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**Performance of the Indian Pharmaceutical Industry Pre and Post TRIPS Era: A Study**

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**Abstract:**

*India has implemented Product Patent regime from 1st January 2005 as per TRIPS agreement. The Indian Pharmaceutical Industry is today undergoing lot of changes after introduction of Patent Act 2005 with Product patent in India. The study discusses the performance of Indian pharmaceutical industry post Trips. The study reveals that pharmaceutical companies are changing their strategies to meet the new competitive business environment and as a result Indian pharmaceutical industry, which currently has strong linkages with the global pharmaceutical market, will become even more strongly integrated.*

**Keywords:** *Pharmaceutical industry, Product Patent, Trips-WTO, R&D\**

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Received: 15/06/11

Accepted: 05/07/11

## INTRODUCTION

### TRIPS AGREEMENT

Agreement on Trade Related Aspects of Intellectual Property Rights (hereafter, the TRIPS Agreement) came into effect on 1 January 1995. WTO was set as a custodian to implementation of Trips by all its member countries. The TRIPS Agreement contains several provisions that enforce stronger intellectual property protection on all member countries. These are mainly contained in Articles 27(1), 27(3) (b), 28, 30 and 31(a) to (f) of the Agreement. TRIPS Agreement obliges all member countries of the World Trade Organization to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced. As India had signed the WTO agreement and since Trade Related Intellectual Property Rights (TRIPS) was a part of WTO agreement, India was bound to implement the provisions of TRIPS agreement provided a transition period of ten year from 1995-2005. This meant that India had to make significant changes in its patent law and respect the Intellectual Property Right's (IPR's) by 2005 [1, 2].

### WHAT IS A PATENT?

Patent is a legal document granted by the government giving an inventor the exclusive right to make, use and sell an invention for a specified period of time. It is also available for significant improvements on previously invented articles.

According to the UN definition, a patent is a legally enforceable right granted by country's government to its inventor. Patent Law represents one branch of a larger legal field known as intellectual property rights. Patent Law centres on the concept of novelty and non-obvious inventions. The invention must be legally useful. The imitators and all independent devisors are

prevented from using the invention for duration of patent [1-3].

### WHY PATENT?

The underlying idea behind granting patents is to encourage innovators to advance the state of technology. Patent protection guarantees profits to inventors in return for investing in the production of socially useful information by granting a temporary monopoly on the product. The patent holder therefore, can prohibit all others from copying the patented product and offering it in the market for a lower price, during the life of the patent [1-3].

### BACKGROUND OF INDIAN PHARMACEUTICAL INDUSTRY WITH RESPECT TO PATENT

The Indian Pharmaceutical industry has transformed itself over the past few decades in India, being almost none existing till 1970's, to now being a prominent provider of Pharmaceutical Products. The Indian Pharmaceutical industry meets approximately 95% of the country's pharmaceutical needs. The present turnover of the Indian Pharma Industry is approximately \$ 9.0 billion of which the share of exports is 40%. Compared to the global picture, the Indian pharmaceutical Industry ranks 4th in terms of volume, and 13th in terms of value, which is highly significant [4-6].

### PRE TRIPS: PATENTS ACT (1970)

Patents Act 1970 in its original form does not differentiate between Process and Product patents for medicines, food and chemicals. One of the important features of the Act was that it did not provide product patents for the three mentioned industries. These industrial sectors were covered by product patent only. In addition the Drug Price control Order, 1970 put a cap on the maximum price that could be charged and ensured that the life saving drugs are available at reasonable prices. The Act of 1970 safeguards the interests of the inventor and consumer in an even-handed manner. Therefore with a regulatory system

focused only on process patents, helped to establish the foundation of a strong and highly competitive domestic pharmaceutical industry which in the grip of a rigid price control framework transformed into a world supplier of bulk drugs and medicines at affordable prices to common man in India and the developing world. The Indian pharmaceutical companies have been doing extremely well in developed markets such as US and Europe [4-6].

#### **POST TRIPS: PATENTS AMENDMENT ACT (2005)**

The Patent Amendment Act 2005 passed by the Parliament in its budget session of 2005 brings the Indian Patent Act in full conformity with the intellectual property system in all respects. The amendment of 2005 extends full TRIPS coverage to food, drugs and medicines. It requires patents to be provided to products as well. The other implications under the new act are the term of a patent protection has been extended to twenty years compared to the seven years which was provided by the act of 1970 and the onus of proving on a legal complaint that the process used by one enterprise is totally different from that which has been used by another would lie on the defendant. Prior to the amendment the responsibility was on the patent holder to establish patent breach [4, 5].

Under the new patent law Indian pharma companies which were free to copy and sell patented molecules or drugs will not be able to do so. Therefore no patented drug launched after 1st January 2005 can be copied and sold, also there are patent applications of MNC Pharma Companies pending in the EMR mailbox which are going to be shortly opened by the patent office. If the patent office grants patents rights then Indian pharma companies selling those molecules will have to stop manufacturing and marketing of those drugs or may have to pay royalty if they continue to manufacture and market those drugs.

Further the government of India is also committed to cGMP(current Good Manufacturing Practices) norms as specified by WHO(World Health Organization) and has subsequently modified Schedule M of the Drugs & Cosmetics Act and now Pharma companies have to follow strict standards in manufacturing practices[6].

#### **SIGNIFICANCE OF THE STUDY**

Competitive processes that drive new-economy industries in many sectors centre on the protection of R&D efforts through intellectual property rights, and on resulting technological change. The pharmaceutical industry, although one such industry, also confronts us with issues that run far beyond shaping technological change. Two diverging questions of public health – that of providing wider access to medicines to all those who need it at affordable prices, and that of granting incentives to invest in the research and development of new therapeutic products can sometimes run contrary to one another in the short-term or mid-term.

Public policy in most countries worldwide has been very sensitive to this trade off between patent protection and restricted access even historically. Data on OECD countries shows that patent protection for pharmaceutical products was introduced within countries only when their GDP per capita had reached a sufficiently high rate. But the TRIPS Agreement does not allow the developing and least developed countries to retain the opportunity of doing so, since it obliges all member countries of the World Trade Organization to introduce patent protection on pharmaceuticals within transition periods recognized under the Agreement. This is one of the main reasons for increasing divisiveness on the impact of higher levels of intellectual property protection as contained within the TRIPS Agreement.

Post-1995, as more and more developing countries became TRIPS compliant, the possibility that generic producers from developing countries offer price competition to the global pharmaceutical industry in the newly-patented drug categories has been reducing.

This brings to the fore a very important question: given that the local pharmaceutical industry in developing countries can no longer offer price competition by manufacturing generic versions of drugs patented elsewhere at cheaper prices, what impact will this have on access to medicines in third countries, such as those in Africa? [2, 7, 8]

Thus it was planned to study the following performance parameters of pharmaceutical industry pre and post TRIPS agreement.

## **STUDY OF PERFORMANCE PARAMETERS PRE AND POST TRIPS**

### **(a) NEW PRODUCT DEVELOPMENT**

#### **Pre TRIPS**

New product development efforts of Indian pharmaceutical companies in process patents era were limited to reverse engineering molecules discovered by other companies. Thanks to absence of product patents, Indian companies did not have to go through long winded drug development process. Nor did Indian companies have to expend any effort on research focus. Indian companies simply zeroed in on blockbuster drugs and tried to come up with an alternative process as fast as they could. The focus of the Indian companies was to launch a copy of a blockbuster drug ahead of their rivals in India and abroad.

Key areas to focus on R&D for Indian companies were as follows:

1. Potential product identification
  - Complex AP.I
  - Complex finished product.
  - Commercial potential of products.
  - Out-licensing opportunity to MNCs
2. Novel Drug Delivery System (NDDS).
3. New Drug Development.

#### **Post TRIPS**

A large number of drugs are going “off patent” in the next few years. According to IMH Health, more than \$60 billion worth of drugs are going “off patent” by

2011. Thus, Indian companies will not be short of new products for at least another two years. Further Indian pharmaceutical companies have also stepped up their efforts in product development for the global generic market and this is visible with the DMF filings at the US FDA. About 30% of the new DMF filings at the US FDA are being filed by Indian companies.

In the long run, however Indian companies may find it hard to make money from drugs coming off patent. Already competition in generic market is intense and likely to increase further in the future. Hence, new molecules rather than generics will drive revenues and profits in the product patents area. Indian companies need to discover new drugs either through their own efforts or research alliances. Perhaps licensing deals with multinationals could also provide Indian companies access to new drugs. Focus on basic research will come with its own issues. Indian companies will have to acquire the skills of identifying research areas that offer excellent revenue and profit potential. This will entail a closer tracking of disease profiles and related therapies as well as keeping a close tab on the research programmes of rivals. Besides, Indian companies will have to pay more attention to economics of drug development process [9].

The actual problem lies in the fact that the product patents fail to introduce research and development in the neglected diseases. Hence while on one side the introduction of product patents will help in development of new and more effective drugs, the problem still remains that the research and development undertaken by the drug manufactures evade the neglected diseases and the diseases which are region specific such as medicines for malaria and tuberculosis which are found prevailing in developing countries like India [9].

**(b) THERAPEUTIC COVERAGE****Pre- TRIPS**

In the absence of product patents, Indian pharmaceutical companies did not feel the need to focus on specific therapeutic areas. Most Indian pharmaceutical companies eschewed narrow focus and tried to cover as many therapeutic areas as possible. Now the product portfolio of many Indian companies has considerable breadth and depth. Given the price controls in the market, diversification worked to the advantage of companies in the domestic markets. In the export markets, a wider product portfolio gave companies the option of picking and choosing from an array of opportunities [9].

**Post TRIPS**

Opinion is divided over the therapeutic strategy that Indian companies should pursue in product patent era. Some companies believe that focus on select therapeutic segment will fetch them greater dividends in terms of new chemical entities and market share. Other companies believe such a strategy is risky given the size of Indian companies and that a big setback in research could sink the company. Instead such companies are pursuing a de-risking strategy of building a wide product portfolio. In the domestic market, such a strategy will result in economies of scale at production and marketing stage, putting the company in a better place to weather competition from multinationals.

**(C) COST OF PRODUCTION****Pre- TRIPS**

Indian pharmaceutical firms use to produce and supply both bulk drugs and finished formulations in the global market at very competitive rates. The Indian pharmaceutical industry is amongst one of the largest industries within developing countries and accounted for 8% of the global output in terms of the volume and ranked 13th in terms of value in 2004. Pharmaceutical multinationals have maintained a low-key presence in Indian market due to absence of product patents and

rigid price controls. In the domestic market, the share of Indian companies has steadily increased from around 20 per cent in 1970 to 70 percent now.

The quality and affordability of generic drugs have made India a virtual pharmacy to the world. Nearly 70 percent of generic drugs manufactured in India are exported to other developing countries. The expansion of AIDS treatment over the past few years has been driven by the accessibility and affordability of generic ARVs (anti-retro viral drugs) from India. Indian firms account for 90% of raw material supplies to the governmental pharmaceutical organization of Thailand for its ARV manufacturing activities, all of the raw material supply for the three main ARV producers in South Africa and along with China, and also dominate the ARV supply scenario for Brazil [9, 10].

Indian pharmaceutical companies have mastered the science of producing drugs cheaply. Indian companies have developed a high level of chemical synthesis skills. The absence of development costs together with efficient production has enabled Indian companies to establish a solid position in bulk drug manufacturing. The industry has thrived so far on reverse engineering skills exploiting the lack of process patent in the country. This has resulted in the Indian pharmaceutical players offering their products at some of the lowest prices in the world. But scale did not receive as much importance as it should have, because the cost of Indian pharmaceutical companies was already low owing to aforesaid reasons.

**Post TRIPS**

Specifically, the introduction of product patent protection in the Indian market may have far-reaching implications on access to medicines at affordable prices in a large number of developing and least developed countries, because a product patent system will make India dependent on the multinational companies for technology and for permission to produce the patented drug. Exorbitant prices will be charged and the Indian pharmaceutical industry will

become subservient to the MNCs. They will lose the position that they had gained in the wake of the Act of 1970. The immediate and the most drastic effect that TRIPS compliance and introduction of the new Act of 2005 will have will be with respect to the health sector in India. Millions of Indians need medicines. Most of them cannot afford to pay high prices. Going by global experience, product patents that are now enforced, can only lead to monopolies and these, in turn, to high prices. India needs to build in enough safeguards even in our current patent law. Perhaps in our haste to join WTO, we neglected many important issues. Even the competition in the generic market will be brutal, resulting in thin margins. The cost of production will hold the key to success in the generic market. The production cost in turn depends on scale. Indian pharmaceutical companies need to build global scale to stand a chance in the generics market [9, 10].

#### **(D) MERGER AND ACQUISITIONS:**

##### **Pre TRIPS**

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 fulfil following motives.

- Improve global competitiveness
- Move up the value chain
- Create and enter new markets
- Increase their product offering
- Consolidate their market shares
- Compensate for continued sluggishness in their home market.

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.

##### **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 [9, 10].

## **(E) EXPORTS**

### **Pre- TRIPS**

Most Indian companies focused on exports. Exports improve the valuation of companies owing to higher margin in overseas markets. Indian companies built fortunes by making cheaper versions of blockbuster drugs and selling them in domestic and export markets. Indian companies built especially strong position in manufacture of bulk drugs. Success in export market allowed some Indian companies to build a strong position in the domestic market organically and through acquisitions of brands and companies. The formulations contribute nearly 55% of the total exports and the rest 45% comes from bulk drugs. Pharmaceutical exports clocked \$7.2 billion in 2007-08, accounting for six per cent of the country's total exports, according to Pharmexcil, the Pharmaceutical Export Promotional Council.

### **Post TRIPS**

In the export markets even after the introduction of product patents, products under patent protection will comprise only 15 percent of the market. So a vast chunk of the market will be still open for competition although margins will be wafer thin. Exports have continued to be a priority for Indian companies. Major blockbuster drugs will come off patent in the near future, creating a big generic opportunity for Indian companies. Also, a growing demand for anti-AIDS drugs in Africa will keep Indian companies busy. Exports have and will continue to provide Indian companies with the strength to withstand the onslaught of multinationals in the domestic market [11-13].

## **CONCLUSION**

Globally the pharmaceutical market is undergoing a transformation led by change in demand patterns, realignment of supply chains, and global regulatory shifts. The Indian Pharmaceutical Industry is entering an era where the value chain components are

reassessed and redesigned to realize optimum value. While the cost of doing business is increasing, the customers are demanding more innovative pharmaceutical products at more competitive prices. The change in patent regime has also become heralded for a change in the industry dynamics. On one hand, patents on blockbuster drugs are expiring and on the other hand, there are insufficient drugs in the pipeline. The changing industry dynamics both at the domestic level as well as the international level has forced the pharmaceutical players to rethink their traditional business strategies.

The pharma industry needs to focus more on R&D and better productivity to capitalize on the immense existing opportunities. India, with its inherent competitive advantages and cost-effective manufacturing capabilities, has now become one of the most preferred destinations for Contract Research and Manufacturing Services (CRAMS). As per the KPMG report, India holds huge potential to tap the \$20 billion CRAMS business, which is expected to reach \$ 31 billion by 2010. India with its essential competitive advantages remains as one of the most preferred outsourcing destinations and is now playing a vital role in manufacturing as well as drug development value chain of various innovator companies. The pharmaceutical industry in India is expected to grow from \$5.5 billion now to \$25 billion by 2010 and \$75 billion USD by the year 2020. By 2020, global integration of most sectors in the world economy would be much more pronounced, and the pharmaceutical industry will not be an exception. In fact the Indian pharmaceutical industry, which currently has strong linkages with the global pharmaceutical market, will become even more strongly integrated.

The future will be extremely promising with many more milestones to come in the journey of the Indian pharmaceutical industry.

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