# Complications in Indian Pharmaceutical Industry with Special Reference to Intellectual Property Rights

Dr. Dinesh Nilkant,
Director, Center for Management Studies,
JAIN (Deemed-to-be University), Bangalore, India
Email Id: dineshnilkant@cms.ac.in

***ABSTRACT:*** ***The IPR is well known as concepts, innovations, and innovative jargons that are founded on the public inclination to seek property status. In order to allow IPR to derive commercial profits from their artistic effort or prestige, they grant elite rights to the inventors or creators of that property. There are several forms of protection against intellectual property such as patent, copyright, trademark, etc. Patent is the approval of an innovation that meets the worldwide creativity, non-obviousness and commercial use standards. In order to help identify, prepare, market, make and, thus, secure the innovation or imagination, IPR is a necessary prerequisite. Any industry should make progress by developing its own advanced IPR policies, management style, techniques, etc., based on its field of expertise. Currently, the pharmaceutical industry has established an IPR policy that requires better attention in the next century. This research focuses mainly on both the challenges of the companies and the opportunities that Indian Pharmaceutical companies have in the form of IPR. The common problems with IPR with particular regard to Indian Pharmaceutical companies have given this study greater opportunities. As Indian pharmaceutical firms are justly starting to invest in R&D and to produce their own patented molecules, it is irrefutable that they want to shield their innovation with patents. The Indian government should also promote and protect foreign corporations' patents. For the industry, and for research and development, patent protection and other types of intellectual property (IP) rights are essential. Without strong fortification companies have no incentives for research and development or the development of new, advanced medicines, particularly pharmaceutical companies.***

***KEYWORDS:*** ***Clinical Trials, Intellectual Property Rights, Generic Drugs, Patent, Research & Development, Copyrights.***

## INTRODUCTION

Indian pharmaceutical industry is increasing at the faster rate. On the other hand, Indian pharma companies are watching for global business chances in the way of export business, contract research and clinical trials. Many Indian companies in full swing realized the prominence of Intellectual Property Rights. The volume of money expended on Research and Development also rising to a greater extent. There are plentiful experimentations confronted by the Indian pharma companies' right from their primary investment to reinforce their Research and Development and up to obtainment of Patent and other IP Protection for their novel innovations. There are many legal formalities are to be supported for drug discovery, documentation, clinical trials etc., Cost of investment, termination of patented drugs, lack of clinical trials, more legal formalities, impediments in procurement of IP Protection are the major problems faced by Indian Pharmaceutical Companies.

For a wide cross section of countries, as outlined above, there should be a precedent to create a full and multidimensional systematic pharmaceutical framework for IPRs.

Country based or outdoor surveys of a broad spectrum of players in research and development/marketing/public affairs/legal, import/export companies, wholesalers and retailers of pharmaceutical products, leading firms of law in the field of research, development/marketing, marketing/public affairs/legal, and researchers in education, medical and medical services and in general medical companies. The API production facilities map as shown in Figure 1.

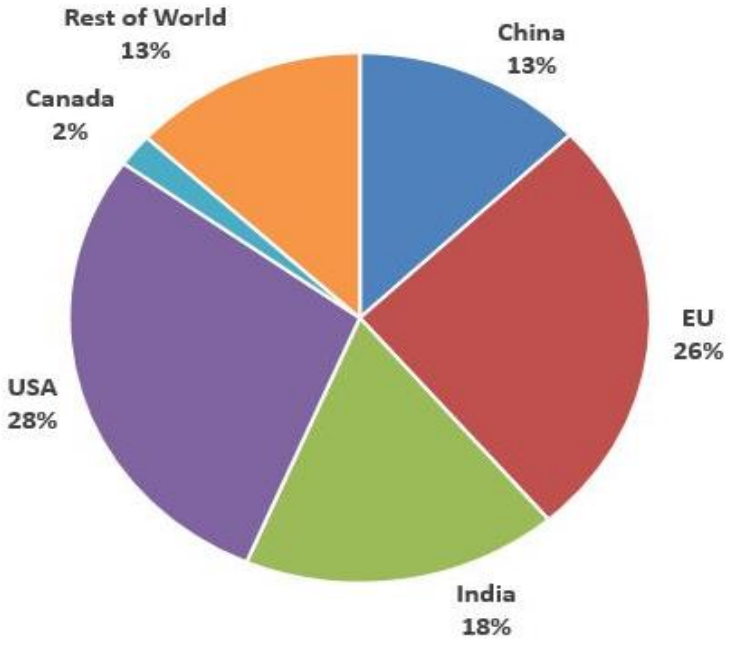


**Figure 1: PI Chart of API Manufacturing facilities for all Drugs by Country or Region, August 2018**

The pharmaceutical industry has unusually extensive expertise, which is generally recognized as extremely sensitive for IPRs to the economy of this market. There have been some advances in recording and interpreting inter-IPR trades, the related regulatory and policy provisions and foreign market expansion and its effect on pricing and access to medicines, research and development, trade and manufacturing. However, there are abundant opportunities in developed countries and countries with conversion economies for more extensive data on this diverse and vital industry.[1]

The Indian pharmaceutical industry faces significant obstacles in a changing field of intellectual property rights. Two of India's biggest economic partners - the US and the EU - commented critically on the elasticity offered by the Indian Patents Act, which gave some room for generic drug manufacturers in the region.

Annual investigation was carried out under Spl. 301 of 1989 by the United States Trade Representative (USTR); India has been either designated as the "Priority Foreign Country," or listed on the "Priority Watch List," in each annual investigation. This first designation shall apply to countries with the greatest adverse repercussions (actual or potential) on related US goods, and to countries in which there are "problems regarding the security of, regulation of or market access for individuals who are reliant on (intellectual property), who have the most costly or egregious activities, policies and practices.[2]

Patent defense has become a worldwide norm for prescription drugs and processes. In the post-trade dimensions of the periods of intellectual property rights in Indian, the pharmaceutical industry has grown. There are, however, questions about reducing the generic supply of drugs and reducing access to medicines in India through a recent patent act. Indeed, India did not acknowledge pharmaceutical product patents for several years until its membership of the WTO. The patent scheme is the safest system to promote pharmaceutical R and D. The pharmaceutical patent is essential to the disclosure scheme in order to advance science. As India is the largest producer and provider of genera, it is not only for India but also for other under development countries that the question of access to medicinal products is crucial. The Indian Government should therefore strive for a suitable equilibrium of public health innovations. The aim of this article is for the public and pharmaceutical experts to collect some information from different sources and to have basic knowledge of pharmaceutical patents.

The Patents Act 1970 provides some explicit protections to counteract this monopoly-related harm. This cat also has a clause for the availability of ample quantities of proprietary materials for end consumers and at the same time for the reasonable price.

[1] Gallini N, Scotchmer S. Intellectual Property: When is it the Best Incentive System? Working Paper n. E01-303, Department of Economics, University of California, Berkeley; 2001.
[2] *Supra 1.*

If the patentee does not do so, CL may be provided to interested parties by the Government of India so that the patents comply with the product condition. While the first CL (Bavarian proprietary medication Nexavar to Natco Pharma Limited) was released in 2012, the history of compulsory authorization is not recent.

It is said in Section 22 of the Patents und Design Act of 1911 that any interested person can apply for CL after 3 years of patent life (Day 1 being the day on which the patent was sealed) if, for instance, the commercial angle of the patent is not fully defined and the Indian population claim/obligation for the patently owned property is not fully established. [3]

Although there has been considerable controversy following India's award of the initial NATCO "CL" and its subsecuted subsidies, there seems to be an impartial trend, with a vital equilibrium between generic manufacturer's interests, patent intention and public interest.

The Indian patent system has so far equated the sensitive equilibrium between the patentee's interest and the Indian population. There are also tales such as imatinib (Novartis), tadafil, rosiglitazone (GlaxoSmithKline), FENOFIBRATE (Abbott), sorafenib (Bayer), about the product patent, EMR and off-patent drugs, and the way in which the manufacturer seeks to prevent the generic selling of its inventions. Effective lesions from these incidents have allowed us to realise the shortcomings of the existing IPR system and then to strengthen the system. The Non-Comprehensive Indicators list as seen in Figure 2.

| | |
|---|---|
| Term of market exclusivity | Patent term<br>Market exclusivity provided by regulatory approval<br>Patent/exclusivity extensions to compensate for regulatory review delays<br>Extensions for pediatric investigation<br>Extensions for orphan drugs<br>Extensions for drugs targeting specific diseases |
| Patentability standards | Scope of claims<br>Obviousness/inventive step<br>Utility/industrial applicability<br>Novelty (and grace periods)<br>Priority rules |
| Patentable subject matter | Products<br>Manufacturing processes<br>Manufacturing intermediates<br>Alternative salts and esters of previously patented compound<br>Use of a product in treating specific diseases<br>Treatment protocols, dosing<br>Packaging/delivery mechanisms<br>Metabolites<br>Naturally occurring substances |

**Figure 2: A Non-Comprehensive List of Indicators that may affect the Strength of Biopharmaceutical IPRs**

1. *Patent Law in India*

For the first time in 1856 in India patent laws were enacted and in 1970 a 1970 Patent Act was passed ("the Patent Act"). India is also a signatory to all prior laws to the Paris Convention for the Defense of the Industry. India is also a signatory to the 1883 Convention on Intellectual Property Rights in Paris and to the Treaty on Patent Cooperation of 1970.The Patents Act allows for the subject-matter of a patent to be any invention that meets the standards of novelty, evil and practicality. Some of the discoveries that cannot be patented under the Patents Act include farming or horticulture, treatment of people, livestock, plants or other substances derived from mere add-on medical, surgical, curative and/or prophylactic procedures, which only add the components' properties, etc.[4]

With respect to medicinal products, patents are awarded either for methods of manufacturing of these substances or for certain substances which may be consumed or used as food, medicines or substances created by chemical processes. There is also no patent rights under Indian law for medicinal drugs.

[3] Intellectual property rights and Indian pharmaceutical industry: Present scenario, Indian J Pharmacol. 2018 Mar-Apr; 50(2): 57–60.
[4] *Ibid.*

In India all inventions under the Patents & Design Act 1911 had a system of commodity patents.[5] However, the government enacted a new Patent Act in 1970, excluding from the eligibility for the application of patents pharmaceuticals and agrochemicals. This exclusion was implemented in order to crack Indian reliance on bulk medicines imported and ad formulations and establish an indigenous pharmaceutical industry in its autonomous sector.

The lack of defense of product patents for pharmaceutical and agrochemical products has had a substantial effect on the Indian pharmaceutical industry and led to considerable reverse-engineering skills in drug products patentable as products in developed countries but capable of protecting them in India.

As a result, India's pharmaceutical and agrochemical sector was quickly expanding, producing cheaper versions of a range of domestic products and gradually moving vigorously on the global generic drug market after foreign patents expired. The drug sector has had a direct effect on the Indian pharmaceutical industry. The Patents law also contains a set of safeguards for the prevention and improvement of the availability of patent rights.

The Patent Act also provides for universal license requirements. If the patent has been sealed for three years, anyone interested in working on a patented invention can request a compulsory license in the invention. Only if the controller is convinced that public reasonable conditions for the patented invention have not been fulfilled, or that the patented invention is not made available for public consideration at a reasonable price, May the patent proprietor order that the license holder issue such license on the terms as may be considered fir.

In addition to the mandatory licensing, the Patent Act provides for a "licenses of right" in which, in some cases, after three years have elapsed from the date of the sealing of a patent, the central Government, on the basis that the reasonable requirements of the public witness, is able to apply for an order that the Patent can be endorsed with a "license of rights."

The patented product is considered to be endorsed with the term "license of right" automatically at the end of 3 years from the date of the patent screening for those ingredients which are not food products as such but which can be used as food items or medications. The aim of endorsing a patent in terms of "licenses of rights" is to allow a patentee to seek a license for an individual interested in working the patented invention in India. A license will be granted on terms settled upon by one another, even if he or she still has a license in accordance with the patent. If the parties cannot agree on the conditions of the license, they may appeal to the patent owner for the resolution of the conditions.

In this way, India is bound to comply with the minimum requirements in the patents and pharmaceutical industry under the TRIPS Agreement. India's Patent Law can also cover all medicinal products' and method innovations' provisions on the availability of patents. Any invention of a pharmaceutical product or process which meets the specified requirements shall be patented for a minimum period of 20 years.

2. *Stating the issue*

There are quite a few pharmaceutical firms of Indian descent. The Indian pharmaceutical industry in India is primarily run and owned by predominant international corporations with subsidiaries. Almost entirely Indians from senior managements are employed by most pharmaceutical firms working in India, including multinational companies. Companies are rather bureaucratic, as is the societal hierarchy. Local drugs are also a combination of public and private firms, like many other industries in India. While all of these businesses are public companies, the ownership of the company passes from father to son. The Indian pharmaceutical industry is growing faster. On the other hand, Indian pharmaceutical companies are looking for global business opportunities in the form of export activities, contract research and clinical studies. Many Indian companies have started to realize the importance of intellectual property rights. The volume of money spent on R&D is also increasing more rapidly. Indian pharmaceutical companies face many challenges from their first investment to strengthen their research and development to obtaining a patent and other intellectual property protections for their new innovations. There are many legal formalities involved in drug discovery, documentation, clinical trials, etc. Investment costs, expiry of patented drugs, missing clinical studies, no more legal formalities, and the biggest challenge faced by Indian pharmaceutical firms is problems relating to the security of intellectual property. IPR has a direct influence on the pharmaceutical industry. Intellectual property rights have a significant effect in terms of acceptance, sales generation and market capitalization on

[5] Patents and Designs Act, 1911.

the success of pharmaceutical firms. Indian pharmaceutical companies are struggling to obtain intellectual property protection for their medicines due to the aforementioned problems. This study mainly focused on the problems faced by companies and the opportunities that intellectual property rights offer to Indian pharmaceutical companies. Common issues related to intellectual property rights, with particular reference to Indian pharmaceutical companies, resulted in a greater opportunity for this study.

The Indian pharmaceutical industry is progressing and is third in volume and thirteenth in size. Indian generic products account for 21 percent of world exports in volume. However, branded generics lead the medicines industry and represent 71 to 79% of the market.

In recent decades, the pharmaceutical industry has undergone exponential growth fueled by a high disease burden, higher disposable income, healthcare infrastructure, etc. Via partnerships, joint ventures, and mergers and acquisitions, the pharma industry will continue to expand organically and inorganically. Via new concepts and business models, the emphasis is on improving performance and productivity. The pharmaceutical industry's main growth factors include advances in health insurance, medical technology, funding for healthcare, and expanding access to healthcare. Such inventions contribute to the discovery of new life-saving medicines and must be protected by intellectual property rights (IPRs). Patents grant exclusive rights to pharmaceutical firms to market medicines and ban the production, sale and manufacture of these for 20 years by anyone. IPR is a requirement for pharmaceutical companies to find, prepare, market and safeguard innovations. It is also an important tool to preserve investment, time and resources, to encourage fair competitiveness and to promote industrial growth and development. IPRs also offer an impetus to research and development for pharmaceutical companies.

The IPR is defended in many ways:

- Protects pharma firms from possible breaches
- Provides equal and appropriate stimulus for innovation
- Provides powerful mechanisms for enforcing patent infringement protection

Generic drug manufacturers replicate biopharmaceutical developments in a depressed economy in IPR protection without time and money to develop novel medicinal products. This makes it difficult to invest in innovative drug R&Ds and costly diseases for generic drug maker to recoup their investments in new drug manufacturing.

A stronger IPR regime enables pharmaceutical firms, from the discovery stage to expansion, to safeguard innovation. Growth, management and protection of intellectual property are becoming a major source of funding for R&D investments. IPRs also play a key role in fusions and acquisitions of target SMEs and are individual assets, which are tradable by means of licenses, joint ventures, etc.

In the pharmaceutical industry, IPR has an important influence on the problems of testing, increase, pricing, delivery, competitive mapping, and new drugs available and pricing.

*3. Upcoming path*

Ideally, the IP scheme should cover the scope of product development. By depending on the IP approach, companies can avoid litigation that could lead to financial harm to the business. Moreover, they will use IP-related goods through marketing and licencing. This fuels demand for low-value drugs and encourages pharmaceutical companies to expand rapidly.

The World Trade Organization's (WTO) growth has led to a massive global trade paradigm change. The TRIPS Agreement was negotiated in the context of the Uruguay Round of trade negotiations under the GATT, and "The pharmaceutical industry was one of the main causes for the inclusion of matters concerning intellectual property in the GATT scheme." The TRIPS Agreement was signed under the GATT. 4 India signed, and needed, the GATT on 15 April 1994.

India is also obliged, with regard to patents and the pharmaceutical industry, to comply with the basic standards laid down in the TRIPS agreement. The Indian legislation on patents also needs to make provisions on patents for both medicinal drugs and procedures on the availability of technologies. For a minimum term of 20 years, patents are granted for the discovery or operation of a pharmaceutical product where it fulfils.

## CONCLUSION

The primary weapon for the creation of economic resources has been intellectual assets. The invention of intellectual properties has helped. Many businesses have significant numbers of intellectual industries focused on expertise. Resources such as brand names, patents or the skills of staff. Those properties represent a significant portion of a company's market value. Accounting practices around the world still have to contend with the fact that Intellectual asset investments are 'capital' investments, and not 'existing' investments. The expenditures. As a consequence of such a therapy, there may be potentially large impact on several businesses often results in the impact of several businesses on profitability or book prices. It is unclear whether the stock price is the market value of stock prices, and whether the value of intellectual property is fully integrated by firms. This paper discusses the Market Assessment of Intellectual Capital in depth. Furthermore, the series of industry controversies has reoriented the need of intellectual asset assessments. Understand the importance part of the market valuation of intellectual property to distinguish in moving businesses based on consumer awareness the position of "intellectual acquisitions" and other financial information. In his attempt to decipher the value of market value items, the econometric model defined for analysis succeeded. The study also found that the components of intellectual assets are significantly incorporated with the Market Word by knowledge-based sectors, such as the pharmaceuticals industry.