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**INTELLECTUAL PROPERTY IN INDIA: A REVIEW**

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**ABSTRACT**

In Patents, it has been observed that innovations in different field of technology work differently in different field of industries. In case of engineering products often contains many patented technologies and patents are often shared among competitors through pooling or cross licensing. However, in the field of pharmaceutical, chemical and biotechnology industries the patent normally cover/protects the particular product or process for achieving that product which involves extensive investment in research and development and requires clinical testing before placing it on the market and not practiced competitors pooling. India joined the World Trade Organization (WTO) in 1995 and automatically became a signatory of the Agreement on Trade-Related Aspects of International Property Rights (TRIPS) in 1995. The Patents (Amendment) Act 2005 takes care of India's TRIPS compliance requirement. The latest amendment in the year 2005 meet India's obligation under the Act TRIPS agreement and provides for product protection in the field of drugs, pharmaceuticals and chemicals. The present paper focuses on the scenario of intellectual property in India in the pharmaceutical conundrum.

**Keywords: Innovations, Pharmaceutical, Chemical, Biotechnology, TRIPS, World Trade Organization**

**INTRODUCTION**

In order to strengthen and enhance global competitiveness and to realize sustainable economic growth in any country, it is important to enhance innovation through

patents and other intellectual property rights [1].

Patent protection in the field of pharmaceutical products is especially

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important compared with other industries because such inventions are often easy to replicate and can be copied with a little change and also have application/implication in domestic and international industries differently.

India's patent law dates back to nearly 150 years. The 1856 Act was known as the Act VI of 1856 on protection of inventions and was based on the British Patent Law of 1852. This Act granted certain exclusive privileges to the inventors of new inventions for a period of 14 years [2].

This Act was later repealed and The Patents and Designs Protection Act were formally made public in 1872. This Act was amended from time to time. It was changed to "The Protection of Inventions Act" in 1883 and in 1888 this was changed to "The Inventions and Designs Act". Finally, in 1911 "The Indian Patents and Designs Act" was promulgated. After India gained independence in 1947, it still followed the old British Law. It was only in 1965 when a patent bill was placed before the Parliament and was passed as the Indian Patent Act of 1970 [3].

The debate on the advisability of (certain aspects of) the patent system has a very long and turbulent history. The introduction of the WTO-TRIPs Agreement (1994) – which implies the implementation of high standards

for the legal protection and enforcement of intellectual property rights, including patents – has by no means quieted down this debate, but rather, has intensified it. At the WTO, as well as in various other forums, a remarkable debate is going on about the potential impact of patents on access to healthcare. In August 2000, the UN Commission on the Promotion and Protection of Human Rights adopted a resolution declaring that there are apparent conflicts between the TRIPs regime, on the one hand and human rights (including the right to health) on the other. Other commentators consider the property right of patent holders as a human right and argue for a further strengthening of those rights. Yet others, who do not frame the problem in terms of rights, defend patents with economic arguments or by invoking fairness. The main question of concern in this paper is to what extent these different arguments can justify the practice of patenting drugs, particularly in developing countries [4-6].

In this changing scenario, research and development activities in this sector has been increased quantitatively as well as qualitatively. Presently, at-least 10 leading Indian pharmaceutical companies are into new drug discovery and some of them have increased their R&D spending by over 5 per cent of their respective sales turnover. There

are other efforts from govt., like providing fiscal incentives to R&D units in pharma sector as well as streamlining procedures related to development of new drug molecules, clinical research and new drug delivery systems. As a result, India is emerging as an alliance and outsourcing destination of choice for global pharmaceutical companies across the value chain [7].

The Doha Declaration was a landmark in the history of WTO in the sense that it recognizes the gravity of the public health concern afflicting many developing countries and the need for the TRIPS Agreement to be part of the wider national and international action to address these problems [8].

### **Pharmaceutical Implications in Intellectual Property**

The accumulated knowledge of traditional medicinal system and large bio-diversity of India offers great advantage to its drug industry. The rapidly changing economic, trade and intellectual property scenario, nationally and internationally, poses many challenges to this industry, including the challenge of becoming leaders and competitors globally. This necessitates a shift in the approach of the industry that is, moving away from manufacturing only known drugs called generics to discovering and

commercializing new molecules called New Chemical Entities (NCE) through innovative process routes utilizing well established expertise human resource and infrastructure. It would mean that the Indian pharmaceutical industry has to focus more on research and development (R&D), so as to enable India to maintain its status in the world pharmaceutical market and move ahead to become a global leader [9].

The WTO-TRIPs Agreement heralds a fundamentally new era for developing countries. In the pharmaceutical sector a product patent refers to the chemical structure of a drug. The final product (the actual drug) is protected, regardless of how it was manufactured and of the purpose it serves. Not surprisingly, a product patent is the most coveted form of protection. Process patents offer protection for the way in which the final product is made and for the way in which the product is used to reach certain goals (e.g. the treatment of specific diseases).

A process patent offers a 'strong' form of protection only if there is no other (financially sound) way of producing the product in question, other than through the process covered by the patent. In the pharmaceutical sector, this is rarely the case [10].

Further aspects are key to patent systems in India:

1. Moral justification of the patent system
2. Local Research and R&D
3. Fiscal contemplations of pharmacy

### **Moral Justification of The Patent System**

Attempts to construct a moral justification of the patent system have been based on three grounds:

#### **Natural rights**

If we look at the implications of this theory for the justification of drug patents, the main question seems to be: how much ‘labor’ is really involved in the research and development (R&D) of drugs? The greater part of pharmaceutical R&D budgets is spent on ‘me-too’ drugs – the slightly altered versions of successful products manufactured by the competition. The *American Food and Drug Administration* (FDA), for example, classifies the applications it receives both as ‘priority drugs’ (considered a significant improvement in relation to the existing drugs) and ‘standard drugs’ (considered similar to existing products). Of all drugs approved by the FDA over the past six years, almost 80% belong to the standard drug category [11].

#### **Distributive Justice**

According to the distributive justice argument, fairness requires that inventors be rewarded because they render a service to society. It would be unfair to allow people a

‘free ride’ at the expense of others who apply themselves to the act of inventing.

Free riders – people who did not invest time or money in the development of an invention – should not be allowed to compete with the inventor under normal market conditions. Therefore society should grant exclusive rights to inventors.

When examined in the context of the justification of drug patents, this argument, too, seems problematic. First, the question arises whether fairness does not also require an equal access to drugs, which is prevented by the working of the patent system.

Another question at issue here is: does justice require that inventors be rewarded with patents, allowing them to decide who may legally use the invention? Put differently: does it follow from the proposition that justice requires the rewarding of inventors that inventors must be granted exclusive rights of ownership on their inventions? Hettinger rightly observes that it does not:

The mistake is to conflate the created object which makes a person deserving of a reward with what that reward should be [12].

Property rights in the created object are not the only possible reward. Alternatives include fees, awards, acknowledgements, gratitude, praise, security, power, status, and public

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financial support rights to the results of R&D, which is, in great part, publicly funded?

In the US, for example, the National Institutes of Health (NIH) (subsidized by the federal government) are great benefactors of the pharmaceutical industry. This year, the NIH will be spending \$23 billion on research, and of course there are other public institutes investing in health-related research. Much of this research is directly beneficial to the industry. According to the NIH, 55% of the research projects leading to the discovery and development of the 5 best-selling drugs in 1995 were performed by researchers whose work had been financed with taxpayers' money.

#### **Utilitarian (Economic) Arguments**

The utilitarian justification, which is considered by many as the most convincing, is essentially based on the following two arguments:

1. The so-called 'incentive-to-invent-and-innovate' argument: in the absence of patents, inventions can be copied by competitors. Consequently, the price must be reduced and the investor does not have the opportunity to regain his investments, let alone make a profit. Thus, the incentive to invent and innovate is eroded. A 'special' incentive is required so that

enough people should be prepared to invest in R&D.

2. The so-called 'incentive-to-disclose' argument: the patent system encourages inventors to disclose their inventions instead of keeping them secret. One of the patentability requirements is that the applicant must disclose the invention in sufficient detail in the application forms [13-16].

#### **Local Research and R&D**

Hardly any drugs for diseases occurring primarily or exclusively in developing countries are being developed. Of the 1223 molecules that were sold worldwide between 1975 and 1996, less than 1% was intended for tropical diseases. R&D of drugs for these diseases is desperately needed. According to some commentators, if developing countries were to grant strong patents for drugs, this would stimulate local research. Not granting strong patent protection may well yield short-term advantages, but it would be harmful in the long run, they say, because such a situation can never bring about drugs that meet the specific needs of the country in question.

The introduction and the application of new technologies are indeed important instruments to help developing countries improve their standard of living. However, the fact that in

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developing countries few new technologies are being developed has more to do with fundamental economical problems (e.g. a lack of skilled workers and the absence of infrastructures capable of absorbing new technologies) than with patent protection standards [17-19].

The classical argument in this context is that those who possess technology are not too keen on transferring their technological knowledge to countries with a 'weak' patent system, for risks involving 'piracy.' If a developing country were to strengthen its patent system, so the argument goes, the industrialized countries will make new medicines available in that country. This prediction, however, does not sound very credible. Drugs that can be produced via conventional processes are already being brought onto the market by local production plants in numerous developing countries. Those drugs of which the production requires sophisticated technologies are generally not copied in developing countries, as the required manufacturing capacities are only available in industrialized countries. Moreover, such drugs are very expensive and therefore accessible only to the rich segment of the population in developing countries. It is therefore highly unlikely that the strengthening of patent protection in

developing countries will bring in technology previously unavailable [20].

As far as the role of patents in the encouragement of foreign investments is concerned, various commentators claim that the absence or the availability of adequate protection of intellectual property rights constitutes a factor which plays an increasingly important part in the investment-related decisions of companies.

#### **Fiscal Contemplations of Pharmacy [21]**

As noted earlier, the so-called 'least developed countries' have been granted a postponement until 2016 to conform their drug related patent provisions to the WTO-TRIPs Agreement, but once the developing countries that can export drugs to them (e.g. India) must acknowledge drug patents – already in 2005 as foreseen in TRIPs – the least developed countries are sure to encounter even more serious problems in obtaining affordable drugs. In this context, compulsory licences will become increasingly vital.

The discussions in the TRIPs Council concerning export strategies went off the rails during a debate about the question for which diseases the export of drugs under compulsory license should be allowed. When the president of the TRIPs Council proposed a draft in December 2002 stating that the

Doha Declaration was not limited to HIV/AIDS, malaria and tuberculosis, the US (as the only among the then 145 WTO members) refused to accept this draft and negotiations were broken off.

### **Pharmaceutical Industries and The Current Regulatory Scenario**

There are several national and international pharmaceutical companies that operate in India [22-28]. Most of the country's requirements for pharmaceutical products are met by these companies. Some of them are briefly described below:

- 1. Ranbaxy Laboratories Limited** is the biggest pharmaceutical manufacturing company in India. The company is ranked at the 8th position among the global generic pharmaceutical companies and has presence in 48 countries including world class manufacturing facilities in 10 countries and serves to customers from over 125 countries. Ranbaxy Laboratories 2009-2010 Q3 Net Profit Results showed a profit of Rs 116.6 crore as compared to Rs 394.5 crore deficits, recorded during the corresponding period last fiscal.
- 2. Dr. Reddy's Laboratories** manufactures and markets a wide range of pharmaceuticals both in India

and abroad. The company has 60 active pharmaceutical ingredients to manufacture drugs, critical care products, diagnostic kits and biotechnology products. The company has 6 FDA plants that produce active pharma ingredients and 7 FDA inspected and ISO 9001 and ISO 14001 certified plants. Dr. Reddy's Q1 FY10 result shows the revenues of the company at Rs. 18,189 million which is up by 21%. During this quarter the company introduced 24 new generic products, applied for 22 new generic product registrations and filed 4 DMFs.

- 3. Cipla** is an Indian pharmaceutical company renowned for the manufacture of low cost anti AIDS drugs. The company's product range comprises of anthelmintics, oncology, anti-bacterials, cardiovascular drugs, antibiotics, nutritional supplements, anti-ulcerants, anti-asthmatics and corticosteroids. Cipla also offers other services like quality control, engineering, project appraisal, plant supply, consulting, commissioning and know-how transfer, support. For the financial year 2008-09 the company registered an increase of

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22% in sales and other income over the previous year.

4. **Nicholas Piramal** is the second largest pharmaceutical healthcare company in India. The brands manufactured by the company include Gardenal, Ismo, Stemetil, Rejoint, Supradyn, Phensedyl and Haemaccel. Nicholas Piramal has entered into joint ventures and alliances with several international corporations like Cheissi, Italy; IVAX Corp; UK, F. Hoffmann-La Roche Ltd., Allergan Inc., USA etc.
5. **Glaxo Smithkline (GSK)** is a United Kingdom based pharma company; it is the world's second largest pharmaceutical company. The company's portfolio of pharma products consist of central nervous system, respiratory, oncology, vaccines, anti-infectives and gastro-intestinal/metabolic products among others. On November 2009, the FDA had announced that the H1N1 vaccine manufactured by GSK would join the list of the four vaccines approved.
6. **Zybus Cadila** also known as Cadila Healthcare is an Indian pharmaceutical company located in Gujarat. The company's 1QFY2010

results show the net sales at Rs880.3cr which is higher than the estimated Rs773cr. The net profit was Rs124.8cr which was increase of 39%; the increase was on account of higher sales and improvement in the OPM.

Drugs and pharmaceutical industry plays a vital role in the economic development of a nation. It is one of the largest and most advanced sectors in the world, acting as a source for various drugs, medicines and their intermediates as well as other pharmaceutical formulations. Being the intense knowledge-driven industry, it offers innumerable business opportunities for the investors corporate the world over. The existence of well-defined and strong pharmaceutical industry is important for promoting and sustaining research and developmental (R&D) efforts and initiatives in an economy as well as making available the quality medicines to all at affordable prices. That is, it is essential to improve the health status of the individuals as well as the society as a whole, so that positive contributions could be made to the economic growth and regional development of a country.

The Indian drugs and pharmaceutical industry, over the years, has shown tremendous progress in terms of infrastructure development, technology base creation as

well as product usage. On the global platform, India holds fourth position in terms of volume and thirteenth position in terms of value of production in pharmaceuticals. The pharmaceutical industry has been producing bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing processes as well as a wide range of pharma machinery and equipments. It has also developed excellent 'good manufacturing practices' (GMP) compliant facilities for the production of different dosage forms. Besides, the amendment to the Patents Act, 1970 [enactment of Patents (Amendment) Act, 2005], has opened up new avenues for the sector. The new patent regime has ushered in the era of product patents for the pharmaceutical sector, in line with the obligations under the World Trade Organisation (WTO) and Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. As a result, the Indian pharmaceutical industry has become self-reliant in several areas and has developed a sounder and technologically advanced R&D segment.

### **Pharmaceutical Policy of 2002 [29-31]**

This policy aims to bring new incentives into the sector beyond those enumerated in the drug Policy, so that policy inputs are directed more towards promoting accelerated growth

of the pharmaceutical industry and towards making it more internationally competitive. Some of the salient features of this policy are:-

1. Abolition of Industrial licensing for all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, subject to stipulations laid down from time to time in the Industrial Policy, except in the cases of:-
  - Bulk drugs produced by the use of recombinant DNA technology.
  - Bulk drugs requiring in-vivo use of nucleic acids as the active principles and Specific cell/tissue targeted formulations.
2. Permission of foreign investment up to 100 per cent, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those referred in the above point, kept under industrial licensing.
3. Availability of automatic approval for 'Foreign Technology Agreements' in

the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those referred in the first point, kept under industrial licensing for which a special procedure prescribed by the Government would be followed.

4. Measures to give impetus to R&D in the drugs sector are as follows:-

- a) Constitution of the Pharmaceutical Research and Development Support Fund (PRDSF) and the Drug Development Promotion Board (DDPB)
- b) A manufacturer producing a new drug patented under the Indian Patent Act, 1970, and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.
- c) A manufacturer producing a drug in the country by a process developed through

indigenous R&D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process etc.

5. The system of the price control would be operated through a single list of price controlled drugs selected on the basis of criteria as laid down in the policy and formulations based there on, with a Maximum Allowable Post-manufacturing Expenses (MAPE) of 100% for indigenous formulations and margin up to 50% for imported formulations.
6. Ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all, including small scale units or those marketing under generic name, to follow the price so fixed.
7. **National Institute of Pharmaceutical Education and Research (NIPER)** as an institute of national importance in order to achieve excellence in pharmaceutical sciences and

technologies, education and training. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute seeks to make efforts to maximize collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.

Due to various policy measures taken by the Government in recent past, research and development (R&D) activities in this sector has not only increased quantitatively but also qualitatively. Presently, at least 10 leading Indian pharma companies are into new drug discovery and some of them have increased their R&D spending by over 5 per cent of their respective sales turnover. There are other efforts like providing fiscal incentives to R&D units in pharma sector as well as streamlining procedures related to development of new drug molecules, clinical research and new drug delivery systems. As a result, India is emerging as an alliance and outsourcing destination of choice for global pharma companies across the value chain.

Hence, the drugs and pharmaceutical is one of the most diversified of all the industrial sectors. The accumulated knowledge of traditional medicinal system and large bio-

diversity of India offers great advantage to the drug industry. The rapidly changing economic, trade and intellectual property scenario, nationally and internationally, poses many challenges to it, including the challenge of becoming leaders and competitors globally [32].

This necessitates a shift in the approach of the industry that is, moving away from manufacturing only known drugs to discovering and commercializing new molecules through innovative process routes. It would mean that the Indian pharma industry has to focus more on R&D, so as to enable India to maintain its status in the world pharma market and move ahead to become a global leader [33].

In other words, the strength of the industry lies in leveraging the country's power in organic synthesis and process engineering as well as developing cost-effective technologies in the shortest possible time for drug intermediates and bulk activities, without compromising on quality.

## CONCLUSION

The objective of this study-cum-research was to understand the significant provisions of the patentability and their implementation practices on both sides and their implications in overall developments in pharmaceutical industry and public health concerns.

Understanding the same will further allow filling any gap to provide more strong and effective IP protection to the pharmaceutical industry both side.

Transformation of the national patent regime in the field of pharmaceuticals will catalyze the domestic research and development in medicine and public health care and new molecules will come-up keeping the pace for generic drug manufacturing and there will be larger scope of business relationship in this field in India.

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### Processing of application for grant of patent in the Patent Office

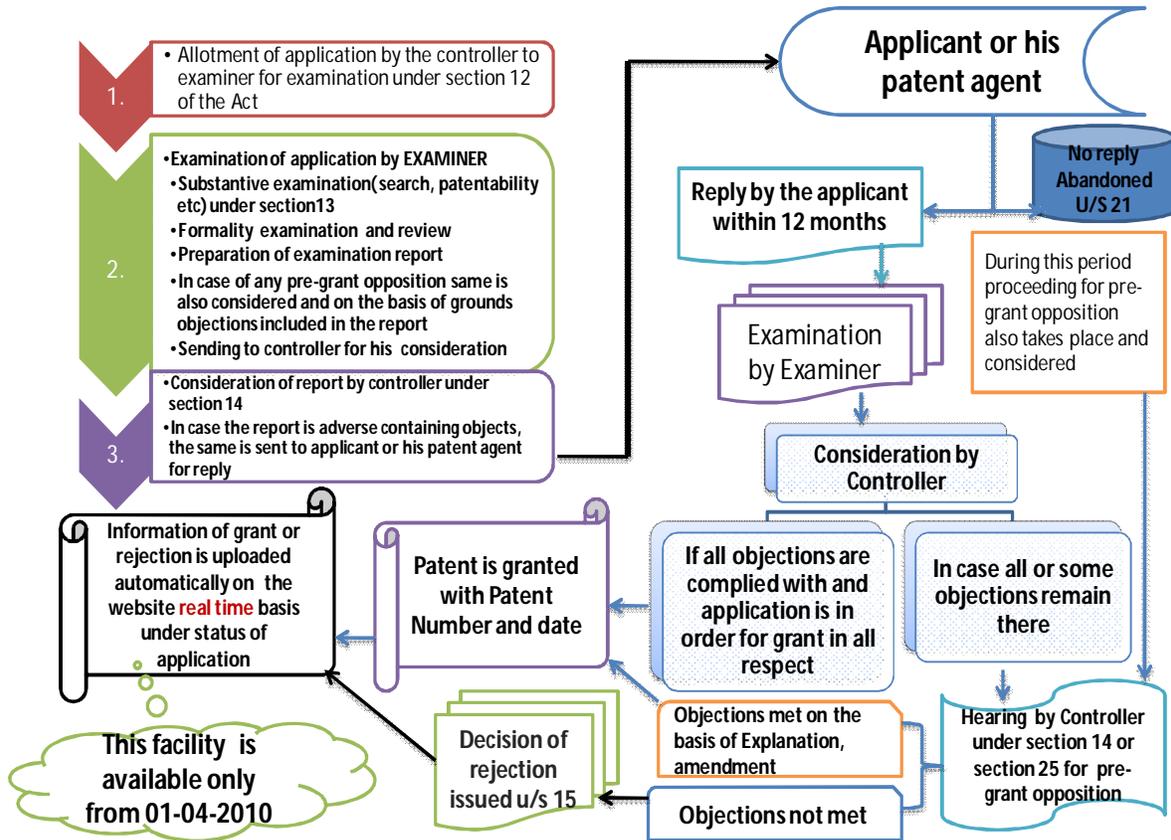


Figure 1: Patent Processing in India [34]