

# Patents Regime in India: Issues, challenges and opportunities in Pharmaceutical Sector

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## Abstract

TRIPS implementation in India has created much furor within pharmaceutical sector in India. With India adhering to TRIPS requirements it is feared that prices of new drugs in India may shoot up and drugs may become out of reach of common man. But TRIPS agreement provides some inherent flexibilities and with prudent application by the government will benefit the society. Flexibilities like Compulsory Licensing, Parallel Imports, and Bolar Exemption can be used judiciously by Indian government to make drugs affordable to masses. Indian companies have some challenges ahead in product patent regime, as multinational pharma giants will launch products in India from their portfolio of global products, which may have higher prices. Various challenges and opportunities lying ahead in post TRIPS era for Indian pharma industry are discussed.

## HISTORY

Patent Act in India is more than 150 years old. The Patent Act was first enacted in the year 1856 under the rule of British and subsequently amended several times. India had inherited The Patents and Designs Act 1911 from the colonial times that provided for protection of all inventions except those relating to atomic energy and a patent term of 16 years from the date of application [1]. After Independence of India there was a need to revise The Patents and Designs Act 1911 to facilitate the local industry and in accordance with the stage of development of the country. The Patents Act in India was framed after years of consideration and on the basis of the recommendations made by the Justice Rajagopal Ayyangar Committee (1958) [2]. The Patent Act 1970, provided for process patents for pharmaceuticals and agro-chemical products and for a short period i.e 7 years for pharmaceutical, agro chemical and food products and 16 years for other categories. This enabled the growth of a strong local generic drug industry, which produced the same drugs as the MNCs at relatively low prices. India, since 1970, had a Patent law that was proclaimed by many as a model for other developing countries. The Indian Law stressed on the obligations of the Patent holder and had strong provisions that prevented the abuse of the Patent holder's monopoly rights. One of the important factors that contributed the growth of Indian pharma industry was the fact that The Patent Act 1970 did not provide for monopoly rights in the area of drugs and agro-chemicals [3] as only

process patents and not product patents were recognized. Thus, by allowing only process patent India today witnesses a thriving generic pharmaceutical industry that is capable of exporting generic drugs to certain developed countries.

## INDIAN PATENTS ACT

India became a member country of WTO in 1994 and thus with the accession at WTO India was compelled to honor TRIPS agreement, which was a part of WTO agreement. India being a developing country was given a grace period of ten years - January 01, 1995 to December 31, 2004 - to fully comply with TRIPS requirements. India amended the Patents Act 1970 twice, in the year 1999 and in 2002 again to comply with the WTO requirements of TRIPS agreement. These amendments in 1999 and 2002 did not completely comply with the WTO requirements and so there was a need to frame an Act that was more compatible with the requirements of TRIPS. After a lot of debates and discussions, Indian Parliament on March 23, 2005 passed the Patents (Amendments) Bill 2005. This in turn paved the way for a radical shift in India from a weak process patent system to a strong TRIPS compliant Product Patent System [4]. The bill was passed in compliance with India's commitment to the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights, or TRIPS [5]. With the third amendment of The Patents Act 1970 in March 2005 by the Indian government, Indian pharmaceutical companies were prohibited to market a generic drug - a drug patented

elsewhere by using a different process. But amended Indian Patents Act has provided measures and safeguards that will not be detrimental to Research and Development activities in the country, specifically in the field of pharmaceutical products. Safeguards are built in to prevent “evergreening” of patents. Evergreening refers to extending patent life of a product beyond its stipulated term of 20 years.

## **GROWTH OF PHARMACEUTICAL INDUSTRY SINCE 1970**

India has achieved tremendous progress in science and technology since independence. The Indian Pharmaceutical Industry today is considered highly progressive industry among India's science-based industries with wide ranging capabilities in the field of drug manufacture and technology. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple pills to complex medicines requiring complex steps to manufacture, medicines for almost all type of ailments are manufactured in India [6]. India today is considered to be global powerhouse of generic drugs. The lack of protection for product patents in pharmaceuticals and agrochemicals had a significant impact on the Indian pharmaceutical industry and resulted in the development of considerable expertise in “reverse engineering” of drugs. As a result, the Indian pharmaceutical industry grew rapidly by developing cheaper or economical versions of a number of patented drugs and supplying these cheaper versions to Indian market and eventually moved aggressively into the international market with generic drugs once the international patents expired [7]. Thus, India has had a vibrant generic industry since 1970 when it lawfully amended its existing Patent Act to disallow patent protection for pharmaceutical products. This move catapulted India from a country importing most of its medicines at some of the highest prices in the world before Independence, to a country that was self-reliant in producing life-saving medicines [8] although it took several years for Indian pharmaceutical companies to make their mark in global pharmaceutical field and being recognized as producer of quality medicines at affordable prices. The Indian Patent law (1970) gave Indian companies the opportunity to reverse engineer molecules that were under patent (without payment of royalty) and to sell them at 8-15% of the price of the patented drug [9]. Generics make up about 15 percent of the India's \$6 billion pharmaceutical industry that has 300 large and moderate-sized firms, plus 10,000 small companies, making 8 percent of the world's drugs. According to pharmaceutical industry statistics, nearly 70 percent of production is by the top 100 firms and

about a third of that is exports, which are rising 25 percent a year [10].

## **PRICES OF DRUGS IN INDIA**

So far India was regarded as a supplier of low cost generic version of patented drugs to countries, which do not have sufficient manufacturing capacity and to some low income and least developed countries in Africa. If the government does not establish measures to bring prices down, the cost of new drugs remains very high, because patents allows monopoly power and prevents competition. Although least-developed countries are not obliged to grant patents on pharmaceuticals until 2016, these countries do not have the technical and financial capacity, nor the economies of scale to produce generic medicines [11]. TRIPS implementation in India and other manufacturing countries will eventually cut the lifeline of affordable drugs unless safeguard measures are implemented to prevent this. TRIPS agreement does not specify or enforce anything regarding the prices of drugs and national governments are free to enact the measure within the ambit of TRIPS provisions to curb the increase in prices of drugs. India should think in this direction and should control the prices charged by the pharmaceutical companies. It is evident that Indian drug maker Cipla offered and supplied anti-retroviral drugs to some African countries at a fraction of price charged by the Multinational companies (MNCs). In the case of antiretroviral medicines to treat HIV, Indian generic production has slashed prices by as much as 98%—from approximately \$10,000 per year to as little as \$140 per year for an initial three-drug combination [12]. In India it is feared that if certain antiretroviral drugs are granted patent, prices of these drugs will rise making it unaffordable to the general public. And in India, a vast majority of population spends for the medicines out of pocket and provision of medical insurance schemes is not in vogue. Indian Union Minister for Commerce and Industry, Sri Kamal Nath, assured that “the prices of medicines will not shoot up due to Patents, because of the strong safeguards and checks and balances.” Further he added “I must also repeat the point often cited that 97 % drugs in market and 100 % of all essential drugs are not covered by patents” [13].

## **TRIPS DECLARATION TO MEET PUBLIC HEALTH IN LEAST DEVELOPED COUNTRIES AND COUNTRIES WITH INSUFFICIENT MANUFACTURING CAPACITY**

Paragraph 6 of the Doha declaration on the TRIPS agreement and Public health provides certain flexibilities to be used by the countries to protect public health concerns. It

states that member countries can use compulsory license, in case of emergency to address supply problems that can arise during health crises. Further it also recognized that WTO members with “insufficient or no manufacturing capacities in the pharmaceutical sector,” could have difficulty using the compulsory licensing provisions of the TRIPS Agreement [14]. Paragraph 6 of the declaration promised to resolve, by the end of 2002, an outstanding issue in the TRIPS Agreement: the terms on which countries can export drugs as part of a compulsory licensing scheme [15]. The mandate given to the TRIPS Council under Paragraph 6 of the Declaration, culminated in the Decision of the General Council on August 30, 2003. The Decision is made up of eleven main paragraphs in addition to an annexure; setting out the determination of manufacturing capacities in pharmaceutical sector. The first paragraph defines terms such as “pharmaceutical products”; “eligible importing member” and “exporting member”. In paragraph 2, the General Council explicitly waived the obligation of member countries under Article 31(f) [16]. Paragraph 2 expressly permits export of pharmaceutical products to eligible importing member upon the fulfilment of certain conditions. These conditions include notification to the TRIPS Council by eligible importing members of specific names and quantities of the products needed, confirmation of lack of sufficient manufacturing capacity, obligation imposed on the exporting country to ensure that the amount of products produced under compulsory licenses are to meet the health needs of the eligible importing members and that all the products are exported to the member which has notified its need of such a product to the TRIPS Council [17].

## TRANSITIONAL ARRANGEMENT

### MAIL BOX PROVISION

Under TRIPS, countries that did not have a product patent regime in place as on January 1, 1995, had to provide for a mailbox. Mailbox was essentially a mechanism for accepting patent applications till a product patent regime was actually put in place. Experts assume, therefore, that most of those patent requests are for already known medicines that have been only slightly modified. When the Patent Office of India opened the mailbox, there were a total of 8,926 patent pleas in the mailbox; a majority of 7,520 belonged to foreign entities. Over the past ten years only a few hundred New Chemical Entities (NCEs) were identified, but approximately 9,000 patent applications for medicines are in India's mailbox [18]. This clearly shows how pharmaceutical companies can have several patents for the same molecule.

While US based entities put 2,324 applications including 2,096 for pharmaceuticals, Indian companies submitted only 1,406 filings including 1,300 for Pharma sector. Among foreign countries, Germany made 1,238 filings including 1,134 filing for Pharma products to occupy the third slot behind US and India followed by UK (631/573), Switzerland (596/538), Japan (503/434), Sweden 364/351), France (322/278), Denmark (306/278) and Belgium (177/170) [19]. Among the pharma companies Pfizer, world's number one pharma company, emerged as the biggest patent applicant with 373 applications. Johnson and Johnson with 262 applications followed Pfizer in filing mailbox pleas. Among Indian companies Dr. Reddy's was the aggressive filer with 205 mailbox applications followed by Panacea Biotech with 75 applications, Dabur 56 applications, Sun Pharma 46 applications, Cipla 45 applications. Surprisingly India's biggest drug maker Ranbaxy was way behind in filing mailbox applications with just 38 applications to its credit [20]. Thus it is evident from the mailbox applications is that the multinational pharmaceutical companies were more interested in getting patent protection in India than the Indian pharmaceutical companies. The mailbox applications filed by some multinational and Indian pharmaceutical companies is shown in Table 1.

**Figure 1**

Table 1: Source: Intellectual Property Rights, A Bulletin from TIFAC, Vol. 11, No. 1-3, January –March, 2005, 13 and Financial Express, March 21, 2005

Indian companies	Number of Mailbox filings	Foreign companies	Number of Mailbox filings
Dr. Reddy's Labs	205	Pfizer	373
Panacea Biotech	75	Johnson and Johnson	262
Dabur India	56	Procter and Gamble	187
Sun Pharma	46	Merck	156
Cipla	45	GSK	115
Ranbaxy	38	El Dupont	95

## FLEXIBILITIES AVAILABLE UNDER TRIPS COMPULSORY LICENSE (CL)

The compulsory licenses are permitted in the TRIPS Agreement under Article 31. The Agreement does not limit the grounds upon which compulsory licenses may be granted and only sets forth the conditions to be applied in the case of granting. This includes specification of grounds of compulsory licensing and the reasonable rate of licensing fees to the patent holder [21]. According to the TRIPS agreement, WTO member countries can use the subject matter of a patent or permit such use by a third party without the authorization of the patent holder [22] in certain cases of

national emergency, public non commercial use or extreme emergency. Indian patent law already includes a compulsory license provision that can be invoked under certain circumstances, including a lack of working the patent in India [23]. The TRIPS agreement does not mention the term 'compulsory license' anywhere in the text. Instead it employs the term, 'Other use without authorization of the patent holder'. The use of compulsory license is restricted to limited period and under certain conditions. TRIPS agreement has defined these certain conditions such as "national emergency or other circumstances of extreme emergency or in cases of public non commercial use" [24]. Indian Patent Act allows for Compulsory License (CL) but so far there are no instances where India has used this flexibility (CL) available in the TRIPS agreement. This may be attributed to non recognition of product patent in India as Indian pharma companies can manufacture generic versions of patented molecules and can export to countries, which do not recognize product patent.

### **BOLAR PROVISION**

Article 30 of TRIPS agreement allows members to provide for limited exceptions to the exclusive rights conferred by a patent, that is, to define acts that would not be deemed as infringing when made without the authorization of the patent owner. Such exceptions may include, for instance, acts of experimentation and the request for marketing approval of a pharmaceutical product before the expiration of the patent [25]. The Bolar exemption strikes a careful balance between promoting invention and ensuring that consumers have timely access to cheaper generics, after the expiry of the patent [26]. This is a TRIPS compliant safeguard and many countries outside the European Union including the US, Canada and Israel allow for the early development and testing of generic medicines to enhance competition in the off patent sector immediately after the basic patent of an originator pharmaceutical product expires. Bolar provision in many ways has facilitated improved affordable access to anti retroviral for AIDS [27].

### **PARALLEL IMPORTATION**

Parallel importation is one such flexibility that can be used by countries to make available certain drugs at lower price compared to what is charged by the patent holder. Under the Agreement, countries can overcome the high price of a patented medicine by either making or importing generic versions of pharmaceuticals (by issuing a compulsory license) or importing a more affordable version from another country (through parallel importation)[28].

## **CHALLENGES FOR INDIAN PHARMACEUTICAL INDUSTRY**

Product Patent regime implies that Indian pharma companies cannot make generic versions of the patented molecule from January 1, 2005. Indian government while drafting the Patents Bill, has taken due care to ensure that drugs that were on the market can be sold in India after 2005 by providing reasonable royalties to the Patent holder. Indian pharma companies so far concentrated on marketing generic versions of drugs and no money was spent on basic Research and Development (R&D). Thus, Indian pharma companies have no experience of developing a new molecule. Further Indian pharma companies are not considered financially strong as it takes almost US \$ 1 billion to develop and market a drug. Entire Indian pharma industry is valued at US \$ 4.5 billion to US \$ 6 billion according to various estimates. Considering this fact, it may be difficult for an Indian company to come up with a new molecule. Indian companies are going to have tough competition from Multinational Corporations who were waiting for implementation of Product Patents in India. Indian companies are facing Generic competition from "Authorized Generics" in the developed markets. Authorized Generics are the generic version of patented molecule marketed by the patent holder itself once the patent on the molecules expire. Indian pharma industry and some experts believe that in addition to the woes of pharma companies, Drug Price Control Order (DPCO) continues to hamper the growth of the industry and erodes the profitability. Thus lack of enough return on investment (ROI) due to DPCO is ascribed as one of the reasons Indian companies were unable to invest heavily in R&D.

## **OPPORTUNITIES FOR INDIAN PHARMA COMPANIES IN PATENTS REGIME**

Despite challenges and hurdles faced by Indian Pharma companies in post TRIPS era, Indian companies could capitalize on the strengths that they have developed for over three decades.

### **GENERIC DRUGS**

Indian companies can still continue to market and export generic drugs that are off patent. US, being one of the largest markets for generic drugs, is the ideal destination for Indian companies. In US alone major blockbuster drugs are going off patent in next few years. Further it is estimated that generic market will reach US \$ 80 billion in coming few years in value terms and Indian companies stand a good chance of tapping a major chunk of this pie.

## **RESEARCH AND DEVELOPMENT (R&D)**

Indian companies have no choice but to invest in R&D. Investment in R&D is inevitable if Indian companies want to compete in the international market. Almost a decade back investment in R&D by Indian companies was dismal, around 2% of sales turnover. Investment in R&D by Indian companies has increased to the tune of 8-10 % in last few years. This is a good sign for Indian pharma companies. Further amount for R&D can be invested for NDDS (Novel Drug Delivery Systems), Analogue Research, NDDR (New Drug Discovery and Research), etc.

## **LICENSING AGREEMENTS**

It is difficult to imagine Indian companies coming out with totally new molecule in near future due to prohibitive cost of developing a new molecule. But companies can enter licensing agreements with Multinational pharma companies for development of molecule. Indian companies can garner royalties out of these licensing agreements. Indian companies can either opt for Out-licensing of molecules for royalty payments or they can In-license some promising molecules. Thus, In-licensing and Out-licensing of potential and promising molecules is a lucrative option. Some Indian companies have already entered into these licensing agreements. Licensing agreements can be arrived at early stage of product development or at a later stage of development of molecule depending on the potential of molecule.

## **MERGERS, ACQUISITIONS AND ALLIANCES**

Pharma companies in India can merge with overseas companies and market the generic drugs in those markets. Further Indian companies can enter into alliances for marketing and distribution of their products in foreign markets. Acquisitions of companies abroad will help Indian companies make inroads to less penetrated and unpenetrated markets. Companies like Sun Pharma, Wockhardt, Zydus Cadila have acquired several companies and entered into alliances with those companies in various markets.

## **CONSOLIDATION AND INTEGRATION OF BUSINESS ACTIVITIES**

To achieve cost effectiveness Indian companies have to constantly look for integration of business activities and consolidation of the business functions. Consolidation of business functions will reduce the operations cost and help compete successfully. Pharma companies need to consolidate their business activities in order to stay focused. The consolidation and integration of business activities will

help sustain Indian pharma companies.

## **LEVERAGING BIOTECH BOOM**

Biotech sector in country is fast growing. Companies have to look for development of biotech drugs apart from traditional drugs. Although proper regulatory guidelines are not in place for development and marketing of biotech drugs, coming days will witness launching more number of products based on biotechnology. Biotechnology companies are increasingly involved in licensing deals for their products with some big pharmaceutical companies to develop and market biotechnology derived products.

## **CONTRACT RESEARCH**

Contract Research for major companies is one of the options open to Indian pharma companies. This option is very important to Small and Medium Enterprises (SMEs) to survive in post TRIPS era in India. Contract research in India is emerging at a rapid pace and many Contract Research Organizations (CROs) are providing services to various companies. Companies with Good Laboratory Practices (GLP) implementation can benefit to a great extent.

## **CONTRACT MANUFACTURING (LOAN LICENSING)**

Loan licensing agreements with major pharmaceutical companies could be a good survival option for Small and Medium Enterprises (SMEs). Many major pharmaceutical companies have entered into this agreement with some smaller companies that do not have enough financial resources. Small and Medium Enterprises can take this opportunity of contract manufacturing for their survival in post TRIPS era.

## **CO-MARKETING AND CO-PROMOTION**

Small and Medium Enterprises (SMEs) can co market or co promote the products for some major pharmaceutical companies in India. Many Indian and Multinational pharma companies have agreements with some SMEs for co-promotion and co-marketing of their major brands. This is one of the options available to SMEs for survival.

## **ALTERNATIVE MEDICINE AND HERBAL PRODUCTS**

Indian pharma companies can take advantage of India's rich biodiversity and can focus on products that are used as alternative medicine or are herbal products. World wide use of herbal products is increasing and sale of herbal products is

increasing in developed countries as well, which provides a great opportunity to domestic pharma companies.

## CONCLUSION

Indian pharma companies have opportunities to survive and grow in product patent regime as amended Indian Patents Act provides various safeguards against abuse of Patents and monopoly rights. Abuse of patents and monopoly rights is prevented to a certain extent by Indian government and this will help Indian companies to fight MNC pharma giants in Post TRIPS regime. Flexibilities available under TRIPS like Compulsory License can be effectively utilized by Indian government to protect public health and certain situations of National emergency. Indian pharma companies can effectively leverage on the opportunities available and continue to be one of the leading pharma industries in the world.

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