Chapter No – 3

Intellectual Property Rights and Indian Pharmaceutical Industry
3.0 Introduction

The Indian pharmaceutical company has changed extremely over the last 50 years, from being traders in imported drugs in the fifties, to major bulk drug producers by the eighties. During this transitional period Indian pharmaceutical units have learnt the technology of bulk drug production by their own research and adaptation, and today they produce more than 250 bulk drugs, emphasizing on import substitution and use of indigenous raw materials. (1) At present the Indian pharmaceutical company has about 300 large units, 1700 medium-size units and about 8000 small-scale units throughout the country. (2) The Indian industry has progressed through the value-added ladder of pharmaceutical production as a result of its domestic policies as well as the presence of supportive factor conditions, namely, the pool of scientific excellence available at low cost. The Indian pharmaceutical company accounted for 70% of the bulk drugs and 80% of the formulations in the country, making India one of the few countries in the world achieving self-sufficiency in drugs. (3) The industry is highly fragmented; no single company has more than 7% market share, and the largest five companies account for just 20% of the total market.(4)

3.1 The Impact of the World Trade Organization on Pharmaceutical Patents

Driver of transform: 2005 patent reform

The development of the Indian pharmaceutical company has been shaped by the position of the Indian government on intellectual property law as outlined in the Indian Patent Act of 1970, under which only process patents were covered. Furthermore, the Act provided only seven years of process patent protection for pharmaceuticals about half of the average 15 years required to develop and test a new drug.
The establishment of the World Trade Organization (WTO) has led to a tremendous paradigm shift in world trade. The agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was negotiated during the Uruguay round trade negotiations of the General Agreement on Tariffs and Trade (GATT) and one of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry. India signed the GATT on 15 April 1994, thereby making it mandatory to comply with the requirements of GATT, including the agreement on TRIPS.

India is thereby required to meet the minimum standards under the TRIPS Agreement in relation to patents and the pharmaceutical industry. India’s patent legislation must now include provisions for availability of patents for both pharmaceutical products and processes inventions. Patents are to be granted for a minimum term of 20 years to any invention of a pharmaceutical product or process that fulfils established criteria. Compulsory license provisions under Indian law will be required to be limited and conditional to comply with the TRIPS Agreement, and the government will grant such licenses only on the merit of each case after giving the patent holder an opportunity to be heard. In addition, there will be no discrimination between imported and domestic products in the case of process patents, and the burden of proof will rest with the party that infringes.

India has decided to avail itself of the full transition period for developing countries and has until 1 January 2005 to extend patent protection to pharmaceutical products. In keeping with the TRIPS commitments, India has started on a process of amending the Patents Act by providing exclusive marketing rights (EMRs) and creating a mailbox system for patent applications for a period of five years or until the patent is granted or rejected, whichever is earlier.

### 3.2 Patents and the Future of the Indian pharmaceutical company

The absence of product patent protection for pharmaceuticals and agrochemicals led many multinationals to limit their portfolios to patent expired products or a few selected patented products.

This resulted in an erosion of their market share because

1. Local manufacturers introduced the most advanced medicines through reverse engineering.
2. Foreign firms were required to pay royalties for international drugs, while Indian companies could access the newest molecules from all over the world and reformulate them for sale in the domestic market.

**Possible options for IPI**

As far as India’s pharmaceutical industry is concerned, various options are possible in the WTO regime.

These are to:

(a) Manufacture off patented generic drugs,
(b) Produce patented drugs under compulsory licensing or cross licensing,
(c) Invest in R&D to engage in new product development,
(d) Produce patented and other drugs on contract basis,
(e) Explore the possibilities of new drug delivery mechanisms and alternative use of existing drugs, and
(f) Collaborate with multinationals to engage in R&D, clinical trials, product development or marketing the patented product on a contract basis and so on.

Besides these strategies, India’s strength lays in process development skills. This expertise utilised within the WTO framework with emphasis on quality standards will provide India a competitive advantage over other Asian countries.

**India’s core competencies**

The core competencies that have led Indian pharmaceutical companies to heightened global visibility are,

1. Complex synthesis capabilities
2. Increasingly good manufacturing practices (GMP)
3. Low-cost production.

**Cost advantages of Indian firms**

Indian firms have lower costs estimated to be one-eighth (in R&D) to one-fifth (in manufacturing) compared to Western firms. The following factors are the basis for this cost advantage:

1. **Fixed asset costs:**

The cost of building a new manufacturing facility complying with international regulatory norms is about one-fourth the cost of setting up a similar facility in the US or Europe. Civil
construction is $8-$12 per square foot versus $75 in the US. (5) Material costs (used for reactors, vessels, and other equipment) may also be lower.

2. **Cheaper labor:**
The cost of an Indian based laboratory analyst/chemist is one-fifth to one-eighth of the US cost. Higher-level Indian scientists are well trained yet earn about a third of their Western counterparts’ salaries. Plant employees cost $120–$150 per month. (6)

3. **Chemistry/process expertise and development costs:**
More than three decades of reverse engineering ‘on-patent’ drugs (process engineering) has made Indian companies extremely proficient in speedy generic drug development, therefore more productive per unit of cost. Lower development costs result in lower regulatory filing costs, and this, combined with the increasing admissibility of Indian bio-equivalence studies to the FDA, puts India at an advantage. (7) On the manufacturing side, continuous process improvement has also resulted in a highly efficient cost structure for India’s bulk actives.
4. **Clinical study costs:**
A large population of treatment naive patients facilitates rapid trial recruitment into large clinical studies. Cost per patient enrolled is approximately one-tenth of the cost in the US. (8) However, neither Indian companies nor international companies have leveraged this cost advantage in any material sense, Indian companies due to nascent drug discovery research and pharmaceutical MNCs due to concerns over intellectual property confidentiality.

5. **Cost of sales force:**
The average salary (including all benefits) of a typical drug representative for the Indian market is $4,000 per year. (9)

**Reason for working with Indian firms**

There are many reasons why MNCs are drawn to functioning with Indian firms. India graduates approx 122,000 chemists and chemical engineers each year, and these graduates have traditionally found jobs focused on reverse engineering. (10) With the implementation of product patent law, Indian pharmaceutical companies will have to find alternative ways to employ some of this capacity.

MNCs can use these skills to reengineer the manufacturing process for already-marketed products or to manufacture bulk-actives or intermediates for use in clinical development. Some firms are attractive as research partners; a few have even attracted out-licensing deals for clinical research.

1. **Cost-effective chemical synthesis:**
Its track record of development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules is excellent. It provides a wide variety of bulk drugs and exports sophisticated bulk drugs.

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8. Pharma Industry Overview
9. Pharma Industry Overview
10. Pharma Industry Overview
2. **Competent workforce:**
   India has a pool of personnel with high managerial and technical competence as also skilled workforce. It has an educated work force and English is commonly used. Professional services are easily available.

3. **Information Technology and education:**
   It has a good network of world-class educational institutions and established strengths in Information Technology.

4. **Globalization:**
   The country is committed to a free market economy and globalization. Above all, it has a 70 million middle class market, which is continuously growing. (11)

5. **Consolidation:**
   For the first time in many years, the international pharmaceutical industry is finding great opportunities in India. The process of consolidation, which has become a generalized phenomenon in the world pharmaceutical industry, has started taking place in India.

6. **Legal & Financial structure:**
   India has a 53 year old democracy and hence has a solid legal framework and strong financial markets. There is already an established international industry and business community.

3.3 **Strategic choices for Indian firms**
   The introduction of product patents has important implications for both Indian and international companies. After 2005, Indian companies will increasingly need to look beyond the domestic generics market to sustain their sales, as their traditional strategy of copying on-patent drugs will no longer be allowed. They will therefore need to look towards export markets and focus on product innovation.

   In pursuing the regulated markets, the more successful Indian firms are faced with a similar strategic choice in how to achieve such growth: whether to co-operate or compete with the large international pharmaceutical companies.
3.1 Strategic choices for Indian firms

However, there are multiple sub strategies that Indian firms can choose within the framework of this strategic dilemma, and the strongest Indian firms have been able to pursue both strategies simultaneously.
3.4 Clinical trials opportunities in India

It has been estimated that the pharmaceutical industry spends up to $800 million to bring a new molecule to market. (12) Perhaps a third of the total goes towards clinical trials, and much of that is spent on Phase III trials that use a lot of human subjects.

1. The life of a patent begins to ebb away from the moment it is filed; each day saved on testing can bring millions of dollars in extra revenues to the patent holders.
2. Clinical trials in India ought to be cheaper and faster than those in developed markets.
3. Contract research organizations can hire researchers, nurses and computer staff at less than a third of Western wages.
4. The Indian population is large, ethnically diverse and suffers from both tropical diseases as well as ailments such as cancer, diabetes and heart disease that also affect rich countries.
5. Overall clinical development costs in India are estimated to be 40–60% lower than those in the West. (13) Specialist contract research organizations such as Quintiles have set up shop in India.

3.5 Benefits to India from modernizing the Indian Pharma Industry

This section discusses some of these benefits, as social, economical and political issues relating to Patent and Indian pharmaceutical company,
A. Social benefits: -

1. The development of the Indian pharmaceutical company would create new jobs, but mainly it would provide access both to modern technology in the field of medicines and to medicines developed indigenously. As a result, it will be able to provide new drug formulations and improved healthcare treatments to Indian patients.

2. In particular, new medicines would be available to treat diabetes, cardiovascular diseases, cancer, and psychological disorders. But even during the drug discovery and development phases, significant funds would be invested in local communities. For example, during Phases I to IV, normal volunteers or patients would participate in clinical trials during which they receive free medicines and are paid to participate. In Phase IV trials, patients who cannot afford expensive medicine will have the opportunity to receive modern medicines.

As a result of changes in the culture and in the social environment, new types of diseases are invading India. India must have a concrete plan to protect itself from these diseases, and the development of the pharmaceutical sector is the first step.

B. Economic benefits:

1. The development of the pharmaceutical industry would help the Indian economy produce more national wealth.

2. Foreign investment would increase, and Indian companies would have the opportunity to collaborate with many companies from around the world. Indirectly, developing the pharmaceutical industry would also help other industries.

3. The related employment opportunities in various fields are no less important. If good jobs were available locally, citizens would not feel the economic pressure to migrate to the United States, Europe, or Japan.

4. Development of clinical trial centers would provide funding from private pharmaceutical industries to local hospitals. In return, a staff of nurses and doctors would be maintained, which would benefit local communities.
According to economics historian Walt Rostow, five stages of economic development exist. The stages are

I. Traditional society
II. The preconditions for takeoff.
III. Economic takeoff,
IV. Which is then matures in the fourth stage.
V. High mass consumption.

Increased spending for the protection of the environment would produce more-hygienic conditions for the population, and protecting the environment from the beginning would avoid the potential for future cleanup costs.

C. Political benefits:

1. Economic growth will bring political stability to India. It will improve international credibility and create a visionary rather than a reactionary political regime.

2. The poverty level in India stands at 27%, which is very high compared with China’s 5% level, for example. (14)

3. Making medicines affordable to all Indian citizens is a noble goal, but one must strive for a fair distribution of low-priced medicines to the masses and high priced modern medicines to wealthier people.

4. The economic development that would result from growth in the pharmaceutical and computer sectors could trigger development of other sectors and indirectly lower the poverty level.

5. India can then achieve macroeconomic growth through education, infrastructure development, improved sanitation, and enhanced public health. In a political sense, these developments will forge a win–win situation for Indian citizens and politicians.

A committee of representative physicians from various internal states, government officials, and key executives from various pharmaceutical companies could likely muster the clout required to meet the health requirements of Indian citizens as well as promote the country’s pharmaceutical
industry. Changing disease patterns must be understood, and policies must be prioritized for the treatment of diseases.

3.6 Risks faced by Indian firms

Despite their existing competitive advantages and promising opportunities on the horizon, Indian firms have certain weaknesses and therefore face certain competitive threats, which can be summarized as follows:

1. Indian companies are relatively new to the generics business in regulated markets and there are concerns regarding their ability to manage large product portfolios, entailing numerous regulatory filings, scaling up manufacturing, forging alliances, and legal skills to win on patent litigations.

2. The US based generic industry may be able to glean the same cost advantages as Indian firms through developing partnerships or green field sites in India. US based generics companies such as Watson, Ivax, and Apotex have already secured manufacturing agreements with Indian bulk active/dosage form manufacturers and in the medium term, this may mitigate some of the cost advantages enjoyed by the fully integrated Indian companies like Dr Reddy’s, Ranbaxy and Sun.(15)
3. The research-based industry has also been increasingly interested in marketing their own generic alternatives to their patented products, spurred by the impending flurry of patent expirations and the knowledge that the majority of the profits of a generic drug are earned in the first six months post patent-expiry.

4. The impending deceleration in patent expirations post 2007 presents another risk to Indian firms.

5. There is a moral hazard/tragedy of the commons problem – being the reputation risk that the entire industry will face if one player cuts corners with regard to GLP or GMP.

6. Pursuing the NCE strategy is risky, not least because Indian firms have a skills shortage in the area of patent writing. It has been suggested that many existing patents written by Indian professionals can be easily circumvented; so even where an Indian company has produced an innovation; it may not be protected in international settings.

7. Indian firms are strong in chemistry, but they are relatively weak in biology and clinical research and development skills, and these are essential to compete in the innovative, NCE drug category.

8. There is a risk that the co-operative strategies employed by some firms could get in the way of the competitive strategies of these firms, especially if Indian firms do not negotiate reasonable contract terms with MNCs and/or fail to ring-fence their competitive advantages.

9. Lastly, there is a risk of protectionism in developed markets, since jobs lost from US and EU will not only be those in manufacturing but also in the more skill intensive research sectors.

3.7 Innovations related incentives

An innovative industry in India can get competitive advantage in the market if it develops the necessary expertise and skills in developing and manufacturing new products, which are
patented. For example, the advantage of a three year excise duty exemption or exemption from Drugs Price Control Order may translate into reserves income which may offset the cost towards R&D. In order to promote R&D and innovation in Indian industries, Government of India provides a number of fiscal incentives and support measures to industries.

With increasing public private partnership in technology development through schemes of Technology Development Board, Drug and Pharmaceutical Board and NMILTI, the following incentives would be extremely useful in promoting the culture of innovation and intellectual property protection in industries, academic and R&D institutions.

1. **Excise duty waiver on patented products**
All goods falling under the Schedule to the Central Excise Tariff 1985 are exempt from the excise duty for a period of 3 years from the date of commencement of commercial production provided such goods are manufactured by a wholly owned Indian company and such goods are designed and developed by such Indian company and the goods so designed are patented in any two countries outside India namely, USA, Japan and any country of the European Union. The manufacturer, before commencing commercial production must obtain a certificate from the Department of Scientific and Industrial Research for claiming the benefit.

2. **Exemption from Drug Price Control Order**
Bulk drugs produced based on indigenous R&D are exempt from drug price control for a period of 5 years from the date of commencement of commercial production provided that they are produced from the basic stage by a process of manufacture developed by the unit through its own R&D efforts. In case of a drug, which has not been produced elsewhere, if developed and produced indigenously, it would be placed outside the price control order for a period of 10 years from the date of commencement of commercial production. In order to establish that a process or a product has been developed through indigenous R&D, novelty of the process or product would have to be ensured. In other words a patent would have to be necessarily obtained for claiming the benefit.

3. **Weighted tax deduction on R&D expenditure**
Weighted tax deduction at150% on R&D expenditure is available to companies engaged in the business of biotechnology, or the business of manufacture or production of drugs, pharmaceuticals, electronic equipment, computers, telecommunication equipment, chemicals and manufacture of aircraft and helicopters. The expenditure on scientific research in relation to
drugs and pharmaceuticals shall include expenditure incurred on clinical trials of drugs, obtaining approval from the regulatory authority under any Central, State or provincial Act and the filing of a patent application in India.

4. **Accelerated depreciation allowance**
Depreciation allowance at a higher rate is available in respect of plant and machinery installed for manufacturing goods based on indigenous technology developed in recognized in house R&D units, Government R&D institutions, national laboratories and Scientific and Industrial Organizations (SIRO). The present rate of depreciation for plant and machinery is 40% as against 25% for other plants and machinery.

5. **Tax holiday to R&D companies**
Tax holiday is available to approved companies engaged in scientific and industrial R&D activities on commercial lines for ten consecutive assessment years. This incentive is applicable to any commercial company that has its main objective and activities in the area of scientific and industrial R&D. This would be applicable to companies approved after March 31, 2000 but before April 1, 2003.

6. **Income tax relief on R&D expenditure**
Under Section 35(1) (i) of the Income Tax Act 1961, the revenue expenditure on scientific research, by recognized R&D units, on activities related to the business of the company is allowed full deduction. Under Section 35(1) (iv) expenses of a capital nature could be deducted totally from the income of the year in which the expenses have been incurred.

7. **Tax deduction for sponsoring research**
Section 35(2AA) of the IT Act 1961 provides for a weighted tax deduction of 125% for expenses on sponsoring research programmes at National laboratories functioning under ICAR, CSIR, ICMR, DRDO, Department of Biotechnology, Department of Atomic Energy, Department of Electronics; IIT and universities.

**Government Tax exemption**

**Tax Regime:**

The following major initiatives have been taken by the Indian Government for the
Pharmaceutical industry after 2005:

- A reduction in excise duty from 16 percent to 8 percent on all goods produced in the pharmaceutical sector.
- Amounts spent on R&D eligible for a 125 percent weighted deduction.
- A reduction in customs duty from 10 to 5 percent and a total exemption of excise duty on certain specified life-saving drugs and bulk drugs used in the manufacture of Anti-AIDS drugs.
- Central sales tax on specified life saving drugs has been reduced to two percent from three percent.

Value Added Tax:

- Drugs and medicines are taxed at 4% except Assam where the rate is 6%.
- Medical devices are taxed at 12.5% in three states Maharashtra, Gujarat and Kerala, whereas in all other states, the tax rate is 4%.
- Some states have introduced a system of levying tax on MRP at a single point i.e. first sale in the state is subject to VAT on the basis of MRP and subsequent sales, in general, are exempt. The MRP system is optional in some states. States such as Madhya Pradesh, Chattisgarh and Orissa levy entry tax on entry of medicines and devices in to these states.

Other Initiatives:

- An allocation of Rs 16, 534 crore for the healthcare sector.
- An increased allocation for the National Rural Health Mission (NRHM) amounting to Rs 12, 050 crore.
- An amount of Rs 993 crore provided for the National Aids Control Programme (NACP) and Rs 1, 042 crore provided for the eradication of polio.
- A 5 year tax holiday for hospitals in the Tier –II and Tier –III cities.

Foreign Direct Investment:

FDI up to 100% is permitted through the automatic route for the manufacture of drugs and pharmaceuticals provided the activity does not attract compulsory licensing or involves the use of recombinant DNA technology and specific cell / tissue targeted formulations. FDI proposals for the manufacture of licensable drugs, pharmaceuticals and bulk drugs produced by
recombinant DNA technology and specific cell / tissue targeted formulations will require prior approval of the Foreign Investment Promotion Board (FIPB) of the Government of India.

**Market Trends:**

- The domestic pharmaceutical market in India has grown at a CAGR of nearly 12% in the last five years.
- The major pharmaceutical companies in India are the main R&D investor in the country. The R&D spend (capital and current) of these major companies has grown at CAGR of 38 percent during the period 2000–01 to 2005–06.
- In 2005–06, the R&D expenditure of 50 major companies totaled $495.19 million growing at a rate of 26 percent over the previous year. The higher growth rate is attributed to product patent implementation in the country in January 2005.
- The Indian prescription drug market in 2006 was worth Rs 27,333 crore (Rs 273.33 billion), up 18 per cent as compared to Rs 23,243 crore (Rs 232.43 billion) in 2005. Bulk of this business came from the sale of drugs that do not enjoy patent protection, a reason for the dominance of domestic companies.

3.8 Growth Scenario in 2010

India's pharmaceutical industry is now the third largest in the world in terms of volume. Its rank is 14th in terms of value. (16) Between September 2008 and September 2009, the total turnover of India's pharmaceuticals industry was US$ 21.04 billion. (17) The domestic market was worth US$ 12.26 billion. (18) The Indian pharmaceutical market reached US$ 10.04 billion in size in July 2010. (19) A highly organized sector, the Indian Pharma Industry is estimated to be worth $4.5 billion, growing at about 8 to 9 percent annually. (20)

Leading Pharmaceutical Companies

In the domestic market, Cipla retained its leadership position with 5.27 per cent share. (21) Ranbaxy followed next. The highest growth was for Mankind Pharma (37.2%). Other leading companies in the Indian pharma market in 2010 are:

16- Ministry of Chemicals and Fertilizers
17- Ministry of Chemicals and Fertilizers
18- Ministry of Chemicals and Fertilizers
19- IMS Health India
20- IMS Health India
21- IMS Health India
3.1 Leading companies in the Indian pharma market in 2010

<table>
<thead>
<tr>
<th>Company</th>
<th>Market Share</th>
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<tbody>
<tr>
<td>Sun Pharma</td>
<td>25.7%</td>
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<tr>
<td>Abbott</td>
<td>25%</td>
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<tr>
<td>Zydus Cadila</td>
<td>24.1%</td>
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<tr>
<td>Alkem Laboratories</td>
<td>23.3%</td>
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<tr>
<td>Pfizer</td>
<td>23.6%</td>
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<tr>
<td>GSK India</td>
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</tr>
<tr>
<td>Piramal Healthcare</td>
<td>18.6%</td>
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<tr>
<td>Lupin</td>
<td>18.8%</td>
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(Source- Pharmaexpress)

Future Prospects

The Indian pharmaceuticals market is expected to reach US$ 55 billion in 2020 from US$ 12.6 billion in 2009. (22) In an aggressive growth scenario, the pharma market has the further potential to reach US$ 70 billion by 2020. (23)

Due to increase in the population of high income group, there is every likelihood that they will open a potential US$ 8 billion market for multinational companies selling costly drugs by 2015. This was estimated in a report by Ernst & Young. The domestic pharma market is estimated to touch US$ 20 billion by 2015. The healthcare market in India is to reach US$ 31.59 billion by 2020.

The sale of all types of pharmaceutical drugs and medicines in the country stands at US$ 9.61 billion, which is expected to reach around US$ 19.22 billion by 2012. Thus India would really become a lucrative destination for clinical trials for global giants. (24)

22- Pharmaceutical drug manufacturers

23- Record of drug manufacturers

24- Pharmaceutical drug manufacturers
There was another report by RNCOS titled "Booming Pharma Sector in India" in which it was projected that the pharmaceutical formulations industry is expected to prosper in the same manner as the pharmaceutical industry. The domestic formulations market will grow at an annual rate of around 17% in 2010-11, owing to increasing middle class population and rapid urbanization. (25)

**Characteristics of Indian pharmaceutical company**

The Indian Pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in the last two decades. The leading 250 pharmaceutical companies control 70% of the market with market leader holding nearly 7% of the market share. It is an extremely fragmented market with severe price competition and government price control. (26) The pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles. There are about 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units). (27) These units produce the complete range of pharmaceutical formulations, i.e., medicines ready for consumption by patients and about 350 bulk drugs, i.e., chemicals having therapeutic value and used for production of pharmaceutical formulations.

Following the de-licensing of the pharmaceutical industry, industrial licensing for most of the drugs and pharmaceutical products has been done away with. Manufacturers are free to produce any drug duly approved by the Drug Control Authority. Technologically strong and totally self-reliant, the pharmaceutical industry in India has low costs of production, low R&D costs, innovative scientific manpower, strength of national laboratories and an increasing balance of trade. The Pharmaceutical Industry, with its rich scientific talents and research capabilities, supported by Intellectual Property Protection regime is well set to take on the international market.
**Steps to strengthen the Industry**

Indian companies need to attain the right product-mix for sustained future growth. Core competencies will play an important role in determining the future of many Indian pharmaceutical companies in the post product-patent regime after 2005.

Indian companies, in an effort to consolidate their position, will have to increasingly look at merger and acquisition options of either companies or products. This would help them to offset loss of new product options, improve their R&D efforts and improve distribution to penetrate markets.

Research and development has always taken the back seat amongst Indian pharmaceutical companies. In order to stay competitive in the future, Indian companies will have to refocus and invest heavily in R&D.

The Indian pharmaceutical company also needs to take advantage of the recent advances in biotechnology and information technology. The future of the industry will be determined by how well it markets its products to several regions and distributes risks, its forward and backward integration capabilities, its R&D, its consolidation through mergers and acquisitions, co-marketing and licensing agreements.

**3.9 Pharmaceutical industry in pre and post TRIPS period:**

**Pharmaceutical industry in pre-TRIPS period:**

The Pharmaceutical Industry witnessed a change after the formation of World Trade Organization (WTO) in 1995 when India, being a signatory member of WTO, adopted Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Indian pharmaceutical company is about 120 years old. Production of modern medicine by indigenous units started with the setting up of Bengal Chemical and Pharmaceutical works in Calcutta (1892), which was followed by the establishment of Alembic Chemical works in Baroda (1907) and Bengal Immunity in 1919.

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26. Pharmaceutical drug manufacturers

27. Pharmaceutical drug manufacturers
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/mixed formulations in India, contending that locally available bulk drugs were not of desired quality. They also patented heavily in the country (28). 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. (29) Between 1947-57, ninety-nine percent of the 1704 drugs and pharmaceutical patents in India were held by foreign multinational enterprises (MNEs) which controlled 80 percent of the market. (30) 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.” (31)
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”. (32) 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. (33)

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. Under this act, only one process that was used in the actual manufacturing could be patented. The period 1970-95, generally known as pre-TRIPS period, was a flourishing phase of Indian pharmaceutical company.

However, the scenario again 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 onto TRIPS. Under TRIPS, all countries have to provide for protection of product patents from January 1, 1995.

However, developing countries like India, which did not have a regime of product patents, could avail a transition period of ten years - until January 1, 2005 Domestically and internationally India resisted conforming to TRIPS and refused to comply with its provisions earlier. 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 agrochemicals. However, perspectives about IPRs in India changed over time 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.(34) 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. (Ramanna 2002; Ramanna 2003; Rangnekar, 2005).
Even some domestic firms like Dr. Reddy’s laboratories and Ranbaxy who had been prospered under the existing patent structure, now started visualizing significant avenues for profit from the new patent regime. 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. Three amendments viz. The Patents (Amendment) Act, 1999, The Patents (Amendment) Act, 2002 and The Patents (Amendment) Act, 2005, were made to the patent Act 1970 with a view to fulfilling India’s obligation of the TRIPS requirements.

**Pharmaceutical industry in post-TRIPS period (1995-2008)**

The period 1995-2008 (i.e. the post-TRIPS period) saw the strongest performance of the Indian pharmaceutical company 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 has risen approximately 420 per cent in 2006 from 1995. (35) In terms of the number of PCT international applications (IAs) filed in 2008, India stood at 18th position. (36) 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. (37) Presently, Indian pharma 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.

32- Ramanna, 2003
33- Eurasian Journal of Business and Economics 2011
34- Ramanna, 2003; Rangnekar, 2005
Exports and Export Intensity

In the analysis of Exports of Pharmaceutical industry in the Post-TRIPS period shows that the growth rate has been 5.29 percent per annum in pre-TRIPS period and 5.68 percent per annum in post-TRIPS period which shows that exports have increased in post-TRIPS period.

3.2 Exports of pharmaceutical industry (Rs Million)

<table>
<thead>
<tr>
<th>S No</th>
<th>Year</th>
<th>Exports</th>
<th>S No</th>
<th>Year</th>
<th>Exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1981-82</td>
<td>1220</td>
<td>14</td>
<td>1994-95</td>
<td>25123</td>
</tr>
<tr>
<td>2</td>
<td>1982-83</td>
<td>1122</td>
<td>15</td>
<td>1995-96</td>
<td>34087</td>
</tr>
<tr>
<td>3</td>
<td>1983-84</td>
<td>1552</td>
<td>16</td>
<td>1996-97</td>
<td>43418</td>
</tr>
<tr>
<td>4</td>
<td>1984-85</td>
<td>2342</td>
<td>17</td>
<td>1997-98</td>
<td>54193</td>
</tr>
<tr>
<td>5</td>
<td>1985-86</td>
<td>1579</td>
<td>18</td>
<td>1998-99</td>
<td>62567</td>
</tr>
<tr>
<td>6</td>
<td>1986-87</td>
<td>1613</td>
<td>19</td>
<td>1999-00</td>
<td>66314</td>
</tr>
<tr>
<td>7</td>
<td>1987-88</td>
<td>3261</td>
<td>20</td>
<td>2000-01</td>
<td>87574</td>
</tr>
<tr>
<td>8</td>
<td>1988-89</td>
<td>4737</td>
<td>21</td>
<td>2001-02</td>
<td>97512</td>
</tr>
<tr>
<td>9</td>
<td>1989-90</td>
<td>8496</td>
<td>22</td>
<td>2002-03</td>
<td>128261</td>
</tr>
<tr>
<td>10</td>
<td>1990-91</td>
<td>10141</td>
<td>23</td>
<td>2003-04</td>
<td>152132</td>
</tr>
<tr>
<td>12</td>
<td>1992-93</td>
<td>15330</td>
<td>25</td>
<td>2005-06</td>
<td>225789</td>
</tr>
<tr>
<td>13</td>
<td>1993-94</td>
<td>20097</td>
<td>26</td>
<td>2006-07</td>
<td>249429</td>
</tr>
</tbody>
</table>

Growth Rates (%)*

<table>
<thead>
<tr>
<th>Period</th>
<th>Pre-TRIPS</th>
<th>Post-TRIPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entire Period</td>
<td>5.29</td>
<td>5.67</td>
</tr>
</tbody>
</table>

(Source: India stat database *self calculated)

Company level analysis show that export intensity of all the nine firms has been increasing in post TRIPS period. Many of these firms have been exporting more than one-half of their sales turnovers. 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. The above results show that Exports of Pharmaceutical firms have improved in the Post-TRIPS period.
3.3 Export intensity of the selected leading pharmaceutical

<table>
<thead>
<tr>
<th>Year</th>
<th>Ranbaxy</th>
<th>DRL</th>
<th>Sun pharm a</th>
<th>Wockh ardt</th>
<th>Cadila</th>
<th>Glenmar k</th>
<th>Torrent</th>
<th>Cipla</th>
<th>Aurob indo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>44.68</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>0</td>
<td>....</td>
<td>....</td>
<td>14.19</td>
<td>31.86</td>
</tr>
<tr>
<td>1999</td>
<td>46.92</td>
<td>....</td>
<td>27.64</td>
<td>....</td>
<td>8.99</td>
<td>8.4</td>
<td>....</td>
<td>19.28</td>
<td>39.27</td>
</tr>
<tr>
<td>2000</td>
<td>46.17</td>
<td>....</td>
<td>25.91</td>
<td>....</td>
<td>8.32</td>
<td>8.77</td>
<td>2.66</td>
<td>18.83</td>
<td>49.2</td>
</tr>
<tr>
<td>2002</td>
<td>65.6</td>
<td>56.37</td>
<td>17.24</td>
<td>35.55</td>
<td>18.37</td>
<td>7.87</td>
<td>9.37</td>
<td>34.38</td>
<td>47.01</td>
</tr>
<tr>
<td>2003</td>
<td>69.84</td>
<td>50.86</td>
<td>29.15</td>
<td>....</td>
<td>12.41</td>
<td>13.42</td>
<td>11.4</td>
<td>30.783</td>
<td>47.31</td>
</tr>
<tr>
<td>2004</td>
<td>67.94</td>
<td>48.9</td>
<td>39.27</td>
<td>....</td>
<td>17.23</td>
<td>23.46</td>
<td>12.02</td>
<td>38.85</td>
<td>47.87</td>
</tr>
<tr>
<td>2005</td>
<td>66.07</td>
<td>47.78</td>
<td>42.45</td>
<td>....</td>
<td>21.56</td>
<td>21.08</td>
<td>18.18</td>
<td>42.3</td>
<td>47.89</td>
</tr>
<tr>
<td>2006</td>
<td>66.96</td>
<td>49.71</td>
<td>42.54</td>
<td>21.05</td>
<td>29.08</td>
<td>18.6</td>
<td>23.63</td>
<td>52.37</td>
<td>55.43</td>
</tr>
<tr>
<td>2007</td>
<td>63.11</td>
<td>44.37</td>
<td>45.37</td>
<td>20.99</td>
<td>41.72</td>
<td>24.26</td>
<td>22.9</td>
<td>51.43</td>
<td>51.02</td>
</tr>
<tr>
<td>2008</td>
<td>63.01</td>
<td>45.91</td>
<td>56.48</td>
<td>....</td>
<td>52.06</td>
<td>33.75</td>
<td>24.77</td>
<td>53.78</td>
<td>57.54</td>
</tr>
</tbody>
</table>

(Source: Annual Reports)

35- WIPO, 2009
36- PCT yearly review, 2008
37- Occasional paper by Export-Import bank of India, 2007
Industry level analysis shows that the growth rate has been 5.29 percent per annum in pre-TRIPS period and 5.67 percent per annum in post-TRIPS period which shows that exports have increased more in post-TRIPS period. Company level analysis show that export intensity of all the nine firms has been increasing in post TRIPS period. Many of these firms have been exporting more than one-half of their sales turnovers. 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. The above results show that Exports of Pharmaceutical firms have improved in the Post-TRIPS period.

**Patenting Scenario**

The analysis of the post-TRIPS (1994-95 to 2007-08) patenting scenario of the pharmaceutical industry of India shows that the patents in drugs and pharmaceutical industry have grown at a higher rate of 6.06 percent per annum as against the 5.57 percent growth of total patents granted. Following Table shows that prior to 1995, except Ranbaxy, 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. 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.

**3.4 Patenting scenario in the post-TRIPS period**

<table>
<thead>
<tr>
<th>Year</th>
<th>Patents granted to drugs and pharmaceuticals (1)</th>
<th>Total patents granted -2</th>
<th>1 as % of 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994-95</td>
<td>232</td>
<td>1759</td>
<td>13.19</td>
</tr>
<tr>
<td>1995-96</td>
<td>132</td>
<td>1533</td>
<td>8.611</td>
</tr>
<tr>
<td>1996-97</td>
<td>71</td>
<td>907</td>
<td>7.828</td>
</tr>
<tr>
<td>1997-98</td>
<td>291</td>
<td>1844</td>
<td>15.78</td>
</tr>
<tr>
<td>1998-99</td>
<td>150</td>
<td>1800</td>
<td>8.333</td>
</tr>
<tr>
<td>1999-00</td>
<td>307</td>
<td>1881</td>
<td>16.32</td>
</tr>
<tr>
<td>2000-01</td>
<td>276</td>
<td>1318</td>
<td>20.94</td>
</tr>
<tr>
<td>2001-02</td>
<td>320</td>
<td>1591</td>
<td>20.11</td>
</tr>
<tr>
<td>2002-03</td>
<td>312</td>
<td>1379</td>
<td>22.63</td>
</tr>
</tbody>
</table>
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: India stat database *self calculated)

3.5 Patents granted to the selected leading pharmaceutical companies by USPTO in post-TRIPS period

<table>
<thead>
<tr>
<th>Year</th>
<th>Ranbaxy</th>
<th>DRL</th>
<th>Torrent</th>
<th>Aurobindo</th>
<th>Wockhardt</th>
<th>Sun pharma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre1995</td>
<td>7</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
</tr>
<tr>
<td>1995</td>
<td>1</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
</tr>
<tr>
<td>1996</td>
<td>1</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
</tr>
<tr>
<td>1997</td>
<td>2</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
</tr>
<tr>
<td>1998</td>
<td>5</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
</tr>
<tr>
<td>1999</td>
<td>4</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
<td>....</td>
</tr>
<tr>
<td>2000</td>
<td>4</td>
<td>....</td>
<td>1</td>
<td>....</td>
<td>....</td>
<td>....</td>
</tr>
<tr>
<td>2001</td>
<td>8</td>
<td>....</td>
<td>3</td>
<td>....</td>
<td>....</td>
<td>....</td>
</tr>
<tr>
<td>2002</td>
<td>7</td>
<td>....</td>
<td>1</td>
<td>2</td>
<td>....</td>
<td>2</td>
</tr>
<tr>
<td>2003</td>
<td>8</td>
<td>7</td>
<td>3</td>
<td>....</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>2004</td>
<td>11</td>
<td>3</td>
<td>....</td>
<td>3</td>
<td>2</td>
<td>....</td>
</tr>
<tr>
<td>2005</td>
<td>7</td>
<td>5</td>
<td>....</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2006</td>
<td>12</td>
<td>7</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>77</td>
<td>22</td>
<td>9</td>
<td>9</td>
<td>11</td>
<td>9</td>
</tr>
</tbody>
</table>

(Source: USPTO)
Regarding patenting, that pharmaceutical industry seems to respond better in post-TRIPS period. The results show that the patents in drugs and pharmaceutical industry have grown at a higher rate of 6.06 percent per annum as against the 5.57 percent growth of total patents granted. Majority of the sample 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.

**Drug Master Filings**

India is on its way to become a global leader in API production. If the manufactures want to sell active pharmaceutical ingredients (APIs) in the US, a DMF filing is required. Although 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. (38)

Following Table indicates the present level of patenting activity in Indian pharmaceutical company has been indicated by a steady rising share of Indian pharmaceutical companies in total DMF filings with USFDA.

---

38- IBEF, Market overview, December 2008
3.6 India’s share in the total DMFs filed with the US FDA

<table>
<thead>
<tr>
<th>Year</th>
<th>Total filings with USFDA</th>
<th>DMF filings from India</th>
<th>India’s share in global DMF filings (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>227</td>
<td>33</td>
<td>14.5</td>
</tr>
<tr>
<td>2001</td>
<td>280</td>
<td>52</td>
<td>18.6</td>
</tr>
<tr>
<td>2002</td>
<td>288</td>
<td>63</td>
<td>21.1</td>
</tr>
<tr>
<td>2003</td>
<td>404</td>
<td>124</td>
<td>30.7</td>
</tr>
<tr>
<td>2004</td>
<td>517</td>
<td>193</td>
<td>37.9</td>
</tr>
<tr>
<td>2005</td>
<td>688</td>
<td>274</td>
<td>39.8</td>
</tr>
<tr>
<td>2006</td>
<td>706</td>
<td>306</td>
<td>43.9</td>
</tr>
<tr>
<td>2007</td>
<td>226</td>
<td>110</td>
<td>48.7</td>
</tr>
</tbody>
</table>

(Source: USPTO)

The current DMF filing scenario of the selected leading pharmaceutical companies has been presented in the following Table.

3.7 Cumulative DMF filings with USFDA by selected leading pharmaceutical companies

<table>
<thead>
<tr>
<th>Company</th>
<th>DMF Filings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2004</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>16</td>
</tr>
<tr>
<td>DRL</td>
<td>55</td>
</tr>
<tr>
<td>Sun pharma</td>
<td>22</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>….</td>
</tr>
<tr>
<td>Cadila</td>
<td>12</td>
</tr>
<tr>
<td>Glenmark</td>
<td>….</td>
</tr>
<tr>
<td>Torrent</td>
<td>….</td>
</tr>
<tr>
<td>Cipla</td>
<td>….</td>
</tr>
<tr>
<td>Aurobindo</td>
<td>5</td>
</tr>
</tbody>
</table>

(Source: Annual Reports, * as on 31st March **as on 31st July #DMF+CEP applications)
Indian firms are also trying to access developed countries with abbreviated new drug applications (ANDAs) for formulations.

3.8 Cumulative ANDA filings by selected leading pharmaceutical companies in post-TRIPS period

<table>
<thead>
<tr>
<th>Company</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranbaxy</td>
<td>150</td>
<td>183</td>
<td>197</td>
<td>239**</td>
<td>240**</td>
<td>241</td>
</tr>
<tr>
<td>DRL</td>
<td>52</td>
<td>65</td>
<td>77</td>
<td>117</td>
<td>122</td>
<td>144</td>
</tr>
<tr>
<td>Sun pharma</td>
<td>11</td>
<td>33</td>
<td>62</td>
<td>107</td>
<td>142</td>
<td>179</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>7</td>
<td>13</td>
<td>39</td>
<td>47</td>
<td>57</td>
<td>67</td>
</tr>
<tr>
<td>Cadila</td>
<td>12</td>
<td>25</td>
<td>36</td>
<td>62</td>
<td>81</td>
<td>92</td>
</tr>
<tr>
<td>Glenmark</td>
<td>....</td>
<td>7</td>
<td>18</td>
<td>28</td>
<td>51</td>
<td>71</td>
</tr>
<tr>
<td>Torrent</td>
<td>....</td>
<td>1</td>
<td>4</td>
<td>6</td>
<td>11</td>
<td>32</td>
</tr>
<tr>
<td>Aurobindo</td>
<td>2</td>
<td>24</td>
<td>51</td>
<td>100#</td>
<td>128</td>
<td>147</td>
</tr>
</tbody>
</table>

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

The above figure 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. The above results clearly highlight that the Indian companies are investing funds on filing DMFs and ANDAs and the trend depicts an increase in filings in the post-TRIPS period.
3.2 ANDA Approvals as % of ANDA filings

These results show that growth of R&D of the industry as a whole is more in the latter period i.e., post-TRIPS period (6.56) as compared to pre-TRIPS period (4.89). In addition to that most of the sample pharmaceutical companies showed the most impressive increase in their R&D intensities over the period 1998-2008. The implication which comes out from this analysis is that these firms have realized the need of R&D in post TRIPS period and as such they have been increasing the percentage of R&D expenditure. The above results show that R&D activity of Pharmaceutical industry as well as of companies has improved in the Post-TRIPS period.

3.10 Generic Drug

A generic drug is a prescription drug which is not manufactured by the originator of the product; the molecule is off patent and available from multiple sources, and the product is known by the chemical name, not a trade name. A generic drug should possess the same active ingredients in the same dosage form and strength as the original brand drug. For generic drugs to be marketed and sold, it needs to demonstrate similar bioequivalence which means that there is a similar absorption rate as the original brand drug. The generic drug also needs to produce the same therapeutic effect and safety profile as the initial or innovator’s brand name product. Equal standards apply for brand name and generic drugs in regards to drug safety, efficacy, purity, stability, manufacturing, and labeling, which are set and enforced by the Food and Drug Administration (“FDA”). (39)
Developing and Marketing Generic Drugs

In developing generic drugs, the manufacturer only needs to demonstrate the bioequivalence of its drug to the branded product, and that the manufacturing process produces acceptable purity and consistency. The development does not involve lengthy and costly clinical trials because generic manufacturers only need to prove bioequivalence. On average, the development of generic drugs takes only 3 years, in contrast to the six to seven years of development time spent on branded products. (40)

The development of generic drug industry:

Generic have always been in existence along with branded pharmaceuticals. However, the industry was restricted to a few small players. The event often acknowledged as the start of the modern generic pharmaceutical industry was the approval of the drug price competition and patent restoration act in 1984. This law often called as “Waxman-Hatch act” permitted manufacturers to live ANDAS for generic versions of all post 1962 approved pharmaceutical products.

The act opened the floodgates for generic competition for pharmaceutical products creating the modern generic pharmaceutical industry. In the first year following approval of the act, the FDA received more than, 1000 applications for generic drugs. The subsequent growth of the generic pharmaceutical industry, from $ 2.6 billion in year 1990 to nearly $10 billion in year 1998 was fueled by the expiration of market exclusivity for an extraordinary number of products, making them available for generic competition. (41)

39- U.S. Generic Drug Industry and Indian Pharmaceutical Companies, Jiny Kim April 26, 2004

40- Unpublished thesis by Monika Khanna thesis, University of Pune
The potential for company earn millions if first to market with good practices, resulted in crisis that virtually destroyed the generic industry. Four year after the passage of “Waxman-Hatch act”, the rush to launch generic versions of branded pharmaceuticals created intense pressures on the FDA to approve products, and on manufacturer seeking to be first to market. In the late 1980’s, some manufacturers falsified application, going so far to alter branded pharmaceuticals and submit these products as their own.

The scandal slowed new product approvals for all generic company with the USFDA approving approximately 80 ANDAs in year 1990, as compared to more than 250 in 1989. (42) As an outgrowth of the scandal, the demand for heightened scrutiny of all aspects resulted in FDA inspections of manufacturer and testing firms, and the analysis of more than 2800 samples of widely used generics. The large number of innovator products due to lose patent protection over the next ten years will foster robust growth in generic industry.

**Cost of generic pharmaceutical:**

Generic pharmaceutical cost 30-60% less than the equivalent, branded product. (43) Yet, the consumer is getting the same product, manufactured to the same high standards, as the branded name products. Company that discovers and develops new drugs claims that the cost of research and development on average exceeds $ 400 million (44). This process can take as long as 12 years to complete. As a result, when innovator sets its price for all brand name pharmaceutical, it seeks to recover development costs as well as dollars spent to market the product, while still returning a profit. For the generic manufacturer, the cost of developing the generic product and getting an approval to make and sell it are considerably lower.
Additions, generic pharmaceutical companies, spend significantly less to market their products. In this way, they offer the same product at a greatly reduced priced. Also generic results in competition that can help lower price. By the year 2005, 40 blockbuster drugs went of patent in US giving additional sales of Rs. 4000 crore in year 2003. In this year USA market is estimated to be US$18 million, which is 40% of world generic market. In this market- 60 % of drugs sold are imported from outside US. Indian pharmaceutical company with 45% less manufacturing costs, 30% low labor cost and 40% less infrastructure cost can top this huge opportunity. Street price of drug in US is 6 times more than India and 4 times more than in Europe than India. (45)

This leads to opening of new doors of opportunities for Indian pharmaceutical firms. This is because of their increasing exports to developed countries and enhancing their manufacturing capabilities not only in India, but also on other countries.

Promising market segment in Indian firms are anti-infective, antiulcers, and antihypertensive. Famous brand from this category like Augmentin, Pepcid, Zestrill worth of US $19 billion (I year 1997) are going off patent. Indian pharmaceutical companies coincidently are having expertise for manufacturing these drugs. This is proving advantageous to the Indian firms. Various factors responsible for this growth are:

1. Global pharmaceutical market is of around Rs. 1, 67,000 crore but there are diminishing returns from products in market known as “Block Busters”. New methods of drug discoveries such as bio information are not yet matured. As a result new drug discovery methods giving “Lead Molecules” are becoming increasing rare.
2. There are new areas of conventional as well as modern drug research tools such as contract research, contract manufacturing, clinical trials are fast developing in country.
3. By year 2012, 35000 crore Rs. Worth of patented drugs are going off patent in USA market. Out of this Indian pharmaceutical companies can grab share of 15 -20 millions.
4. By setting conductive atmosphere as it happens in information technology sectors, government may gain significant returns from these developments.(46)
Options available:

After drug goes off patent when new player enter in to market, prices of drug drops by around 35%. With further entry of competitors in market segment of drug prices of particular drug reduce by almost 50-70%. This benefits both consumer and generic manufacturers.

There are two classes of generic as

1. Bulk generic: these are raw material for formulation of generic and are sold in wholesale.
2. Formulation generic: these are sold in tablet, injection etc.

India’s competitive advantage characteristics:

The key are

- Products enjoy low limit margins compared with patented prescription drug. It is high volume market with low profit margins.
- Products are at a constant disadvantage against those of Innovator Company.
- Process development skills are of critical importance.
- The emphasis is on a lean cost structure that is dominated by manufacturing costs.

Indian’s opportunity:

- Indian companies are well positioned to exploit the generic market. Their competitive advantages arise from the areas like high process development skills. This ability enables company to develop cost effective and non infringing processes for products going generics. India has a history of developing such processes due to the prevalence of product patents.
- Low manufacturing cost base – the best of manufacturing is lower in India due to low labor costs and lower equipment costs.( especially reactors, boilers etc)
- India is having largest number of USFDA approved manufacturing plants outside USA.
- Indian companies are consolidating their position in supply of generic pharmaceuticals in USA market as well as in least developed countries LDC) in supply of active pharmaceutical ingredients as well as generic formulation.
• Mergers and acquisition of manufacturing facilities by Indian companies in foreign countries is helping in creating manufacturing base in Europe and USA.

**Drawbacks:**

• Parent patent holder files additional process patent for products to retain patent claim producing barriers for generic marketers.
• Establishing USFDA plant cost 5 times more than Indian standards.
• Legal aspects in US are also costly affaire. For each drug, patent holders are figuring out innovative ways for extending their patent rights.
• Litigation in US district court cost anything between US $ 1 -5 million and take up to 30 million.
• Indian pharmaceutical companies are lagging in cumulative efforts at national and international levels to persuade many policy matters.
• Many firms are devoid of pragmatic clear vision about their role in total future industrial set up.
• Due to macroeconomic policies development of market in sluggish.
• There is extreme competition in domestic sector.
• Multinational generic majors like Santoz and Teva are setting their manufacturing and research and development plants in India. This will gradually neutralize cost advantage enjoyed by Indian companies.
• Profile margins are subject to wide variations due to exclusivity loss of drugs and competition from generic to drugs.
• Market penetration of generic in European market is not yet establish.

**3.11 Mergers and Acquisitions Trend in India**

There are also entry barriers for companies from the developing countries and acquisitions make it easy for these organizations to find a foothold in the developed markets. For instance, there is a cultural and language barrier in Europe and Europe is high on the radar of Indian pharmaceutical companies. The sheer heterogeneity of Europe and the fragmented nature of its pharmaceutical market make acquisitions an easy route for entry into this region and the US being the largest pharmaceutical market in the world will always interest the Indian pharma companies for its sheer size.
Mergers and Acquisitions (M&A) interest in India is currently very high in the pharma industry. Size and end-to-end connectivity are major detriments in the global markets. To achieve them, Western MNC’s have to look to Indian companies. India’s changing therapeutic requirements and patent laws will provide new opportunities for big pharma for launching their patented molecules. While, India’s strong manufacturing base will stand global generic companies in good stead as a low-cost development and manufacturing destination. After traversing the learning curve through partnerships and alliances with international pharmaceutical firms, Indian pharmaceutical companies have now moved up a step in the value chain and are looking at inorganic route to growth through acquisitions.

**Incentives for Mergers and Acquisitions by Indian companies**

- Build critical mass in terms of marketing, manufacturing and research infrastructure
- Establish front end presence
- Diversification into new areas: Tap other geographies / therapeutic segments / customers to enhance product life cycle and build synergies for new products
- Enhance product, technology and intellectual property portfolio
- Catapulting market share

The Indian companies excel as far as the back end of the pharmaceutical value chain is concerned i.e. manufacturing APIs and formulations. Acquisitions are the quickest way to front end access. What is interesting is the fact that apart from market access i.e. marketing and distribution infrastructure, the acquiring company also gets an established customer base as well as some amount of product integration (the acquired entities generally have a basket of products) without the accompanying regulatory hurdles. Over the last two years, several Indian companies have targeted the developed markets in their pursuit of growth, especially via the inorganic route.

Companies such as Ranbaxy, Wockhardt, Cadila, Matrix, and Jubilant have made one or more European acquisitions, while others such as Torrent are also scouting for potential targets. Besides gaining a faster entry into the target market, one of the basic strategies behind the acquisitions remains that of leveraging India’s low cost advantage by shifting the manufacturing base to India. At the same time, the acquired companies also serve as an effective front end for Indian companies in these markets acquisitions by Indian Companies. (47)
Pre TRIPS merger and acquisition

The Indian companies excel as far as the back end of the pharmaceutical value chain is concerned i.e. manufacturing APIs and formulations. What the Indian companies are short of is the front-end distribution and marketing infrastructure in the developed world. Acquisitions are the quickest way to front end access. Indian Drug manufacturers persuaded foreign acquisitions to bridge this gap and to fulfill following motives.

1. Improve global competitiveness
2. Move up the value chain
3. Create and enter new markets
4. Increase their product offering
5. Consolidate their market shares
6. Compensate for continued sluggishness in their home market

There are entry barriers for companies from the developing countries and acquisitions make it easy for these organizations to find a foothold in the developed markets.
3.11 Mergers and Acquisitions by Indian companies

<table>
<thead>
<tr>
<th>Announce Date</th>
<th>Target</th>
<th>Acquirer</th>
<th>Reason</th>
<th>Deal Value ($ mn)</th>
<th>Target Country</th>
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<tbody>
<tr>
<td>Feb-06</td>
<td>Betapharm</td>
<td>Dr Reddy's Labs</td>
<td>Front-end in Germany</td>
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<td>Germany</td>
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<td>Dec-05</td>
<td>Bouwer Bartlett</td>
<td>Glenmark</td>
<td>Front-end in South Africa</td>
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<td>Dec-05</td>
<td>Able Labs</td>
<td>Sun Pharma</td>
<td>Mfg Facility in US, Turnaround potential</td>
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<td>US</td>
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<td>Nov-05</td>
<td>Nihon Pharma</td>
<td>Ranbaxy</td>
<td>Increasing stake to 50% to take advantage of Japanese Generic Opportunity</td>
<td>NA</td>
<td>Japan</td>
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<tr>
<td>Nov-05</td>
<td>Roche's API Facility in Mexico</td>
<td>Dr Reddy's Labs</td>
<td>Increasing presence in Contract Mfg</td>
<td>58.97</td>
<td>Mexico</td>
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<td>Oct-05</td>
<td>Aresia</td>
<td>Nicholas Piramal</td>
<td>Increasing presence in Contract Mfg</td>
<td>17.1</td>
<td>UK, Canada</td>
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<td>Oct-05</td>
<td>Servylac SA</td>
<td>Glenmark</td>
<td>NA</td>
<td>NA</td>
<td>South Africa</td>
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<td>Oct-05</td>
<td>Target Research</td>
<td>Jubilant Organysys</td>
<td>Capitalizing on CRO opportunity</td>
<td>33.5</td>
<td>NA</td>
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<tr>
<td>Sep-05</td>
<td>Explora Labs SA</td>
<td>Matrix Labs</td>
<td>Explora's expertise in bio-catalysis would help in deep high potency API's</td>
<td>NA</td>
<td>Switzerland</td>
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<td>Sep-05</td>
<td>Valeant Mfg</td>
<td>Sun Pharma</td>
<td>Controlled substance mfg facility</td>
<td>NA</td>
<td>US</td>
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<tr>
<td>Jul-05</td>
<td>Trinity Labs Inc</td>
<td>Jubilant Organysys</td>
<td>US FDA facility in US, pipeline of ANDA's</td>
<td>12.3</td>
<td>US</td>
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<td>Jun-05</td>
<td>Heumann Pharma Gmbh &amp; Co Gen</td>
<td>Torrent</td>
<td>Entry in German Market</td>
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<td>Germany</td>
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<td>Jun-05</td>
<td>Doc Pharma NV</td>
<td>Matrix Labs</td>
<td>Front-end in Europe</td>
<td>263</td>
<td>Belgium</td>
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<td>Jun-05</td>
<td>Generic Product Portfolio</td>
<td>Ranbaxy</td>
<td>Spanish Generic Market-18 products</td>
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<td>Jun-05</td>
<td>Biopharma</td>
<td>Strides Ancolab</td>
<td>Entry into new market - Venezuela</td>
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<td>Mar-05</td>
<td>Une-Cilo Hormonal Brand</td>
<td>Glenmark</td>
<td>Establish brand presence in Brazilian market</td>
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<td>Feb-05</td>
<td>Stridas Latvia</td>
<td>Strides Ancolab</td>
<td>Additional 12.5% stake to establish presence in Brazilian market</td>
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<td>Feb-05</td>
<td>Mchem Pharma Group</td>
<td>Matrix Labs</td>
<td>Backward integration, ARV mfg in China</td>
<td>NA</td>
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<td>Dec-04</td>
<td>Rheda Anesthetic Business</td>
<td>Nicholas Piramal</td>
<td>International product line</td>
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<td>Jun-04</td>
<td>Psi Supply NV</td>
<td>Jubilant Organysys</td>
<td>NA</td>
<td>NA</td>
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<td>May-04</td>
<td>Trigenesis Therapeutics Inc</td>
<td>Dr Reddy's Labs</td>
<td>Niche technology</td>
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<td>US</td>
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<td>May-04</td>
<td>Escarpa Gmbh</td>
<td>Wockhardt</td>
<td>Front-end in Germany</td>
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<td>Apr-04</td>
<td>Laboratories Klinner Do Brasil</td>
<td>Glenmark</td>
<td>Entry in Brazil</td>
<td>5.2</td>
<td>Brazil</td>
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<td>Dec-03</td>
<td>RPG Aventis Ss</td>
<td>Ranbaxy</td>
<td>Front-end in France</td>
<td>84</td>
<td>France</td>
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<tr>
<td>Jul-03</td>
<td>Alpharma Sss</td>
<td>Caledia Healthcare</td>
<td>Front-end in France</td>
<td>6.2</td>
<td>France</td>
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<tr>
<td>Jul-03</td>
<td>CP Pharmaceuticals</td>
<td>Wockhardt</td>
<td>Front-end and mfg in Europe</td>
<td>17.7</td>
<td>UK</td>
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(Source- pharmaexpress)
Post TRIPS

The rules of pharmaceutical business are changing. Indian pharmaceutical companies can no longer get away with plundering intellectual properties of multinational companies. Pharmaceutical business has become a new ballgame altogether after the introduction of product patents in January 2005. Companies are reaching out to their counterparts to take mutual advantage of the other’s core competencies in R&D, Manufacturing, Marketing and the niche opportunities offered by the changing global pharmaceutical environment. The pace of change has never been as rapid as it is now. To adapt to these changing trends, the Indian pharmaceutical and biotechnology companies have evolved distinctive business models. Size and end-to-end connectivity are major detriments in the global markets. To achieve them, Western MNC’s have to look to Indian companies. India’s changing therapeutic requirements and patent laws will provide new opportunities for big pharmaceutical for launching their patented molecules. While, India’s strong manufacturing base will stand global generic companies in good stead as a low-cost development and manufacturing destination. Besides consolidation in the domestic industry and investments by the US and European firms, the spate of mergers and acquisitions by Indian companies has ushered an era of the "Indian Pharmaceutical MNC". After traversing the learning curve through partnerships and alliances with international pharmaceutical firms, Indian pharmaceutical companies have now moved up a step in the value chain and are looking at inorganic route to growth through acquisitions. Many top and mid tier Indian companies have gone on a global "shopping spree" to build up critical mass in International markets. Also, given the easy access to global finance the Indian companies are finding it easier to fund their acquisitions. Mergers and Acquisitions (M&A) interest in India is currently very high in the pharmaceutical industry.
3.12 Summary

Thus, this resulted in the methodical weakening of patent rights for pharmaceutical products in India and led to the exodus of several international research-based pharmaceutical firms. The obligations imposed on India under the TRIPS Agreement are going to have a significant impact on India’s successful bulk and formulation-oriented pharmaceutical industry. Indian companies will have to compete with the multinationals by focusing on drug development and thereby producing their own patented products. On the other hand, Indian companies could focus on producing patented drugs under license from foreign companies or concentrate on generating revenues from producing generic drugs. Currently, conflicting views exist within the Indian drug companies with regard to India’s transition into the product patent regime. Some of the existing pharmaceutical companies believe that product patents will pave the way for innovation in India, while others hold the view that the high cost of R&D will suppress the growth of the Indian pharmaceutical company. The key to survival for Indian pharmaceutical companies would be the exponential growth of R&D expenditure. Indian companies need product patent protection to encourage research in developing inexpensive drugs that suit the Indian disease profile. The larger firms are increasing their total R&D expenditure as a percentage of sales and they are beginning to move in the direction of new molecule discovery rather than concentrating solely on development research. The advent of product patents is bound to be a boost for multinational companies that have previously been reluctant to invest in India in the absence of product patent protection, and it will increase competition in the domestic market.

The process of liberalization initiated in 1991 has helped develop policies that are focused on attracting capital from overseas and making India a global industrial base. The resultant inflows of foreign direct investment and technology transfers have created an environment for dynamic growth and increased competitiveness of Indian industry. India is slowly moving into global markets and competing with international quality standards and prices. Although R&D is an important factor to ensure a competitive boundary in the international arena, the future of the Indian pharmaceutical company hinges on patent protection.