ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Pharma Industry And Patenting Prosecution: An Indian Perspective.

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ABSTRACT

Patent is an exclusive right given to a person for an invention in any branch of technology whether product or process which is patentable if it meets the Criteria of being NOVEL, involving an INVENTIVE STEP and being capable of INDUSTRIAL APPLICATION. The laws which govern the intellectual property in India are well established at all levels- statutory, administrative and judicial. India is in agreement with World Trade Organisation (WTO) and also member of various treaties like Paris convention, PCT, Budapest Treaty. India is also part of Trade Related Aspects of Intellectual Property Rights (TRIPS) which came into force from 1st January 1995 and governs with minimum standards for protection and enforcement of intellectual property rights in member countries sufficiently required to promote effective and adequate protection of intellectual property rights. This review gives an overview of development of patent law in India due to TRIPS agreement as well as criteria of patentability and different types of pharmaceutical patents currently being granted to pharmaceutical companies in India. 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.

Keywords: Intellectual Property Rights, Patents; Patent Applications; Pharma Industry; Licence

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ISSN: 0975-8585

INTRODUCTION

Innovation has become a keyword in all kinds of industries in India. The Government of India, through its 'Make in India, campaign, is further promoting innovation in Indian pharma industries. India has become one of the most attractive destination for investment and business due to its innovations and new inventions. Intellectual Property (IP) is a kind of intangible property created with the efforts of human mind or intellect property which is tangible can only be protected through IP rights. [1] 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. [2] The IPR are segregated into 5 different types of areas i.e. patent, trademark, copyright, geographical indications and industrial designs which are governed by The Patents Act 1970 and Patents Rules 1972. It came into force on 20th April 1972 former known as Indian Patents and Designs Act 1911. The Patents Act earlier associated with only process patents with regard to inventions related to drugs, medicines, food and chemicals. The emergence of pharmaceutical companies to larger extent gave a new path to India which became signatory to many international agreements to strengthen the industry in regard to patent law in association with globalization. The first and the foremost step towards the goal achievement was becoming the member of the Trade Related Intellectual Property Rights (TRIPS) system. The TRIPS agreement introduced intellectual property law into the international trading system for the first time and remains the most comprehensive international agreement on intellectual property to date specially in concern to Pharmaceuticals. Finally, after round of talks it resulted in the Doha Declaration. The Doha declaration is a WTO statement that clarifies the scope of TRIPS, with a goal "to promote access to medicines for all. "as per article 4. [3]

Later India also became signatory of the Paris Convention to enter convention countries and the Patent Cooperation Treaty to file single application for many countries on 7th December 1998. Signed the Budapest Treaty on 17th December 2001 for deposit of biological material was also one of the significant step to match the standards of global market. This review gives an overview of development of patent law in India due to TRIPS agreement with the latest amendments. It also provides the criteria of patentability and number of pharmaceutical patents currently being granted to pharmaceutical companies in India. Other relevant provisions related with patenting of pharmaceuticals like section 3(d), transfer of the patent rights, compulsory licensing etc. are also explained.

TYPES OF PATENT APPLICATIONS

a) Provisional Application

An application filed to Patent Office to claim a "Priority Date" (First to File), This application may or may not contain claims and abstract. It is filed at a stage when an invention is not complete in all aspects. This application is relatively inexpensive to prepare and file, helps enables the inventor not only to study market potential but also gives him more time to complete his research. The complete application is with filed within 12 months or else it will be treated as abandoned under section 9(1).

b) Complete Application

A patent application containing the complete specification, abstract and claims of the invention is called a complete application and this can be filed directly if the invention is complete in all aspects or indirectly after provisional.

c) Convention Application

An application filed to one or more of the convention countries under section 133, it is called a convention application aiming a priority date based on the same or substantially similar application filed in Indian Patent Office This application should be filed within twelve months from the date of first filing.

d) Patent Cooperation Treaty (PCT) – International Application

It is an international application for filing patent applications t in up to 152 countries which are signatory to it. PCT enables an applicant to file in multiple countries by single PCT application

The application is to be filed in English language within 12 months from the date of filing in India.

e) PCT-National Phase Application

Within 31 months from the priority date, the application enters the National Phase PCT application, which resembles a national filing in a respective country. An international application according to the Patent Cooperation Treaty (PCT) , can enter the national phase in India within 31 months from the international filing date or priority date (whichever is earlier). This application filed before the Controller in the Indian Patent Office claiming the priority and international filing date is called PCT National Phase application. The filing date of the application shall be the international filing date accorded under the Patent Cooperation Treaty. [6]

f) Foreign Filing License:

No person resident in India shall, except under the authority of the written permit can file any application outside India for the grant of a patent unless:

i. An application for a patent for the same invention has been made in India not less than 6 weeks before the application is filed outside India, and
ii. Either no secrecy direction has been given under Section 35(1) in relation to the application in India or all such directions have been revoked. [7,8]

A request for foreign filing license may be filed on prescribed form 25 with detailed description of the invention and the drawings, if any, and the prescribed fee. [9,10]

CATEGORIES OF PHARMACEUTICAL PATENTS:

a) Composition/ Formulation Patents:

These are the patents which involves a special innovative method to prepare a formulation and/or quantity of its key components. For example, An Indian patent no. 2567/CHE/2012, that tells about a shampoo composition with its claim telling the composition as:

A shampoo composition with superior conditioning attributes comprising ingredients in addition to water

(i) pre-emulsified silicones, (ii) at least one fatty acid ester, (iii) atleast one amidoamine

Where in the ratio of fatty acid ester to amidoamine is in the range of from 2:0.5 to 0.5:2;
(iv)at least one cationic polymer, and (v) atleast one surfactant selected from anionic, non-ionic, zwitter ionic or amphoteric surfactants or mixtures thereof. [11]

b) Drug compound patents

These patents claim a drug compound by its chemical structure per se. These types of Patents are called as Markush type claims. A Markush claim is a claim which recites all alternative embodiments of a single invention. It is, however, important that the patentability criteria are satisfied for each alternative of a Markush claim.

A simple example, 'an alcohol selected from the group consisting of methanol, ethanol, and isopropanol'. These are the type of patents which provide protection in best broadest way and protects the invention avoiding preparation of such drug by any method of route of synthesis.

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, combination of triazole compound or its salt with another triazole compound providing an antimicrobial composition comprising a synergistically effective compound as claimed in the Indian patent 262165. [12]

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. 272075. [13]

"The invention relates to the taste masking of drugs to reduce its bitterness, increase its palatability and thus to improve patient compliance. It relates to the use of ion exchange resins to mask the bitterness of drugs by preparing drug-resin complexes. Such complexes can be used to formulate various palatable oral drug dosage forms of the bitter drugs."

e) Process Patents

Pharmaceutical patents are generally granted to either a Product or a Process which is novel, inventive and involves an industrial applicability. A process patent claims the process per se, rather than a product. For example, Indian application number: 595/DEL/2001(US 7,241,885 B2). [14] It only covers a new and inventive process to produce a particular product. It provides a process for the preparation and isolation of pure crystalline Imipenem monohydrate by crystallizing Imipenem monohydrate from a solution thereof which contains an organic solvent, aqueous solvent, or a mixture.

TYPES OF PATENT OR PATENT CLAIM PARTICULARLY RELEVANT TO PHARMACEUTICALS

a) Product patent or claim

This claims the active chemical substance as a new chemical entity and is generally regarded as being superior claim. If there is a product claim on the drug then none but the patent holder or licensee can make, sell or import the chemical for any use without infringing the product patent.

This type of patent claim is now allowed in most commercially important countries, although it is a recent event in many others. The novel drug is claimed either by chemical name or by chemical structure, or both. The drug may be claimed by a Markush type claim. This comprises a core chemical structure with several optional chemical groups that may be attached to the core structure. This is known as a generic claim to a compound. A drug will be covered by the generic claim and there may be a specific claim to the chemical as well. Markush structures are sometimes very general that they can cover millions of actual chemicals.

b) Product by process patent or claim

This type of claim 'claims' a chemical or other process used to manufacture the drug whenever the drug is made by the patented process. It is the 'next best' type of claim as it also confers protection against importation of a product.

c) Process patent

Process patent claims the chemical or other process used to manufacture the drug. The chemical product itself is not covered. Because of the difficulty of proving that another company is using the patented process, many countries have a 'burden of proof reversal' clause where the potential infringer has to prove that the patented process is not being used.

d) Formulation patent

This claims the pharmaceutical dosage form on the drug, commonly a composition type specially the formulation of a particular drug or class of drugs, or a general formulation applicable to many drugs with

different actions, such as slow release technologies, transdermal patches, etc. There may also be formulation process patents covering the manufacturing processes used to make the formulation.

e) Method of use

This covers the use of the drug to treat a disease. This type of claim is originally allowed in the USA and Germany but is now being accepted in other countries including the UK. However, a careful wording of the claim in European patent application allows this type of claim avoiding a direct method of treatment claim.

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 [15].

a) Patent assignment

a. An assignment of a patent means the assignment of rights in form of a share in a patent, a mortgage, licence or the creation of any other interest in a patent shall be valid only if the same are in writing and the agreement between the parties concerned is written in the form of a document specifying all the terms and conditions governing their rights and obligations and has been duly executed. 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 license

By Patent licencing a patentee, permit others to make, use, sell or exercise, the invention which otherwise would not be allowed. Licensing of a patent transfer rights which may be limited to some factors such as time, geographical area, or field of use depending upon terms and conditions decided in assignment deed. Licensing may be a voluntary license or compulsory license.

1. **Voluntary license:** As the term Voluntary, it is the licence granted by a patentee with his own wish to seek any type of benefit not limited to monetary, which empowers another person to make, use, sell or exercise the patented invention as the conditions decided 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.

2. **Compulsory license**- Compulsory license may be made under the following provisions of Indian patent act:
   - Section 84.
   - Section 92A

Compulsory license u/s 84: A compulsory license is a license which can be granted to a third party by the Controller of Patents under certain conditions. under section 84 of the Patents Act, 1970 (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 [6].

However, compulsory license can be granted only after the expiration of three years from the date of the grant of a patent. Such an application may also be made by the licencee, The grant in this type of licence is made when the Controller is satisfied, upon consideration of an application, that a prima facie case has been made out, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall publish the application in the official journal. After this the patentee or any other person desiring to oppose the application may, within two months from the date of publication in journal may oppose.

The landmark case study for the grant of country's first compulsory licence by Indian Patent Office to Natco Pharma Ltd. under the amended Indian Patents Act (2005), allowed Natco to make and sell in India, a

similar version of Bayer's Nexavar (an advanced kidney cancer drug) with patent number 215758 granted to M/S Bayer Corporation. [16]

The judgment by Mr P. H. Kurian's as the Patent Controller, reasoned for the grant of Compulsory Licence is that the patent-holder, Bayer, had not met the reasonable requirement of the public. It had not "worked the patent" or manufactured it to a reasonable extent in India. Besides, the drug was not available at an affordable price

Natco will have to pay Bayer royalty at six per cent of net sales, every quarter including other conditions that NATCO can't 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.

(ii) Compulsory license for export of patented pharmaceutical products under exceptional circumstances u/s 92A:

Such type of Compulsory licence is to deal with health concerns of different countries. It shall be available for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. [17]

In exceptional circumstances Compulsory license may also be granted on notification by Central Government such as in context to public interest namely national emergency, extreme urgency example scarcity of petroleum products, earthquake etc, and public non-commercial use.

The Controller will notify and grant licenses without any consideration as in other cases in respect of patents on such terms and conditions that the article is available to the public at lowest price.

Intellectual Property Appellate Board (IPAB)

The Intellectual Property Appellate Board (IPAB) came into force with effect from April 2, 2007. Section 117A provides for appeals to the Appellate Board. IPAB is an administrative body that has the appellate jurisdiction over the decision of the Controller of Patents. However, IPAB has no statutory powers to trial infringement proceedings. As per section 117G of the IPA, all cases that are related to decisions or orders of the Controller which are pending in the High Court must be transferred to IPAB. The IPAB accept appeals against the decision of the Controller or Central Government of India in various matters such as, any decisions related to refusal of amendment in application (u/s 15) , division of application (u/s 16) , dating of application (u/s 17), anticipation issues (u/s 18) , cases of potential infringement (u/s 19), Substitution of applicants (u/s20), amendment or revocation in opposition u/ 4 sub section of 25 , Mention of inventor as such (u/s 28) , co-owners of the patent (u/s51) , Patent of addition(u/s 54) , any amendment of application or specification (u/s 57) , restoration of lapsed patents and disposal of related application., (u/s 60 and 61), surrender of patents (u/s 63), revocation of patent in public interest (u/s 66) , registration of assignment (u/ss 3 of 69) , correction of clerical errors (u/s 78) grant of compulsory license (u/s 84) , revocation of patent for non-working (u/s 85) , grant of compulsory license by controller (u/s 88) ,licensing (u/s 91) , special provisions of compulsory license (u/s 92) and termination of compulsory license (u/s 94)

Patent Rights:

The Act provides the patentee exclusive for patent protection for inventions relating to both processes and products which prevent the third party to infringe the right related to use of patented article in any form it.

Registration of Assignment:

Under the Act, registration of assignment can be done in transferring the rights of patented invention as movable property. The license Agreement has to be registered under section 69 of the Patents Act at the appropriate Patent Office by filing prescribed form with the prescribed fee.

Commercial Working of Patents:

Section 146(2) provides every patentee and licensee to furnish to the controller periodical statement of the extent to which the patented invention has been worked on commercial basis in India in Form 27. Such statements are a mandatory requirement, Failure of which can lead to a penalty. It can also attract to provisions of grant of compulsory license under section 84. A statement of working would remain confidential till such time and if at all it is published by the controller.

Revocation of the patent for nonworking

After considering the application for the grant of compulsory license, few points are considered

a) Time elapsed since the sealing of the patent;
b) Any measures taken by the patentee or any licensee to make full use of the invention;
c) Ability of applicant to work the invention in terms of capital and risk
d) Desiring party has tried to obtain a license from a patentee on reasonable terms and conditions within a reasonable period.

After satisfaction of controller that CL conditions not met, he may order to revoke the patent.

Patent Infringement: -

Last but not the least the rights of patentee are protected and is liable to legal procedures if violation occurs by any third party. Patent infringement is the commission of a prohibited act with respect to a patented invention without permission from the patent holder. It occurs when someone violates the patent rights an inventor has in his invention by making, using or selling the invention without the patent owner's permission (or if the patent has been licensed), in a way not permitted by the license. In case of Infringement the patentee can claim damages such as compensatory damages, increased damages- up to three times the compensatory damages can be recovered in cases of willful or deliberate infringement and preliminary injunction. [18]

Amendment in Section 3(d) of the Patent Act

Role of Section 3(d) of the Patents Act, 1970. (This section was amended under the Patents (Amendment) Act, 2005) is an important act in Pharmaceuticals: "It states that 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 of 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 primary purpose of section 3(d) was to prevent "evergreening of Patents". "Evergreening is a term used to mark the practices which involve petty changes to an existing product and claimed as a new invention. This type of small change alleged it to a new invention and used to extend the patentee's exclusive rights over the product, preventing competition" An example of this is Case Analysis on Novartis A.G Vs. Union of India, 2007, which was rejected for the grant of patent of their compound imatinib mesylate, In the case they filed a patent for imatinib mesylate, which was a salt form of the free base imatinib, and Novartis claimed all pharmaceutical salt forms of imatinib in its1993 patents, the Indian application therefore lacked novelty and inventiveness. The second major ground for rejection was based on Section3(d) of the 2005

Amendment, which required that new forms of a known substance could only be patented as a product if they demonstrated "enhanced efficacy". [19]

Novartis disclosed information that imatinib mesylate had a 30% increase in bioavailability (the percentage of the drug absorbed into the bloodstream) as compared with imatinib, the Patent Office found this insufficient to meet the "enhanced efficacy" requirement of Section 3(d), which relates efficacy with Therapeutic Efficacy in case of Pharmaceuticals. 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 to made available essential drugs at affordable prices.

Pharma Industry and Patenting

As Pharma companies spent Billions of rupees on research, the outcome of which can be form of a new, inventive and useful product or process. So, the protection of the invented Product or process is really important. Chemical and pharmaceutical industries are prominent leaders in IPR issues especially patent filings as per the annual reports of Indian Patent office.

Intellectual Property has been recognized as an economic and technological development indicator for any multinational which demonstrates an increase in creativity and impact in Indian research and technology.

This can be very well reviewed by publications of scientific literature like patents. CSIR is leading in Indian patent filing, During the period from 1967 to 2007, CSIR filed 5931 Patents.

Pharmaceutical industry accounts for about 2.4 and 10 per cent of the global pharmaceutical industry in terms of value and volume respectively as reported by Indian Brand Equity Foundation (IBEF). [20]. Table 1 and figure 1 indicates the worldwide pharmaceutical patent filing trend (2010-15) in which China leads in filing followed by USA and PCT international filing.

Table 1: The Worldwide pharmaceutical patent filing trend (2010-15) in which China leads in filing followed by USA and PCT international filing.

Country	Patents Filed
BR Brazil	18047
IN India	23800
CA Canada	25520
AU Australia	45510
KR S Korea	50169
EP Europe	112432
JP Japan	114910
WO PCT	134173
US USA	188578
CN China	239133

ISSN: 0975-8585

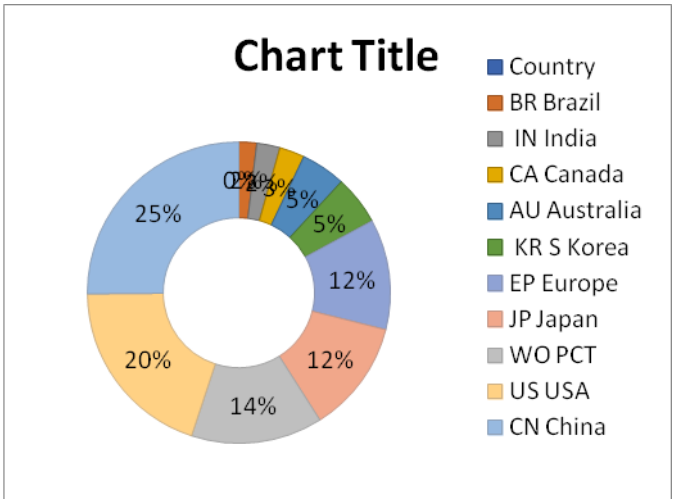

Figure 1: Worldwide Innovation Filing Trends 1995-2015[21]

Table 2: Top ten companies filing Patents in Pharma: As per Patent Lens Report [22] are: -

S No.	Pharmaceutical Firm	Patents filed
1	Dr. Reddy's Laboratories Limited	234
2	Ranbaxy Laboratories Limited	233
3	Dr. Reddy's Laboratories Inc	222
4	Cadila Healthcare Limited	183
5	Cipla Limited	179
6	Council of Scientific & Industrial Research	177
7	Lupin Limited	159
8	Council of Scientific and Industrial Research	157
9	Sun Pharmaceutical Industries Limited	129
10	Wockhardt Limited	110

As per 2016-17 Annual report of IPO, the total number of patents granted during the year was 9,847 out of which 1,315 were granted to Indian applicants. [23] Out of the total granted patents, 2,673 patents were granted to applications relating to the Chemical and related fields, 551 to Pharmaceuticals and, 333 to Biotechnology. Table 2 indicates top ten companies filing Patents in Pharma as per Patent Lens Report.

CONCLUSION

Intellectual property rights specially in terms of Patents is the foundation of the pharma industry as the industry solely rely on the innovation that can be converted to the commercialization extent to generate revenues. Patents are necessary to promote innovation and economic growth. According to surveys carried out the patents contribute 70%-80% of overall revenues of the pharma companies.

Patents in the pharma industry are generally treated equivalent to their property which may even be transferred in exchange of royalty to generate a return on investment. Indian Patent law plays an integral role in the pharmaceutical industry to safeguard the inventions of the company, thus help in producing drugs that meet patient needs. The laws help to meet the pharmaceuticals to be available at reasonable affordable price to public and also meets the requirement in any emergency situations.

A strong patent protection laws can secure the invention not only from the potential infringers but avoiding the Ever greening of Patents.

ISSN: 0975-8585

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