRIPS Agreement enforced product patents in India. The TRIPS agreement in 1995 totally reversed the protective environment which the Indian pharmaceutical firms had been enjoying so far. With various Industry bodies and groups changing their previous anti-patent stand and now taking a pro-patent stand (Ramanna, 2003; Rangnekar, 2005), a paradigm shift occurred in the industry and caused a marked shift in India's policy around 1998-99. As a result, major changes have occurred at the industry level and at the firm level in the post-TRIPS period.

The theoretical framework for this research is based upon the literature of evolution of policy. Policies can play a major role in stimulating and supporting the innovation process. Researchers have looked from different angles at how policy can affect firm level strategies Some researchers accepted this policy change in a healthy way (Tancer,1999; Smith, 2000; Kamath, 2002; Kubo, 2004; Chadda, 2005; Dhar and Gopakumar, 2006; Pradhan , 2006). However there are others who are apprehensive of the adoption of TRIPS and its implications (Chaudhury, 2005; Abrol, 2004; Pradhan, 2003; Kumar, 2002; Fink, 2001; Bhaduri, 2006). The present study synthesizes the policy implications in three major areas, i.e., patents, R&D and exports. The focus of most of the earlier studies has been limited and a comprehensive study to evaluate the impact of TRIPS on north west region has not been done earlier. This region is very important, as it is a unique combination of Excise-Free Zones and non- Excise-Free Zones (The central govt. declared the backward regions of Baddi and Kala Amb of Himachal Pradesh as tax free zones to expedite the industrial development of these areas). Hence the present study tries to study the impact of TRIPS in the north west region of India. An analysis of earlier literature highlights that Indian pharmaceutical industry is dominated by formulations which constitute 73 percent of total drugs produced in India. Between 2002-07, the domestic formulation industry grew at a CAGR of 14 percent from a US 4.3 billion $ in 2002 to US 8.4 billion $ in 2007. (Indian Pharmaceutical Vision 2015, 2010) The sample firms chosen in the north west region are all producing formulation, which constitute an important proportion of drugs and pharmaceuticals.

The present study tries to examine whether TRIPS agreement has improved the patenting, R&D and exports in the pharmaceutical industry of India, whether the policy change is good for India. In continuation to the already existing literature on patents **(Dhar and Gopakumar, 2006; Gupta, 2007; Chadda, 2005),** this study has tried to focus on ANDA filings and DMF filings and approvals in addition to the patents filed and obtained. The post-TRIPS patenting activities of the pharmaceutical industry of India are analysed from for the sample of one hundred firms from north west region of India.

In the R&D, this research, again in continuation to the already existing literature **(Kubo, 2004; Grace, 2004; Chaturvedi and Chatway, 2006)** has tried find out whether R&D expenditure in the industry has improved after the implementation of TRIPS. Building further on this framework R&D intensity for the selected leading pharmaceutical companies has also been analysed in the post-TRIPS period. R&D perspective of one hundred sample firms from north west region of India has been analysed.

On the export side, again this research is an addition to the already existing research **(Lalitha, 2002; Pradhan, 2006)**. The study by **Chadha (2005)** examines the export performance of 177 Indian pharmaceutical firms for the post- liberalization period 1991-2004 and indicates a positive impact on exports. Here also the present research extends the analysis by taking export status of the sample firms in north west.

2.6 Concluding Remarks

This chapter gives a brief summary of the literature review of the studies favouring TRIPS and studies expressing concerns over TRIPS. Based on the review, the study underlines the existing gaps and presents a rationale and theoretical framework for undertaking the research in this area.

CHAPTER-III

RESEARCH DESIGN AND METHODOLOGY

This chapter covers the data collection, selection of sample and survey areas, research questions, development of the hypotheses and methods for data analysis. The purpose of this analytical study is to analyse the impact of TRIPS on the Pharmaceutical Industry of India in the post TRIPS period. Section 3.1 covers the data collection of both primary as well as secondary data. Section 3.2 deals with validity and reliability of the questionnaire. Section 3.3 defines the research questions. This is followed by development of hypotheses in section 3.4. Finally, section 3.5 covers the tools and techniques used for data analysis.

3.1 Data Collection

The study is based on both primary data and secondary data. Secondary data have been collected from the Indiastat database, annual reports and websites of pharma companies and other pharma websites. Secondary data have been used for analysing the trends in patents, R&D and exports of the Pharmaceutical Industry of India in the post TRIPS era. Data from annual reports of the companies, WIPO and IPO have been used for analysing the performance of the selected leading pharmaceutical companies of India on the same parameters in the post-TRIPS period.

For primary data a sample of one hundred firms was required and approximately double the questionnaires were sent so that at least we get hundred corrected questionnaires to cover up for the non response bias. The Sample was chosen to cover Excise-free-zones as well as non-excice-free zones. So around 180 firms were approached and 110 firms returned the questionnaire, out of which 100 complete in all respects have been taken up for analysis. The response rate is 55.6 percent which is pretty good for primary data collection. The study covers the major areas in north west India, where pharmaceutical firms are located, viz., Mohali, Dehra Bassi, Lalru in Punjab; Baddi, Kala Aamb in Himachal Pradesh; and Ambala in Haryana.

3.1.1 Selection of Sample and Survey Areas

A sample of one hundred firms has been chosen for analysis. The study tries to cover the major areas in northwest India, where pharmaceutical firms are located. The north

west region mainly comprises excise-free zones and non-excise-free zones ever since the central government announced the excise free zones in 2003 with the objective to help the development of backward and hilly areas of north west India. The present research covers the excise-free zones of Badi and Kala Amb in Himachal Pradesh and non-excise-free zones of Mohali, Dehra Bassi, Lalru in Punjab and Ambala in Haryana. The period of data collection was June to December 2008. Table 3.1 describes the number of responding units.

Table 3.1 : Sample Pharmaceutical Firms from the North West Region

	Place of Pharmaceutical firms	**State**	**No. of units**
Excise free zones	Baddi	Himachal Pradesh	27
	Kala Amb	Himachal Pradesh	30
	Total		**57**
Non-Excise free zones	Lalru	Punjab	6
	Mohali	Punjab	6
	Dehra Bassi	Punjab	6
	Ambala	Haryana	25
	Total		**43**
	Grand Total		**100**

Analysis of primary data has been done on the basis of

3.1.2 Size-wise Classification

In size-wise classification, the firms are classified as large, medium and small scale firms on the basis of annual sales turnover. The firms with an annual sales turnover of more than Rs. 300 crores have been classified as large scale firms, with an annual sales turnover between 100 to 300 crores as medium scale firms and with an annual sales turnover of less than Rs. 100 crores have been classified as small scale firms. Table 3.2 shows the size-wise classification of the sample pharmaceutical firms.

Table 3.2: Size-Wise Classification

Firm size	EFZ	%	NON- EFZ	%	TOTAL	%
Large	8	100%	--	--	8	100%
Medium	19	79.2%	5	20.8%	24	100%
Small	30	44.1%	38	55.9%	68	100%
Total	57	57%	43	43%	100	100%

In size-wise classification, there are 8 large scale firms, 24 medium scale firms and 68 small scale firms. Out of 57 firms from excise-free-zones, 8 are large sized firms, 19 are medium sized firms and 30 are small sized firms. Out of 43 firms from non-excise-free zones, 5 are medium sized firms and 38 are small sized firms.

3.1.3 Age-wise Classification

In age-wise classification, the firms are classified according to the year of their establishment. The firms established before 1980 are classified as old, those established in the period 1980 and 1995 come under the category of medium and the firms established after 1995 come under the category of new firms. Many units at Baddi were set up as additional units of already existing firms after the announcement of excise-free zones. For age-wise classification this research takes into consideration, the year of establishment of the parent company of these firms. Table 3.3 shows the age-wise classification of the sample pharmaceutical firms.

Table 3.3: Age-wise Classification

Age	EFZ	%	Non-EFZ	%	Total	%
Old	4	50.0%	4	50.0%	8	100%
Medium	8	25.0%	24	75.0%	32	100%
New	45	91.7%	15	8.3%	60	100%
Total	57	57.0%	43	43.0%	100	100%

According to age-wise classification 8 are old firms, 32 are medium firms and 60 are new firms. Out of 57 firms from excise-free zones 6 are old firms, 13 are medium firms and 38 are new firms. Out of 43 firms from non-excise-free zones 2 are old firms, 19 are medium firms and 22 are new firms.

3.2 Validity and Reliability of the Questionnaire

Table 3.4 Item-Wise Reliability

S No	Items	No of Items	Cronbach Alpha
1	Overall performance of the firms	5	.802
2	Impact of TRIPS on Patents, Exports and R&D	5	.811
3	Impact of TRIPS : Other Perspectives	15	.778
	Overall	**25**	**.798**

The questionnaire has been segmented into four sections. Section A covers the organization profile. Section B covers the overall performance of the firms and has five items. Sections C and D deal with impact of TRIPS. Section C covers Impact of TRIPS on patents, R&D and exports. It has five items and has a reliability score of .811. Section D covers Impact of TRIPS: other perspectives. It has fifteen items with a reliability score of .778. The overall reliability of the questionnaire has been .798. Face and content validity have been used for the questionnaire. The questionnaire had been validated by the peers and has a good validation score. The changes suggested were incorporated in the questionnaire and responses recorded.

Table 3.5 Internal Consistency and Convergent Validity of Independent Variables

Construct	No of Items	Mean	Variance	Minimal item to total correlation	Cronbach Alpha
IP11	06	2.93	2.96	0.820	.832
IP12	03	3.30	2.05	0.788	.788
IP13	03	3.12	1.58	0.782	.801
IP14	02	3.60	1.42	0.768	.768
IP15	02	4.13	2.15	0.756	.651
IP16	02	3.37	2.42	0.761	.690

Table 3.5 indicates the measures that have been clubbed to form independent variables. Factor analysis has helped in the selection of variables which have been clubbed to form independent variables used for regression analysis. These variables are as follows.

i. **IP 11: TRIPS, R&D and new opportunities**: This includes five items.
   - In-house R&D activities
   - Proportion of turnover spend on R&D in the last three years
   - Cost of production as a result of signing of TRIPS
   - Impact of TRIPS on various issues related to Indian pharmaceutical Industry
   - New opportunities created due to TRIPS

ii. **IP 12: Products under DPCO and performance of R&D:** This has three items, namely:
   - Impact on the no. of products of the firm covered under drugs price control order (DPCO)
   - Performance of R&D activities
   - Therapeutics of the drugs firms are dealing with

iii. **IP13: Product category, nature of order and threats:** This has the following items:

- Impact on no. of products introduced by the firm
- Bulk orders from big companies
- Threats due to TRIPS in form of competitions from foreign companies

iv. **IP14: Changes in technique and technical personnel employed**: The items included in this independent variable are:

- Shift to better technology due to TRIPS
- Total technical persons employed

v. **IP15: Changes in sales and exports**: This includes the following two items:

- Changes in sales in last three years
- Change in total exports

vi. **IP 16: Preparedness for TRIPS:** This includes two items. These are:

- Need for patents
- Challenges posed by TRIPS

These variables have acceptable convergent validity.

Table 3.6: Internal Consistency and Convergent Validity of Dependent Variable

Construct	No of Items	Mean	Variance	Minimal item to total correlation	Cronbach alpha
DP11	03	3.05	2.04	0.816	.757

Similarly Table 3.6 indicates the results for the dependent variable, i.e., consisting of overall performance during TRIPS consisting of three items, viz., present sales, market share and overall impact on performance.

3.3 Research Questions

1. Is the post-TRIPS period associated with a higher number of patents by the Indian pharmaceutical firms/ industry?
2. Is the post-TRIPS period associated with an increase in the R&D activities by the pharmaceutical firms/industry?
3. Has there been an increase in the exports of the pharmaceutical firms/industry in the post-TRIPS era?

3.4 Development of the Hypotheses

Based on these research questions, the following hypotheses have been tested.

H_1: Post-TRIPS period may be associated with higher number of patents.

H_2: R&D may have improved in the post-TRIPS period.

H_3: Exports may have increased in the post-TRIPS period.

3.5 Tools and Techniques

Data have been analysed with the help of SPSS (statistical package for social sciences) package. Statistical tools like Chi-square ($\chi 2$) test, ANOVA, Factor analysis and Regression analysis have been applied to test the hypotheses.

3.5.1 Growth Rates have been calculated as:

$$Y = ab^t$$

$$\text{Log } Y = \text{Log } a + t \text{ Log } b$$

3.5.2 Chi-Square ($\chi 2$) Test

Chi-square ($\chi 2$) test is strongly recommended when the researcher wants to know whether the association between two variables is significant or not. For example, the present research, at firm level analysis, intends to know whether the performance of different research parameters is independent of firm size or not. Hence, Chi-square ($\chi 2$) test has been used to get the precision. Similarly for finding association between firm age and other research parameters, Chi-square test has been used.

3.5.3 The Analysis of Variance (ANOVA)

Analysis of variance (ANOVA) is a set of techniques for studying cause and effect of one or more factors (independent variables) on a single dependent variable. In the present study one-way ANOVA has been used. F-test under the ANOVA has been conducted to check whether there is a significant difference across the different levels of firms on the basis of firm size and firm age.

3.5.4 Factor Analysis

The technique of Factor analysis provides a fascinating way of reducing the number of variables in a research problem to a smaller and more meaningful number by

combining related ones into factors. It relieves the researcher from the confusion arising through overlapping measures of the same underlying variables. Moreover, the cost of further research may be reduced by focusing efforts on fewer variables for study.

In the present study, factor analysis has been used on primary data to study the impact of TRIPS on the Indian pharmaceutical sector and factors influencing pharmaceutical performance were reduced to six only from more than twenty variables. It helped the researcher to concentrate on the important variables being studied.

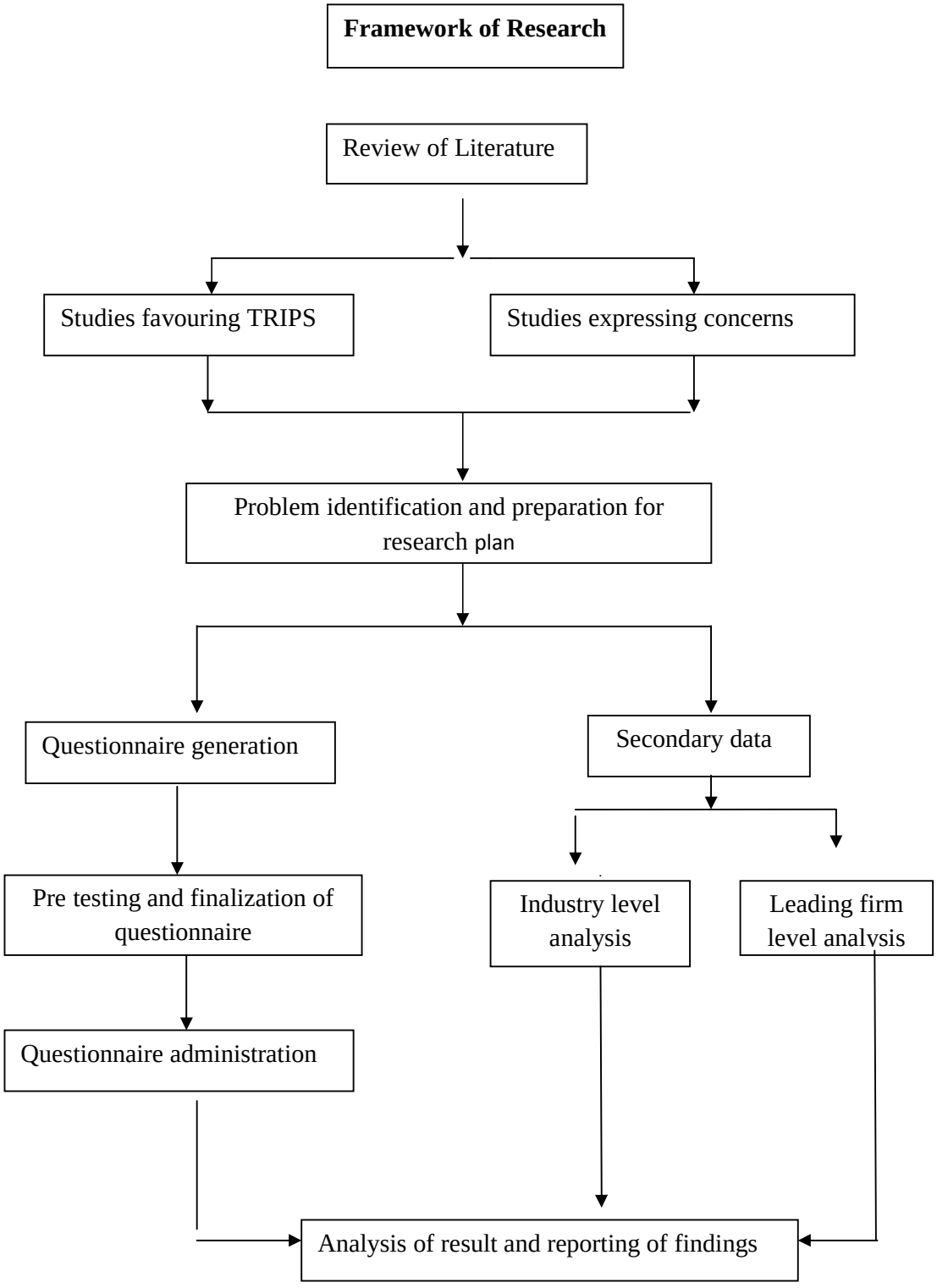
3.5.5 Regression Analysis

Step-wise regression has been used to study the performance of pharmaceutical firms in the post-TRIPS period. The dependent variable is the overall performance and six independent variables used in the study are: i) TRIPS, R&D and new opportunities; ii) Products under DPCO and performance of R&D; iii) Product category, nature of order and threats; iv) Changes in technique and technical personnel employed; v) Changes in total sales and exports; and vi) Preparedness for TRIPS.

3.6 Concluding Remarks

This chapter sums up the research design and methodology used for data analysis. It sets the momentum for research by defining the research questions and developing the hypotheses. The framework of research has been presented in Figure 3.1

Figure: 3.1


Framework of Research
Review of Literature
Studies favouring TRIPS
Studies expressing concerns
Problem identification and preparation for research plan
Questionnaire generation
Secondary data
Pre testing and finalization of questionnaire
Industry level analysis
Leading firm level analysis
Questionnaire administration
Analysis of result and reporting of findings

CHAPTER IV

RESULTS AND DISCUSSION

The present research tries to study the performance of the Pharmaceutical Industry of India with reference to the north-west region in the post-TRIPS period. Section 4.1 covers the industry level analysis on patents, R&D and exports. Section 4.2 highlights the performance of the selected leading pharmaceutical companies in the post-TRIPS period. Nine firms have been selected on the basis of their sales performance and profitability ratios. Section 4.3 covers the firm level analysis of selected hundred firms from the northwest region of India in post-TRIPS period. Finally section 4.4 covers the concluding remarks.

4.1 Industry Level Analysis

Table 4: Pharmaceutical Industry: Production at a glance (1981-82 to 2004-05)

Year	Percentage share of bulk drugs	Percentage share of Formulations
1980-81	16.7	83.3
1981-82	16.8	83.2
1982-83	17.2	82.8
1983-84	16.8	83.2
1984-85	17.1	82.9
1985-86	17.6	82.4
1986-87	17.6	82.4
1987-88	17	83.0
1988-89	14.9	85.1
1989-90	15.8	84.2
1990-91	16	84.0
1991-92	15.8	84.2
1992-93	16.1	83.9
1993-94	16.1	83.9
1994-95	16.1	83.9
1995-96	17.4	82.6
1996-97	17.2	82.8

1997-98	17.9	82.1
1998-99	18.5	81.5
1999-2000	19.1	80.9
2000-01	19.8	80.2
2001-02	20.5	79.5
2002-03	21.3	78.7
2003-04	21.8	78.2
2004-05	22.0	78.0

Source: Indiastat database

The table shows that Indian pharmaceutical industry is mainly dominated by formulations though the percentage of formulations in total pharmaceutical production has slightly been decreasing after 1995.

4.1.1 Patents in the Pharmaceutical Industry in the Post-TRIPS Period

4.1.1.1 Patenting Scenario of the Pharmaceutical Industry

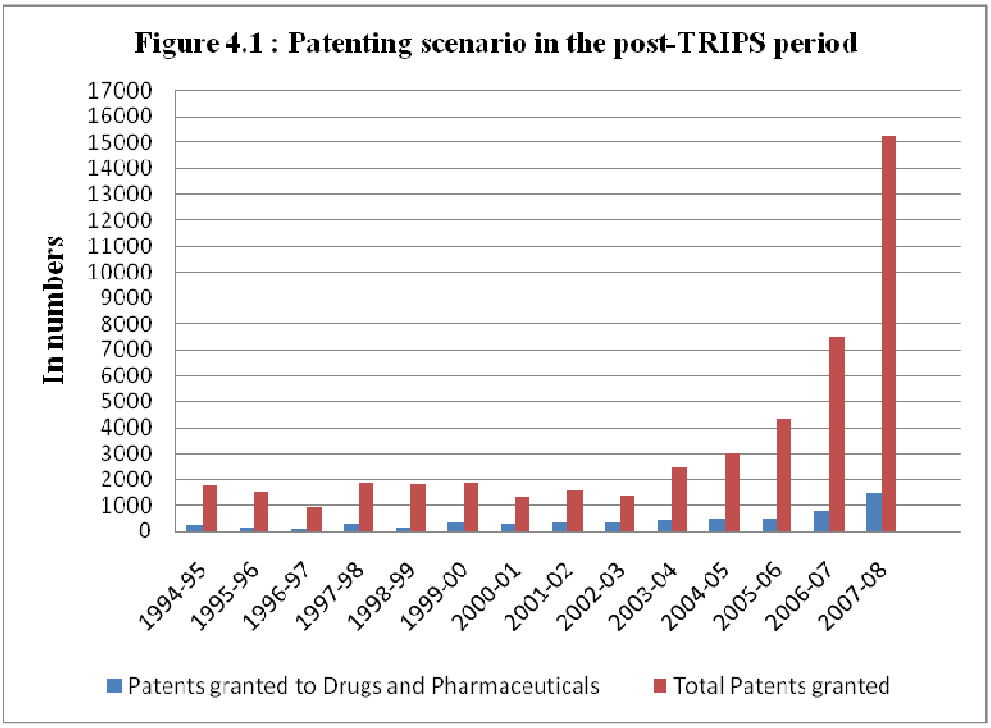
The present study analyses the post-TRIPS (1994-95 to 2007-08) patenting scenario of the Pharmaceutical Industry of India (Table 4.1). The analysis has also been done to find out the percentage of patents granted to pharmaceuticals as a percentage of total patents granted for the same period.

The patenting scenario of the Pharmaceutical Industry depicts a change in the patenting culture with the patents in drugs and Pharmaceutical Industry growing at a higher rate of 6.06 percent per annum as against the 5.57 percent growth of total patents granted. Patents granted to drugs and pharmaceuticals as a percentage of total patents granted varied from 7.83 percent to 22.63 percent. The highest percentage (22.63 percent) has been recorded in 2002-03.The same has been presented graphically in Figure 4.1.

Table 4.1 : Patenting Scenario in the Post-TRIPS Period

Year	Patents granted to drugs and pharmaceuticals (1)	Total patents granted (2)	1 as % of 2
1994-95	232	1759	13.19
1995-96	132	1533	8.611
1996-97	71	907	7.828
1997-98	291	1844	15.78
1998-99	150	1800	8.333
1999-00	307	1881	16.32
2000-01	276	1318	20.94
2001-02	320	1591	20.11
2002-03	312	1379	22.63
2003-04	419	2469	16.97
2004-05	453	3021	14.99
2005-06	457	4320	10.58
2006-07	798	7539	10.58
2007-08	1469	15261	9.626
Growth Rates*	**6.06**	**5.57**	

Source: Indiastat database *self calculated



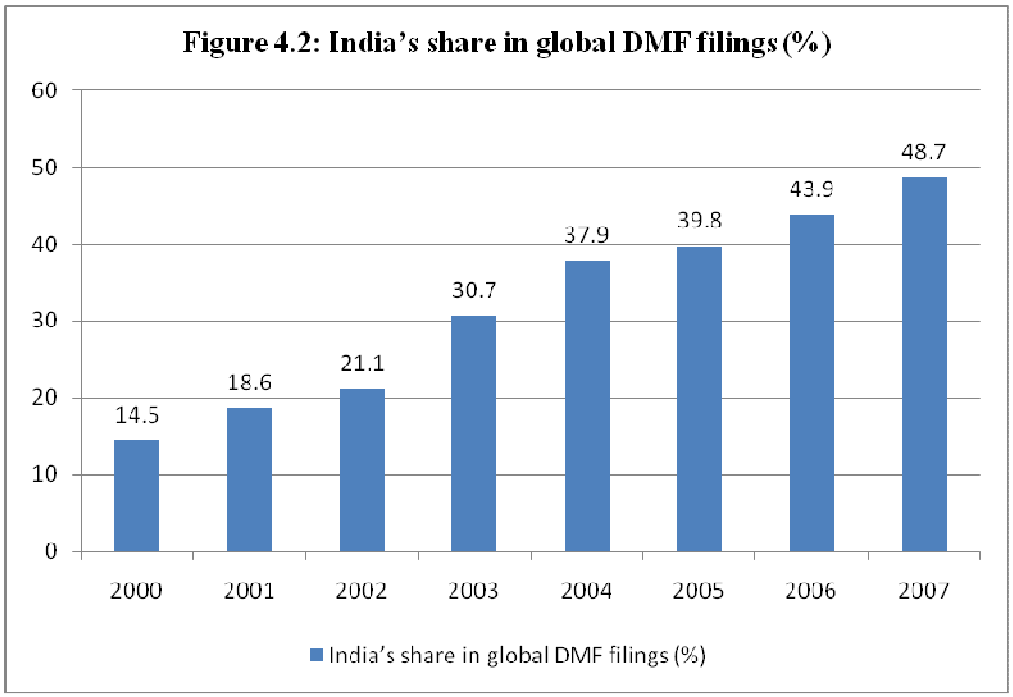
4.1.1.2 Drug Master Filings (DMF Filings) by the Pharmaceutical Industry

A DMF filing is required if the manufacturer wants to sell active pharmaceutical ingredients (APIs) in the US. Indian pharmaceutical companies started filing DMFs in the US around the 1980s, but until the late 1990s, only a few DMFs were filed. Since then the rate of filing has accelerated. DMFs filed from India as a percentage of total DMFs filed with the United States Food and Drug Administration (US FDA) has increased steadily especially in the period 2000 to 2007 (IBEF, Market Overview, December 2008). Table 4.2 indicates not only the present level of patenting activity in Indian Pharmaceutical Industry but commitment (pipeline) for the future has also been indicated by a steadily rising share of Indian pharmaceutical companies in total DMF filings with USFDA.

Table 4.2: India's Share in the total DMFs Filed with the US FDA

Year	Total DMF filings with the USFDA	DMF filings from India	India's share in global DMF filings (%)
2000	227	33	14.5
2001	280	52	18.6
2002	288	63	21.1
2003	404	124	30.7
2004	517	193	37.9
2005	688	274	39.8
2006	706	306	43.9
2007	226	110	48.7

Source: Ernst & Young , 2008



4.1.2 R&D in the Pharmaceutical Industry

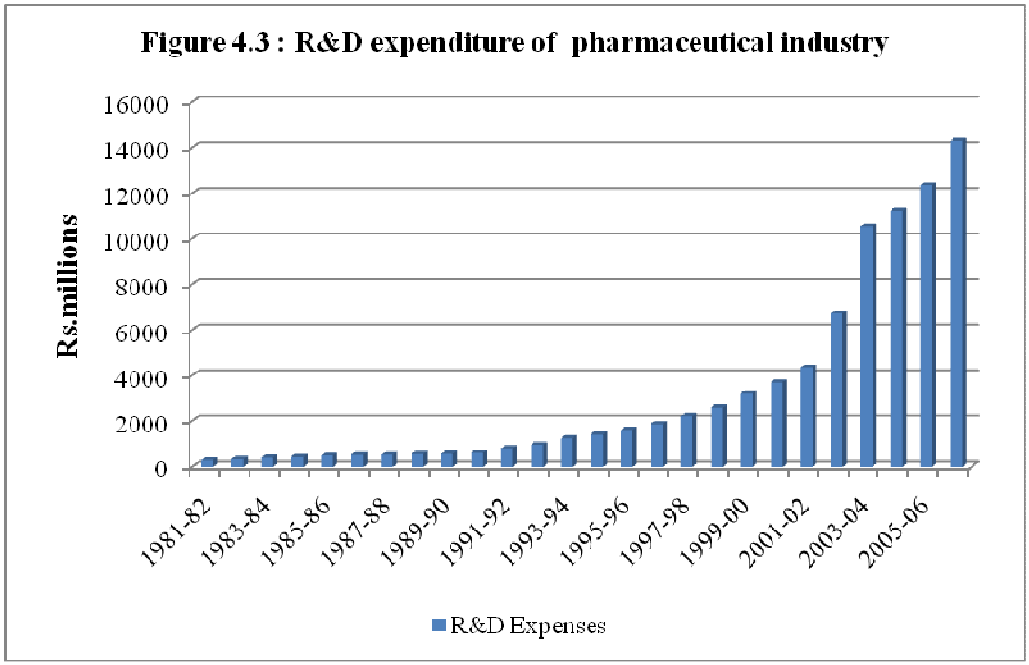
R&D investment plays a crucial role in the growth of any industry. As the Pharmaceutical Industry is knowledge intensive, the role of R&D assumes greater significance. Though the product patent was introduced from 2005, many pharmaceutical companies realized the need of increasing their R&D efforts much earlier.

Table 4.3: R&D Expenditure of the Pharmaceutical Industry (Rs Million)

S No	Year	R&D expenditure	S No	Year	R&D expenditure
1	1981-82	293	14	1994-95	1405
2	1982-83	322	15	1995-96	1607
3	1983-84	400	16	1996-97	1859
4	1984-85	426	17	1997-98	2203
5	1985-86	480	18	1998-99	2604
6	1986-87	508	19	1999-00	3209
7	1987-88	514	20	2000-01	3703
8	1988-89	540	21	2001-02	4351
9	1989-90	561	22	2002-03	6721
10	1990-91	606	23	2003-04	10543
11	1991-92	805	24	2004-05	11243
12	1992-93	952	25	2005-06	12352
13	1993-94	1250	26	2006-07	14305
Growth Rates (%)*					
Period I Pre-TRIPS		**3.88**	**Period II Post-TRIPS**		**5.07**
Entire Period		**6.05**			

Source: Indiastat database *self calculated

Table 4.3 shows that R&D expenditure of the Indian pharmaceutical sector, which was Rs. 293 millions during 1981-82, has increased to Rs. 1250 millions by 1993-94. In the later years, R&D expenditure of the industry increased further to reach a level of Rs. 14305 millions by the end of 2006-07. The growth rate of R&D has been 3.88 percent per annum in the pre-TRIPS period (1981-82 to 1993-94) and 5.07 percent per annum in the post-TRIPS period (1994-95 to 2006-07). These results show that the growth of R&D of the industry as a whole is more in the latter period, i.e., the post-TRIPS period. Figure 4.3 depicts the trends in R&D expenditure. The graph clearly depicts increase in R&D expenditure in the post-TRIPS period.



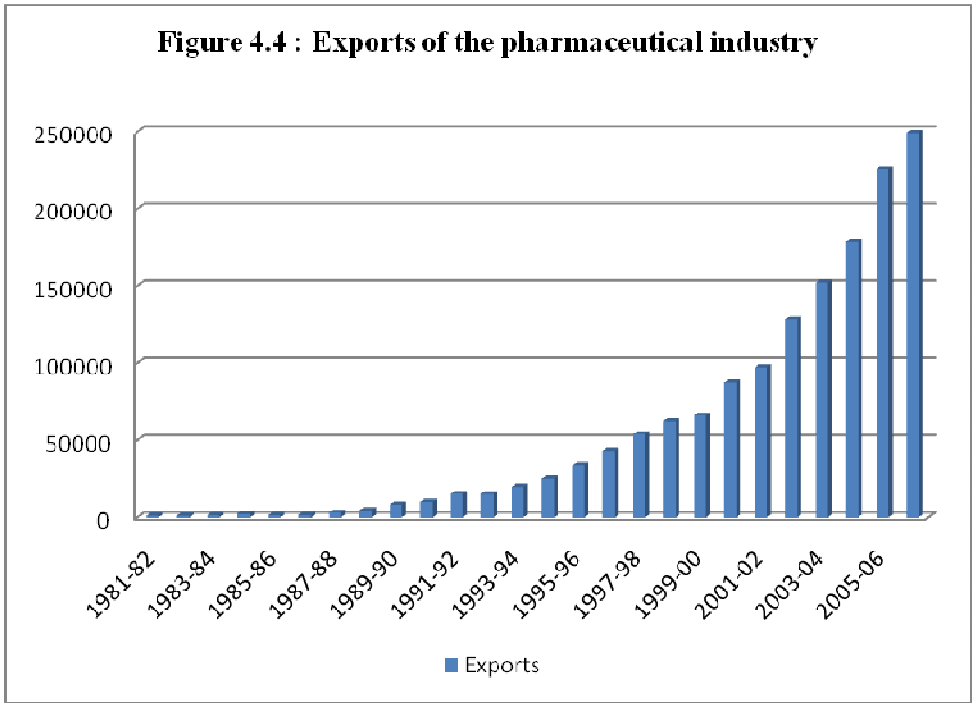
4.1.3 Exports of the Pharmaceutical Industry

The Indian Pharmaceutical Industry performed strongly on exports in the post-TRIPS period. Table 4.4 shows the industry's exports worth Rs. 1220 millions in 1981-82 increased to Rs. 249429 millions in 2006-07 with an annual growth rate of 9.02 percent. The growth rate has been 4.90 percent per annum in the pre-TRIPS period and 5.03 percent per annum in the post-TRIPS period. These results show that growth of exports of industry as a whole has been higher in the post-TRIPS period.

Table 4.4: Exports of the Pharmaceutical Industry (Rs Million)

S No	Year	Exports	S No	Year	Exports
1	1981-82	1220	14	1994-95	25123
2	1982-83	1122	15	1995-96	34087
3	1983-84	1552	16	1996-97	43418
4	1984-85	2342	17	1997-98	54193
5	1985-86	1579	18	1998-99	62567
6	1986-87	1613	19	1999-00	66314
7	1987-88	3261	20	2000-01	87574
8	1988-89	4737	21	2001-02	97512
9	1989-90	8496	22	2002-03	128261
10	1990-91	10141	23	2003-04	152132
11	1991-92	15501	24	2004-05	178578
12	1992-93	15330	25	2005-06	225789
13	1993-94	20097	26	2006-07	249429
Growth Rates (%)*					
Period I Pre-TRIPS		**4.90**	**Period II Post-TRIPS**		**5.03**
Entire Period		**9.02**			

Source: Indiastat database *self calculated



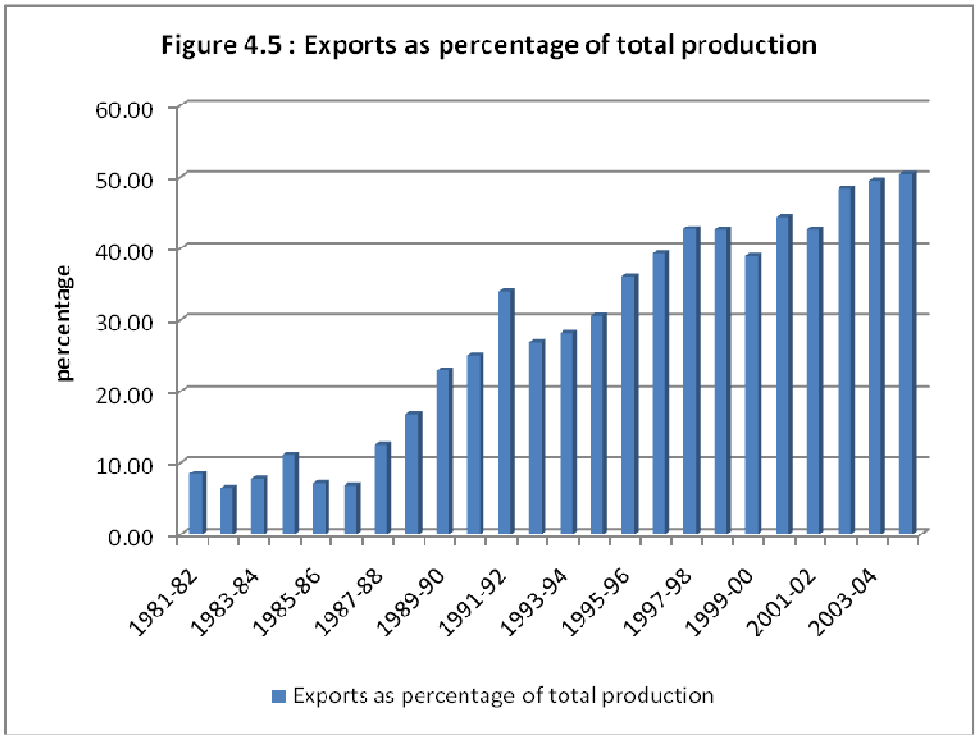
The trends have been depicted in Figure 4.4. The trends clearly indicate a sharp increase in exports in the post-TRIPS period.

Not only the exports have increased significantly in post-TRIPS period, but the percentage of export in total production (export intensity) has also improved in the post-TRIPS period. Table 4.5 shows that export intensity which was just 8.47 in 1981-82, increased to more than fifty percent (50.41 percent) in 2004-05. The same has been graphically depicted in figure 4.5

Table 4.5: Exports as Percentage of the Total Production

Year	Total production (Rs. Millions)	Exports (Rs. Millions)	Exports as percentage of the total production
1981-82	14403	1220	8.47
1982-83	17232	1122	6.51
1983-84	20052	1552	7.74
1984-85	21156	2342	11.07
1985-86	22047	1579	7.16
1986-87	23613	1613	6.83
1987-88	25981	3261	12.55
1988-89	28304	4737	16.74
1989-90	37005	8496	22.96
1990-91	40603	10141	24.98
1991-92	45706	15501	33.91
1992-93	57008	15330	26.89
1993-94	71509	20097	28.10
1994-95	82204	25123	30.56
1995-96	94536	34087	36.06
1996-97	110473	43418	39.30
1997-98	126807	54193	42.74
1998-99	146914	62567	42.59
1999-00	170263	66314	38.95
2000-01	197372	87574	44.37
2001-02	228877	97512	42.60
2002-03	265433	128261	48.32
2003-04	307142	152132	49.53
2004-05	354218	178578	50.41

Source : Indiastat database



4.1.4 Results of the Industry Level Analysis

Results of the pharmaceutical industry as a whole depict that

i) Patents have increased in the pharmaceutical industry of India in the post-TRIPS period.
ii) Growth of R&D of the industry as a whole has been higher in the post-TRIPS period as compared to the pre-TRIPS period.
iii) Growth of exports of the industry as a whole is higher in the post-TRIPS period as compared to the pre-TRIPS period**.**

4.2 Analyses of the Selected Leading Pharmaceutical Companies

It was in the post-1995 phase that the large companies in the industry, especially the generic producers, have performed strongly on all fronts. What appears as most striking is that this robust performance by these companies has come during a phase when they were facing an uncertain future with the process-patent regime being dismantled following India's accession to the WTO. Nine leading pharmaceutical companies have been selected for analyses. These companies have been selected on

the basis of sales and profitability ratios in the post TRIPS period and their changing perspectives in terms of patents, R&D and exports have been taken for explaining their performance in the post-TRIPS scenario. The profitability ratio has been calculated as the percentage of net profits to sales.The analysis has helped in inter-firm comparison of these firms of all these perspectives. These companies are: i) Ranbaxy; ii) Dr. Reddy's Laboratory (DRL); iii) Sun Pharmaceutical Industries Limited; iv) Wockhardt Limited; v) Cadilla Healthcare Limited; vi) Glenmark Pharmaceuticals Limited; vii) Torrent Pharmaceuticals Limited; viii) Cipla; and ix) Aurobindo Pharma.

4.2.1 Profiles of the Selected Companies

i) Ranbaxy

Ranbaxy is ranked amongst the top ten global generic companies and has a presence in 23 of the top 25 pharma markets of the world. The company is headquartered in India. Ranbaxy was incorporated in 1961. Ranbaxy went public in 1973. Ranbaxy's first joint venture was set up in Lagos (Nigeria) in 1977. In 1985, Ranbaxy Research Foundation was established and Stancare, Ranbaxy's second pharmaceutical market division started functioning. In 1987, production started at Ranbaxy's Toansa plant (Punjab) and with this Ranbaxy became India's largest manufacturer of antibiotics/antibacterials. In 1988, Ranbaxy's Toansa Plant got US FDA approval. In 1990, Ranbaxy was granted its first US patent, for doxycyline.

In 1995, Ranbaxy filed its first ANDA. In 1997, Ranbaxy crossed a sales turnover of Rs. 10,000 millions. In 1998, Ranbaxy entered USA, the world's largest pharmaceutical market, with products under its own name. In the same year, Ranbaxy filed its first investigational new drug (IND) application with the Drugs Controller General of India for approvals to conduct phase 1 clinical trials. In 1999, Ranbaxy commenced trials for its New Chemical Entity (NCE). In 2000, Ranbaxy acquired Bayer's generic business in Germany, and entered into Brazil, the largest pharmaceutical market in South America. In 2001, Ranbaxy set up a manufacturing facility in Vietnam. In 2003, Ranbaxy launched cefuroxime axetil after approval from the USFDA. It was the first approval granted to any generic company for this product. In 2003, Ranbaxy and Glaxo SmithKline Plc entered into an alliance for drug

discovery and development. In 2004, Ranbaxy acquired a wholly owned subsidiary RPG (Aventis) SA and began operations in France as a Top 10 generic company. In 2005, Ranbaxy launched operations in Canada and acquired a generic product portfolio from EFARMES of Spain. In 2006, Ranbaxy acquired Be Tabs pharmaceuticals of South Africa, unbranded generic business of GSK in Italy and Spain, and Terapia of Romania.

In 2008, Ranbaxy submitted six ANDAs in USA; Ranbaxy has the largest basket of products in the US market with 141 approved drugs and another 98 marketing applications pending for approval. Ranbaxy Laboratories**,** a leading pharmaceutical company of India, continued with its focus on developing innovative, environment friendly and cost-effective technologies for high-value active pharmaceutical ingredients (APIs). As on 31-3-08, the company had filed 271 drug master files, comprising 48 APIs across various countries and by 2008 the company had filed 185 patents. The sales scenario (Table 4.6) of the last eleven years depicts that sales for Ranbaxy have increased from Rs. 13344 millions in 1998 to Rs. 44616 million in 2008, growing at a rate of 2.03 percent per annum. The profitability ratio of the company has also improved from 8.77 to 23.51 for the same period.

Table 4.6: Sales and Profitability Ratio of Ranbaxy

Year	Sales (Rs. Millions)	Profitability ratio
1998	13344	8.77
1999	15601	12.63
2000	17377	10.54
2001	20554	12.26
2002	28205	22.13
2003	35346	22.50
2004	36159	14.63
2005	35373	6.33
2006	40598	9.39
2007	41852	14.77
2008	44616	23.51
Growth Rate*	**2.03**	

Source: Annual reports * self calculated

ii) Dr. Reddy's Laboratory (DRL)

DRL is India's leading pharmaceutical company with presence in over 100 countries. The company manufactures a range of products such as active pharmaceutical ingredients, generic and branded finished dosages, specialty pharmaceuticals, and biopharmaceuticals. DRL was founded in 1984. In 1986, it went public and entered international markets with exports of Methyldopa. In 1987, the company obtained its first USFDA approval for Ibuprofen API and started its formulations operations. In 1988, it acquired benzex laboratories private limited to expand its bulk actives business. In 1990, it entered a new territory when, for the first time in India, it exported norfloxacin and ciprofloxacin to Europe and far east. In 1993, Dr. Reddy's Research Foundation was established and the company started its drug discovery programme. In 1995, the company set up a joint venture in Russia. DRL submitted its first ANDA in 1997. In the same year, the company became the first Indian pharmaceutical company to out-license an original molecule when it licensed anti-diabetic molecule, DRF 2593 (Balaglitazone), to Novo Nordisk. In 1998, DRL licensed anti-diabetic molecule, DRF 2725 (Ragaglitazar), to Novo Nordisk. In 1999, the company acquired American Remedies Limited, a pharmaceutical company based in India. In the year 2000, it became the first Asia Pacific pharmaceutical company, outside Japan, to be listed on the New York stock exchange. In 2003, DRL launched ibuprofen, the first generic product to be marketed under the "Dr. Reddy's" label in the US. In 2006, DRL achieved revenue of US$ 1 Billion.

The year 2008-09 saw the highest number of approvals for the company's ANDA filings. The company got 23 final approvals from the US and 4 from Canada, in addition to 4 tentative approvals from the US. As of 31 March 2009, the Company's US generic pipeline comprises 68 ANDAs pending with the USFDA including 9 tentative approvals. Regarding APIs, the company has filed 55 DMFs in 2008-09. Of these, 21 were filed in US, 5 in Canada, 19 in Europe and 10 in other countries. Upto 2009, the company had cumulative filings of 351 DMFs, with 148 in the US. Table 4.5 shows that the sales of the company has increased from Rs. 3327 millions in 1998 to Rs. 49237 millions in 2008 registering a growth rate of 2.91 percent per annum. The profitability ratio of the company has been highest for the year 2002.

Table 4.7: Sales and Profitability Ratio of DRL

Year	Sales (Rs. Millions)	Profitability ratio
1998	3327	15.36
1999	4117	12.87
2000	4817	12.47
2001	10982	13.21
2002	16415	27.73
2003	18073	20.14
2004	20086	14.09
2005	19133	3.45
2006	24089	8.76
2007	64193	18.34
2008	49237	9.65
Growth Rate*	**2.91**	

Source: Annual reports * self calculated

iii) Sun Pharmaceutical Industries Limited

Sun pharma is an international specialty pharmaceutical company. The company's product portfolio consists of four categories of products: Indian branded generics, US generics, international branded generics and active pharmaceutical ingredients (APIs). The company's first research center, Sun pharma advanced research center (SPARC), was set up in 1993 in Baroda in the western state of Gujarat in India. The work done here has been instrumental for the rapid growth of Sun pharma. A second research center in Mumbai develops generics for the developed markets. As on 31-3-08, Sun Pharma and its US subsidiary Caraco, have filed 142 ANDAs, whereas ANDAs for 53 products have been approved. Till March 2008, the company has 101 filings for DMF and CEP. As on march 31, 2009, the company has filed 233 patents and 76 patents have been granted. Table 4.8 shows that sales and profitability ratio of Sun pharmaceutical have improved consistently over the period 1998-2008.

Table 4.8: Sales and Profitability Ratio of Sun Pharma

Year	Sales (Rs. Millions)	Profitability ratio
1998	2343	23.93
1999	3229	18.32
2000	4405	19.09
2001	6133	22.02
2002	7891	21.29
2003	8928	27.91
2004	9837	32.15
2005	11856	33.42
2006	16365	35.09
2007	21365	36.70
2008	33578	44.30
Growth Rates*	**2.79**	

Source: Annual reports * self calculated

iv) Wockhardt Limited (WL)

Wockhardt is one of the top global pharmaceutical and biotechnology companies. It has its headquarter in India and three subsidiaries in UK, US and Ireland. Wockhardt has six dedicated manufacturing plants built in accordance with international standards. It has a competent, multi-disciplinary research team of over 450 skilled scientists. It owns 6 breakthrough biotechnology products and more than 250 patent filings. It has a strong presence in international pharmaceutical market. Its product portfolio comprises of biopharmaceuticals, formulations, vaccines, nutrition products, and active pharmaceuticals ingredients (API). It possesses 11 manufacturing plants in 3 countries viz. India, Ireland and UK. The four successful acquisitions done by Wockhardt in the European market have strengthened the global position of the company. Wockhardt is amongst the top five global companies to have received 23 abbreviated new drug application (ANDAs) approvals from the United States Food And Drug Administration (USFDA) in 2008. As of March 31,2008, the company has got approval for 38+ products abbreviated new drug application(ANDAs) from the United States Food And Drug Administration (USFDA). Table 4.9 shows that sales of

Wockhardt have increased at a growth rate of 2.39 per annum, while profitability ratio has been highest in 2007.

Table 4.9: Sales and Profitability Ratio of Wockhardt

Year	Sales (Rs. Millions)	Profitability ratio
1998	2762	18.83
1999	3289	14.02
2000	3575	13.17
2001	6494	15.72
2002	6786	16.08
2003	10237	10.85
2004	13427	8.35
2005	15613	13.52
2006	17208	17.56
2007	17293	22.33
2008	26507	5.25
Growth Rate*	**2.39**	

Source: Annual reports * self calculated

v) Cadilla Healthcare Limited (CHL)

Cadilla, incorporated in 1995, is part of the Zydus Cadila Group. The company operates in both the areas of active pharmaceutical ingredients (APIs) and formulations. The company's headquarter is located at Ahmedabad. Cadilla operates eight manufacturing facilities out of which four formulation plants are located at Ahmedabad, Goa, Baddi and Sikkim; two APIs plants at Ankleshwar and Dabhasa; one Agiolax plant in Goa and an API plant in Mumbai to manufacture key intermediates of Pantoprazole.

The Zydus Cadila group operates in four continents spread across USA, Europe, Japan, Brazil, South Africa and 25 other emerging markets. The company is one of the leading player that caters to various therapeutic areas such as cardiovascular, gastrointestinal, respiratory, pain management, anti-infectives, oncology, neurosciences, dermatology and nephrology segments. The company has received approvals from the United States Food and Drug Administration (USFDA) to market three products in quick succession namely, lamotrigine chewable tablets of 2 mg, 5

mg and 25 mg, lamotrigine tablets of 25 mg, 50 mg and 150 mg and divalproex sprinkle capsules 125 mg. The company will market all the three drugs through its US subsidiary Zydus Pharmaceuticals (USA) Inc. Cadilla has built up a robust generic pipeline for the US market. In 2008-09, the company has filed 19 ANDAs with the USFDA, taking the total to 92 ANDA filings. It has also filed 14 US DMFs with the USFDA, increasing the cumulative filings to 76 DMFs. At the same time, it has received 10 ANDA approvals from the USFDA, taking the total to 42. During the year 2008-09, company has filed over 100 patents in the US, Europe and other countries, taking the cumulative filings to over 450. The company currently ranks 5th in the Indian pharmaceuticals market with a market share of 3.6 percent. Table 4.10 highlights the sales and profitability ratio of Cadilla.

Table 4.10: Sales and Profitability Ratio of Cadilla

Year	Sales (Rs. Millions)	Profitability ratio
1998	2863	11.89
1999	3455	12.75
2000	4572	10.28
2001	4527	13.72
2002	5284	12.69
2003	9358	9.30
2004	10913	13.11
2005	10903	12.11
2006	12764	12.93
2007	14507	14.14
2008	16813	14.04
Growth Rate*	**2.21**	

Source: Annual reports * self calculated

vi) Glenmark Pharmaceuticals Limited

Glenmark was founded in 1977 with a capital of Rs. 1 million and a staff of just three. In 1979, Glenmark launched its first product, Candid Cream (Clotrimazole), in topical antifungal dermatology segment. The company has its headquarters in Mumbai and enjoys global presence in regulated international markets as well. The company is into the business of manufacturing and marketing of formulation products

and active pharmaceutical ingredients (APIs). It supplies APIs to about 45 markets and formulations to about 70 markets worldwide. It has formulations manufacturing plants in Goa, Nasik, Baddi and Sao Paolo (Brazil) and API manufacturing plants in Kukumbh, Solapur and Ankleshwar. Glenmark's R&D centre in Mumbai has intellectual property of over 350 scientists. The R&D team of Glenmark has developed a novel drug lead for asthma in a short span of three years. Glenmark's focus on strategic planning and development has generated a robust pipeline in varying stages of maturity. In 2007–08 alone, Glenmark filed 23 abbreviated new drug application (ANDAs) with the USFDA of which seven were paragradh IV filings. As of 31March 2008,the company has filed 51 cumulative ANDAs and it has got approval for 38 products so far. Regarding APIs, till date the company has filed over 30 US drug master files (DMFs). Till 2008, the company has made cumulative filings of 37+ Global DMFs, with 30 in the US.

Table 4.11: Sales and Pofitability Ratio of Glenmark

Year	Sales (Rs. Millions)	Profitability ratio
1998	803	13.75
1999	1002	13.00
2000	1386	15.94
2001	2003	11.50
2002	2869	8.04
2003	3715	8.89
2004	3814	11.02
2005	6123	17.48
2006	7582	11.61
2007	12536	24.74
2008	20095	31.46
Growth Rate*	**3.18**	

Source: Annual reports * self calculated

Table 4.11 depicts the sales and profitability ratio of Glenmark. The company's sales have grown at an annual growth rate of 3.18 percent per annum. Profitability ratio of the company has been highest for 2008.

vii) Torrent Pharmaceuticals Limited (TPL)

Torrent was started in 1959 as Trinity laboratories. The company changed its name to present one in 1971. Torrent is flagship company of the Torrent group, a leader in cardiovascular and central nervous system segments. It also has presence in gastro-intestinal, diabetology, anti-infective and pain management segments. Its manufacturing facilities are located at Indrad (Gujarat) and Baddi (Himachal Pradesh). These units have received various certifications for its quality management such as ISO 9001, ISO 14001 and OHSAS 18001 and ISO/IEC- 17025. Torrent bagged the Gold Trophy at IDMA quality excellence award 2003 for both formulations and API manufacturing facilities. The company bagged the 'Best Suppliers' award by the Sri Lankan state pharmaceutical corporation. The company's R&D Centre is engaged in the discovery of new chemical entities (NCEs) and is also developing new processes and suitable formulations for known active pharmaceutical ingredients. Till 2009, the company has filed 32 ANDAs and 15 DMFs in US. 733 patents have been filed for NDDS technology, drug discovery projects and innovative process of API and formulations for various markets and 204 patents have been granted so far. Table 4.12 depicts the sales and profitability ratio of Torrent. Sales have grown at an annual growth rate of 3.31 percent per annum. The profitability ratio has been highest in 2008.

Table 4.12: Sales and Profitability Ratio of Torrent

Year	Sales (Rs. Millions)	Profitability ratio
1998	3475	9.21
1999	3003	11.33
2000	4135	11.14
2001	4006	10.25
2002	3958	12.66
2003	3868	13.47
2004	4306	14.88
2005	4725	11.23
2006	6776	9.75
2007	8824	12.81
2008	9695	16.10
Growth Rate*	**3.31**	

Source: Annual reports * self calculated

viii) Cipla

Cipla is 2nd largest pharmaceutical company in India in terms of retail sales. It has presence in over 170 countries across the world. Its product range includes pharmaceuticals, animal health care products, bulk drugs, flavours and fragrances, and agrochemicals. Cipla was registered as a public limited company on August 17, 1935. It's first product was launched into the market in 1937. In 1952, the company set up its first research division for attaining self-sufficiency in technological development. In 1960, it started operations at second plant at Vikhroli, Mumbai.

In 1968, Cipla manufactured ampicillin for the first time in India. In 1976, it launched medicinal aerosols for asthma. In 1982, Cipla's fourth factory became operational at Patalganga, Maharashtra. In 1984, the company developed anti-cancer drugs, vinblastine and vincristine in collaboration with the national chemical laboratory, Pune. In 1991, Cipla pioneered the manufacture of the antiretroviral drug, zidovudine. In 1994, Cipla's fifth factory began commercial production at Kurkumbh, Maharashtra. In 1997, it launched transparent rotahaler, the world's first such dry powder inhaler device. In 2000, Cipla became the first company, outside the USA and Europe to launch CFC-free inhalers. In 2002, the company set up four state-of-the-art manufacturing facilities set up in Goa. In 2003, it launched TIOVA (Tiotropium bromide), a novel inhaled, long-acting anticholinergic bronchodilator. In 2005, Cipla set up a state-of-the-art facility for manufacture of formulations at Baddi, Himachal Pradesh. Cipla manufactures anabolic steroids, analgesics/antipyretics, antacids, anthelmintics, anti-arthritis, anti-inflammatory drugs, anti-TB drugs, antiallergic drugs, anticancer drugs, antifungal, antimalarials, antispasmodics, antiulcerants, immunosuppressants etc. The company’s sales and profitability ratios have been depicted in Table 4.13. The results highlight that the company’s sales have grown at a rate of 2.25 percent per annum. Profitability ratio for the firm has been highest for the year 2006.

Table 4.13: Sales and Profitability Ratio of Cipla

Year	Sales (Rs. Millions)	Profitability ratio
1998	5144	19.83
1999	6171	18.64
2000	7593	17.52
2001	9674	18.51
2002	14376	16.35
2003	18421	13.46
2004	20903	14.69
2005	24825	16.52
2006	28910	21.03
2007	34389	19.43
2008	39984	17.56
Growth Rate*	**2.25**	

Source: Annual reports * self calculated

ix) Aurobindo Pharma

Aurobindo was founded on 26th December 1986. The company has its headquarters in Hyderabad. Aurobindo started its operations as a private company with a single manufacturing unit of semi-synthetic penicillins (SSPs) in 1988-89. Aurobindo is into the business of producing and marketing active pharmaceutical ingredients (Bulk actives), intermediates and specialty generic formulations. It is among the largest manufacturers of ampicillin and cloxacillin in India. To become a vertically integrated pharmaceutical company, it has made huge investments in APIs and formulations infrastructure. To expand its international franchise, Aurobindo has established joint venture/subsidiaries in USA, Brazil and China. In 2005, Aurobindo had received USFDA clearance for its AIDS drug. With the manufacturing and marketing of over 100 active pharmaceutical ingredients (APIs), Aurobindo is one of the largest asian API manufacturers. The R&D centre of Aurobindo is located on the outskirts of Hyderabad. Its R&D centre is focused on the areas of analytical research, pharmacology, dosage form development, bio-equivalence studies, organic synthesis and drug delivery systems. Aurobindo filed highest number of ANDAs from India in 2007-08. In the same year it also filed highest number of DMFs from India. By 2008, a total of 128 ANDAs have been filed and 67 have been approved with the USFDA.

By the same year, the company has 122 filings for US DMF and 1017 Global DMF Filings. A total of 318 patents have been have been filed till 2008.

Table 4.14: Sales and Profitability Ratio of Aurobindo

Year	Sales (Rs. Millions)	Profitability ratio
1998	2951	8.14
1999	5503	9.09
2000	7467	10.05
2001	9967	6.83
2002	10368	6.66
2003	11906	8.66
2004	13413	9.47
2005	11594	3.11
2006	14727	4.76
2007	22505	10.18
2008	24354	11.95
Growth Rate*	**1.94**	

Source: Annual reports * self calculated

4.2.2 Patenting Activity of the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period

Table 4.15: Worldwide Patent Filing by the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period

Year	Ranbaxy	Cipla	DRL	Cadilla	Wockhardt	Sun pharma	Aurobindo
1999	14	0	3	1	2	1	0
2000	31	5	5	2	0	0	0
2001	53	15	5	3	3	2	0
2002	69	13	25	9	14	0	5
2003	127	21	69	14	14	2	6
2004	208	28	77	19	18	8	9
2005	259	56	49	29	25	4	2

Source: EPO

The Table 4.15 shows that patenting activities of the leading pharmaceutical companies have improved consistently. The best among the performers is the top spender on R&D, viz. Ranbaxy. Global patent filings of the company have increased from a mere 14 during 1999 to more than 250 during 2005. Besides Ranbaxy, Cipla and DRL have also contributed to the increase in the patent applications filed by the leading Indian companies.

Table 4.16: Patents Granted to the Selected Leading Pharmaceutical Companies by USPTO in the Post-TRIPS Period

Firms	Ranbaxy	DRL	Torrent	Aurobindo	Workhardt	Sun pharma
Pre 1995	7	-	-	-	-	-
1995	1	-	-	-	-	-
1996	1	-	-	-	-	-
1997	2	-	-	-	-	-
1998	5	-	-	-	-	-
1999	4	-	-	-	-	-
2000	4	-	1	-	-	-
2001	8	-	3	-	-	-
2002	7	-	1	2	-	2
2003	8	7	3	-	3	2
2004	11	3	-	3	2	-
2005	7	5	-	1	2	1
2006	12	7	1	3	4	4
Total	77	22	9	9	11	9

Source: USPTO

Not only the patent filing has improved, but patents granted to leading pharmaceutical companies have also improved in the post TRIPS period. Table 4.16 shows that prior to 1995, except Ranbaxy, the majority of Indian pharma companies did not have US patents. However in the post-TRIPS period, more firms like DRL, Torrent, Aurobindo, Wockhardt and Sun have also marked their presence in patents granted. The majority of the pharma companies got patents after 2000. This may be attributed to the fact that the process of acquiring patents takes a few years. One of the plausible reasons could be filing of patents immediately after India adhered to the TRIPS agreement

4.2.2.1 ANDA Filings by the Selected Leading Pharmaceutical Companies

Patent applications filed in the U.S. are an important index of domestic inventive activity and Indian firms are spending huge resources to secure non-infringing process patents in foreign countries. After tapping the developing countries, they are now trying to access developed countries with drug master filings (DMFs) for bulk actives supply and abbreviated new drug applications (ANDAs) for formulations. In order to make an early entry into the U.S. market for a drug going off-patent, Indian firms have been filing ANDAs under Paragraph II and Paragraph III. (Chadha, 2006). Until recently only a few Indian companies, particularly Ranbaxy and DRL had ANDAs with USFDA in their own names. The situation has dramatically changed in the last few years. Now, besides the above mentioned firms, other firms like Cipla and Sun pharma, Cadilla, Aurobindo and Glenmark have also been coming forward for ANDA filings. All these firms have created a pipeline of ANDA filings to maintain their hold in the U.S. market.

Table 4.17: Cumulative ANDA Filings* by the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period

Company	**2004**	2005	2006	2007	2008	2009
Ranbaxy	150	183	197	239**	240**	241
DRL	52	65	77	117	122	144
Sun Pharma	11	33	62	107	142	179
Wockhardt	7	13	39	47	57	67
Cadilla	12	25	36	62	81	92
Glenmark	--	7	18	28	51	71
Torrent	--	1	4	6	11	32
Aurobindo	2	24	51	100#	128	147

Source: Annual Reports, *as on 31st March **as on 31st Dec. # as on 31st July

Table 4.17 shows the cumulative ANDA filings by the the the selected leading pharmaceutical companies from 2004 to 2009. The results show that Ranbaxy is leading in ANDA filings followed by Sun Pharma, Aurobindo. DRL and other firms. It is pertinent to mention here that although Cipla has also been filing ANDAs continuously as is clear from the available literature, the researcher could not get reliable data for year wise ANDA filings of Cipla. Hence the same has not been reported here.

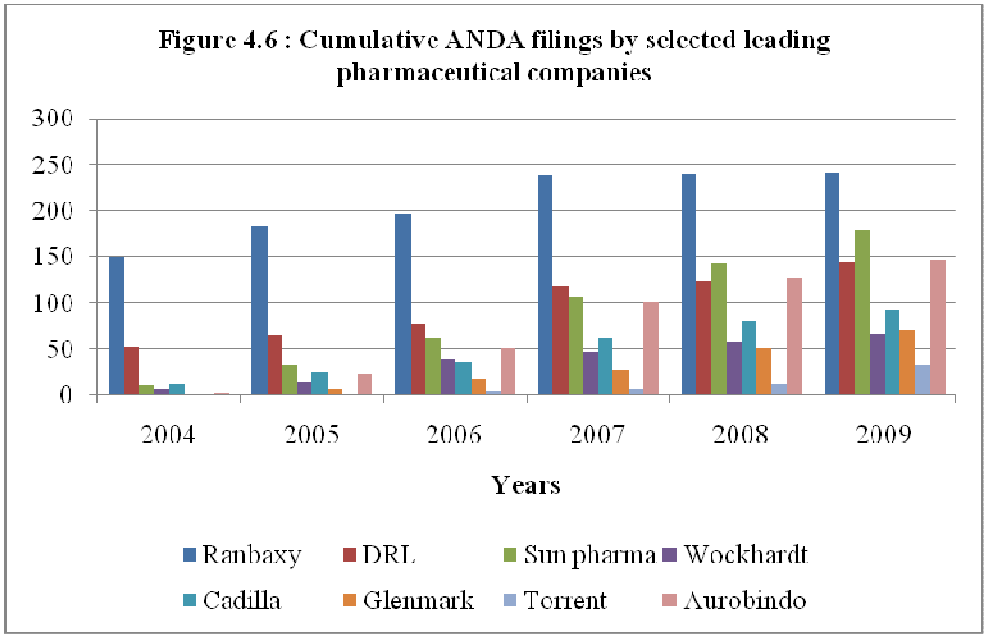


Figure 4.5 also shows that the cumulative ANDA filings by these companies have been increasing.

4.2.2.2 ANDA approvals by the Selected Leading Pharmaceutical Companies

Research-based Indian pharmaceutical companies and their subsidiaries are increasingly cornering a large percentage of approvals for ANDAs from the US FDA during the last five years. The Indian companies have invested huge funds in R&D and up-gradation of facilities as per US FDA norms during the last couple of years and now are getting returns in the form of higher approvals for their products.

Table 4. 18: ANDA Filings and Approvals by the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period

Company	ANDA filings*	ANDA approvals*
Ranbaxy	240	142
DRL	122	70
Sun Pharma#	142	53
Wockhardt	57	23
Cadilla	81	34
Glenmark	51	40
Torrent	11	4
Aurobindo	128	67

Source : Annual Reports, #Sun Pharma includes its subsidiary Caraco
* as on 31-3-08

Table 4.18 shows that in 2008, Ranbaxy had the largest basket of products in the US market with 142 approved drugs. DRL has 122 cumulative ANDAs filed till 2008. 2007-08 also saw the highest number of approvals for the company's ANDA filings which includes 13 final approvals from the US. With this total ANDA approvals of the company had reached to 70. In 2007-08, the first technology based ANDA has been filed by Sun Pharma. Till 2008 Sun Pharma, and its subsidiary Caraco had filed 142 ANDAs, whereas ANDAs for 53 products have now been approved.

Wockhardt is amongst the top five global companies to have received 23 abbreviated new drug application (ANDAs) approvals from the United States Food and Drug Administration (USFDA) in 2008. By 2008, the company had filed 57 ANDA filings. Cadilla has built up a robust generic pipeline for the US market. Till 2008, out of 81 cumulative ANDA filed, Cadilla has 34 product approvals and 15 of them have been launched in the market. The company filed around 18 ANDAs and received approval for 12 ANDAs in 2008 only. Glenmark's focus on strategic planning and development has generated a robust pipeline in varying stages of maturity. In 2007-08 alone, Glenmark had filed 23 abbreviated new drug applications (ANDAs) with the USFDA. Till 2008, the company has filed 51 cumulative ANDAs and got approval for 38 products. Torrent has filed 11 ANDAs in US till March 2008. Cipla has filed

57 ANDAs till 2008. Aurobindo filed the highest number of ANDAs from India in 2007-08. The company filed 128 ANDAs and 67 have been approved with the USFDA. In 2007-08, 46 ANDAs were filed and ANDAs for 17 products were approved for the US.

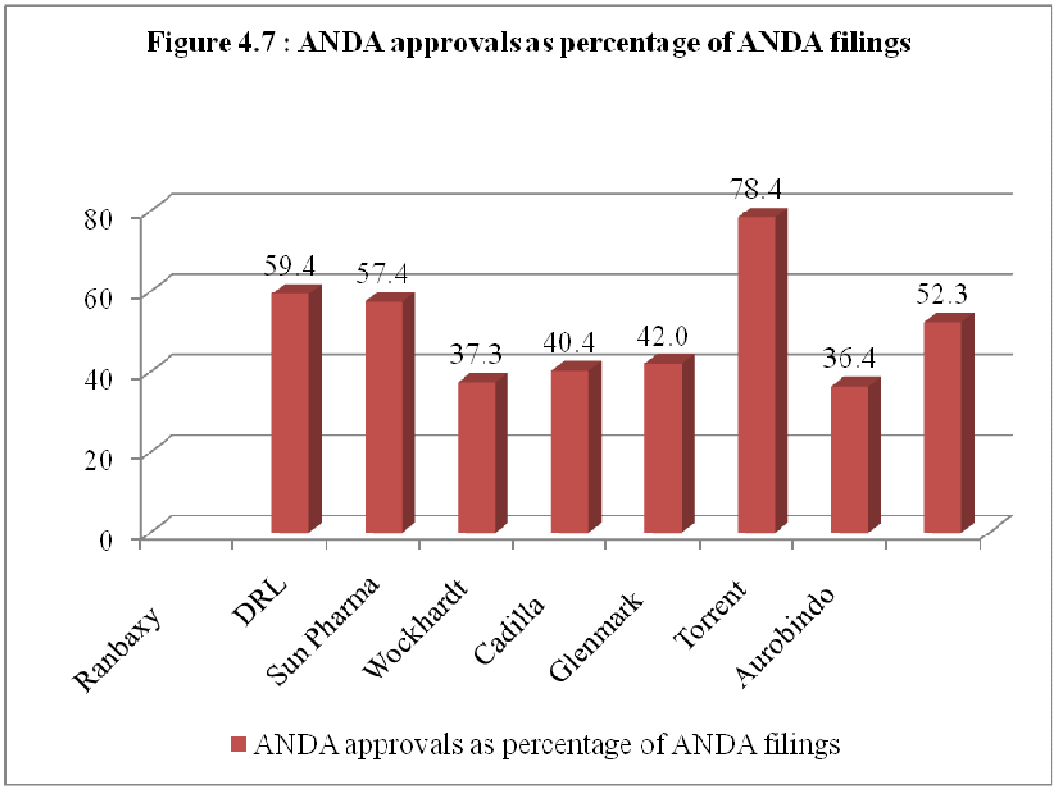


Figure 4.6 shows that these leading companies have been getting a good percentage of their ANDA filings approved. Another thing worth mentioning is that most of these companies have been getting more than 35 percent of their ANDA filings approved.

4.2.2.3 DMF Filings by the Selected Leading Pharmaceutical Companies

India is on its way to become a global leader in API production. The Indian API manufacturing industry is projected to make sales of USD 4.8 billion by 2010, exhibiting an average yearly growth rate of over 19 percent.(Annual Report Sun Pharma, 2009). Though there was a global slowdown in the API market in 2008 due to the recession, long term prospects continue to be promising (Annual Report Sun

Pharma, 2009). The current DMF filing scenario of the the the selected leading pharmaceutical companies has been presented in Table 4.19.

Table: 4.19: Cumulative DMF filings* with USFDA by the Selected Leading Pharmaceutical Companies

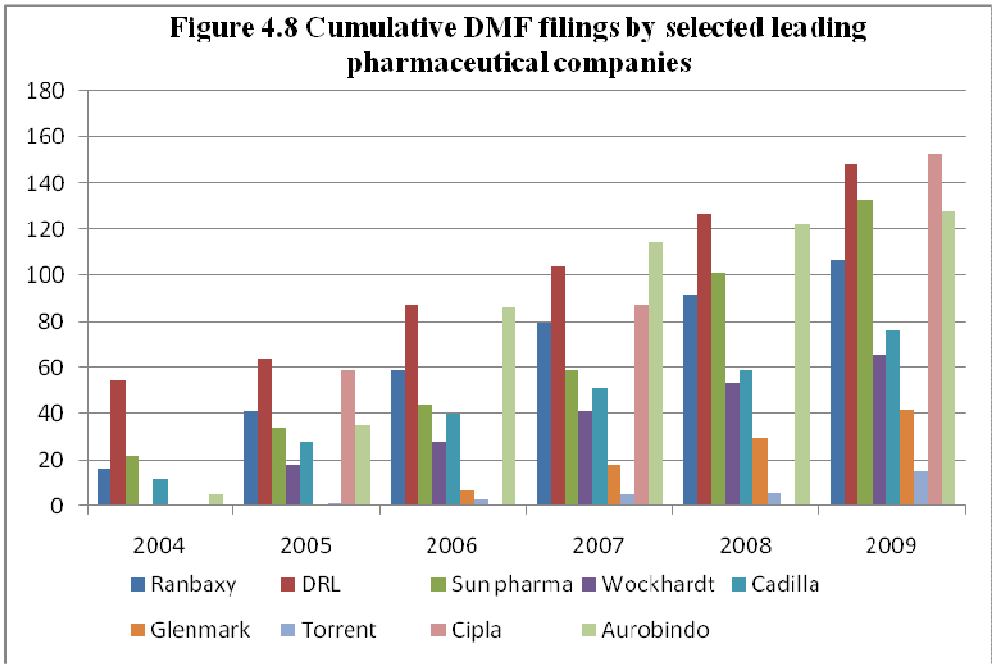
Company	DMF Filings					
	2004	2005	2006	2007	2008	2009
Ranbaxy	16	41	59	80	92	107
DRL	55	64	87	104	127	148
Sun Pharma	22	34	44	59	101#	133#
Wockhardt	--	18	28	41	53	66
Cadilla	12	28	40	51	59	76
Glenmark	--	--	7	18	30	42
Torrent	--	1	3	5	6	15
Cipla	--	59	--	87	--	153
Aurobindo	5	35	86	114**	122	128

Source: Annual Reports, * as on 31st March **as on 31st July
#DMF+CEP applications

Table 4.19 shows that Ranbaxy, a leading pharmaceutical company of India, continued with its focus on developing innovative, environment friendly and cost-effective technologies for high-value APIs. The company has filed 107 drug master files in U.S. till 2009.

DRL has the largest API pipelines in the Indian pharma industry and has filed 21 DMFs with the USFDA in 2008-09 only. This took the total number of DMFs on file with the USFDA to 148 in 2009.

Sun Pharma has filed 133 DMF/ CEP till 2009. Wockhardt has filed 66 DMFs till March 2009.Cadilla has filed 14 US DMFs with the USFDA, taking the cumulative filings to 76 DMFs till March 2009.



Regarding APIs, till March 2008, Glenmark has filed over 30 US DMFs. By 2008, the Company has made cumulative filings of 37+ Global DMFs, with 30 in the US. In 2008–09, 12 USDMFs have been filed taking the cumulative filing with US to 42. The company is actively increasing its research capacities. Torrent has filed 6 DMFs in US till 2008. Cipla has filed 153 DMFs with USFDA by 2009. In the DMF filings also, Aurobindo showed strong performance and has filed the highest number of DMFs from India in 2007-08. Till 2008, the company has 122 filings for US DMF and 1017 Global DMF Filings.

The above results clearly highlight that the Indian companies are investing funds on filing DMFs and the trend depicts an increase in DMF filings in the post-TRIPS period.

4.2.3 R&D of the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period

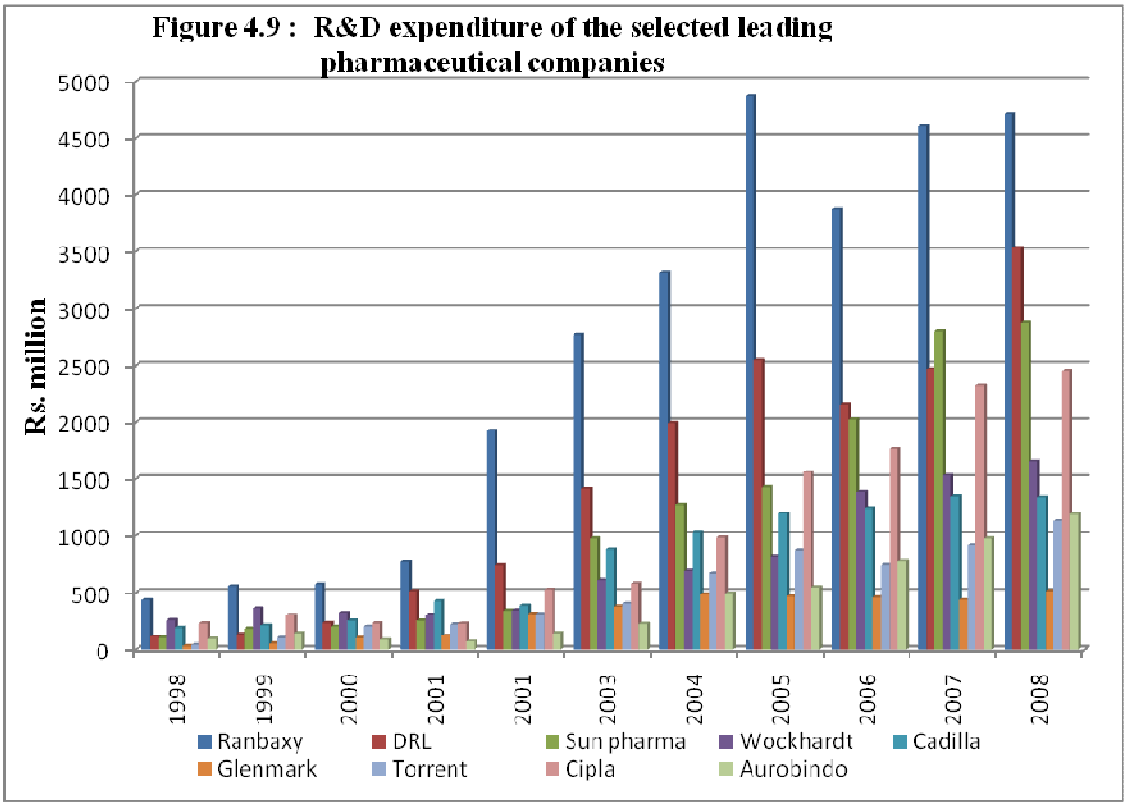
Changes in patent laws under the TRIPS obligations, preventing the reverse engineering of patented molecules, have forced Indian firms to enhance their R&D efforts and investments. Table 4.20 shows that the large Indian pharmaceutical

companies such as Ranbaxy, Cipla and DRL have increased their R&D spending significantly over the years. While R&D expenditure of Ranbaxy increased from Rs. 434 millions in 1998 to Rs. 4711 millions in 2008, for DRL it increased from Rs 113 millions to Rs. 3531 millions for the same period. Similarly all the firms showed a rapid and consistent increase in R&D expenditure over the same period. The present research shows that in terms of growth rates, the highest growth in R&D expenditure has been recorded by Aurobindo (3.03 percent), followed by Cipla (2.86 percent) and Workhardt (2.85 percent)

Table: 4.20: R&D Expenditure of the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period (Rs. Millions)

Year	Ranbaxy	DRL	Sun pharma	Workhardt	Cadilla	Glenmark	Torrent	Cipla	Aurobindo
1998	434	113	103	256	192	31	42	231	92
1999	554	133	184	362	213	52	101	302	144
2000	572	232	201	323	253	102	202	231	86
2001	772	514	253	304	424	123	221	227	69
2001	1924	741	342	345	385	314	312	526	143
2003	2766	1418	974	606	883	376	404	578	226
2004	3311	1992	1272	693	1034	487	673	984	495
2005	4869	2545	1431	811	1192	467	874	1557	545
2006	3867	2156	2022	1387	1243	456	745	1766	776
2007	4602	2469	2794	1528	1343	435	916	2324	975
2008	4711	3531	2876	1652	1336	513	1132	2445	1186
Growth Rates*	**2.23**	**2.35**	**2.69**	**2.85**	**2.20**	**1.82**	**2.13**	**2.86**	**3.03**

Source: Annual Reports * self calculated



Along with expenditure on R&D, R&D intensity of these companies has been calculated. The results of the same suggest that there has been an increase in R&D intensity of these companies since 1998. This is an indication that the leading companies in the Pharmaceutical Industry of India have been allocating increasing amounts of their sales turnover towards R&D spending.

Table 4.21: R&D Intensity* of the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period

Year	Ranbaxy	DRL	Sun pharma	Workhardt	Cadilla	Glenmark	Torrent	Cipla	Aurobindo
1998	3.22	3.31	4.27	9.27	6.71	3.88	1.21	4.47	3.12
1999	3.53	3.22	5.59	11.05	6.17	5.20	3.33	4.86	2.62
2000	3.28	4.78	4.55	8.96	5.47	7.39	4.84	3.03	1.07
2001	3.75	4.64	4.08	4.62	9.29	6.00	5.50	2.28	0.60
2002	6.81	4.51	4.31	5.01	7.20	10.84	7.85	3.62	1.35
2003	7.81	7.80	10.87	5.87	9.41	9.97	10.36	3.09	1.85
2004	9.16	9.91	12.92	5.16	9.44	12.78	15.65	4.71	3.65
2005	13.74	13.28	12.07	5.20	10.92	7.63	18.52	6.24	4.66
2006	9.51	8.93	12.35	8.02	9.72	5.94	10.93	6.09	5.23
2007	10.99	3.83	13.06	8.79	9.24	3.43	10.32	6.75	4.31
2008	10.56	7.17	8.55	6.23	7.91	2.54	11.66	6.10	4.85

Source: Annual Reports * R&D as percentage of gross sales

Table 4.21 shows that R&D intensity of some of the leading pharmaceutical companies**.** Most of the sample pharmaceutical companies showed the most impressive increase in their R&D intensities.

4.2.4 Exports of the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period

After analysing the trends in patent filings and R&D scenario, the export perspectives of these pharmaceutical companies have also been observed. The rising exports of Indian pharmaceutical manufacturers are an indicator of local technological capability, particularly in process innovations. With their cost-effective process innovations and reverse engineering of brand-name drugs, Indian companies have emerged as competitive suppliers in the world for a large number of generic drugs. The export focus of Indian companies, propelled by the recognition of process patents in different countries, has made them penetrate a number of countries based on their low-cost structure.

Table 4.22: Exports of the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period (Rs. Millions)

Company	Ranbaxy	DRL	Sun pharma	Workhardt	Cadilla	Glenmark	Torrent	Cipla	Aurobindo
1998	5961	--	--	--		--	--	737	945
1999	7323	--	890	--	317	86	--	1195	2165
2000	8025	--	1146	--	386	124	110	1436	3676
2001	10293	4302	1186	1716	714	185	292	2586	5454
2002	18507	9254	1368	2415	975	236	373	4948	4872
2003	24686	9197	2604	--	1168	498	442	5669	5635
2004	24564	9821	3867	--	1882	894	517	8123	6429
2005	23379	9148	5034	--	2355	1298	858	10506	5556
2006	27183	11975	6963	3627	3713	1413	1606	15149	8165
2007	26419	28486	9692	3639	6057	3043	2025	17683	11487
2008	28116	22604	18967	--	8751	6787	2409	21507	14015
Growth Rates*	**1.84**	**2.13**	**3.06**	**n.a.**	**2.88**	**3.32**	**2.19**	**2.59**	**2.04**

Source : Annual Reports * self calculated n.a. not available

Table 4.22 depicts the year-wise exports of the selected leading pharmaceutical companies for the period 1998-2008. The results show that there has been a drastic increase in exports of these leading pharmaceutical companies in the post-TRIPS period. Inter company comparison highlights that the highest growth has been recorded by Sun pharma followed by Cadilla. In terms of volume of export growth, Ranbaxy and DRL are dominating the scene.

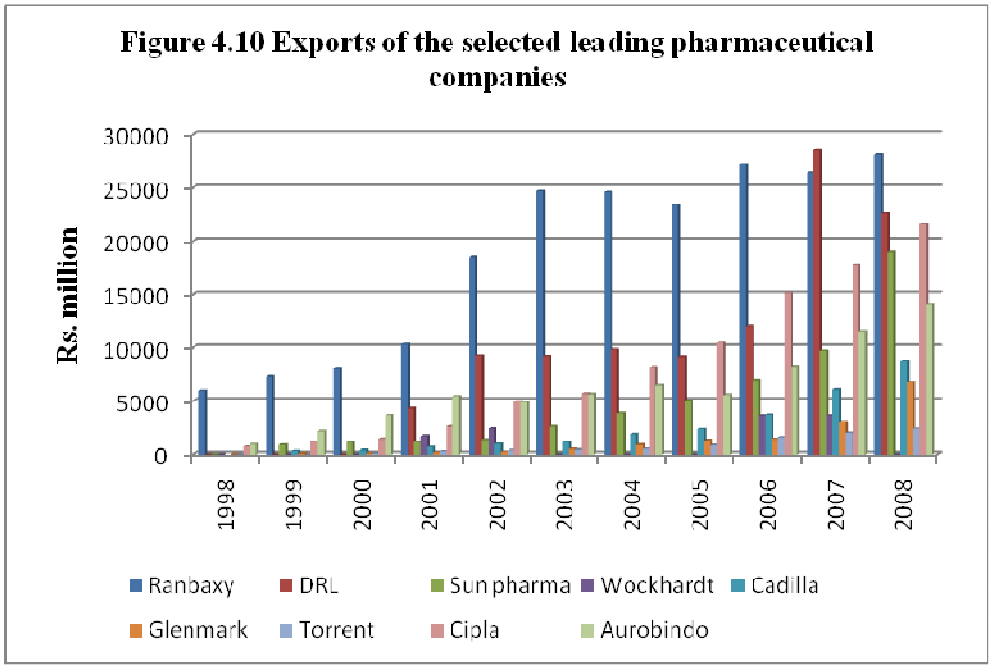


Figure 4.10 shows that exports of these companies have been increasing for the period 1998-2008.

Table 4.23: Export Intensity of the Selected Leading Pharmaceutical Companies in the Post-TRIPS Period

Year	**Ranbaxy**	**DRL**	**Sun Pharma**	**Worhhardt**	**Cadilla**	**Glenmark**	**Torrent**	**Cipla**	**Aurobindo**
1998	44.68	--	--	--	0.00	--	--	14.19	31.86
1999	46.92	--	27.64	--	8.99	8.40	--	19.28	39.27
2000	46.17	--	25.91	--	8.32	8.77	2.66	18.83	49.20
2001	50.07	39.16	19.25	26.35	15.71	9.25	7.25	26.68	54.72
2002	65.60	56.37	17.24	35.55	18.37	7.87	9.37	34.38	47.01
2003	69.84	50.86	29.15	--	12.41	13.42	11.40	30.73	47.31
2004	67.94	48.90	39.27	--	17.23	23.46	12.02	38.85	47.87
2005	66.07	47.78	42.45	--	21.56	21.08	18.18	42.30	47.89
2006	66.96	49.71	42.54	21.05	29.08	18.60	23.63	52.37	55.43
2007	63.11	44.37	45.37	20.99	41.72	24.26	22.90	51.43	51.02
2008	63.01	45.91	56.48	--	52.06	33.75	24.77	53.78	57.54

Source: Annual Reports

Table 4.23 shows that for the four companies of this segment, viz., Ranbaxy, DRL, Cipla and Aurobindo, have been exporting more than one-half of their sales turnover. The share of Sun pharma and Cadilla has also been more than fifty percent in 2008. It appears that, for these companies, foreign markets are equally important as their domestic market and this gave them the impetus to improve their operating efficiencies.

4.2.5 Results of the Analysis of the Selected Leading Pharmaceutical Companies

The above analysis highlights that patenting activities of these leading pharmaceutical companies have improved consistently. Not only the patent filing has increased, the patents granted have also increased in the post-TRIPS period. In the case of ANDA filings with USFDA, the situation has dramatically changed in the last few years. Now, besides Ranbaxy and DRL, other firms like Cipla, Sun Pharma, Cadilla, Aurobindo and Glenmark have also been coming forward with more ANDA filings. Along with ANDAs filings, ANDA approvals have also been increasing continuously. The post-TRIPS period is also indicating enhanced DMF filings by these selected leading pharmaceutical companies of India.

The results of the study highlight that the large Indian pharmaceutical companies such as Ranbaxy, Cipla, DRL have increased their R&D spending significantly over the years. Inter company comparisons indicate that the highest growth for R&D expenditure has been recorded by Aurobindo (3.03 percent), followed by Cipla (2.86 percent) and Workhardt (2.85 percent)

Along with the increase in R&D expenditure, the R&D intensity of the selected leading pharmaceutical companies indicates that the big companies have been allocating an increasing amount of their sales turnover towards R&D spending. Along with enhanced patent filing and increased R&D expenditure and R&D intensity, the results also indicate an improvement in exports and export intensity by the selected leading pharmaceutical companies in the post-TRIPS period.

4.3 Firm Level Analysis

The results of the above analysis highlight that R&D, patents and exports of the Pharmaceutical Industry have increased in the post-TRIPS period. Similar results emerge from the analysis of the selected leading pharmaceutical companies of India.

The results clearly indicate an increase in patents, R&D expenditure and exports in the post-TRIPS period. Similar analysis on the same parameters has been performed for a sample of one hundred firms chosen from north west region of India. The results of size-wise and age-wise analysis of the survey are depicted below.

4.3.1 Patenting Activity of the Sample Firms in the Post-TRIPS Period

Patenting activity of the Pharmaceutical Industry as well as of the leading pharmaceutical companies has improved considerably in post-TRIPS period. Not only the patent filings have increased, but patents granted have also increased in the post-TRIPS period as has been shown by the results of this study. However on this front, small scale firms lagged behind their medium and large scale counterparts. (Table 4.24)

Table 4.24: Firm Size and Filing of Patents in the Last Three Years

Firm size	Did you file any patents in the last three years?		
	Yes	No	Total
Large	8 100.0%	---	8 100.0%
Medium	4 16.7%	20 83.3%	24 100.0%
Small	---	68 100.0%	68 100.0%
Total	12 12.0%	88 88.0%	100 100.0%

The results of the size-wise analysis show that small scale firms have not filed any patents in the last three years, i.e., after the implementation of Product Patent Act 2005. Patents have only been filed by large and medium firms. The above results are indicative of the fact that patent filing is mostly a privilege of the large pharmaceutical firms only. 16.7 percent of medium scale firms and all the large scale firms have filed patents in the last three years.

Table 4.25: Firm Age and Filing of Patents in the Last Three Years

Age of the Firm	Did you file any patents in the last three years?		
	Yes	No	Total
Old	5 62.5%	3 37.5%	8 100.0%
Medium	3 9.4%	29 90.6%	32 100.0%
New	4 6.7%	56 93.3%	60 100.0%
Total	12 12.0%	88 88.0%	100 100.0%

The age-wise analysis shows that 62.5 percent of old firms had filed patents in the last three years. This percentage was only 9.4 for medium firms and 6.7 for the new firms.

In terms of patent filings, the sample firms from north west region do not depict a very healthy picture as patent filing has been reported by large and older firms. The cost of patenting could be one of the reasons for this.

4.3.2 R&D Perspective of the Sample Firms in the Post-TRIPS Period

In the context of the new TRIPS regime, technology plays an important role in the survival and growth of the pharmaceutical firms. Even the small firms are urgently required to up-grade their internal sources of technology like expanding the in-house R&D activities, employing more skilled labour, providing training to their technical manpower, etc. As far as R&D intensity is concerned, small pharmaceutical firms considerably lagged behind their large counterparts in undertaking innovative activities.

Table 4.26: Firm Size and In-house R&D

Firm size	In-house R&D						
	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased	Total	
Large	--	--	--	--	8 100.0%	8 100.0%	Chi-Square: 83.077*** df: 6 p < .001
Medium	---	--	--	20 83.3%	4 16.7%	24 100.0%	
Small	---	8 11.8%	24 35.3%	36 52.9%	--	68 100.0%	
Total	---	8 8.0%	24 24.0%	56 56.0%	12 12.0%	100 100.0%	

*** Significance level .1percent

H_i: There is a relationship between firm size and impact on in-house R&D as a result of signing TRIPS.

All the large scale firms agreed that in-house R&D has shown a substantial increase. 83.3 percent medium scale firms responded that in-house R&D has shown a marginal increase and 16.7 percent accepted that it has substantially increased. 24 small firms are of the view that in- house R&D has not changed, while 36 reported that it has marginally increased. The value of Chi-square is 83.077 which is significant, depicting that there is a significant relationship between firm size and in-house R&D, i.e., as the firm size increases, the in-house R&D also increases.

Table 4.27: Firm Age and In-house R&D

Age of the Firm	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased	Total	Chi-Square: 33.730*** df : 6 p < .001
Old	--	--	--	4 50.0%	4 50.0%	8 100.0%	
Medium	--	--	8 25.0%	20 62.5%	4 12.5%	32 100.0%	
New	--	8 13.4%	16 26.7%	32 53.3%	4 6.7%	60 100.0%	
Total	--	8 8.0%	24 24.0%	56 56.0%	12 12.0%	100 100.0%	

*** Significance level .1percent

H_{ii} : There is a relationship between firm age and impact on in house R&D as a result of signing TRIPS.

Regarding in-house R&D, 50 percent of the old firms accepted that it has increased only marginally. 62.5 percent of the medium firms also responded that in-house R&D has shown a marginal increase. 53.3 percent of the new firms reported that in-house R&D has increased marginally. In total, 56 percent of the total firms responded that it has marginally increased, and 12 percent responded that in-house R&D has substantially increased as a result of signing of TRIPS. The value of Chi-square is 33.730 (df: 6), which is significant. It depicts that there is a significant relationship between firm age and in- house R&D.

Both size-wise and age-wise analysis of In-house R&D depict that the majority of the firms accepted that in-house R&D has marginally increased. All the large firms and fifty percent of the older firms accepted that it has substantially increased. So with signing TRIPS, the in-house R&D of most of the firms is improving and, therefore, size and age do influence in-house R&D.

Table 4.28: Firm Size and Performance of R&D

Firm size	Performance of R&D						
	Very high	High	Moderate	Low	Very Low	Total	Chi Square: 62.307*** df: 8 p < .001
Large	4 50.0%	4 50.0%	--	---	---	8 100.0%	
Medium	4 16.7%	8 33.3%	--	12 50.0%	---	24 100.0%	
Small	4 5.9%	4 5.9%	30 44.1%	20 29.4%	10 14.7%	68 100.0%	
Total	12 12.0%	16 16.0%	30 30.0%	20 20.0%	22 22.0%	100 100.0%	

*** Significance level .1percent

H_{iii}: There is an association between firm size and performance of R&D.

Size-wise analysis depicts that the large firms rated their R&D performance as very high or high. Four medium firms rated it as very high; eight firms rated it as high. Only eight out of 68 small firms rated performance as high and very high, while thirty firms were of the view that performance was low or very low. Value of Chi square 62.307 is significant for 8 df, which again depicts that there is a strong association between firm size and performance of R&D highlighting that as the firm size increases, the performance of R&D also improves.

Table 4.29: Firm Age and Performance of R&D

Age of the Firm	Performance of R&D						
	Very high	High	Moderate	Low	Very low	Total	Chi Square: 26.433**
Old	4 50.0%	--	4 50.0%	--	--	8 100.0%	
Medium	4 12.5%	4 12.5%	4 12.5%	8 25.0%	12 37.5%	32 100.0%	df: 8
New	4 6.7%	12 20.0%	22 36.7%	12 20.0%	10 16.7%	60 100.0%	p < .01
Total	12 12.0%	16 16.0%	30 30.0%	20 20.0%	22 22.0%	100 100.0%	

** Significance level 1percent

H_{iv}: There is an association between firm age and performance of R&D.

Age-wise analysis is indicative of the fact that 50 percent of the old firms rated their R&D performance as very high, another 50 percent rated it moderate. 25 percent medium firms rated it as very high/high, while 37.5 percent firms felt that the performance was low. From new firms, only 6.7 percent firms rated it as very high, 20.0 percent firms rated it as high, 36.7 percent firms rated it as moderate, 36.7 percent firms were of the opinion that the R&D performance has been low/very low. In total 12.0 percent firms rated it as very high, 16.0 percent rated it as high, 30.0 percent rated it as moderate, 42.0 percent firms felt that the R&D performance has been low/very low. Value of Chi square is 26.433 which is significant for 8 df, which

again depicts that there is a strong association between age of the firm and performance of R&D. Overall results highlight that there is still much to be done about improving the performance of these firms on the R&D front.

Table 4.30: Firm Size and Proportion of Turnover Spent on R&D in the Last Three Years

Firm Size	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased	Total	
Large	--	--	--	--	8 100%	8 100.0%	Chi-Square :91.325***
Medium	--	--	---	20 83.3%	4 16.7%	24 100.0%	
Small	--	12 17.6%	32 47.1%	24 35.3%	--	68 100.0%	df: 6
Total	--	12 12%	32 32%	44 44%	12 12%	100 100%	p < .001

*** Significance level .1percent

H_v: There is an association between firm size and the proportion of turnover spent on R&D in the last three years.

There was an overall agreement amongst all the large scale firms that the proportion of turnover spent on R&D in the last three years has substantially increased. Out of 24 medium firms twenty are of the view that the proportion of turnover spent on R&D in the last three years has marginally increased and four firms accepted that it had substantially increased. The response was not similar for the small scale firms. There were 24 firms who accepted that it had increased marginally. Chi- square of 91.325 (df:6) depicts that the association between firm size and the proportion of turnover spent on R&D is significant.

Table 4.31: Firm Age and Proportion of Turnover Spent on R&D in the Last Three Years

Age of the Firm	Substantially Decreased	Marginally Decrease	Remained Same	Marginally Increased	Substantially Increased	Total	Chi-Square : 59.747***
Old	--	-	3 37.5%	4 50.0%	1 12.5%	8 100.0%	df: 6
Medium	--	3 9.4%	6 18.8%	21 65.6%	2 6.3%	32 100.0%	p< .001
New	--	9 15.0%	23 38.3%	19 31.7%	9 15.0%	60 100.0%	
Total	--	12 12%	32 32%	44 44%	12 12%	100 100.0%	

H_{vi}: There is an association between firm age and proportion of turnover spent on R&D in the last three years.

The age-wise analysis highlights that 5 older firms, 23 medium firms and 28 new firms accepted that the proportion of turnover spent on R&D has improved. Overall results highlight that 56 percent firms are of the view that it has improved.

Results of the R&D perspectives highlight that

i) Size-wise as well as age-wise analysis depict that there is an association between proportion of turnover spent on R&D and firm size and between proportion of turnover spent on R&D and firm age.

ii) Size-wise analysis depicts a relationship between firm size and in-house R&D. Age-wise analysis also depict a relationship between firm age and in-house R&D.

iii) In terms of performance on R&D front, the new and small firms have rated their R&D performance as low. The results of Chi-square depict an association of R&D performance with firm size and firm age.

Thus the results of the firm level analysis of the Pharmaceutical Industry in the north west region highlight that the R&D scenario is improving in the post TRIPS period and the large and older firms are spending a higher proportion of their turnover on R&D.

4.3.3 Export Perspective of the Sample Firms in the Post-TRIPS period

Exports of the pharmaceutical industry, as well as of the leading pharmaceutical companies, have improved considerably in the post-TRIPS period. Not only the exports have increased, but export intensity has also improved in the post-TRIPS period as is shown by the results of this study. However, the results of the sample firms from north west region are indicative of the fact that again on this front, small scale firms lagged behind their medium and large scale counterparts.

Table 4.32: Firm Size and Focus on Exports

Firm size	Focus on Exports		
	Yes	No	Total
Large	8 100.0%	---	8 100.0%
Medium	8 33.3%	16 66.7%	24 100.0%
Small	---	68 100%	68 100.0%
Total	16 16.0%	84 84.0%	100 100.0%

The size-wise analysis depicted in Table 4.32 highlights that all the 8 large scale firms focused on exports. 33 percent of the medium sized firms focused on export, whereas the same was not true for small scale firms.

Table 4.33: Firm Age and Focus on Exports

Age of the Firm	Focus on Exports		
	Yes	No	Total
Old	6 75.0%	2 25.0%	8 100.0%
Medium	4 12.5%	28 87.5%	32 100.0%
New	6 10.0%	54 90.0%	60 100.0%
Total	16 16.0%	84 84.0%	100 100.0%

Similar results have been observed from age-wise analysis where the older firms reported focusing on exports (Table 4.33)

4.3.4 Impact of TRIPS: Other Perspectives

Besides patents, R&D and export perspective, the other aspects covered in this research are:

i) Compliance to Schedule M
ii) Cost of production
iii) Shift to better technology
iv) Share in domestic market
v) Therapeutics of drugs in the last three years
vi) Impact of MRP based excise duty on the existing units
vii) Drugs produced by the company
viii) Category of product
ix) No of products introduced in the last one year
x) Products of the firm covered under DPCO
xi) Sales in the last three years
xii) Overall impact of TRIPS
xiii) New opportunities created due to TRIPS
xiv) Threats due to TRIPS

The reason for covering all these aspects is to get a complete overview of the implications of TRIPS on the Indian pharmaceutical industry. These all, in one way or another, have their implications on patenting, R&D and exports of the firms. Besides, this will also help in understanding the new opportunities or threats facing the pharmaceutical firms. These aspects are explained as under.

i) Compliance to Schedule M

Schedule M represents a set of regulations as per the Indian Drugs and Cosmetics Act, 1940 to ensure safety and efficacy of drug products and biologics that are manufactured in India. The revised schedule M, that came into effect from July 1, 2005, will ensure total cGMP (current good manufacturing practices) where high levels of quality control and quality assurance standards will be maintained in the manufacturing of the drugs. The Union government insisted on the compliance of drug manufacturing firms to Schedule M and made the compliance mandatory in

order to make the quality of drugs produced in India match world standards. The minimum cost of upgrading one drug manufacturing firm to comply with Schedule M requirements was estimated to be over Rs. 15 million. State FDA's had forced all units to comply with the new Schedule-M requirements.

Was Schedule M a Hasty Decision?

Schedule M was conceived on the lines of USFDA. Many experts are of the view that although schedule M was a good regulation, it was nevertheless a hasty decision on the part of the government. It does have its benefits with quality improvements and other factors but it should have been gradually phased in. It took the FDA nearly 15 years to implement the schedule in the US. This overnight implementation of Schedule M is the biggest problem faced by small scale firms in pharmaceutical industry in India. **(Cygnus, 2006)** The present study has tried to test through the response rate of the firms whether Schedule M was a hasty decision on the part of the government.

Table 4.34: Firm Size and Schedule M: W**as it a Hasty Decision?**

Firm size	Firm size and schedule M						
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total	Chi-square :11.269
Large	4 50.0%	--	4 50.0%	--	--	8 100.0%	(df: 6)
Medium	8 33.3%	4 16.7%	8 33.3%	4 16.7%	--	24 100.0%	p =.080
Small	20 29.4%	24 35.3%	12 17.6%	12 17.6%	--	68 100.0%	
Total	32 32.0%	28 28.0%	24 24.0%	16 16.0%	--	100 100.0%	

The results of the study highlight that the majority of the firms have not been against schedule M. When asked about whether schedule M has been a hasty decision on the part of the government, 50 percent of the large scale firms strongly disagree, whereas

50 percent are neutral about it. From medium sized firms, 33 percent strongly disagree, 17 percent disagree and 33 percent are neutral. Only 17 percent of the sample firms accepted that it has been a hasty decision on the part of the government. Even from small size firms only 18 percent firms accepted that it was a hasty decision on the part of the government. 29 percent strongly disagreed and 35 percent disagreed. The results of Chi-square do not depict any association between firm size and opinion on the Schedule M being a hasty decision.

Table 4.35: Firm Age and Schedule M: Was it a Hasty Decision?

Age of the Firm	Firm size and schedule M						Chi- square: 18.552**
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total	
Old	--	4 50.0%	--	4 50.0%	--	8 100.0%	(df: 6)
Medium	8 25.0%	8 25.0%	8 25.0%	8 25.0%	--	32 100.0%	p <.01
New	24 40.0%	16 26.7%	16 26.7%	4 6.7%	--	60 100.0%	
Total	32 32.0%	28 28.0%	24 24.0%	16 16.0%	--	100 100.0%	

** Significance level 1percent

The results of the age-wise analysis also highlight that the majority of the firms has not been against the implementation of Schedule M. When asked about whether Schedule M has been a hasty decision on the part of the government, 50 percent of the old firms agreed with it. From medium firms 50 percent strongly disagreed/disagreed. From new firms only 6.7 percent agreed that it was a hasty decision on the part of the government. Here the value of Chi- square is significant which depicts a significant association between firm-age and Schedule M being a hasty decision imposed by the government. This, in a way, highlights that pharmaceutical firms are preparing themselves for the change, Schedule M being one of them.

ii) Cost of Production

One of the impacts of TRIPS, as has been reflected by many studies (Pradhan, 2007), has been to find out whether the TRIPS agreement has lead to increase in cost of production. The results of size-wise analysis depict that all firms, small, medium and

large felt that cost of production as a result of signing of TRIPS has increased. All large firms, 33.3 percent of medium scale firms and 42.6 percent of small scale firms reported that it has increased substantially after the signing of TRIPS.

Table 4.36: Firm Size and Cost of Production as a Result of Signing TRIPS

Firm size	Cost of Production as a result of Signing of TRIPS					Total	Chi Sq: 49.150*** p < .001 d.f:4 F:16.093*** p < .001 d.f:2
	Substantially decreased	Marginally decreased	Remained same	Marginally increased	Substantially increased		
Large	--	--	--	--	8 100%	8 100%	
Medium	--	--	--	16 66.7%	8 33.3%	24 100.0%	
Small	--	--	15 22.1%	24 35.3%	29 42.6%	68 100.0%	
Total	--	--	15 15%	40 40%	45 45%	100 100%	

*** Significance level .1percent

The results of Chi-square suggest that there is an association between firm-size and impact on cost of production as a result of signing TRIPS. The ANOVA test has also been used and the results of F-test suggest that there is a significant difference across the different levels of firms on the basis of size and impact on cost of production as a result of signing TRIPS.

Table 4.37: Firm Age and Cost of Production as a Result of Signing TRIPS

Age of the Firm	Cost of Production as a result of Signing of TRIPS					Total	Chi Sq: 19. 314** df:4 p< .01 F: 6.155** df:2 p< .01
	Substantially decreased	Marginally decreased	Remained same	Marginally increased	Substantially increased		
Old	--	--	1 12.5%	5 62.5%	2 25.0%	8 8%	
Medium	--	--	5 15.6%	15 46.9%	12 37.5%	32 32%	
New	--	--	9 15.0%	20 33.3%	31 51.7%	60 60%	
Total	--	--	15 15%	40 40%	45 45%	100 100%	

** Significance level 1percent

The results of age-wise analysis depict that more than 85 percent of all firms, old, medium and large, accepted that cost of production as a result of signing of TRIPS has increased. The results of Chi-square suggest that there is an association between firm age and impact on cost of production as a result of the signing of TRIPS. The results of F-test suggest that there is a significant difference across the different levels of firms on the basis of age and impact on cost of production as a result of signing of TRIPS.

Overall results highlight that 85 percent firms agree that the cost of production as a result of signing of the TRIPS has increased.

iii) Shift to Better Technology

Next the focus of research was shifted to find out whether there is an association between firm size and shift to better technology as a result of the signing of TRIPS.

Table 4.38: Firm Size and Shift to Better Technology

Firm Size	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total	Chi-Square :22.362** (df: 6) P <.01
Large	--	--	--	4 50.0%	4 50.0%	8 100.0%	
Medium	--	--	--	20 83.3%	4 16.7%	24 100.0%	
Small	--	8 11.8%	16 23.5%	24 35.3%	20 29.4%	68 100.0%	
Total	--	8 8.0%	16 16.0%	48 48.0%	28 28.0%	100 100.0%	

** Significance level 1percent

100 percent of the large and the medium scale firms agreed with the view that they have shifted to better technology. Even from the smaller firms, 65 percent of small firms accept this view. Here the value of Chi- square is significant which shows that there is an association between firm size and shift to better technology.

Table 4.39: Firm Age and Shift to Better Technology

Age of the Firm	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Total	Chi-Square: 17.877** p< .01 d.f =6
Old	--	--	2 25.0%	--	6 75.0%	8 100.0%	
Medium	--	4 12.5%	4 12.5%	20 62.5%	4 12.5%	32 100.0%	
New	--	4 6.7%	10 16.7%	28 46.7%	18 30.0%	60 100.0%	
Total	--	8 8.0%	16 16.0%	48 48.0%	28 28.0%	100 100.0%	

** Significance level 1percent

The age-wise analysis shows that 75 percent of the old firms strongly agree that they have shifted to better technology as a result of the signing of TRIPS. From medium firms 75 percent agreed/strongly agreed with this view, whereas 80 percent of new firms agreed/strongly agreed with this view. Value of Chi-square is significant which shows that there is a strong association between age of the firm and shift to better technology as a result of the signing of TRIPS.

Both size-wise and age-wise analysis of firms depict that there is a shift to better technology as a result of the signing of TRIPS. This is a healthy attitude in the pharmaceutical firms, which will ultimately help in improving the R&D and quality of the product.

iv) Share in Domestic Market

Table 4.40: Firm Size and Share in Domestic Market

Firm size	Is the share in domestic market declining?		
	Yes	No	Total
Large	--	8 100.0%	8 100.0%
Medium	4 16.7%	20 83.3%	24 100.0%
Small	12 17.6%	56 82.4%	68 100.0%
Total	16 16.0%	84 84.0%	100 100.0%

Regarding the share of firms in domestic markets, all the large scale firms responded that their share in the domestic market is not declining. This percentage is 83 in case of medium firms as 17 percent reported a decline in share in the domestic market. In the case of small firms, 17 percent felt that their share in domestic market is declining. The majority of the firms in the sample accepted that their share in domestic market is not declining.

Table 4.41: Firm Age and Share in Domestic Market

Age of the Firm	Is the share in domestic market declining?		
	Yes	No	Total
Old	--	8 100.0%	8 100.0%
Medium	--	32 100.0%	32 100.0%
New	16 26.7%	44 73.3%	60 100.0%
Total	16 16.0%	84 84.0%	100 100.0%

Old and medium firms have not reported any decrease in their share in domestic market. Only in case of new firms, 26.7 percent felt that their share in domestic market is declining. The results highlight that 84 percent of the firms have reported that their share in domestic market is not declining.

v) Therapeutics of the Drugs in the Last Three Years

There is high concentration in therapeutic product markets and as a result competition in the Pharmaceutical Industry does exist and is often intense. The exact nature of the competition differs from one therapeutic market to another, ranging from product competition to promotional competition to price competition, depending on the state of technology, the existence of patents, the hold of brand-names and, sometimes, government policy. In general, however, competition in pharmaceuticals is based on the development of new products and on promotion and can be described strongly oligopolistic, with the leading firms possessing considerable market power. Product market is oligopolistic as a few firms are producing similar products, but competition is intense.

Table 4.42: Firm Size and Therapeutics of the Drugs in the Last Three Years

Firm size	Therapeutics of the drugs in the last few years					Total	Chi sq: 53.14*** p<.001
	Substantially decreased	Marginally decreased	Remained same	Marginally increased	Substantially increased		
Large	--	--	4 50.0%	4 50.0%	--	8 100.0%	F:7.788** p<.01
Medium	--	--	8 33.3%	12 50.0%	4 16.7%	24 100.0%	
Small	--	--	16 23.5%	40 58.8%	12 17.6%	68 100.0%	
Total	--	--	28 28.0%	56 56.0%	16 16.0%	100 100.0%	

*** Significance level .1percent ** Significance level 1percent

The results of the size wise analysis highlight that 50 percent of the large scale firms are producing the same therapeutics of the drugs in the last three years. However, 50 percent said that the number of therapeutics has marginally increased. 33.3 percent of the medium scale firms have reported that they are producing the same therapeutics of the drugs in the last three years, 50 percent accepted that the number of therapeutics has marginally increased, whereas 16.7 percent are of the view that the number of therapeutics has substantially increased. 23.5 percent of the small scale firms have reported that they are producing the same therapeutics of the drugs in the last three years, 58.8 percent reported that the number of therapeutics has marginally increased, whereas 17.6 percent said that the number of therapeutics has substantially increased. The results of the Chi-square highlight an association between firm-size and impact on therapeutics of the drugs in the last three years. There is a significant difference of means as the F-test is also significant.

Table 4.43: Firm Age and Therapeutics of the Drugs in the Last Three Years

Age of the Firm	Therapeutics of the drugs in the last few years					Total	Chi Sq: 23.869***
	Substantially decreased	Marginally decreased	Remained same	Marginally increased	Substantially increased		
Old			4 50.0%	4 50.0%	--	8 100.0%	df: 4
Medium	--	--	4 12.5%	28 87.5%	--	32 100.0%	p < .001
New	--	--	20 33.3%	24 40.0%	16 26.7%	60 100.0%	
Total	--	--	28 28.0%	56 56.0%	16 16.0%	100 100.0%	

*** Significance level .1percent

The results of age-wise analysis highlight that 50 percent of the old firms are producing the same therapeutics of the drugs as in the last three years. However 50 percent said that the number of therapeutics has marginally increased. 87.5 percent of medium firms have also reported that the number of therapeutics has marginally increased. 40 percent of the new firms have reported that the number of therapeutics has marginally increased and another 26.7 percent reported that the number of therapeutics has substantially increased. The results of the Chi- square highlight an association between firm-age and impact on therapeutics of the drugs in the last three years. The majority of the firms reported that therapeutics of the drugs in the last three years have marginally increased.

vi) Impact of MRP Based Excise Duty on the Existing Units

The next level of problem which the small scale pharmaceutical units face is that, even if they upgrade their manufacturing facilities to Schedule M standards, the levy of excise duty on MRP has made the business of these SSI units still miserable. The reason is that the tax paid by the small units and large firms is the same irrespective of the selling price.

In January 2005 the government introduced the MRP based excise duty for the pharmaceutical units in the country. As per this policy, government has levied a 40 per cent excise duty on the maximum retail price (MRP) of drugs and not on the manufacturing expenses (i.e., on ex-factory price) which had been the practice earlier. Under the new excise scheme, most small scale units are likely to cross the excise

exemption limit of Rs 1 crore thus effectively defeating the basic purpose of the small scale exemption limit (Express Pharma Pulse, 2005). Under the earlier ex-factory price based excise duty structure, the majority of small units had a turnover of about Rs 50 lakhs. Now based on MRP, that includes marketing and distribution expenses, their turnover is likely to reach Rs. 1 crore. As small units are operating at low profit margins and are incurring additional expenses to upgrade their manufacturing facilities to be GMP compliant, this MRP based excise regime is going to affect them negatively. So the respondent firms were enquired about the impact of MRP based excise duty on their unit. (Pradhan, 2007)

Table 4.44: Firm Size and Impact of MRP Based Excise Duty on the Existing Units

Firm size	Impact of MRP based excise duty on the existing Unit				Total	
	Quite Substantial	Substantial	Marginal	No Impact		Chi Sq: 1.787
Large	8 100.0%	-	-	-	8 100.0%	p=.393
Medium	16 66.7%	8 33.3%	-	-	24 100.0%	
Small	46 67.6%	22 32.4%	-	-	68 100.0%	F:.912 p=.409
Total	70 70.0%	30 30.0%	-	-	100 100.0%	

The results of the Chi- square do not depict any association between firm size and impact of MRP based excise duty on existing units. It means that MRP based excise duty has affected all the firms irrespective of their size. The results of F-test suggest that there is no significant difference across the different levels of firms on the basis of size and impact of MRP based excise duty on existing units.

Table 4.45: Firm Age and Impact of MRP Based Excise Duty on the Existing Units

Age of the Firm	Impact of MRP based excise duty on the existing unit					Chi-square: 21.746***
	Quite substantial	substantial	Marginal	No Impact	Total	
Old	6 75.0%	2 25.0%	--	--	8 100.0%	p<..001
Medium	32 100.0%	--	--	--	32 100.0%	d.f =2
New	32 53.3%	28 46.7%	--	--	60 100.0%	
Total	70 70.0%	30 30.0%	--	--	100 100.0%	

*** Significance level .1percent

The results of the age-wise analysis show that all the 100 firms surveyed whether old, medium or new agreed that MRP based excise duty had a substantial impact on their existing unit. The results of the Chi- square highlight an association between firm age and impact of MRP based excise duty on the existing units.

vii) Drugs Produced by the Firm

The pharma industry can be broadly divided into organised and unorganised sectors. Most of the players in the unorganised sector are involved in formulations manufacturing, since this is not technology intensive. These players mainly cater to local demand and compete on price. So the next question was framed to understand the nature of drugs produced by the company

Table 4.46: Firm Size Drugs Produced by the Firm

Firm size	Drugs produced by the company			
	Bulk drugs	Formulations	Both	Total
Large	--	8 (100.0%)	--	8 (100.0%)
Medium	--	24 (100.0%)	--	24 (100.0%)
Small	--	68 (100.0%)	--	68 (100.0%)
Total	--	100 (100.0%)	--	100 (100.0%)

All the 100 firms in the sample were producing only formulation. Small pharma firms produce only formulations as they are not in a position to afford the heavy investment required for the production of bulk drugs. Medium firms generally prefer to produce formulations because profit margin is higher. Large pharma firms can produce both. However, in this work, the medium and large scale units that were selected were producing formulations only.

viii) Category of Product:

In the domestic market, because of the largely generic nature of the Indian pharmaceutical industry, the focus of domestic firms continues to be on off-patent drugs.

Table 4.47: Firm Size and Category of Product

Firm size	Category of product			Total
	Generic Products	Branded Products	Both	
Large	4 (50.0%)	4 (50.0%)	--	8 (100.0%)
Medium	4 (16.7%)	8 (33.3%)	12 (50.0%)	24 (100.0%)
Small	--	16 (23.5%)	52 (76.5%)	68 (100.0%)
Total	8 (8.0%)	28 (28.0%)	64 (64.0%)	100 (100.0%)

Table 4.47 shows that the majority of the firms have been producing both generic products and branded products.

ix) Number of Products Introduced in the Last One Year

Table 4.48: Firm size and Number of Products Introduced in the Last One Year

Firm size	Number of products introduced in the last one year					Total
	<5	6-10	11-20	21-40	>40	
Large	--	4 50.0%	--	4 50.0%	--	8 100.0%
Medium	--	--	16 66.7%	8 33.3%	--	24 100.0%
Small	8 11.8%	12 17.6%	24 35.3%	8 11.8%	16 23.5%	68 100.0%
Total	8 8.0%	16 16.0%	40 40.0%	20 20.0%	16 16.0%	100 100.0%

The results of size-wise analysis show that overall 40 percent firms responded that they have introduced 11-20 products in the last one year. 66.7 percent of the medium firms and 35 percent of the small firms belong to this category. 20 percent of firms reported that they have introduced 21-40 products in the last one year, 50 percent of the large firms, 33.3 percent of the medium firms, 11.8 percent of the small firms belong to this category. 16 percent said that they have introduced more than 40 products in the last one year. The surprising results are that 23.5 percent of the small firms have introduced more than 40 products.

However, on the other side, 16 percent said that they have introduced only 6-10 products in the last one year, 50 percent of the large firms, and 17.6 percent of the small firms belong to this category. On the other extreme there are 8 percent firms which could introduce less than 5 products in the last one year. 11.8 percent of the small firms belong to this category. Overall results highlight that the firms are introducing new products and the number is increasing.

Table 4.49: Firm age and Number of Products Introduced in the Last One Year

Age of the Firm	**Number of products introduced in the last one year**					Total	Chi square: 51.333***
	<5	6-10	11-20	21-40	>40		
Old	--	--	--	--	8 100.0%	100.0%	df: 8
Medium	4 12.5%	8 25.0%	12 37.5%	8 25.0%	--	32 100.0%	
New	4 6.7%	8 13.3%	28 46.7%	12 20.0%	8 13.3%	60 100.0%	p < .001
Total	8 8.0%	16 16.0%	40 40.0%	20 20.0%	16 16.0%	100 100.0%	

*** Significance level .1percent

The results depict that all the older firms have introduced more than 40 products in the last one year. The majority of the new firms have introduced 11-20 products in the last one year. The value of Chi square is significant which highlights an association between firm age and number of products introduced in the last one year.

x) Products of the Firm Covered Under DPCO

Small scale units were exempted from DPCO prior to 1995 but DPCO 1995 included small units also in its ambit. DPCO is applicable to all units irrespective of their size and turnover. In practice the impact of DPCO is relatively greater on the small-scale units than on the large units because of the differences in production volume between the two (Lalitha, 2001). Larger units with a wide range of production of items have the advantage to balance the production between the items under price control and those which are not. Since most of the small units do not have such flexibility, they get adversely affected. Also, larger units have the capacity to argue their case with the government to justify the higher prices based on their cost of production or other reasons and charge higher prices. Smaller units have also cited reducing profit margin due to DPCO. (Lalitha, 2002)

Table 4.50: Firm Size and Products of the Firm Covered Under DPCO

Firm size	Products of the company covered under DPCO						
	0-10%	11-30%	31-50%	51-70%	70% & above	Total	Chi Square: 26.530**
Large	--	4 50.0%	4 50.0%	--	--	8 100.0%	
Medium	4 16.7%	--	8 33.3%	8 33.3%	4 16.7%	24 100.0%	df: 8
Small	4 5.9%	20 29.4%	32 47.1%	4 5.9%	8 11.8%	68 100.0%	p< .01
Total	8 8.0%	24 24.0%	44 44.0%	12 12.0%	12 12.0%	100 100%	

** Significance level 1percent

The results show that 50 percent of the large firms have 11-30 percent of their products under DPCO, whereas 50 percent of the firms have 31-50 percent of their products under DPCO. From medium size firms, 16.7 percent firms have less than ten percent of their products under DPCO, 33.3 percent of the firms have 31-50 percent of their products under DPCO, whereas 33.3 percent of the firms have 51-70 percent of their products under DPCO and 16.7 percent of the firms have more than 70 percent

of their products under DPCO. A majority of the small firms i.e., 32 firms had 30-50 percent products covered under DPCO. The results of the Chi-square highlight an association between firm age and products of the company covered under DPCO at one percent.

Table 4.51: Firm Age and Products of the Firm Covered Under DPCO

Age of the firm	Products of the company covered under DPCO						Chi- Square: 36.073***
	0-10%	11-30%	31-50%	51-70%	70% & above	Total	P<.001
Old	--	--	4 50.0%	4 50.0%	--	8 100.0%	d.f =8
Medium	4 12.5%	--	16 50.0%	4 12.5%	8 25.0%	32 100.0%	
New	4 6.7%	24 40.0%	24 40.0%	4 6.7%	4 6.7%	60 100.0%	
Total	8 8.0%	24 24.0%	44 44.0%	12 12.0%	12 12.0%	100 100%	

*** Significance level .1percent

The results show that 50 percent of the old firms have 31-50 percent of their products under DPCO, whereas 50 percent of the firms have 51-70 percent of their products under DPCO. From medium firms, 50 percent of the firms have 31-50 percent of their products under DPCO, and 12.5 percent of the firms have 51-70 percent of their products under DPCO and 25 percent of the firms have more than 70 percent of their products under DPCO. From new firms, 40 percent of the firms have 31-50 percent of their products under DPCO, 6.7 percent of the firms have 51-70 percent of their products under DPCO and another 6.7 percent of the firms have more than 70 percent of their products under DPCO. The value of Chi square is significant which highlights an association between firm age and products of the company covered under DPCO. Overall results highlight that Indian pharmaceutical firms are still having more than 31 percent products under DPCO.

xi) Sales in the Last Three Years

Table 4.52: Firm Size and Sales in the Last Three Years

Firm Size	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased	Total
Large	--	--	--	--	8 100.0%	8 100.0%
Medium	--	--	--	4 16.67%	20 83.83%	24 100.0%
Small	6 8.82%	--	6 8.820%	24 35.29%	32 47.06%	68 100.0%
Total	6 6.0%	--	6 6.0%	28 28.0%	60 60.0%	100 100.0%

In the last three years, 83 percent of the medium firms have reported substantial increase, whereas 17 percent have reported marginal increase in sales. 47.06 percent of the small scale firms have reported substantial increase in sales, whereas 35.3 percent have reported marginal increase in sales in the last three years. However all the large firms have reported substantial increase in sales in the last three years.

xii) Overall Impact of TRIPS

Table 4.53: Firm Size and Opinion about the Impact of TRIPS

Firm size	Opinion of the impact of TRIPS					Total	Chi-Square: 1.170*** p<.001 d.f =8
	Prices of all drugs will go up	Prices of certain drugs will go up	No change in prices	More R&D activity will take place	Companies will expand their size by merger/ acquisition		
Large	--	--	--	--	8 100.0%	8 100.0%	
Medium	4 16.7%	12 50.0%	--	8 33.3%	--	24 100.0%	
Small	20 29.4%	32 47.1%	12 17.6%	4 5.9%	--	68 100.0%	
Total	24 24.0%	44 44.0%	12 12.0%	12 12.0%	8 8.0%	100 100.0%	

*** Significance level .1percent

Then firms have been asked to give their opinion about the impact of TRIPS on the Indian pharmaceutical industry, 100 percent of the large firms responded that the firms will expand their size by merger/acquisition. From medium size firms, 16.7 percent firms reported that prices of all the drugs will go up, while 50 percent claimed that prices of certain drugs will go up. However, 33.3 percent of the firms claimed that more R&D activity will flow as a result of signing TRIPS. From small size firms, 29.4 percent firms reported that prices of all the drugs will go up while 47.1 percent claimed that prices of certain drugs will go up. 17.6 percent claimed that there will be no change in prices. Only 5.9 percent of the firms claimed that more R&D activity will take place as a result of signing TRIPS. Value of Chi square is significant for 8 df, which depicts that there is a strong association between firm size and opinion on the impact of TRIPS. Overall analysis depicts that the majority of the firms has been of the view that prices of the drugs will increase.

Table 4.54: Firm Age and Opinion about the Impact of TRIPS

Age of the Firm	Opinion on the impact of TRIPS					Total	Chi Square: 40.644*** df: 8 p< .001
	Prices of all drugs will go up	Prices of certain drugs will go up	No change in prices	More R&D activity will take place	Companies will expand their size by merger/ acquisition		
Old	4 50.0%	--	--	4 50.0%	--	8 100.0%	
Medium	12 37.5%	20 62.5%	--	--	--	32 100.0%	
New	8 13.3%	24 40.0%	12 20.0%	8 13.3%	8 13.3%	60 100.0%	
Total	24 24.0%	44 44.0%	12 12.0%	12 12.0%	8 8.0%	100 100.0%	

*** Significance level .1percent

Age-wise analysis of opinion on the impact of TRIPS on the Indian Pharmaceutical Industry reveals that two old firms reported that more R&D activity will take place and six reported that firms will expand their size by merger/acquisition. From medium firms, 37.5 percent firms accepted that prices of all the drugs will go up, while 62.5 percent accepted that prices of certain drugs will go up. From new firms, 13.3 percent firms accepted the viewpoint that prices of all the drugs will go up while 40 percent claimed that prices of certain drugs will go up. 13.3 percent firms said that firms will expand their size by merger/ acquisition as a result of signing TRIPS. Only 13.3 percent of the firms claimed that more R&D activity will take place as a result of signing TRIPS. The majority of the firms agreed that prices of drugs will go up. The results highlight that TRIPS will lead to increase in the price of drugs and only 12 percent of total firms claimed that it will lead to enhanced R&D activities.

Value of Chi square is 40.644 which is significant for 8 df and depicts that there is a strong association between age of the firm and opinion on the impact of TRIPS.

xiii) Opportunities Created due to TRIPS

First Schedule M, then enhanced cost of production, followed by MRP based excise duty, now the research focus shifted to trying to enquire whether the TRIPS agreement offered any opportunities to the firms.

Table 4.55: Firm Size and New Opportunities Created due to TRIPS

Firm size	New opportunities created due to TRIPS					Total	Chi-Square: 69.074*** p<.001 d.f =8
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree		
Large	--	--	--	--	8 100.0%	8 100.0%	
Medium	4 16.7%	4 16.7%	--	12 50.0%	4 16.7%	24 100.0%	
Small	32 47.1%	12 17.6%	12 17.6%	8 11.8%	4 5.9%	68 100.0%	
Total	36 36.0%	16 16.0%	12 12.0%	20 20.0%	16 16.0%	100 100.0%	

*** Significance level .1percent

While responding to the question whether the new opportunities have been created by TRIPS, the majority of the firms has not accepted the viewpoint. The firms still seem to be a little apprehensive of the TRIPS agreement, but the same viewpoint has been accepted by large scale firms. Even from medium firms, the percentage of firms who agreed/strongly agreed to it (66.7 percent) has been more than those who disagreed/strongly disagreed to it (33.4 percent). But this is the not the case with the small firms. Here the percentage of firms who disagreed/strongly disagreed to it (64.7 percent) was more than those who agreed/strongly agreed to it (17.7 percent). Some 17.6 percent firms are neutral about it. Many large and medium scale firms accepted the view that new opportunities have been created by signing of TRIPS, while the small firms were a little apprehensive about it. Value of Chi square is significant for 8 df which again depicts that there is a strong association between firm size and opinion on new opportunities being created due to TRIPS.

Table 4.56 : Firm Age and New Opportunities Created due to TRIPS

Age of the Firm	New opportunities created due to TRIPS					Total	Chi Square: 24.421**
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree		
Old	4 50.0%	--	--	4 50.0%	--	8 100.0%	df: 8
Medium	16 50.0%	4 12.5%	0 .0%	4 12.5%	8 25.0%	32 100.0%	p = .006 < .01
New	16 26.7%	12 20.0%	12 20.0%	12 20.0%	8 13.3%	60 100.0%	
Total	36 36.0%	16 16.0%	12 12.0%	20 20.0%	16 16.0%	100 100.0%	

** Significance level 1percent

Once again the results highlight that the majority of the firms accepted the viewpoint that new opportunities have been created due to TRIPS. When asked about whether they feel that new opportunities have been created due to the signing of TRIPS there were divergent views of medium firms. From medium firms, the percentage of firms who disagreed/strongly disagreed to it has been 62.5 percent and is quite high. The picture is more or less similar for new firms, where 46.7 percent of firms disagreed/strongly disagreed to it and 33.3 percent firms agreed/strongly agreed to it. Value of Chi square is 24.421 **s**ignificant for 8 df which again depicts that there is a strong association between age of the firm and opinion on new opportunities being created due to TRIPS.

xiv) Threats Due to TRIPS

Table 4.57: Firm Size and Threats Due to TRIPS

Firm size	Threats due to TRIPS					Total	Chi-Square: 28.554*** P<.001 d.f =8
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree		
Large	--	--	4 50.0%	--	4 50.0%	8 100.0%	
Medium	--	--	--	16 66.7%	8 33.3%	24 100.0%	
Small	4 5.9%	8 11.8%	20 29.4%	16 23.5%	20 29.4%	68 100.0%	
Total	4 4.0%	8 8.0%	24 24.0%	32 32.0%	32 32.0%	100 100.0%	

*** Significance level .1percent

When asked about whether there are any threats by signing TRIPS, even the large firms could not categorically say no. These firms might have visualized a threat in the form of competition from the big MNCs. 50 percent of the large firms strongly agreed that they would face threats due to TRIPS. From medium size firms, 66.7 percent agreed, while another 33.3 percent strongly agreed. From small firms, 52.9 percent strongly agreed/agreed to it while 17.7 percent strongly disagreed/disagreed to it and remaining 29.4 percent of the small firms are neutral about it. Overall the majority of the firms (64 percent) have accepted that TRIPS might lead to certain threats. Value of Chi Square is significant for 8 df which depicts that there is an association between firm size and opinion on threats due to TRIPS.

Table 4.58: Firm Age and Threats Due to TRIPS

Age of the Firm	Threats due to TRIPS					Total	Chi Square: 18.194*
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree		
Old	--	--	--	4 50.0%	4 50.0%	8 100.0%	df: 8
Medium	--	4 12.5%	4 12.5%	8 25.0%	16 50.0%	32 100.0%	
New	4 6.7%	4 6.7%	20 33.3%	20 33.3%	12 20.0%	60 100.0%	p < .05
Total	4 4.0%	8 8.0%	24 24.0%	32 32.0%	32 32.0%	100 100.0%	

* Significance level 5 percent

When asked about whether there were any threats because of signing of TRIPS, 100 percent of the old firms strongly agreed/ agreed that they would find threats due to TRIPS. From medium firms, 75 percent firms agreed/strongly agreed to it. From the new firms, 53.3 percent strongly agreed/agreed to it, while 13.4 percent strongly disagreed/disagreed to it. Overall results highlight that the majority of the firms accepted that they faced threats due to implementation of TRIPS. Value of Chi square 18.194 is significant for 8 df which depicts that there is an association between firm age and opinion on threats due to TRIPS.

4.3.5 Impact of TRIPS on Pharmaceutical Industry: Results of Factor Analysis of Small Firms

The data collected through questionnaire have also been analysed by factor analysis to study the impact of TRIPS on the Indian pharmaceutical sector (Table 5.10). The results highlight that six factors, namely; i) TRIPS, R&D and new opportunities; ii) Products under DPCO, performance of R&D, and therapeutics of drugs; iii) Product category, nature of order and threats; iv) Changes in technique and technical personnel employed; v) Changes in sales and exports; and vi) Preparedness for TRIPS , extracted 76.39 percent of variation.

Table 4.59: Factors Influencing Pharmaceutical Performance

S No	Factor Name	Factors components	Eigen Values	% of Var.	Item loading	Mean	SD
1	TRIPS, R&D and new opportunities	In-house R&D activities	4.355	25.616	.804	3.72	0.77
		Proportion of turnover spend on R&D in the last three years			.663	2.16	1.49
		Cost of production as a result of signing of TRIPS			.690	3.76	1.07
		Impact of TRIPS on various issues related to Indian pharmaceutical Industry			.777	2.36	1.20
		New opportunities created due to TRIPS			.779	2.64	1.52
Mean of TRIPS, R&D and new opportunities						2.93	
2	Products under DPCO, performance of R&D and Therapeutics of the drugs you are dealing with	Impact on the no. of products of the firm covered under Drugs Price Control Order (DPCO)	2.561	15.067	.891	3.38	0.84
		Performance of R&D activities			.794	3.24	1.29
		Therapeutics of the drugs you are dealing with			.743	3.51	1.34
Mean of Products under DPCO and performance of R&D						3.37	
3	Product category, nature of order and threats	Impact on number of products introduced by the firm in the last one year	2.085	12.263	.926	4.20	1.02
		Bulk orders from big companies			.550	1.88	0.87
		Threats due to TRIPS in form of big competitions from foreign companies			.857	3.30	1.10
Mean of Product category and nature of order						3.12	
4	Changes in technique and technical personnel employed	Shift to better technology due to TRIPS	1.653	9.722	.857	3.96	1.29
		Total technical persons employed			.618	3.24	0.87
Mean of Changes in technique and technical personnel employed.						3.60	
5	Changes in sales and exports	Sales in last three years	1.324	7.789	.861	4.30	1.24
		Exports in last three years			.582	3.96	0.19
Mean of Changes in total sales and exports						4.13	
6	Preparedness for TRIPS	Need for patents	1.009	5.936	.788	4.14	0.72
		Challenges posed by TRIPS			. 781	3.76	1.14
Mean of preparedness for TRIPS						3.95	

Factor I , TRIPS, R&D and new opportunities consists of: i) In-house R&D activities with loading of .804; ii.) Proportion of turnover spent on R&D (.663); iii) Cost of production as a result of signing of TRIPS (.690); iv) Impact of TRIPS on various issues related to Indian Pharmaceutical Industry (.777); and v) New opportunities created due to TRIPS (.779).

Two important components in this factor are: i) in-house R&D activities; and ii) cost of production as a result of signing of TRIPS. Both these components had mean 3.72 and 3.76 which are higher than the factor mean of 2.93. The results of the study depict that though the cost of production has increased, at the same time in-house R&D activities have also improved after signing TRIPS.

The second factor is products under DPCO, performance of R&D and therapeutics of drugs and had an eigen value of 2.561 with a variance of 15.067 percent. Three components of this factor are: i) Impact on the no. of products of the firm covered under drugs price control order [DPCO] (.891); ii) Performance of R&D activities (.794); and iii) Therapeutics of the drugs the firms are dealing with (.743). Based on the mean score the factor impact on the number of products of the firm covered under drugs price control order [DPCO] had a mean score of 3.38 and therapeutics of the drugs the firms are dealing with a mean score 3.51 are higher than the mean score of all three variables (3.37).

The third factor that emerged from the factor analysis is product category, nature of order and threats with eigen value of 2.085. This explained 12.263 percent of variance. The components of this factor are: i) Impact on number of products introduced by the firm (.926); ii) Threats due to TRIPS in the form of competition from foreign companies (.857) and iii) bulk orders from big companies in the last three years (.550). Two components, impact on number of products introduced by the firm in the last three years having a mean score of 4.20 and threats due to TRIPS in the form of competition from foreign companies having a mean score of .3.30 are important. Both these components had higher means than the factor mean of 3.12. It shows that in spite of the threats due to TRIPS in the form of severe competition from foreign companies, the number of products introduced by the firms is increasing.

The fourth factor, namely, changes in technique and technical personnel employed, had an eigen value of 1.653 and this factor explained 9.722 % of variance. Two components of this factor are: i) shift to better technology due to TRIPS (.857) and ii) total technical persons employed (.618). Out of these two components, shift to better technology due to TRIPS is more important, as it has a factor loading of .857 and mean score of 3.96 which is higher than the factor mean 3.60. This is quite obvious as the majority of the respondents expressed their opinion that they have shifted to a better technology due to the signing of TRIPS.

The fifth factor, viz., changes in total sales and exports had an Eigen value of 1.324. This factor explained 7.789 percent of variance. This factor has two variables: i) sales in last three years (.861); and ii) exports focus (.582). Out of these two factors sales in the last three years with a mean score of 4.30 has been higher than the mean score of this factor (4.13). The results of the study highlight that due to the signing of TRIPS, respondent firms have reported an increase in sales in the last three years.

The last factor that emerged from factor analysis has been preparedness for TRIPS. This factor had an Eigen value of 1.009 and explained 5.936 percent of variation. This factor covered two variables, namely, i) Need for patents (.788) and ii) Challenges posed by TRIPS (.781). Need for patents had a relatively higher mean score (4.14) than the factor mean which is 3.95. It might be due to this reason that the patents of all large and medium firms have registered an increase in post-TRIPS period.

The overall mean of all factors is 3.51. Three important factors on the basis of ranking on mean score include: i) changes in sales and exports ii) preparedness for TRIPS, and iii) changes in techniques and technical personnel employed. The results of factor analysis highlight that need for patenting, change in sales and switch to new technology have higher impact on the Pharmaceutical Industry of India.

4.3.6 Results of the Regression Analysis

Table 4.60: Results of the Regression Analysis

Model Summary										
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.623[a]	.388	.382	.424	.388	62.077	1	98	.000	
2	.825[b]	.681	.674	.308	.293	88.883	1	97	.000	
3	.836[c]	.699	.690	.300	.019	5.908	1	96	.017	2.197
a. Predictors: (Constant), IP13										
b. Predictors: (Constant), IP13, IP12										
c. Predictors: (Constant), IP13, IP12, IP16										
d. Dependent Variable: DP11										

The dependent variable is **Overall performance during TRIPS** consisting of three items, viz., present sales, market share and overall impact on performance. Factor analysis helped to choose the independent variables for the model. These are explained below.

i. **IP 11: TRIPS, R&D and new opportunities**: This includes five items.
   - In-house R&D activities
   - Proportion of turnover spend on R&D in the last three years
   - Cost of production as a result of signing of TRIPS
   - Impact of TRIPS on various issues related to Indian pharmaceutical Industry
   - New opportunities created due to TRIPS

ii. **IP 12: Products under DPCO and performance of R&D:** This has three items, namely:
   - Impact on the no. of products of the firm covered under drugs price control order (DPCO)
   - Performance of R&D activities

- Therapeutics of the drugs firms are dealing with

iii. **IP13: Product category, nature of order and threats:** This has the following items:
   - Impact on no. of products introduced by the firm
   - Bulk orders from big companies
   - Threats due to TRIPS in form of competition from foreign companies

iv. **IP14: Changes in technique and technical personnel employed**: The items included in this independent variable are:
   - Shift to better technology due to TRIPS
   - Total technical persons employed

v. **IP15: Changes in total sales and exports**: This includes the following two items:
   - Changes in sales in last three years
   - Change in exports

vi. **IP 16: Preparedness for TRIPS:** This includes two items. These are:
   - Need for patents
   - Challenges posed by TRIPS

The results for Step-wise regression (Table 4.60) depict that the model chooses three independent variables. These are: IP13: Product category, nature of order and threats, IP 12: Products under DPCO and performance of R&D and IP 16: Preparedness for TRIPS. The model explains 69 percent of the variation. This explains that this combination of three variables significantly predict the overall performance during the TRIPS period.

4.4 Concluding Remarks:

Data analysis done at the industry level depicts the changing scenario of the pharmaceutical industry. The results highlight an increase in patenting activity, increase in exports and enhanced R&D spending in the post-TRIPS period. The results of selected leading firms also highlight similar trends. This has been followed by survey results. The empirical analyses have been carried out to find association between firm size and impact of TRIPS. Age-wise analysis has also been done. For closer examination of relationships between dependent and independent variables,

multiple regression analysis has been done using the step-wise method to avoid multicollinearity. The regression results have highlighted that three significant predictors of the overall performance during TRIPS period are: i) IP13: Product category, nature of order and threats; ii) IP 12: Products under DPCO and performance of R&D; and iii) IP 16: Preparedness for TRIPS.

CHAPTER-V

CONCLUSIONS, LIMITATIONS AND FURTHER STUDY

This chapter highlights the major findings in section 5.1. Section 5.2 deals with the testing of hypotheses and presents a complete view of the research. Section 5.3 covers the limitations of the research and, finally, section 5.4 identifies the areas of future research.

5.1 Major Findings

The major findings of the study are listed below.

Section 5.1.1 reports the findings at the industry level. Section 5.1.2 covers the findings of the selected leading pharmaceutical companies and section 5.1.3 deals with the findings of the sample survey of one hundred firms selected from the north west region of India.

5.1.1 Findings at Industry Level

Results of the pharmaceutical industry as a whole depict that:

i) Patents have increased in the pharmaceutical industry of India in the post-TRIPS period.
ii) Growth of R&D of the industry as a whole has been higher in the post-TRIPS period, as compared to pre-TRIPS period.
iii) Growth of exports of the industry as a whole is higher in post-TRIPS period as compared to the pre-TRIPS period**.**

5.1.2 Findings of the Selected Leading Pharmaceutical Companies

The results of the present study show that patenting activities of the leading pharmaceutical companies have improved consistently. Not only the patent filing has increased, the patents granted have also increased in post-TRIPS period. In the case of ANDA filings with USFDA, the situation has dramatically changed in the last few years. Now, besides Ranbaxy and DRL, other firms like Cipla, Sun Pharma, Cadilla, Aurobindo and Glenmark are also increasing ANDA filings. All these companies

have created a pipeline of ANDA filings to maintain their hold in the U.S. market. Aurobindo has filed the highest number of ANDAs from India in 2007-08. ANDAs filings as well as ANDA approvals have been increasing continuously. Wockhardt is amongst the top five global companies to have received 23 ANDA approvals from the USFDA in 2008. In the same year, Ranbaxy has been the company with a largest basket of products in the US market with 141 approved drugs and another 98 marketing applications pending for approval. In 2007-08 DRL saw the highest number of approvals for the company's ANDA filings, including 13 final approvals from the US and 4 from Canada, in addition to 7 tentative approvals from the US.

In the case of DMF filing, also, the selected leading pharma companies are coming forward in the post-TRIPS period. DRL has the largest API pipelines in the Indian pharma industry and has filed 21 DMFs with the USFDA in 2008-09. Aurobindo filed the highest number of DMFs from India in 2007-08. Till 2008, the company has 122 filings for US DMF and 1017 Global DMF Filings.

The results of the present study suggest that the large Indian pharmaceutical companies such as Ranbaxy, Cipla and DRL have increased their R&D spending significantly over the years. R&D expenditure of Ranbaxy has increased from Rs. 434 millions in 1998 to Rs. 4711 millions in 2008, for DRL it increased from Rs 113 million to Rs. 3531 million for the same period. In terms of R&D growth rates, the highest growth has been recorded by Aurobindo (3.03 percent), followed by Cipla (2.86 percent) and Workhardt (2.85 percent). There has been an increase in R&D intensity of the the the selected leading pharmaceutical companies as well since 1998. This is an indication that the leading companies in the Pharmaceutical Industry of India are allocating increasing amounts of their sales turnover towards R&D spending.

The present study also reflects the rising exports of Indian pharmaceutical companies. These could be an indicator of local technological capability, particularly in process innovations. With their cost-effective process innovations and reverse engineering of brandname drugs, Indian companies have emerged as competitive suppliers in the world for a large number of generic drugs. The export focus of Indian companies, propelled by the recognition of process patents in different countries, has made them

penetrate a number of countries based on their low cost structure. Inter company comparison highlight that the export growth rate has been highest for Sun Pharma, followed by Cadilla.

5.1.3 Findings of the Sample Survey Selected From the North West Region of India

The major findings of the sample study are reported under the two headings

5.1.3.1 Impact of TRIPS on patenting, R&D and exports

5.1.3.2 Impact of TRIPS: other perspectives

5.1.3.1 Impact of TRIPS on Patenting, R&D and Exports

Firm level analysis highlights an improvement in the perception of Indian firms regarding patenting, R&D and exports. Although in terms of patenting and exports, only a few large and old firms are indulging in these activities, but even the new and small firms have been accepting the viewpoint of increasing needs of patents and exports in the future. Slowly they are going in for a change, as is visible from their viewpoints of acceptance of schedule M and MRP based excise duty. Regarding R&D perspective, all firms, whether old or new, large or small, have improved their spending on R&D as has been reflected by enhanced R&D expenditure and increased proportion of turnover spent on R&D.

5.1.3.2 Impact of TRIPS: Other perspectives

i) Compliance to Schedule M: W**as Schedule M a hasty decision?**

Central government made GMP (Schedule M) compulsory in drug manufacturing sector from 2005, which was in the wake of TRIPS compliance as it was conceived on the lines of USFDA. Schedule M ensures total cGMP (current Good Manufacturing Practices) where high levels of quality control and quality assurance standards will have to be maintained in the manufacturing of the drugs irrespective of firm size. The respondents have been asked about whether Schedule M had been a hasty decision implemented by the government, without giving them the time to respond to this change.

a) Results of size-wise analysis show that there is no association between firm size and schedule M being a hasty decision imposed by the Govt. The results of Chi-square do not depict any association between the two. The majority of the firms have not accepted that Schedule M was a hasty decision.

b) Age-wise analysis depicts that there is an association between firm age and schedule M being a hasty decision. The results of Chi-square depict an association between the two.

ii) Cost of Production as a Result of the Signing TRIPS

a) One of the impacts of TRIPS as has been reflected by many studies has been, to find out whether the TRIPS agreement has lead to increase in cost of production. The results of Chi-square suggest that there is an association between firm size and impact on cost of production as a result of the signing of TRIPS, as the value of Chi-square (49.150) is significant for 4 df. The results of F-test suggest that there is a significant difference across the different levels of firms on the basis of size and impact on cost of production as a result of the signing of TRIPS. Even the results of factor analysis suggest that cost of production has increased as a result of signing of TRIPS.

b) The same has been tested for age-wise analysis, i.e., whether there is an association between firm age and impact on cost of production as a result of the signing of TRIPS. The results of Chi-square point out that there is an association between firm age and impact on cost of production as a result of the signing of TRIPS, as the value of Chi-square 19.314 is significant for 4 df. The results of F-test suggest that there is a significant difference across the different levels of firms on the basis of age and impact on cost of production as a result of the signing of TRIPS.

iii) Shift to Better Technology

a) Next the focus of research shifted to finding out whether there is an association between firm size and shift to better technology as a result of the signing of TRIPS. Once again the results of Chi-square, significant at one percent, reflect an association between the two.

b) Age-wise analysis shows an association between firm age and shift to better technology as a result of signing of TRIPS. Value of Chi-square is significant at one percent level of significance. These are pointers to the fact that there is a strong association between age of the firm and shift to better technology as a result of the

signing of TRIPS. Size-wise as well as age-wise analysis show that TRIPS has resulted in a shift to better technology. This is a healthy attitude and will be instrumental in improving the R&D and quality of the product.

iv) Impact on Therapeutics of the Drugs

a) There is high concentration in therapeutic product markets and this often leads to intense competition in the pharmaceutical industry. Here the results of the Chi- square highlight an association between firm-size and impact on therapeutics of the drugs in the last three years. There is a significant difference of means as the F-test is significant at 1 percent level of significance.

b) The results of the Chi- square highlight an association between firm-age and impact on therapeutics of the drugs in the last three years.

v) Impact of MRP Based Excise Duty on the Existing Units

With the objective of providing impetus to industrialization, the central government declared some backward regions of Himachal Pradesh, Jammu & Kashmir, Sikkim and Uttaranchal in 2005 as excise free zones. At the same time it declared MRP based excise duty for the pharmaceutical units and levied a 40 per cent excise duty on maximum retail price (MRP) of drugs and not on the manufacturing expenses (i.e., on ex-factory price), the practice earlier. The impact of such a policy on the small pharmaceutical units outside excise free zones was strongly negative (Pradhan, 2007).

a) The results of size-wise analysis underscore that there is no association between the firm size and impact of MRP based excise duty on existing unit. The results of the Chi- square do not depict any association between the two. It means that MRP based excise duty has affected all the firms irrespective of their size. Even the results of F-test suggest that there is no significant difference across the different levels of firms on the basis of size and impact of MRP based excise duty on the existing unit.

b) The results of Chi- square of the age-wise analysis highlight an association between firm-age and impact of MRP based excise duty on the existing unit.

vi) Impact of DPCO

Small scale pharmaceutical firms were exempted from DPCO prior to TRIPS. However DPCO 1995 included small units also in its orbit. Therefore it is genuine to assume that small pharmaceutical firms were worst affected by the signing of TRIPS agreement. In addition to it, the impact of DPCO is relatively greater on the small-scale units than on the large units because of the differences in production volume between the two (Lalitha, 2001).

a) The present study also tried to find an association between the firm size and products of the company covered under DPCO. The results of Chi-square highlight an association between firm-size and products of the company covered under DPCO.

b) Age-wise results of the Chi-square highlight an association between firm age and products of the company covered under DPCO at one percent. The value of Chi - square is significant which highlight an association between firm-age and products of the company covered under DPCO.

vii) Overall Impact of TRIPS

a) Regarding the overall impact of TRIPS the perception of all large as well as small firms has been that TRIPS will result in increase in the prices of the products. There is a strong association between the firm size and opinion on the impact of TRIPS. Value of Chi square is significant for 8 df, depicting that there is a strong association between firm size and opinion on the impact of TRIPS.

b) Similar results are highlighted by age-wise analysis as the majority of the firms accepted that prices of drugs will go up. Hence, there is a strong association between age of the firm and opinion on the impact of TRIPS. Value of Chi square is 40.644 which is significant for 8 df.

viii) New Opportunities due to TRIPS

a) First Schedule M, then enhanced cost of production, followed by MRP based excise duty. The respondent firms have been asked about whether the TRIPS agreement offered any opportunities to the firms. Many large and medium scale firms accepted the view that new opportunities would be created by the signing of TRIPS. Results of

Chi-square reflect that there is an association between the firm size and opinion on new opportunities being created due to TRIPS.

b) Regarding age-wise analysis this question evoked a mixed response. Once again the results of Chi-square reflect an association between age of the firm and opinion on new opportunities being created due to TRIPS. Value of Chi-square is 24.42**1** **s**ignificant at 1 percent level of significance for 8 df. This all meant a lot for the competing pharmaceutical firms trying to maintain their status.

ix) Threats due to TRIPS

a) The majority of the firms (64 percent) have accepted that TRIPS agreement is not free from certain threats. Value of Chi Square (28.554) is significant for 8 df, empirically supporting an association between the firm size and opinion on threats due to TRIPS.

b) Age-wise analysis further enunciated the truth that majority of the firms accepted that they faced threats due to implementation of TRIPS. Value of Chi-square is 18.194, which is significant at 5 percent level for 8 df, which shows that there is an association between firm age and opinion on threats due to TRIPS.

The summary of results presented above support that the Indian Pharmaceutical Industry has been gearing up for the change and has been improving its position in terms of patent filings, R&D and exports. But this is not true on all fronts. There are many problems faced by the small and new firms, who still need more time to adjust to the changing scenario. However, there is a hope as even these firms have responded by improving their R&D expenditure and employing more technical persons.

5.2 Testing of Hypotheses: The specific hypotheses examined in this study are as follows:

H_1: Post-TRIPS Period May be Associated with Higher Number of Patents.

This hypothesis has been tested at three levels.

a) At Industry Level

The hypothesis is supported by the results of the Pharmaceutical Industry of India highlighting that patents granted to drugs and pharmaceuticals have grown at a higher

rate of 6.06 percent for the post-TRIPS period, i.e., 1994-95 to 2006-07, as against growth rate of 5.57 percent of total patents granted. (Table 4.1, ch. 4)

b) At the Level of the Selected Leading Pharmaceutical Companies

This hypothesis is further supported by the results of the selected leading pharmaceutical companies. The results underscore the fact that patents granted by United States Patent and Trademark Office to leading Indian pharmaceutical companies are increasing after 1995, i.e., after signing TRIPS and more obviously after 2002. (Table 4.16, ch.4) Moreover ANDA and DMF Filings with USFDA by almost all the leading pharmaceutical companies included in the selected sample firms have also increased.(Table 4.17 and 4.19, ch.4)

c) At Firm Level

This hypothesis is supported by the results of 'factor analysis' which show that the variable, need for patents, with an item loading of .788, of the factor 'preparedness for TRIPS' had a relatively higher mean score (4.14) than the factor mean which is 3.95. Moreover the step-wise regression analysis depicts that the model chooses three independent variables and the dependent variable. IP 16: Preparedness for TRIPS is one of the predictors of the model.

So the hypothesis has been accepted as the results highlight that patents have increased in the post-TRIPS period.

H_2 : R&D May Have Improved in the Post-TRIPS Period.

This hypothesis has also been tested at three levels.

a) At Industry Level

Industry's R&D was worth Rs. 293 million in 1981-82 and increased to Rs.14305 million in 2006-07 increasing at an annual growth rate of 6.05 percent. Industry's R&D growth rate was 3.88 percent in pre-TRIPS period and 5.07 percent in post-TRIPS period**.** These results show that growth of R&D of industry as a whole is higher in the post-TRIPS period (Table 4.3, ch.4).

b) At the Level of the Selected Leading Pharmaceutical Companies

The hypothesis was further supported by the results of the elected leading pharmaceutical companies. The results show that R&D expenditure of almost all the selected leading pharmaceutical companies has increased significantly in the span of eleven years (1998-2008) in the post-TRIPS period (Table 4.20, ch.4). Not only R&D expenditure has increased in the post-TRIPS period but R&D intensity has also improved. (Table 4.21, ch.4)

c) At Firm Level

The following hypotheses have been tested with Chi-square test at the firm level:

H_i : There is an association between firm size and impact on in house R&D as a result of signing of TRIPS.

The value of Chi-square (83.077) is significant and it depicts that there is a relationship between firm size and in-house R&D, i.e., as the firm size increases, the in-house R&D also increases.

The hypothesis is further supported by the **r**esults of factor analysis as the variable in-house R&D activities had a higher mean (3.72) than the factor mean of TRIPS, R&D and new opportunities where the mean is 2.93.

H_{ii} : There is an association between firm size and the proportion of turnover spent on R&D in the last three years.

Chi- square of 91.325 (df:6) depicts that the association between firm size and the proportion of turnover spent on R&D is significant, i.e., as the firm size increases, the proportion of turnover spent on R&D also increases.

H_{iii} : There is an association between firm size and performance of R&D.

Value of Chi square is 62.307 which is significant for 8 df, which again depicts that there is an association between firm size and performance of R&D, i.e., as the firm size increases, the performance of R&D also improves.

The above results show that the R&D has increased in the post-TRIPS period. So the hypothesis has been proved at the firm level analysis as well. So the second

hypothesis that R&D may have increased in post-TRIPS period has also been accepted.

H_3: Exports May Have Increased in the Post-TRIPS Period.

Once again this hypothesis was tested at all the three levels.

a) At Industry Level

The results highlight that the growth rate of export for the Pharmaceutical Industry has been 4.90 percent in pre-TRIPS period and 5.03 percent in post-TRIPS period, again throwing light on the fact that growth of exports of the Pharmaceutical Industry as a whole has been higher in the post-TRIPS period**.** (Table 4.4; Ch.4) This has further been supported by export-intensity, as it has also improved in the post-TRIPS period (Table 4.5; ch.4).

b) At the Level of the Selected Leading Pharmaceutical Companies

The results show that the exports of the leading pharmaceutical companies have increased in the post-TRIPS period as is shown by their respective growth rates over the period 1998-2008. (Table 4.22; ch 4) Results here are evidence of the fact that the exports of almost all the companies are positive and growing at a rate of more than 2 percent. Not only exports have increased in post-TRIPS period but export intensity has also improved.(Table 4.23; ch. 4)

c) At Firm Level

The results of primary data highlight that out of the 100 firms included in the sample, only 16 firms were focusing on exports. Out of these 16 firms, 8 were large firms and 8 were medium size firms. Only large scale firms and a few medium sized firms were indulging in exports, while the small firms were only catering to domestic requirements.

So the above hypothesis has been partially proved.

In the end it can be summarized that there has been an increase in patenting, R&D and exports in the post -TRIPS period. The firms in the Pharmaceutical Industry visualize new opportunities in the post-TRIPS period. The period has been associated with an improvement in R&D, as has been reported by the findings of industry level analysis

as well as for the selected leading pharmaceutical companies. The firm level analysis of the north west region depicts that the firms have reported a shift to better technology, an increase in in-house R&D, an increase in proportion of turnover spent on R&D, an increase in the number of products introduced and enhanced sales figures in the last one year as well as in the last three years. These results are also evident from studies of Kubo, 2004; Dhar and Gopakumar, 2006; Mani, 2006; Chaturvedi and Chataway, 2006.

Firm-level analysis also depicts that the firms accept the viewpoint that the post - TRIPS period has been associated with new opportunities as well as threats. However, the analysis has also reflected that the firms in the north west region of India are preparing themselves for the change. The results depict that the firms do not perceive Schedule M as a hasty decision and are rather willing to accept it and they do not perceive MRP based excise duty on the existing unit as a threat.

Firm-level analysis further depicts that there may be some adverse implications as firms reported that there will be an increase in the prices of drugs and an increase in the cost of production. Thus it can be concluded that there is a paradigm shift in the Pharmaceutical Industry in the post-TRIPS era, as this period is associated with a change in the viewpoint of various industry bodies and groups like CII, ASSOCHAM and FICCI and they have shifted to a pro-patent view. The firms in the Pharmaceutical Industry are filing more patents. The increasing DMF and ANDA filings further support the changing perspectives and a new paradigm of patent-culture. The study by Gupta (2007) also indicates a similar trend.

Factor analysis has been conducted for the primary data collected from 100 firms, through the survey from the north west region of India. Factor analysis extracted six factors. These are: i) TRIPS, R&D and new opportunities; ii) Products under DPCO and performance of R&D; iii) Product category, nature of order and threats; iv) Changes in technique and technical personnel employed; v) Changes in total sales and exports; and vi) Preparedness for TRIPS. These six factors account for 76.39 percent of total variation.

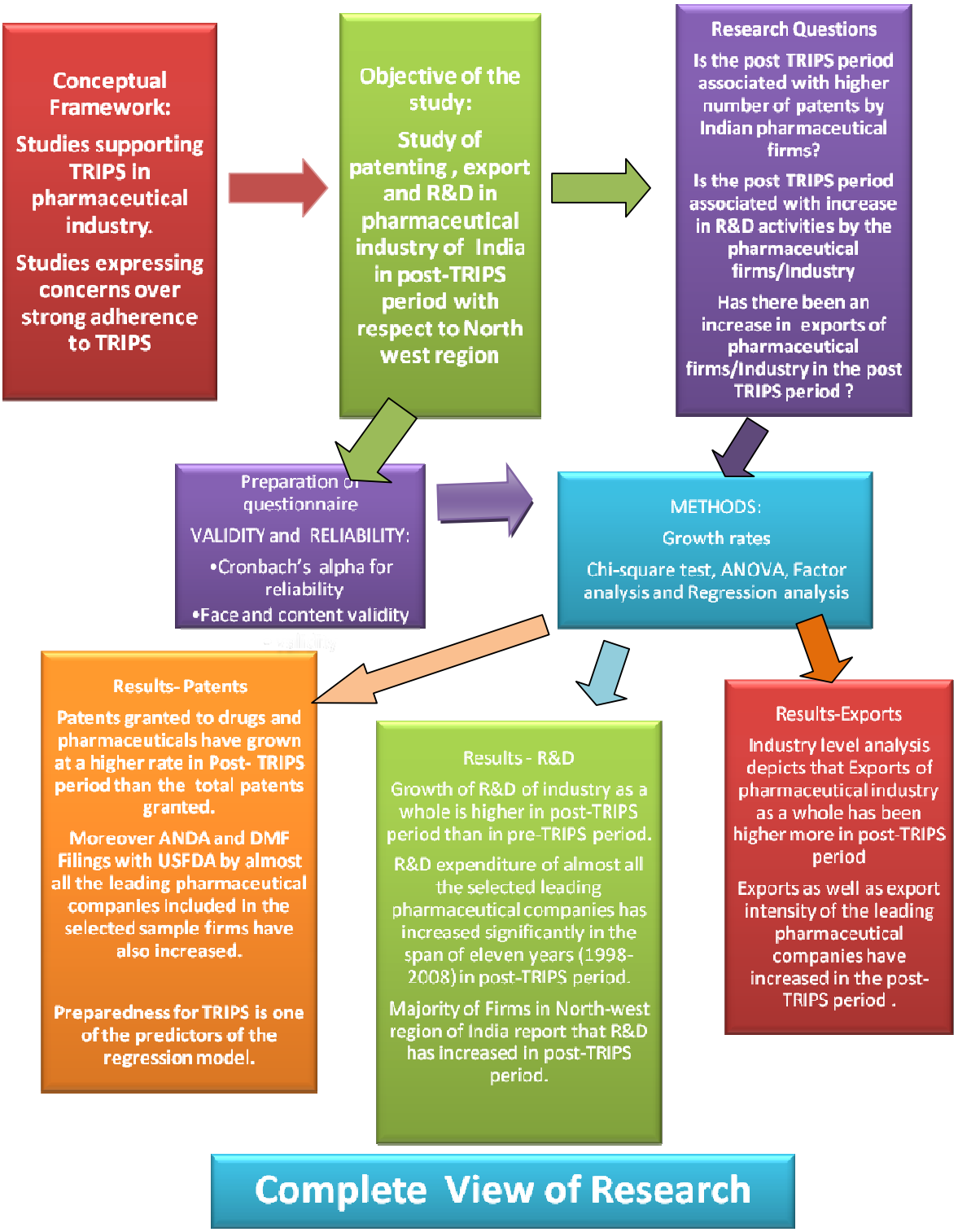
Three important factors on the basis of ranking on mean score include: i) changes in total sales and exports; ii) preparedness for TRIPS; and iii) changes in techniques and

technical personnel employed. The results of factor analysis highlight that need for patenting, change in sales and switch to new technology have higher impact on the Pharmaceutical Industry of India.

Changing perspectives and pragmatics of the Pharmaceutical Industry depict that firms are now improving their R&D capabilities and are ready to face the new challenges by preparing themselves for these changes. Small and new firms face certain threats but even they are now showing change as survival now will depend on competitiveness. 'Change or perish' is the new notion for success in this competitive global world. but it is more on the positive side.

Thus the results of the present study highlight that impact of TRIPS on the Pharmaceutical industry of India has been good. The results of the present study clearly highlight that in case of patents, R&D and exports the growth rates are higher in the post-TRIPS period. The results of the leading pharmaceutical firms also highlight increasing trends in patents, R&D and exports in the post TRIPS scenario. The impact of TRIPS as depicted by the survey analysis highlights that India is moving towards adopting global manufacturing practices. Schedule M was not considered a hasty decision even by the smaller firms. Most of the firms accepted that they are shifting to better technology. It shows that they are adapting themselves to the change.

Post TRIPS Patenting Regime and Pharmaceutical Industry of India with Reference To North West Region: Changing Paradigms, Perspectives and Pragmatics



5.3 Limitations of the Study

Like most research, a study can hardly be perfect. As such, this study also has limitations. However, these limitations also present opportunities for future research. One of the important limitations of the study, as is there in most of the cases, is that of non-availability of certain data. Like all studies, the present study also suffers from non-availability of certain data. For example, Latest data on both patents applied and patents granted was not available. Another limitation has been that the results of the study are true for the sample chosen from the north west region of India only, although, to supplement it, the study has taken perspectives of the selected leading pharmaceutical companies as well as the industry as a whole.

5.4 Recommendation For Future Research

Future research should be focused on in-depth study of patenting activity, R&D and exports by taking case studies of some selected pharmaceutical companies. A study based on technology management strategies used by these sample firms can be of great help for the policy makers as well as for the pharmaceutical firms.

BIBLIOGRAPHY

Abrol, D. (2004). **"Post-TRIPs Technological Behaviour of the Pharmaceutical Industry in India",** Science Technology Society, Vol. 9, No. 2, pp 243-271

Adede, A.O. (2001) **"The Political Economy of the Trips Agreement: Origins and History of Negotiations",** ICTSD, ACTS & QUNO, July 2001

Aggarwal, A.(2004) **"Strategic Approach to Strengthening the International Competitiveness in Knowledge Based Industries: The Indian Pharmaceutical Industry",** RIS-DP 80/2004

Aggrawal, P. and Saibaba, P.(2001) **"TRIPS and India's Pharmaceuticals Industry",** Economic and Political Weekly, Vol.36, No. 39, pp 3787-3790

Basant, R. (2007) **"Intellectual Property Rights Regimes: Comparison of Pharma Prices in India and Pakistan",** Economic and Political Weekly Vol. 42, No. 39, pp 3969-3977

Basu, D. (2006) **"Patent Laws: Developing Countries Suffer the most",** The Statesman , June 15 2006.

Bhaduri, S.(2006) **"Trips in India : Reasons and Rhetorics",** Vidyasagar University Journal of Commerce, Current Issue, Vol. 11, pp 28-38

Chadha, A.(2005) **"TRIPS and Patenting Activity: Evidence from the Indian Pharmaceutical Industry",** National University of Singapore, Department of Economics, working paper no 0512 retrieved from http://nt2.fas.nus.sg/ecs/pub/wp/wp0512.pdf.

Chadha, A. (2006) **"Destination India: The Right Choice For the Pharmaceutical Industry",** Delhi Business Review , Vol. 7, No. 1

Chandrasekhar,C.P. and Ghosh, J.(2003) **"WTO Drugs Deal: Does it Really Benefit Developing Countries?"** Business Line, Sept 09, 2003

Chaturvedi,K. and Chataway,J.,2006 , " **Innovation In The Post-Trips Regime In Indian Pharmaceutical Firms: Implications for Pharmaceutical Innovation Model"**, International Journal of Business Innovation and Research , Volume 1, Number 1-2 , pp 27-50

Chaudhuri, S.(2007) **"Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS",** Working Paper Series, No. 614/ September 2007 retrieved from http://www.iimcal.ac.in/res/upd/Sudip%20Wp%20614.pdf

Chaudhuri, S.(2005) **"TRIPS and Changes in Pharmaceutical Patent Regime in India",** Working Paper No 535, January, 2005

Chaudhuri,S.(2002) **"TRIPS Agreement and Amendment of Patents Act in India",** Economic and Political Weekly, Vol.37, No 32 , pp 3354-3360.

Chaudhuri,S., Goldberg, P. & Zia , p. (2003) **"The Effects of Extending Intellectual Property Rights Protection to Developing Countries: A Case Study of Indian Pharmaceutical Market",** NBER Working Paper Series, Working Paper No.10159, National Bureau of Economic Research, Cambridge

Chaudhuri,S.(2006) **"Industrial Policy , Globalisation and India's Pharmaceutical Industry",** conference on Post Liberalisation Constraints on Macroeconomic Policies, organized by IDEAS and UNDP, Muttukadu, Chennai, 27-29 January, 2006.

Chawala, N.(2007) **" Excise Free Zone - Myth or Reality",** Express Pharma,16-31 July 2007 retrieved from www.expresspharmaonline.com

Cygnus(2006) **"A Tough Time for Pharmaceutical SSI Units in India",** May 2006 retrieved from http://www.ipapharma.org/pp/Pharma_Professional_May_2006.pdf

Desai, A.V. (1980) **"The Origin and Direction of Industrial R&D in India"** Research Policy Volume 9, Issue 1 , January 1980, pp 74-96

Dey, S.(2007) **"Excise or No Excise?"** Express Pharma, 16-31 August, 2007 retrieved from http://www.expresspharmaonline.com/20070831/market01.shtml

Dhar, B. and Gopakumar, K.M. (2006) **"Post-2005 TRIPS Scenario in Patent Protection in The Pharmaceutical Sector: The Case of the Generic Pharmaceutical Industry in India",** the UNCTAD/ICTSD Project on Intellectual Property Rights and Sustainable Development, November, 2006

Dhillon, S. (2004), **"Economic Implications of Intellectual Property Rights From the Developing Countries"** Proceedings of the National Seminar on Intellectual Property Rights, Thapar institute of Engineering and Technology, Patiala.

Dubey, D.P (1999) **"Globalisation and its Impact on the Indian Pharmaceutical Industry",** Revolutionary Democracy, Vol. 5, No. 1, retrieved from http://revolutionarydemocracy.org/rdv5n1/pharmacy.htm.

Ernst & Young (2008) **"Pharmaceuticals",** a presentation prepared jointly by India Brand Equity Foundation (IBEF) and Ernst & Young Pvt. Ltd.

Export Import Bank of India (2007) **"Indian Pharmaceutical Industry: Surging Globally",** Occasional Paper No 119, Quest Publications.

FICCI Report, (2005) **"Competitiveness of the Indian Pharmaceutical Industry in the New Product Patent Regime",** FICCI Report for National Manufacturing Competitive Council, 2005.

Fink, C. (2000) **"How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries",** World Bank Policy Research Working Paper No 2352.

Ganguli, P.(2003) **"Global Pharmaceutical Industry-Intellectual Wealth and Asset Protection",** International Journal of Technology Management,Vol.25, No ¾, pp 284-313

Glasgow, L.J. (2001) **"Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone too far?"** IDEA- The Journal of Law and Technology, Vol. 41, No 2, pp 227-258

Grace, C.(2004) **"The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines",** DFID Health System Resource Centre: London 2004

Gupta, V.K. (2000) **"Trends in Post WTO Patenting by India in USA"** Current Science, Vol. 78, No 8, pp 955-966

Gupta, D.B.(2007) **"Exciting Opportunities for the Indian Pharmaceutical Industry",** Indian Chemical Engineer ,Vol. 49 No. 2 April-June 2007, pp. 154-157

Henderson (1997) **"TRIPS and the Third World: The Example of Pharmaceutical Patents in India",** European Intellectual Property Review, Vol. 19, No 11, pp 651-663

IPR and Technology Bulletin (2008) **"Erosion of Exclusive Marketing Rights – Boon for the Pharmaceutical Sector",** Issue VII

Jaisankar, T.S.(2007) **"Schedule M was a Hasty Decision"** Express Pharma, 15 Sep 2007 retrieved from http://www.expresspharmaonline.com/20070915/management05.shtml

Jayakumar, P.B.(2008) **'Small-Scale Pharma Firms Struggling for Survival',** Business Standard ,7 Feb., 2008 retrieved from http://www.business-standard.com/india/storypage.php?autono=312882

Jayakumar, P.B.(2006) **'Hostile Environs Force Small Firms Flee',** Pharmabiz , May 2006 retrieved from http://www.pharmabiz.com/article/detnews.asp?Arch=a&articleid=33147&sectionid=50

Jayashree, W.(1996), **"Introducing Product Patents in The Indian Pharmaceutical Sector, Implications for Prices and Welfare",** World Competition; Law and Economics Review, Vol. 20, No 2, pp 5-21

Jayashree, W.(1997), **"Implementing the TRIPS Agreement Policy Options Open to India",** Economic and Political Weekly, Vol. 32, No.39, pp 2461-2468

Kamath, N. (2002) **"Operation Successful but Patient Dead?",** MSC Thesis, Oxford University, 2001-02 retrieved from http://users.ox.ac.uk/~edip/kamath.pdf on 15th sept.2006

Kaplan,W.A, et.al.(2003) **"Is Local Production of Pharmaceuticals a Way to Improve Pharmaceutical Access in Developing and Transitional Countries? Setting a Research Agenda",** Boston University, School of Public Health, April 2003

Khader,F.A.(2008) "**Transcending Differences: The Challenge for Pharmaceuticals in the Post-TRIPS Indian Patent Regime",** Journal of Intellectual Property Rights, Vol. 13, pp 424-431

Kiran, R. and Mishra, S. (2010) **"New IPR Regime and Challenges of the Small Pharma Industry",** Interdisciplinary journal of Contemporary Research in Business, Vol.1, No 10, pp 42-60.

Kiran, R. and Mishra, S (2009) **"Performance of the Indian Pharmaceutical Industry in Post-TRIPS Period: A Firm Level Analysis"** International Review of Business Research Papers", Vol.5, No.6, pp.148-160

Kiran, R. and Mishra, S (2009) **"Changing Pragmatics of the Indian Pharmaceutical Industry in Pre and Post-TRIPS Period"** International Journal of Business & Management, Vol. 4, No 9, pp 206-220

Kiran, R. and Mishra, S (2008) **"Patenting in Pharmaceutical Industry of India: Changing Perspectives in the Post TRIPS Period"** 'Oorja', Vol.6, No. 1, pp 38-47

Kubo, K. (2004) **"Product Patents and Vertical Integration in the Post Trips Indian Pharmaceutical Industry",** retrieved from http://are.berkeley.edu/jobmarket/ken.pdf

Kumar N. (1996) **"Intellectual Property Protection, Market Orientation and Location of Overseas R&D activities by Multinational Enterprises",** World Development, Vol. 24, No 4, pp 673-688

Kumar N. (2001) **"WTO Regime Host Country Policies and Global Patterns of MNE Activity : Recent Quantitative Studies and India's Strategic Response",** Economic and Political Weekly, Vol. 36, No 1, pp 39-50

Kumar, N. (2002) **"Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries",** RIS-DP 25/2002.

Lalitha N. (2002) **"Drug Policy 2002: Prescriptions for Symptoms,''** Economic and Political Weekly, Vol. 37, No.30, PP 3102-3104

Lalitha N. (2002) **"Trips and Pharmaceutical Industry: Issues and Prospects",** GIDS, 2002

Lalitha, N. (2002) **"Indian Pharmaceutical Industry in WTO Regime: A SWOT Analysis",** Economic and Political Weekly, Vol. 37, No.34, PP 3542-3555

Lall S.and Albaladejo M. (2002) **"Indicators of the Relative Importance of IPRs in Developing Countries"** QEH Working Paper Series – QEHWPS85 Oxford April 2002 retrieved from http://www3.qeh.ox.ac.uk/pdf/qehwp/qehwps85.pdf

Lanaszka, A.(2003) **"The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries"** International Political Science Review, Vol 24, No. 2, pp181–197

Lanjouw, J. (1998) **"The Introduction of Pharmaceutical Product Patent in India: Heartless Exploitation of the Poor and Suffering?"** NBER Working Paper No.6366,retrieved from http://www.nber.org/papers/w6366

Lanjouw, J. (2002) **"Intellectual Property and the Avalibility of Pharmaceuticals in Poor Countries",** a draft to be published in innovation policy and the Economy, Vol.3

Mani, S.(2006) **"The Sectoral System of Innovation in Indian Pharmaceutical Industry",** working paper 382 retrieved from http://cds.edu/download_files/wp382.pdf

Mehrotra (1989) **"Patent Acts and Technological Self Reliance: The Indian Pharmaceutical Industry"** Economic and Political Weekly, Vol 24, No 19, pp 1059-1064

Nagappa, A.N. (2006) **"The Patents (Amendment) Act, 2005–Fears and Challenges",** Editorial, Pharmabiz. Com, September 21, 2006

Nair, G.G.(2008) **"Impact of TRIPS on Indian Pharmaceutical Industry",** Journal of Intellectual Property Rights, Vol 13, pp 432-441

Nauriyal, D.K. (2006) **"TRIPS Compliant New Patent Act and Indian Pharmaceutical Sector: Directions in Strategy and R&D",** Indian Journal of Economics & Business, Special Issue China & India

Nolan, P. (2002) **"China and the Global Business Revolution",** Cambridge Journal of Economics, Vol.26, No 1, pp 119-137

OPPI - YES Bank Report, "Pharmaceutical Industry: Vision 2015" retrieved from http://www.indiaoppi.com/Pharmaceutical%20Report_Final%2030092008%20v2.pdf on 1-10-2010

PCT (2008) **"The International Patent System: Yearly Review",** Developments and Performance in 2008.

Pradhan, J. P. (2003) **"Liberalization, Firm size and R&D Performance: A Firm level Study of Indian Pharmaceutical Industry,"** RIS-DP 40/2003.

Pradhan, J.P.(2007) **"New Policy Regime and Small Pharmaceutical Firms in India",** ISID Working Paper No 2007/02 retrieved from http://isidev.nic.in/pdf/wp0702.pdf

Pradhan, J.P. (2006) **"Strengthening Intellectual Property Rights Globally: Impact on India's Pharmaceutical Exports",** ISID Working Paper No 2006/02

Pradhan, J.P. (2006) **"Global Competitiveness of Indian Pharmaceutical Industry: Trends and Strategies"** ISID working paper, 2006/05

Rai, R.K.(2008) **"Battling with TRIPS : Emerging Firm Strategies of Indian Pharmaceutical Industry Post-TRIPS",** Journal of Intellectual Property Rights, Vol. 13, pp 301-317

Raju, K.D.(2004) **"WTO-TRIPS Obligations and Patent Amendments in India: A Critical Stocktaking"** Journal of Intellectual Property Rights, Vol. 9, No 3, pp 226-241

Ramani, S and Venkataramani, M.S. (2001) **"Rising to the Technological Challenge: Possibilities for Integration of Biotechnology in the Indian Pharmaceutical Industry",** The International Journal of Biotechnology, Vol. 3, No.1/2, pp. 95-115.

Ramanna, A. (2002) **"Policy Implications of India's Patent Reforms: Patent Applications in the Post-1995 Era"** Economic and Political Weekly, Vol. 37, No 31, pp 2065-2075

Ramanna, A. (2003) **"Interest Groups and Patent Reform in India"** Indira Gandhi

Institute of Development Research, Mumbai Working Papers, web page : http://www.igidr.ac.in/

Rangnekar, D. (2005) **"No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime"** CSGR Working Paper No. 176/05

Reddy, S. (2006) **"The Costs to India of Complying with World Intellectual Property Rights: Effects on the Pharmaceutical Industry and Access to Drugs"** Economics Thesis, May 2006.

Sampath, G.(2005) **" Economic Aspects of Access to Medicines After 2005 : Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry",** Intech Publications, retrieved From http://www.who int/entity/intellectual Property/Studies / Padmashree Sampath Final. Pdf.

Sampath , G. (2006) **"India's Product Patent Protection Regime: Less or More of Pills for the Poor?"** Working paper Series, #2006-019 retrieved from http://www.merit.unu.edu/publications/wppdf/2006/wp2006-019.pdf

Shankaran, S.(2000) **"What is the Generic Market all about",** Business Line's Investment World from the Hindu group of publications.

Srinivasan, S. (1999) **"How Many Aspirins to the Rupee?",** Economic and Political Weekly, Vol 34. No 9, pp 514-518

Smith, E.(2000) **"Opening Up to the World : India's Pharmaceutical Companies Prepare for 2005"** Asia Pacific Research Centre, Institute for International Studies, Stanford University retrieved from http://APARC. Stanford. Edu.

Tancer, R. (1999) **"Investing in the Indian Pharmaceutical Industry",** The American Graduate school of International Management, 1999, Thunderbird, retrieved from http://www.thunderbird.edu/pclf/ case series/a03990015.PAF.

Vaijayanthi, M.C.(2006) **"New Pharma Policy may Pose Setback for Baddi",** Project Monitor, January 9, 2006 retrieved from http://www.projectsmonitor.com/detailnews.asp?newsid=10313

Walker, S. (2001) **"The TRIPS Agreement, Sustainable Development and the Public Interest"** Discussion Paper, IUCN Environmental Policy and Law Paper No. 41, 2001.

WIPO (2009) **"World Patent Report: A Statistical Review"** by World Intellectual Property Organization

Wishwas, R.(1995) **"Drug Prices: Sharp Rise after Decontrol",** Economic and Political Weekly, Vol 30, No 47, pp 2977-2980

Zaveri, N.B. (2002) **"WTO Agreements on TRIPS"** The World Economy, Vol. 23 No 5, pp.733-752.

Zuniga, Z.P. & Combe, E. (2002) **"Introducing Product Patent in Pharmaceutical Sector: A First Evaluation of the Mexican Case"** Region et Developpement, Vol.0, No 16, pp 191-221

Appendix- I

SPSS output for Multiple Linear Regression Analysis (Step-wise)
Dependent Variable : DP11
Independent Variables : IP11, IP12, IP13, IP14, IP15, IP16

Correlation Matrix

		DP11	IP 11	IP12	IP13	IP14	IP15	IP16
DP11	Pearson Correlation	1.000	-.038	.599**	.623**	-.038	.196*	.278**
	Sig. (1-tailed)		.352	.000	.000	.355	.025	.003
	N	100.000	100	100	100	100	100	100
IP 11	Pearson Correlation	-.038	1.000	-.218*	.141	.516**	.194*	.054
	Sig. (1-tailed)	.352		.015	.082	.000	.027	.298
	N	100	100.000	100	100	100	100	100
IP12	Pearson Correlation	.599**	-.218*	1.000	.097	.123	-.067	.404**
	Sig. (1-tailed)	.000	.015		.169	.111	.254	.000
	N	100	100	100.000	100	100	100	100
IP13	Pearson Correlation	.623**	.141	.097	1.000	-.018	.251**	.311**
	Sig. (1-tailed)	.000	.082	.169		.428	.006	.001
	N	100	100	100	100.000	100	100	100
IP14	Pearson Correlation	-.038	.516**	.123	-.018	1.000	-.081	.226*
	Sig. (1-tailed)	.355	.000	.111	.428		.212	.012
	N	100	100	100	100	100.000	100	100
IP15	Pearson Correlation	.196*	.194*	-.067	.251**	-.081	1.000	.015
	Sig. (1-tailed)	.025	.027	.254	.006	.212		.442
	N	100	100	100	100	100	100.000	100
IP16	Pearson Correlation	.278**	.054	.404**	.311**	.226*	.015	1.000
	Sig. (1-tailed)	.003	.298	.000	.001	.012	.442	
	N	100	100	100	100	100	100	100.000

**. Correlation is significant at the 0.01 level (1-tailed).

*. Correlation is significant at the 0.05 level (1-tailed).

Appendix -II

Results of Regression Analysis

Model Summary[d]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.623[a]	.388	.382	.424	.388	62.077	1	98	.000	
2	.825[b]	.681	.674	.308	.293	88.883	1	97	.000	
3	.836[c]	.699	.690	.300	.019	5.908	1	96	.017	2.197

a. Predictors: (Constant), IP13

b. Predictors: (Constant), IP13, IP12

c. Predictors: (Constant), IP13, IP12, Ip16

d. Dependent Variable: DP11

ANOVA[d]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	11.175	1	11.175	62.077	.000[a]
	Residual	17.642	98	.180		
	Total	28.818	99			
2	Regression	19.611	2	9.806	103.314	.000[b]
	Residual	9.206	97	.095		
	Total	28.818	99			
3	Regression	20.145	3	6.715	74.330	.000[c]
	Residual	8.673	96	.090		
	Total	28.818	99			

a. Predictors: (Constant), IP13

b. Predictors: (Constant), IP13, IP12

c. Predictors: (Constant), IP13, IP12, Ip16

d. Dependent Variable: DP11

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	T	Sig.
		B	Std. Error	Beta		
1	(Constant)	1.064	.330		3.228	.002
	IP13	.807	.102	.623	7.879	.000
2	(Constant)	.399	.250		1.597	.113
	IP13	.739	.075	.570	9.889	.000
	IP12	.285	.030	.544	9.428	.000
3	(Constant)	.407	.244		1.672	.098
	IP13	.795	.076	.613	10.400	.000
	IP12	.316	.032	.602	9.838	.000
	IP16	-.094	.038	-.156	-2.431	.017

a. Dependent Variable: DP11

Excluded Variables

Model		Beta In	T	Sig.	Partial Correlation	Collinearity Statistics
						Tolerance
1	IP 11	-.128[a]	-1.623	.108	-.163	.980
	IP12	.544[a]	9.428	.000	.691	.991
	IP14	-.026[a]	-.331	.742	-.034	1.000
	IP15	.042[a]	.515	.608	.052	.937
	IP16	.093[a]	1.124	.264	.113	.904
2	IP 11	.000[b]	.001	1.000	.000	.926
	IP14	-.096[b]	-1.670	.098	-.168	.984
	IP15	.096[b]	1.626	.107	.164	.928
	IP16	-.156[b]	-2.431	.017	-.241	.763
3	IP 11	.017[c]	.283	.778	.029	.914
	IP14	-.070[c]	-1.210	.229	-.123	.939
	IP15	.091[c]	1.582	.117	.160	.927

a. Predictors in the Model: (Constant), IP13

b. Predictors in the Model: (Constant), IP13, IP12

c. Predictors in the Model: (Constant), IP13, IP12, IP16

d. Dependent Variable: DP11

Appendix -III

QUESTIONNAIRE ON POST TRIPS PATENTING REGIME AND PHARMACEUTICAL INDUSTRY OF INDIA WITH REFERENCE TO NORTH WEST REGION: CHANGING PARADIGMS, PERSPECTIVES AND PRAGMATICS

Dear Sir/Madam

We are conducting research to study the impact of TRIPS on Indian pharmaceutical sector. Your valued response/opinion would help us to understand the impact and suggest suitable strategies for Indian pharmaceutical industry. (Please tick your choice)

1. Section A: Organization's Profile						
Organization's Name						
Organization's Address						
Survey Respondent's Name and Designation						
Respondent's E-mail/Address						
Experience						
Section B : Overall Performance of the firm						
1.	**Type of Industry**	**Large Scale**	**Medium Scale**	**Small Scale**		
2.	**Year of Establishment**	**Till 1980**	**1981-94**	**1995 onwards**		
3.	**Type of Industry**	**Proprietary**	**Partnership**	**Public Limited Co.**	**Pvt. Ltd Company**	
4.	**Sales (last one year)**	Substantially Decreased	Marginally Decreased	Remained the same	Marginally Increased	Substantially Increased
5.	**Sales in (last three years)**	Substantially Decreased	Marginally Decreased	Remained the same	Marginally Increased	Substantially Increased
6.	**Market share in the last three years**	Substantially Decreased	Marginally Decreased	Remained the same	Marginally Increased	Substantially Increased
7.	**Turnover in the last three years**	Substantially Decreased	Marginally Decreased	Remained the same	Marginally Increased	Substantially Increased

8.	**Overall performance during TRIIPS**	Substantially Decreased	Marginally Decreased	Remained the same	Marginally Increased	Substantially Increased
Section C: TRIPS – Knowledge of TRIPS and Its Impact on Patents, Research & Development and Exports						
9.	**Do you know that India has signed TRIPS?**	Yes		No		
10.	**Do you feel that signing of TRIPS may have strong implications for small pharmaceutical companies?**	Yes		No		Don't know
11.	**Did you file for any patents after 1994?**	Yes		No		
12.	**Do you perceive a need for patents after implementation of TRIPS**	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
13.	**Your in-house R&D activities in the last three years have**	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased
14.	**Proportion of turnover spend on R&D in the last few years has**	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased
15.	**Performance of R&D in Post-TRIPS period**	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased
16.	**Focus on Exports**	Yes		No		
17.	**Exports in the last three years**	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased
Section D :TRIPS: Other Perspectives						
18.	**Do you think schedule M was a hasty decision?**	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
19.	**Cost of production as a**	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased

	result of signing of TRIPS?					
20.	**Do you think there is a Shift to better technology due to TRIPS**	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
21.	**Is the share in domestic market declining?**	Yes		No		
22.	**Has there been an increase in the number of skilled persons employed?**	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
23.	**The therapeutics of the drugs you are dealing with in the last three years has**	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased
24.	**Impact of MRP based excise duty on the existing Units**	Quite Substantial	Substantial	Marginal	No Impact	
25.	**Drug produced by the firm**	Bulk drugs	Formulations	Both		
26.	**Category of Product**	Generic Products	Branded Products	Both		
27.	**Number of products introduced by your company in the last 1 year.**	<5	6-10	11-20	21-40	>40
28.	**Number of products introduced by the firm in the last three years.**	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased
29.	**The number of products covered under Drugs Price Control Order (DPCO) is**	0-10%	11-30%	31-50%	51-70%	70% & above
30.	**Firm Size and sales in the last three years**	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased
31.	**Is the firm getting bulk**	Yes			No	

	order from big companies after signing of TRIPS?					
32.	**Bulk order from big companies in the last three years**	Substantially Decreased	Marginally Decreased	Remained Same	Marginally Increased	Substantially Increased
33.	**Your opinion on the impact of TRIPS on various issues related to Indian Pharmaceutical Industry (please tick)**	Prices of all drugs will increase	Prices of certain drugs will increase	No change in prices	Increase in R&D activity	Increase in mergers / acquisitions etc
34.	**Do you think new Opportunities have been created due to TRIPS**	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
35.	**Do you find any threats due to TRIPS in form of competitions from foreign companies**	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
36.	**Do you think you can face challenges posed by TRIPS?**	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

Thanks

Appendix- IV

List of Publications:

1. Ravi Kiran and Mishra, Sunita (2010) **"New IPR Regime and Challenges of the Small Pharma Industry",** *Interdisciplinary journal of Contemporary Research in Business,* Vol.1, No 10. pp 42-60.

2. Ravi Kiran and Sunita Mishra (2009) **"Performance of the Indian Pharmaceutical Industry in Post- TRIPS Period: A Firm Level Analysis",** *International Review of Business Research Papers,* Vol.5, No. 6, pp 148-160

3. Ravi Kiran and Mishra, Sunita (2009) **"Changing Pragmatics of The Indian Pharmaceutical Industry in Pre and Post-TRIPS Period"** *International Journal of Business & Management,* Vol. 4, No 9, pp 206-220

4. Ravi Kiran and Mishra, Sunita (2008) **"Patenting in Pharmaceutical Industry of India : Changing Perspectives in the Post TRIPS Period"** *Oorja,* Vol.6, No. 1, pp 38-47