Pharmaceutical Patent Regime in India

[1]Sonal Sodhani and [2]Harshit Chitlangia
[1]Student 3rd Year BA LLB, [2]Student 2nd Year MBA
[1]New Law College, BVDU, Pune, India
[2]Amity University, Ranchi, India

Abstract:
A new idea, expression, development or an innovative thought which comes out of human mind can be regarded as Intellectual property. Thus, Intellectual property rights (IPR) are those rights given to the creator that enables him to have exclusive use of his work, thereby, safeguarding his intellectual property. Copyrights, trademarks and patents are some of the various protections available for intellectual properties. Patent is an acknowledgment given to the creator for his work, which has originality and is non-conspicuousness.
Various industries, like pharmaceuticals, are continuously working on new innovations and techniques for development. For better protection, identification, commercialization and insurance of such creativity and efforts, IPR becomes quite essential. A progressing IPR technique can be witnessed in the pharmaceutical industry these days which requires a better approach in the near future.
This paper tends to provide a brief overview of advancement of patent law in India, specifically in the pharmaceutical industry, in consequence of TRIP agreement. The paper also delves to study and describe conditions of patentability and various kinds of patents granted in India to pharmaceutical industry aiming to provide basic concept of pharmaceutical patenting. Other significant laws in respect of pharmaceutical patenting, transfer and exchange of the rights so granted by the patents, mandatory licensing and likewise are discussed with appropriate cases.

Keywords:
IPR, Patents, Pharmaceutical products, TRIPS, Research & Development (R&D).

I.Introduction

Any authentic work, such as, literary, scientific creation or artistic, which originates from a human mind can be regarded as Intellectual property (IP).Intellectual property rights (IPR) alludes to the legal rights given to the inventor or maker to safeguard his innovation or creation for a specific period of time.[1]IPR grants an exclusive right of fully using the work to the creator or his legate, for a specific timeframe. IP has a significant role to play in today's economy. The need to give due significance to the scholarly works in respect of inventions in order to exude public welfare from it, is also likewise established. There has been a quantum jump in innovative work and research costs with a related hop in speculations required for putting a new invention in the market place.[2]The inventor's stake on his invention have turned to be very high, and hence, it is important to safeguard the interests of the inventors and therefore, protect their knowledge from unlawful use, for some time. This would guarantee recuperation of the research and development (R&D) and also, other related expenses along with providing adequate benefits for continuous interest in the field of R&D.[3] IPR is a massive tool, to safeguard speculation, money, hard work and time contributed by the innovator/maker while making the intellectual property (IP). Hence, by ways of promoting fruitful competition and empowering developments in various industries, IPR helps developing the economy of the nation. This paper outfits a short insight on IPR and product patency emphasising on pharmaceutical industry.

II.IPR, Patents and need in Pharmaceuticals

"If people don't get a fair return in innovation, they won't invest in finding new cures for disease — this will be disastrous for patients" – Ranjit Shahani, Managing Director, Novartis India Ltd.[4]

Considering all the areas related to scientific developments, pharmaceuticals best portrays globalization and need of having strong IP protection system most closely. Unless companies are provided with sufficient returns, no company shall be interested in risking their IP becoming an open property, as bringing a new drug in the market costs not less than millions to billions dollars along with the risks at the formative stage. Similar to the way raising of assets and resources are an important corporate activity, it is essential to make protecting and making of IP an important corporate affair. The coming future which is to bring the knowledge revolution with itself, is to demand a demand a special platform for IP and treatment in the general decision-making process.[5]

In the recent years, pharmacy companies have been encountering patent challenges, thus constituting a threat to pharmaceutical development and increasing ambiguity about market exclusivity and prosecution cost for commercially lucrative drugs. For example, Novartis AG lost a patent fight against Torrent Pharmaceuticals in the US over the drug Gilenya, which was one of the high income producing drugs.[6] These patent battles can be tended to by embracing effective and efficient patent strategy by renounced pharmacy companies by acquiring patents for techniques of manufacture and active ingredients.

III.Development of Patent Laws in India

The pharmaceutical industry in India has been an example for the development of an indigenous and self-reliant industry.[7] Because of favourable government policies, local firms have been able to beat the predominance of Multinational Corporations in the pharmaceutical market. This is altogether different from the situation prevailing pre-Independence, where industry was dominated by foreign companies, prevailing drug prices were highly elevated and technique for production of basic drugs were denied to India.[8]

Post-Independence India started working in the field of IP and laid down laws for Intellectual Property Rights and Patent grants. Indian Patent Act, 1970 is the main law governing the patent grants in India. Earlier, there was no patent grants given on products. As per the provisions of this Act, initially, only process patents (i.e. patents on process) could be conceded for all the developments and innovations in the field of chemicals, drugs and food.[9]

India being a part of World Trade Organisation (WTO), in 1995, signed the TRIPS (Trade Related aspects of Intellectual Property Rights) Agreement.[10] A basic standard of IP laws were recommended by TRIPS which were to be followed by all the signatories to the agreement. India being a signatory of the TRIPS agreement was under a contractual obligation to bring changes to its Patents law to make it consistent with the provisions of the agreement.[11]

To bring India in consistency with the TRIPS agreement, three consecutive amendments were made in the Indian Patent Act in 1999, 2002 and 2005 respectively[12]. The first amendment brought with it two major changes in patent laws: firstly, it introduced Exclusive Marketing Rights (ERMs),[13] and secondly, it acquainted what came to be known as the ‘mailbox facility’ or ‘pipeline protection’ whereby applications for pharmaceutical and agro-chemical product patents were acknowledged amid the ten year transition period and a filing date was doled out to each.[14] During this phase, product patent was not recognised and pharmaceuticals were solely protected through process patents. In the case of *Cadila Pharmaceuticals Ltd. v. Instacare Lab. Pvt. Ltd.*,[15]the court held that it is the process which is protected through patents and not the combinations of drugs as such.

As TRIPS gave an additional period of five years for amendment, except for the patent rights on pharmaceutical products, India came in congruity with all other significant provisions of TRIPS after the Second Amendment.[16]Re-characterizing what should be the subject matter for patency, increasing the patent protection term up to 20 years and alteration of the licensing system were some of the key issues dealt in this amendment.[17]

The Third Amendment in 2005 was the most crucial amendment in regards with pharmaceutical patents. Introducing the product patent regime under Article 65(4), India completely came into terms with the TRIPS provisions after the third amendment.[18] With the coming of the aforementioned provision, patency of the products in various chemical innovations and pharmaceuticals is now recognized. Third amendment also revoked the disputable Section 5(1) of the Act. However, a significant rise in drug prices and an unfavourable effect on access to vital drugs and medicines was expected.[19]

Not only that, the scope for compulsory licenses got broadened to incorporate various other circumstances along with medical emergencies and crisis. Making and exporting patented pharmaceutical products to a country with insufficient or no manufacturing capacity in for the conceded pharmacy product which is needed for medical issues and addressing general health, now comes under the broad scope of compulsory licensing, provided that the said license is granted to them by the importing nation or such country by notice or likewise has permitted the import of such patented product from India.[20]

With these changes in the Act came the dawn of a new era of patents for products in India. The Indian Pharmaceutical Alliance (IPA)[21] noted that harmony was made between the interests of both the consumers and those of inventors.

IV.Criteria for Patentability

There are certain conditions or pre-requisites which must be fulfilled by an innovation or a creation for being granted a patent. Such conditions or prerequisites are referred to as criteria of patentability. In accordance to the Indian Patent Act, a patentable invention is defined as "a new product or process involving an inventive step and capable of industrial application"[22]. The various conditions and criteria for patentability are mentioned below:

a) Originality: For a subject to be granted patent must be original and have world novelty. The innovation must not be revealed or disclosed anywhere before the date of filing of the patent. Any work shall be considered to be as new and original only if the same has not been published or documented or used, in any means, anywhere within the country or across the globe.[23]

b) Innovation: Any work that is to be patentable must have an element of creation and innovation. Any advancement through creation or development makes the work unique and different from the knowledge or the idea pre-existing, or having economic significance, or maybe, both. Such inventive step shall make the work not so obvious to the one who is 'skilled in the art.'[24]

c) Application in Industries: An invention must be such that can be helpful for further development of the nation. For a work to be patentable, it must be efficient enough to be used or to be made in an industry.[25]. For instance, it is not possible to make or use a new technique that expels tumour cells from the body of the patient industrially applicable, hence the same cannot be patented.

V.Types of Pharmaceutical Patents in India

One of the most intense "knowledge driven" sectors is the pharmaceutical industry. Researches which are taken out by this industry are by nature uncertain and exorbitant. The end product of these researches may take the form of a completely new and valuable process or product. With such a level of uncertainty and risks, patent rights over the new and innovated product and process is highly essential in the pharmaceutical companies. In this cut-throat competition which is prevailing in the market, it is important for these companies to safeguard their work form unlawful use and unauthorised access for commercial or business use. Pharmaceutical products and processes can be protected through various patents which are granted for the same in India. These various types of pharmaceutical patents are, herein, listed below:

- Drug Compound Patent

Chemical structure of drug compound are protected under this patent. These types of patent claims are generally referred as "Markush type" claims. A lot of "functionally equivalent" chemical substances are permitted in different parts of a drug compound. A Markush claim is calim over these chemical substances.

Once a product is patented under drug compound patent, no other company is permitted to make, by any amalgam, any such drug, nor is selling or production of any composition which contain the patented drug allowed till the time the patent granted on the drug expires.[26]Thus, giving drug compound patent the widest scope to safeguard and protect a company's product.

- Formulation Patent

The particular techniques used in making of a formulation or the key ingredients are protected under such patents. For instance, an immediate-release pharmaceutical 3, 7-diazabicyclo formulation was claimed in the Indian Patent No. 203993.[27]

- Technology Patent

Certain technical problems like taste masking, stabilization etc. may occur during the process of making drugs. Such problems are dealt with certain specific techniques, and technology patent is based on such techniques, which are used to curb these technical problems. For instance, a pharmaceutical composition having a masked taste was patented in the Indian Patent No. 227933.[28]

- Synergistic Combination Patent

When two or more drugs interact in a manner that when they work together the total effect of the two is much greater and boosted up than the sum of the two or more, drug synergy is said to occur. Such new interactive combinations in pharmacy are entitled to get a patent. For instance, a synergistic antibacterial formulation and to a method of making the same was patented in the Indian Patent No. 197822.[29]

- Polymorph Patent

An already known compound can have various crystal structures or physical forms. These different crystal structures and physical forms of the compounds are called as polymorphs. Reduction of impurities and increase in stability of the compound are among the basic reasons for the preparations of polymorphs. Section 3(d) of Indian Patents Act deals with the grants of these patents[30]. This section prevents a grant of patents to those innovations which are done with new forms of know substances if they do not significantly differ from each other in properties in respect of efficiency. Thus, fulfilling its goal of 'preventing ever greening of patent'.[31]

- Process Patent

An innovative and a new process to form and produce is a product is protected under process patent. It does not protect the product as such. For instance, synthesis of 3-hydroxy 5B-H steroidal sapogenins was covered in Indian Patent No. 223217.[32]

- Biotechnology Patent

Use of biological materials and living organisms in the production and formation of pharmaceutical products are included in biotechnology. Immunological, diagnostic, therapeutic and wide range of such products are protected under biotechnology patents.[33]

VI.Transfer of Patent Rights

Similar to properties, a patentee can transfer the rights vested on him to any other person either through grant of license or assignment.[34] Such grant of licence or assignment should be in writing and specifically mentioning all the terms and conditions that shall govern the parties' rights and obligations.[35]

- Patent Assignment

Patent assignment, in simple terms, can be said to be an agreement where the assignor agrees to transfer the ownership and all the rights vested in the property to the assignee.

- Patent License

Transfer of bundle of rights which are restricted or limited by various factors like geographical area, time span or area of use, is done through patent licensing. A patentee may permit someone to exercise or use his innovation, which in other cases is not permitted, by granting him license to do the same. Patent license can be of two types: i. Voluntary license ii. Compulsory license.[36]

(a) Voluntary license

When the patent license is granted to another person with free will of the patentee, it is called voluntary license. In this case, the patentee transfers a bundle of his rights to another person and permits him to use or exercise the innovation, by his own free will.

(b) Compulsory license

It is involuntary transfer of rights by an unwilling seller to a willing buyer, such transfer being enforced and imposed by the government. A statutory license that can be granted by Controller of patents to any other person is termed as compulsory licensing, Section 84 of Indian Patent Act deals with compulsory licensing.[37] The section makes it clear that compulsory licensing can be granted only after the end of three years from the date patent was granted. In this kind of license, the government permits another person to use or exercise the invented process or product without the assent of the owner of the patent.

According to Indian Patent Act, compulsory licensing maybe granted on following grounds:

"(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
(b) that the patented invention is not available to the public at a reasonably affordable price, or
(c) that the patented invention is not worked in the territory of India." [38]

In a landmark case decided in 2012[39], the then Controller of Patents, issued the first compulsory license in India. Patent was granted to M/S Bayer Corporation in patent no. 215758 and was issued to Natco Pharma Ltd. through compulsory licensing. Bayer used to sell a drug named Sorafenibtosylate under the brand of Nexavar. This patent was in relation to the same drug. Diseases like Renal Cell Carcinoma (RCC) and Hepatocellular Carcinoma (HCC) indicates Nexavar.[40]

The outcome of such compulsory licensing is that generic version of Nexavar in RCC and HCC can be freely made by Nacto without any restrictions. At the end of each quarter, Nacto, on its net sales, is to pay a total of 6% royalty to Bayer. Also, the price for a monthly dose of 120 tablets has been restricted to Rs. 8800. In addition to this, Nacto would supply medicines for 600 nearby patients for free as a condition under compulsory licensing.

The above decision was based on the ground '*that the reasonable requirements of the public with respect to the patented invention have not been satisfied,'*[41]as hardly not much of liver and kidney cancer patients could buy or have access to the drug sold by Bayer. Rs. 2.8 lakhs was being charged for a month of therapy of the drug by the Bayer, which was too expensive to be available for public. The amount charged for this patented innovation was considered to be unreasonably high. Not only that, the said product was not manufactured in India by the Bayer but was brought from foreign countries.

VII. Compulsory license for export for patented pharmaceutical products

This is discussed under Section 92A of the Indian Patent Act 1970. According to this provision, in order to address general health related issues of any country which is lagging behind and have inadequate manufacturing units with regards to pharmaceutical sector for a particular product, compulsory licensing can be granted for the export of such patented product to that country. However, such a license shall be granted only if such a country, itself, has granted the license or has permitted the imports, by way of notice or otherwise, from India.[42] The receipt for the same shall be submitted to the Controller and he may then grant a compulsory license only for the purpose of manufacture and export of a particular product patented in the pharmaceutical sector, prescribing certain terms and conditions, as may be required.

As per the provisions of this section, there are three essential requisites for compulsory license to be granted, which are:

i. Such license is only granted on pharmaceutical products which are patented
ii. This license is granted only for manufacture and export of such patented products to a country which is lagging behind in manufacturing such drugs due to inadequate or no manufacturing units[43]
iii. The purpose of export is to help such a country in dealing with the general public health issues.

VIII. Conclusion

With various amendments in the Patent laws over a decade, India witnessed a significant growth in the pharmaceutical industry and in the area of research and development.[44] With signing of the TRIPS agreement and coming up of product patent regimes a wide range of pharmaceutical products along with processes can be now protected through patents. Keeping a sink between the interests of both, the consumer and the inventor, the amended Indian Patent Act sets an ideal paragon for legislations on patent. However, the inventor must be careful while applying for the patent. He must carefully scrutinize and confirm if all the patentability criteria have been deliberated and taken for consideration. One can transfer the rights on an intellectual property by transfer of patents or licensing to any other person or company, once the patent is granted on their work. With the coming of compulsory licensing in picture, companies can export their patented pharmaceutical products to countries with insufficient manufacturing units for the desired product. This not only helps addressing the global health issues in a better way, but also, adds to the revenue of the exporting company to make good of the investment made for the research of the particular process or product, and thereby, being an incentive for the investors to go on with more research and inventions.

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