

## Patenting of Pharmaceuticals: An Indian Perspective

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### Abstract

Patent is one of the major forms of Intellectual Property Rights (IPRs) used in the pharmaceutical industry. Trade mark, industrial design, geographical indication and copyright are other forms of IPRs available in India. Grant of patent in India is governed under the Patents Act, 1970. Significant changes like provision of product patents and increase in the term of patent to 20 years were introduced in the Indian patent law, after India signed TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement in 1995. This review provides a brief overview of development of patent law in India as a consequence of TRIPS agreement. Criteria of patentability and different types of pharmaceutical patents currently being granted in India are described with the aim to provide the fundamental knowledge of pharmaceutical patenting to the researchers. Other relevant provisions related with patenting of pharmaceuticals like section 3(d), transfer of the patent rights, compulsory licensing etc. are explained with suitable example.

### Key words:

Intellectual Property Rights, patent, TRIPS, criteria of patentability, compulsory license

### How to Cite this Paper:

**Vipin Mathur** "Patenting of Pharmaceuticals: An Indian Perspective", Int. J. Drug Dev. & Res., July-September 2012, 4(3): 27-34

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**Article History:**-----

**Date of Submission: 21-06-2012**

**Date of Acceptance: 11-07-2012**

**Conflict of Interest: NIL**

**Source of Support: NONE**

### 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

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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.

#### 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.

#### DEVELOPMENT OF PATENT LAW IN INDIA

The principal law for patenting system in India is the Patents Act, 1970. Initially, according to the provisions of this law no product patent but only process patents could be granted for inventions relating to food, drugs and chemicals. However, since 2005 product patenting is allowed in India.

India being a member country of World Trade Organization (WTO) signed TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement in 1995. TRIPS prescribed the minimum standards of IP

laws to be followed by each of its member countries. India being a signatory of the TRIPS agreement was under a contractual obligation to amend its Patents law to make it compliant with the provisions of the agreement. The first amendment in this series was in the form of the Patents (Amendment) Act, 1999 to give a pipeline protection till the country starts giving product patents. It laid down the provisions for filing of applications for product patents in the field of drugs and agrochemicals with effect from 1<sup>st</sup> January 1995 as mailbox applications and introduced the grant of Exclusive Marketing Rights (EMRs) on those patents. To comply with the second set of TRIPS obligations India further amended the Patents Act, 1970 by the Patents (Amendment) Act, 2002. Through this amendment provision of 20 years uniform term of patent for all categories of invention was introduced. This amendment also made other changes in the principal Act like definition of the term “invention” was made consistent with TRIPS agreement and provision for reversal of burden of proof in case of infringement suit on process patent was added in the Act. The third set of amendments in the patent law was introduced as the Patents (Amendment) Act, 2005. Through this amendment product patent regime was introduced in India. Mere discovery of new form, new property or new use of a known substance was made patentable under certain conditions, provisions related to pre grant and post grant oppositions were modified and provision for the grant of compulsory license for export of patented pharmaceutical products in certain conditions was introduced [3].

#### CRITERIA OF PATENTABILITY

Patents are granted to those inventions which satisfy certain conditions called as criteria of patentability. According 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” [4]. Therefore, following are the basic requirements for any invention to be patentable.

- a) **Newness:** To be patentable the subject matter of the invention must not be known before the date of patent filing. An invention is considered new if it is not published in any document or not used in the country or elsewhere in the world [5].
- b) **Inventive Step:** It is defined as the feature of an invention that involve technical advancement as compared to existing knowledge or having economic significance or both, that makes the invention not obvious to a person skilled in the art [6].
- c) **Industrial Applicability:** The invention must be capable of being made or used in an industry [7]. For example, a new and inventive method of removing tumor cells from patient’s body is industrially not applicable, thus can not be patented.

#### 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. This classification is based on the list of Pharma patents provided by the Indian patent office on its website.

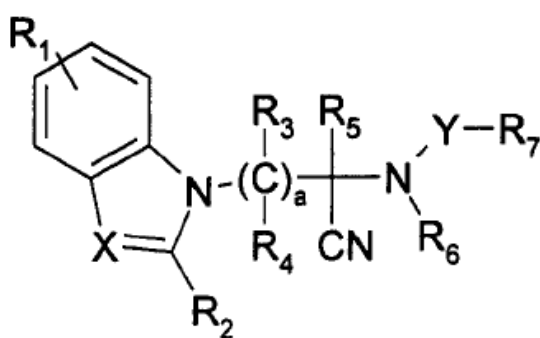
##### a) Drug compound patents

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.

For example, Figure 1 displays the chemical structure of a new drug compound useful for the control of parasites, claimed in the Indian patent no. 202989 [8].



**Figure 1:** Drug compound claimed in Indian Patent 202989

### 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  $\beta 2$  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  $\beta 2$  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.

For example, Indian patent no. 237261 claims the crystalline form B<sub>4</sub> of atorvastatin magnesium characterized by X-ray powder diffraction pattern [12]. Said crystalline form shows purity greater than 98%.

**Role of Section 3(d) in polymorph patenting:**

Grant of polymorph patents in India is mainly governed by the section 3(d) of the Patents Act, 1970. This section was amended under the Patents (Amendment) Act, 2005. The section [13] states:

“the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

The section 3(d) aims to prevent the “ever greening of patents” by providing that only those pharmaceutical derivatives that demonstrate significantly enhanced “efficacy” can be patented. The section 3(d) ensures that the new forms can be patented only if they are really meritorious, and thus patents shall not be granted for trivial inventions. It throws light on the Indian government’s policy of rewarding the inventors/ researchers on their true intellectual efforts and at the same time preserving the public interest and making them available essential commodities such as drugs at affordable prices.

**f) Biotechnology patents**

Biotechnology involves the use of living organisms or biological materials in the preparation of pharmaceutical products. Biotechnology patents

cover a wide range of diagnostic, therapeutic and immunological products.

For example, Indian patent no. 234072 claims an aqueous, human serum albumin-free Interferon solution containing an interferon-alpha, a non-ionic detergent, a buffer for adjusting pH 4.5-5.5, benzyl alcohol and optionally an isotonicizing agent [14].

Incidentally, above Indian patent no. 234072 was the first product patent granted by the Indian Patent office after the enactment of product patent regime in 2005. The patent is owned by F. Hoffmann-La Roche Ltd., Switzerland.

**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  $\delta$ -lactone of formula 3,6-dialkyl-5,6-dihydro-4-hydroxy-2h-pyran-2-one[15].

**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 [16].

**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.

**(i) Voluntary license:** When the patentee at his/her own wish, empowers another person to make, use or exercise the patented invention by a written agreement, it is called a voluntary license. The Indian patent office and the central government do not have any role in such license.

**(ii) Compulsory license u/s 84:** A compulsory license is a statutory license which can be granted to a third party by the Controller of Patents under certain conditions. Compulsory license under the Patent system is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the government. Under compulsory license the government allows someone else to produce the patented product or process without the consent of the patent owner. Compulsory license may be granted on the following grounds mentioned under section 84 of the Patents Act, 1970 viz. (i) the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (ii) the patented invention is not available to the public at a reasonably affordable price, or (iii) the patented invention is not worked in the territory of India<sup>[17]</sup>.

However, compulsory license can be granted only after the expiration of three years from the date of the grant of a patent.

**Case summary (Natco Pharma Ltd., India vs Bayer Corporation, USA)<sup>[18]</sup>:** In a land mark decision on 9<sup>th</sup> March 2012, Mr. P. H. Kurian, the then Controller of Patents issued the order of grant of first compulsory license for patents in India. The compulsory license was issued to Natco Pharma Ltd. in patent number 215758 granted to M/S Bayer Corporation. This patent relates to drug Sorafenib tosylate sold under the brand name Nexavar by Bayer. Nexavar is indicated in Renal Cell Carcinoma -

RCC (kidney cancer) and Hepatocellular Carcinoma – HCC (liver cancer).

After getting this compulsory license Natco is now free to manufacture and sell a generic version of Nexavar in RCC and HCC. Natco will have to pay a 6% royalty on the net sales to Bayer at the end of each quarter. Further, it can not charge more than Rs 8800 for a monthly dose of 120 tablets of the drug. Natco has also committed to donate free supplies of the medicines to 600 needy patients each year as a condition of the compulsory license agreement.

Above decision was based on the grounds for the grant of compulsory license mentioned under section 84 of the Patents Act, 1970. Controller found that the reasonable requirements of the public with respect to the patented invention had not been satisfied since only 2% of the total kidney and liver cancer patients were able to access the Bayer's drug. The Controller determined that the patented invention was not available to the public at a reasonably affordable price because Bayer was charging about Rs 2.8 lakhs for a therapy of one month of the drug. The Controller also found that the patented invention was not worked in the territory of India since Bayer was not manufacturing the product in India rather it was importing it from outside India.

**(iii) Compulsory license for export of patented pharmaceutical products u/s 92A:** Section 92A of the Patents Act, 1970 states that compulsory license may be issued for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided that such country has granted compulsory license or allowed the importation of patented pharmaceutical products from India<sup>[19]</sup>. The Controller shall, on receipt of an application in the prescribed manner may grant a compulsory license solely for manufacture and export of the concerned

pharmaceutical product to such country under the specified terms and conditions.

This provision addresses the public health concerns of the countries having insufficient or no manufacturing capacity in the pharmaceutical sector to implement the decision of the TRIPS council on Para 6 of the Doha Declaration on TRIPS Agreement and Public Health. As per this provision the compulsory license is available only for (a) the patented pharmaceutical product (b) manufacture and export to any country having insufficient or no manufacturing capacity in the pharmaceutical sector and (c) the product addressing the public health problems in such country.

### 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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