

Growth of Patenting of Pharmaceuticals in Indian Perspective

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ABSTRACT

The Indian pharmaceutical industry is a successful, high-technology-based industry that has witnessed consistent growth over the past three decades. The current industry players comprise several privately owned Indian companies that have captured a substantial share in the domestic pharmaceutical market due to factors such as favorable government policies and limited competition from overseas. However, the liberalisation of the Indian economy is revolutionizing Indian industries as they begin to emerge from domestic markets and gear up for international competition. The Indian pharmaceutical industry is a prime example of an industry that is being forced to revisit its long-term strategies and business models as India opens its markets to global trade. Factors such as protection of intellectual property are increasing in significance due to the growing recognition of the need to ensure protection of valuable investments in research and development (R&D). Efforts are being made in India to curb problems of weak enforceability of existing intellectual property legislations, and the Indian government is moving towards establishing a patent regime that is conducive to technological advances and is in keeping with its global commitments.

1. Introduction

Intellectual Property (IP) is a kind of intangible property created with the efforts of human mind or intellect. Intellectual Property Rights (IPRs) are the rights derived due to creation of the intellectual property. These rights are conferred upon the creator (inventor, author etc.) of these properties. It should be noted that although the intellectual property is intangible but the material form of the intellectual property which is tangible can only be protected through IP rights. Like any other property intellectual property is also an asset, thus it can be bought, sold, mortgaged, licensed, exchanged or gifted to others. The intellectual property owners have exclusive rights over their intellectual property, which means nobody else can lawfully use the intellectual property created by them without their permission. Patent, trade mark, industrial design, geographical indication and copyright are some of the major forms of Intellectual Property Rights available in India [1]. A trade mark is a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person or enterprise from those of others. An industrial design relates to the aesthetic or outward appearance of the product. It is what makes a product attractive or appealing to customers. A geographical indication identifies the agricultural, natural or manufactured goods, originating from a definite territory, region or locality. Copyright means the exclusive right to do or authorize to do certain acts in relation to literary, dramatic, musical or artistic work, cinematograph film and sound recording. Out of all the forms of Intellectual Property Rights, patents are considered as most valuable assets in the pharmaceutical industry.

2. Meaning of patent:

Patents are granted for protection of the inventions. Patent is an exclusive right granted by the government to the applicant for an invention. A patent can be applied by the

inventor or any other person/ company assigned by the inventor. It is the right to exclude others from unauthorized making, using, offering to sale, selling or importing the invention. Patent is a negative right that means patent is not a right to make, use or sell the invention, rather it is a right that empowers the patentee (patent owner) to prevent or stop the use of his/ her invention by third parties without his/ her permission. Patent includes right to license others for the purpose of making, using or selling the patented invention. A patent is a contract between an applicant/ inventor and the government wherein the government provides right of protection of the invention for a limited period of time after the full disclosure of the invention by the applicant/ inventor. Thus, patenting provides a strategy for protecting inventions without keeping the invention secret [2]. Patent offers technical solution to a technical problem. Patent is granted only to those inventions which satisfies certain conditions known as criteria of patentability. Patents have limited term of 20 years counted from the date of filing the patent application. Patent is a territorial rights thus it can be enforced only in the country where it is granted. Therefore, any legal action against the infringement or violation of the patent rights can be sought only in that country only. For getting patent protection in different countries patent has to be applied in each of the countries. Patent Cooperation Treaty (PCT) provides a route to file an international patent application through with patent can be filed in a large number of countries through a single patent application. However, after filing the PCT application grant of patent remains under the discretion of the individual patent office only.

3. Patent Law In India

Patent rights were introduced in India for the first time in 1856 and, in 1970, the Patent Act 1970 ("the Patents Act") was passed, repealing all previous legislations. India is also a

signatory to the Paris Convention for the protection of industrial property, 1883, and the Patent Cooperation Treaty, 1970. The Patents Act provides that any invention that satisfies the criteria of newness, non-obviousness and usefulness can be the subject matter of a patent. Some of the non-patentable inventions under the Patents Act include methods of agriculture or horticulture, processes for the medicinal, surgical, curative, prophylactic or other treatment of human beings, animals or plants or substances obtained by a mere admixture, resulting only in the aggregation of the properties of the components, etc. With regard to pharmaceuticals, in the case of substances intended for use or capable of being used as food, drugs or medicines or substances produced by chemical processes, patents are granted only for the processes of manufacture of such substances and not for the substances themselves. Hence, pharmaceutical products are currently not granted patent protection under Indian law. India had a product patent regime for all inventions under the Patents and Designs Act 1911. However, in 1970, the government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from eligibility for patents. This exclusion was introduced to break away India's dependence on imports for bulk drugs and formulations and provide for development of a self-reliant indigenous pharmaceutical industry.

4. Impact of the world trade organization on pharmaceutical patents

The establishment of the World Trade Organization (WTO) has led to a tremendous paradigm shift in world trade. The agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) was negotiated during the Uruguay round trade negotiations of the General Agreement on Tariffs and Trade (GATT) and "one of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry".⁴ India signed the GATT on 15 April 1994, thereby making it mandatory to comply with the requirements of GATT, including the agreement on TRIPS. India is thereby required to meet the minimum standards under the TRIPS Agreement in relation to patents and the pharmaceutical industry. India's patent legislation must now include provisions for availability of patents for both pharmaceutical products and processes inventions. Patents are to be granted for a minimum term of 20 years to any invention of a pharmaceutical product or process that fulfills established criteria. Compulsory license provisions under Indian law will be required to be limited and conditional to comply with the TRIPS Agreement, and the government will grant such licenses only on the merit of each case after giving the patent holder an opportunity to be heard. In addition, there will be no discrimination between imported and domestic products in the case of process patents, and the burden of proof will rest with the party that infringes. India has decided to avail itself of the full transition period for developing countries and has until 1 January 2005 to extend patent protection to pharmaceutical products. In keeping with the TRIPS commitments⁵, India has started on a process of amending the Patents Act by providing exclusive marketing rights (EMRs) and creating a mailbox system for patent applications

for a period of five years or until the patent is granted or rejected, whichever is earlier.

5. Patents and the future of the Indian pharmaceutical industry

The absence of product patent protection for pharmaceuticals and agrochemicals led many multinationals to limit their portfolios to patent expired products or a few selected patented products. This resulted in an erosion of their market share because local manufacturers introduced the most advanced medicines through reverse engineering. Foreign firms were required to pay royalties for international drugs, while Indian companies could access the newest molecules from all over the world and reformulate them for sale in the domestic market.⁷ Thus, this resulted in the systematic weakening of patent rights for pharmaceutical products in India and led to the exodus of several international research-based pharmaceutical firms. The obligations imposed on India under the TRIPS Agreement are going to have a significant impact on India's successful bulk and formulation-oriented pharmaceutical industry. Indian companies will have to compete with the multinationals by focusing on drug development and thereby producing their own patented products. Alternatively, Indian companies could focus on producing patented drugs under license from foreign companies or concentrate on generating revenues from producing generic drugs. Currently, conflicting views exist within the Indian drug companies with regard to India's transition into the product patent regime.⁸ Some of the existing pharmaceutical companies believe that product patents will pave the way for innovation in India, while others hold the view that the high cost of R&D will stifle the growth of the Indian pharmaceutical industry.

6. Transfer of the Patent Rights

Since patent is a form of property, the rights vested with it can be transferred from the patentee to any other person through assignment or grant of license. The Indian Patent Act requires that an assignment or license of a patent must be in writing, clearly specifying all the terms and conditions governing the rights and obligations of the parties.

a) Patent assignment: Assignment in general, is the act of transferring to another the ownership of one's property, means the interest and rights to the property. Assignment of patent rights is defined as a transfer by the patentee of all or part of its right, title and interest in a patent or patent application to any other person. The person to whom the right in patent is assigned is called the assignee and the person who assigns the right is called the assignor.

b) Patent licenses: A patentee may, by a license, permit others to make, use, or exercise, the invention which otherwise would not be allowed. Licensing of a patent transfers a bundle of rights which are limited as to time, geographical area, or field of use. A patent license may be a voluntary license or compulsory license.

7. Types of pharmaceutical patents in India

The Pharma industry is one of the most intense "knowledge driven" sectors. Pharmaceutical research is very costly and unpredictable in nature. Outcome of the research can be in the form of a new, inventive and useful product or process. In this highly competitive market, it is imperative for the pharmaceutical companies to protect their inventions from any unauthorized commercial use by acquiring patent rights over the invented product or process. Pharmaceutical patents in India can be classified under following categories.

- a) Drug compound patents:** These patents claim a drug compound by its chemical structure per se. These patent claims are usually referred as Markush type claims. A Markush claim is a claim with multiple "functionally equivalent" chemical entities allowed in one or more parts of the drug compound. Drug compound patents provide the broadest possible protection to the company's product, since other companies are not allowed to prepare such drug by any route of synthesis or produce/ sell any formulation comprising this drug before the expiry of said patent.
- b) Formulation/ composition Patents:** These patents claim a specific technology to prepare a formulation and/or quantity of its key ingredients. For example, following ayurvedic anti-retroviral composition for treatment of Acquired Immuno Deficiency Syndrome was claimed in the Indian patent no. 203986 [9]. "Guduchi or Giloe (cordifolium): 5 mg-2 gm Panash or Kathal (jack fruit): 2 mg-5 gm Tulsi or Krishna Tulsi (Holy Basil): 5 mg-5 gm Kuda or Kutaja (Kurchi): 2 mg-2 gm Bhui Amla or Bahu Patra (Gooseberry): 5 mg-2 gm, in combination with pharmaceutical acceptable excipients."
- c) Synergistic combination Patents:** Drug synergy occurs when two or more drugs interact with each other in such a way that it enhances or magnifies one or more effects of those drugs. Patents can be obtained on new synergistic combinations of the drugs. For example, a synergistic combination of roflumilast and salmeterol was claimed in the Indian patent no. 206328 [10] as follows: "A medicament comprising a PDE inhibitor, which is to be administered orally, from the PDE4 inhibitors group combined with a β_2 adrenoceptor agonist in fixed or free combination, wherein the PDE inhibitor is roflumilast, a pharmacologically tolerable salt of roflumilast and/or the N-oxide of roflumilast and the β_2 adrenoceptor agonist is salmeterol or a pharmacologically tolerable salt thereof".
- d) Technology Patents:** These patents are based on the techniques used to solve specific technology related problems like stabilization, taste masking, increase in the solubility etc. For example, following taste

masked formulation was claimed in the Indian patent no. 227933[11]. "A pharmaceutical formulation having a masked taste, the masking of which persists during administration of the formulation, in particular in the form of a suspension in an aqueous vehicle, characterized in that it comprises at least the following elements:

- a) A cellulosic polymer which is soluble in organic solvents but practically insoluble in water, regardless of the pH; a methacrylic polymer which is soluble in an acid medium and practically insoluble at a neutral or alkaline pH and an active ingredient distributed in a homogeneous manner and in the molecular state in the mixture, which is in the form of an atomized matrix;
- b) An alkaline agent of an organic nature or an alkaline salt, which is pharmaceutically acceptable;
- c) An adsorbent agent"
- e) Polymorph Patents:** Polymorphs are different physical forms or crystal structure of an already known compound. Polymorphs are usually prepared to reduce impurities or increase stability of the compounds.
- g) Process patents:** A process patent does not claim the product per se, rather it only covers a new and inventive process to produce a particular product. For example, Indian patent no. 206678 claims a process to synthesize δ -lactone of formula 3,6-dialkyl-5,6-dihydro-4-hydroxy-2H-pyran-2-one.

8. Conclusion

The India patent law is an exemplary piece of patent legislation that is aimed to balance the interests of both the common man and the inventors. After the introduction of product patent regime a wide range of pharmaceutical products can be patented in India. Before applying for the patent the researchers shall carefully take into consideration the criteria of patentability and advice of a patent expert is highly desirable in this respect. Once acquired patent rights can be transferred through assignment or licensing to other persons or companies. Organizations such as academic institutions and universities not having sufficient manufacturing or marketing capacities can use patents as an effective tool for the technology transfer. These organizations can outsource their patented products/ processes to third parties and in return they can earn revenues to recoup the investments made in the development of such products/ processes. Compulsory license provide an opportunity to market the patented products under certain conditions.

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