Review Article

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A Review on the Indian Patent System and Its Implication on the Pharmaceutical Industry

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Abstract:

A patent is the main design of Intellectual Property Rights employed in the pharmaceutical industry. Claims of patents in India are imposed under the Patents Act of 1970. The goal of patent authorization is to inspire and progress in the industry and associated modern technologies. Intellectual property rights can help grow the economy due to their industrial applicability in regard to businesses within the country as well as exports. The Indian pharmaceutical industry, is a distinctly uneven one, is influenced by others and there were difficulties in regards to intellectual property rights in the context of the world trade organization.

This review illustrates a brief outline of patent law in India due to the significance of Trade-Related Aspects of Intellectual Property Rights (TRIPS) contracts and the benefits of patentability as well as different types of pharmaceutical patents are described accordingly. Other appropriate necessities linked with patenting of pharmaceuticals like, pre and post-trade related aspects of Intellectual Property Rights, compulsory licensing etc. are also explained. The objective of this paper is to study the patent act of the pharmaceutical industry and several patents granted in India in the pharmaceutical industry, aiming to provide information in the context of pharmaceutical patenting.

Keywords: compulsory license, intellectual property, patent, pharmaceutical industry, Trade-Related Aspects of Intellectual Property Rights

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Introduction

A patent is a legal document given by the government, in regard to an invention or creation of something new for a specific time period, in regards to an invention discovered by an applicant. It delivers protection, of such discovery, to the applicant. A patent is approved for a limited time period, i.e., up to twenty years. A patent defense signifies that the discovery cannot be used, mass-marketed, or sold to others without the patent keeper's approval. The patent keeper has the right to choose who may – or may not – use the patented invention for the duration in which the invention is protected[1].

The pharmaceutical industry is a technological industry and it is a successful sector which has been witnessing consistent growth over the past decades, even though the whole Intellectual property rights (IPR) sector is a newer concept for the world[2].

India's approval in the World Trade Organization and its promise to execute the Trade-Related Aspects of Intellectual Property Rights (TRIPS) concession has seen a variation in the Indian pharmaceutical industry.

The manufacturing industry had to acquire the patent of the product in all areas of industry; furthermore, some are not able to process patents[3].

The development of patent laws in india

The Patenting System of India is unique in comparison with the patenting systems of the rest of the world. This particularity makes the audit of patents filed in India crucial for firms that can operate within the country. These were revised from time to time. After the independence of India, novel patent laws were made in the form of the Indian 'Patent Act, 1970'. Patents are taking centre stage in regards to the nation's scientific, industrial and economic development. The Indian patent act encourages and protects creative, innovative and commercially relevant inventions and thus facilitates inventors to get a return in regards to their innovative activities[4].

A brief comparison between indian and international patents.

First to file/first to invention

In the Indian patent system, when two or more people apply for a patent on an alike invention, the patent will be granted to the person who first files the application. This is the case even if the second person came up with the invention earlier than the second person.

In accordance to the international patent system, when two or more applications are filed for alike inventions, a resolution will be made as to who invented the invention first. In the international system, the grant of a patent goes to the person who designed the creation first and not to the person who first filed for the patent application.

Grace period

In the Indian patent system, patent submission will be rejected, if the invention had been accessible by the public before the submission of the patent was filed in the patent office.

In the international patents system, a one-year grace period means that the creator of the creation has the ability to publish the invention for a period of one year before the filing of the application of the patent; short of distressing his/ her patent rights.

Requirement of novelty, utility and non-obviousness/inventive steps

The Indian patent system has certain features in common in regards to inventions that are patentable in individual countries; novelty, non-obviousness, or inventive steps and the utility of the invention.

In the international patents system there are certain common features in regards to the patentable inventions of people in their respective countries. Novelty, Non-obviousness, or inventive steps and utility of the inventions invented by a person; in the international system, the essential requirement of utility is only in regards to utility patents[5].

Pharmaceutical industry patenting system

The Indian pharmaceutical industry is an advanced technology-based industry with evidenced expansion, over the past three decades, in spite of it functioning under intense price related competition and government price controls. To understand the concerns of the pharmaceutical industry, it is useful to conduct a compact analysis of the primary regulation and the economics of patents[6].

A patent is a special right granted to the creator to construct, manufacture, employ, & advertise the invention, as long as the invention complies with definite conditions specified in the law. There are some selective rights that indicate that nobody can use, make, market and manufacture the invention without the permission of the patent holder. In India, the patent is adequate for only twenty years and while it can be conveyed, it cannot be renewed. When the patent is designated in a country, that country is able to produce & advertise the invention in that country which is associated with the protected data lines and the organizations provide the significance to suitable the profits of their funds in R & D[7].

Simultaneously, patenting in the pharmaceutical industry is becoming normalized in the northern parts of the world, furthermore, many countries in the southern world regions struggled to make patents accessible for pharmaceutical products[8,9].

Silent features of the Indian Patent Act 1970, 2002, 2005

The Patent Act, 1970, provides protection for the creativity of its creators, and it also promotes creativity. Prior to 1970, the pharmaceutical industries in India were controlled by foreign corporations. The Indian pharmaceutical industry, on the other hand, experienced tremendous expansion between 1970 and 2005. The Patent Act of 1970 was responsible for this development.

In 2002, a second amendment was established which consists of a uniform 20 years term for patents in respect for all inventions. Its scope also includes non-patentable inventions including traditional knowledge. Furthermore it was made compulsory to account for the geographical origin of biological material and that there is consent from sources.

The third and most recent amendment is the Patents (Amendment) Act 2005. This amendment introduces full patent protection for pharmaceutical products, from the 1st of January 2005. There was no product patent in India before 2005. It also provides a compulsory license for the manufacture and export of pharmaceutical products to any country that has an, insufficient or none, manufacturing capacity. Generic industries that were successful in reverse engineering patents, were not allowed after the amendment[10].

Intellectual property rights (IPR)

The patent system of a country is a section of its all-round rules set, regulating intellectual property rights. The intellectual property framework grants patent rights in regards to innovations from the human mind, literary works, inventions, and imaginative works, designs and typical signs utilized in trade. Intellectual property (IP) is divided into two distinct groups: industrial property rights, which comprises patents, trademarks, industrial designs, utility

models, trade secrets, new variations of the manufacturing site and geographical indications; and copyright and associated human rights, which informs creative works. The different types of IPR are Patents, Trademark, Copyright, Geographical indications and Industrial designs[11].

The classification of patents

There are three types of patents and each type of patent protects a particular invention. Although, more than one type of patent can be available for one invention. These patents are explained below.

Utility patents

New and useful procedures, compositions of matter, equipment, and manufacturers all come under this type of patent. Almost all people apply for this type of patent. It can also be used to obtain new improvements to existing utility patents[12,13].

Design patents

These types of patents are provided for a completely distinctive, innovative and ornate design applied to an article of production. By taking this type of patent the patentee restricts others from creating, using, or selling the design. This sort of patent can only be obtained where the design is indivisible from its object[13].

Plant patent

By taking this type of patent the patentee restricts others from creating, using, or selling the plant for a period of up to twenty years from the date of patent filing[13,14].

Classification of patent application under the Patent Act, 1970

1. Provisional application

It is an initial application that's filed before the patent office so as to declare precedence. When extra time is needed by the inventor to enhance the invention, this type of application is filed. In this application, an entire provision should be filed within 12 months from the date of filing the provisional application. If an individual fails to do so, the application will be cancelled[1,13].

2. Ordinary or non-provisional application

A non-provisional application patent is filed before the office by an applicant if he or she doesn't have any priority to claim.

3. Conventional application

The patent application filed in the Patent Office, which claims a precedence date that is based on the corresponding application filed in various countries is known as a conventional application. In the Indian Patent Office an applicant should file a request within twelve months from the date of the initial filing of a similar application in the convention country, in order to get the status of the convention.

4. Patent Cooparation Treaty (PCT) international application

At one go, it is a smooth patent submission process in many countries. It is valid in up to 142 countries and is governed by the PCT. The benefit of filing this type of application is that only a single international patent application is required and can be filed in order to take safeguard invention[13,14].

5. PCT national phase application

This type of request must be filed before the priority date or the international filing date i.e. within 30 or 31 months, by the inventor in each country in which he or she wants to seek protection.

6. Application for a patent of addition

This kind of submission is made, when an applicant comes up with an enhancement or alteration in his discovery described or disclosed in the main application for which he or she has acquired a patent. After the grant of the parent patent, the addition patent is granted without any extra renewal charge during the period of the main patent[2,13].

7. Divisional application

If an applicant holds more than one invention on its own, the application is divided into two or more parts for each of the inventions respectively in order to fulfil the official objection and is separated from the parent application. Therefore, it is called a divisional application.

Benefits of patenting

The progression of creative discoveries and works of art: an actual IP system will be able to deliver more time to achieve the innovator's creations and ideas to develop their occupational or start-up business before other organizations imprint it[15].

Inspiration to originator: Patents boost the patentee by giving them praise for their origination and benefit their earning ability by advertising their invention, which also raises their possibilities for future innovation[15,16].

Patent infringement: Noticing Infringement can play a vital role in achieving an advanced economic return. There are two choices offered if someone breaches a patent.

Entry barriers: Recognised patent gives the inventor the right to block others from the replication of that discovery in the countries which have approved their patent.

Donate a patent: while donating a patent it is important to be careful before giving others a patent or any association. This may similarly diminish the value on obligations[18,19].

Patent filing procedure in India

Publication: To publish a journal the applicant must fill out the form with the details of the respective patent office and submit the application before the deadline for filing in the patent office. After this procedure, the journal is published and is available to the public[20,21].

Examination: The details filled by the applicant are examined and the first report is published after the reports are sent to the patent office. In case, if the applicant fails to do so then a six month extension is provided to the applicant[22,23].

Opposition to patent: After the first examination report they search the record for a similar patent to check that the same work was not done earlier.

Grant of license: The patent is issued for twenty years to the applicant if the journal meets all the demands of the patent and satisfies the patent office[19,24].

Pharmaceutical patent

Pharmaceutical patents are patents that are primarily concerned with medicines. It consists of active medicaments, novel preparations and methods used. Public health has always been at the forefront of any government's concerns and therefore, a high emphasis is placed on the accessibility of drugs, thus escalating the price at which society would be willing to pay for that drug. This problem has been done away with by the contract on Trade-Related Aspects of Intellectual Property Rights, which provided for a blanket period of twenty years. However, keeping in mind the importance of drugs being available in growing areas, this contract also brought about the concept of compulsory licensing. Thus, patent protection for pharmaceuticals serves as a prime example of altering the duration of the patent and its accessibility at the same time[25,26].

Type of pharmaceutical patent

Pharmaceutical industries are the greatest industries, and are known for their expertise. The pharmaceutical patent provides patent rights to the creator of the product that secures their product from illegal use. Their products and processes are protected by many patents which are also approved in India. The following categories of pharmaceutical patents are as follows:[27]

Drug compound patent

The patent defines a particular drug by its chemical form and the claims are generally referred to as "Markush type" claims. There are a lot of "functionally equivalent" chemical substances that are acceptable in diverse parts of a drug compound which do not allow the unofficial production and sale of the drug by any other methods.

Formulation patent

The patent ensures a definite method of formulation of the drug and its active components. For example, an immediate-release pharmaceutical 3, 7-diazabicyclo formulation was claimed in the Indian Patent No. 203993.

Polymorph patent

This patent consists of variants of the identical structure of the identified drug which are typically prepared to control degradation or to increase its firmness. This type of polymorph is generally prepared to decrease the impurities and increase the stability of the compound.

Process patent

The patent covers the process and manufacture of the product. For example, synthesis of 3-hydroxy 5B-H steroidal sapogenins was covered in Indian Patent No. 223217.

Technology patent

The patent covers the definite technological methods that are used to resolve technical issues like alteration or taste masking. Various defects come under specific techniques, and these patents are based on such techniques, which are used to reduce these technical problems. For instance, a pharmaceutical composition resulting in a characteristic taste was patented in Indian Patent No. 227933.

Biotechnology patent

It is the patent that ensures the production of a pharmaceutical product by a living organism and by their biological by-products, and covers a large variety of natural products. Immunological, diagnostic, therapeutic and a wide range of such products are preserved under this patent.

Synergistic combination patent

Drug synergy occurs if the drug interaction is compatible to each other. This patent covers various new forms of drug synergy combinations. A synergistic antibacterial formulation and a method of making the same was patented in the Indian Patent No. 197822 example.[28,29]

Pharmaceutical industry in India in pre-trips era

After independence, foreign companies took over control of the industry, which resulted in increased drug prices. Almost all patent drugs in India were given by foreign companies that run the pharmaceutical market (approx 95%). Foreign companies import the drugs in bulk quantity from their own country and prepare formulations in India[30-32].

To analyze patents and provide recommendations on the form of the Indian patent system, two skilled committees were recognized in free India. One is The Patent Enquiry Committee and another one is the Ayyangar Committee. These committees provide a patent system, which focuses on the availability of resources at budget prices, which are valuable to India. By the suggestion of these committees the Patent Act of year 1970 was created. The period 1970-1995, commonly known as pre-TRIPS period, was a successful phase of the Indian pharmaceutical manufacturing. Many patents work has been granted during this era and the number of patents granted in this era that is from years 1970-1995 is 1759[33,34].

Pharmaceutical industry in India in post trips era

In 1995, the World Trade Organization came into action. Being an organizer member of World Trade Organization, India automatically became a guarantor of the TRIPS bond.[35]

The indestructible performance of these industries was seen in the post-TRIPS stage, in the period of 1995-2008. TRIPS adherences of the intellectual property right regime do not affect the novelty aptitude of the local pharmaceutical company which enhances both the research budget and patenting. The modern rush in patent applications in India in the post-1995 stage, has received attention in policy analysis. They contain the main possibilities in the estimation of locals for the management of the new patent regime. Many patents have been granted during this era, 1995-2008, is 13502[36,37].

Compulsory licensing

Compulsory licensing is one of its significant concessions. In this the patented product can be produced, imported or distributed by a private firm or government agency without the owner's permission. Every patent involves a method or procedure for the manufacture of substances intended for use, or capable of being used, as food, medicines, or drugs, or substances prepared or produced by chemical procedure shall be considered to be authorized "Licenses of Right" from the date of termination; which is 3 years from the date of sealing the patent. In quite a few cases, it is compulsory that the patent holder has to provide details of working in regards to the patented invention to the authority to confirm that a compulsory license is not granted for an invention or to bring awareness to a third party who is interested for a compulsory license to be aware that the creation is being worked and may not be chosen for a compulsory license[38,39].

The future prospect of the Indian pharmaceutical industry

The non-evolution of product patent protection for pharmaceuticals led various groups to limit their selections to patent expired products or a few selected patented products, due to this, destruction of their market share occurred as the local manufacturers introduced the most superior medicines through reverse engineering. Foreign businesses need to pay crowned heads for international drugs, whereas for the purpose of selling in the domestic market, Indian companies could acquire and assemble the newest molecules worldwide. The compulsions imposed on India under the TRIPS contract are set out to have a crucial impression on India's fortunate majority and formulation-oriented pharmaceutical commerce. The Indian Foundation has to participate with corporations by concentrating on drug development and thereby generating their own patented goods. Instead of Indian companies concentrating on making patented drugs under license from foreign companies or focusing on generating profits from manufacturing generic drugs[40,41].

Conclusion

Indian patent law is an ordinary section of the patent constitution, which is the ambition to balance the significance of both the ordinary person and the inventors. It is not in front of the ordinary person is acknowledged of intellectual property rights. An understandable consideration of IPR is the significance that industrial assets and copyright is well secured in order to expand the wealth of the country. Before begging for patent, the researchers should wisely take into deliberation the principles of patentability and a consultation with a patent expert is very much required in this respect. With numerous modifications in the Patent laws throughout the decade, India instigated a significant evolution in the pharmaceutical trade and in the scope of

research and development. Through the signing of the TRIPS agreement & coming up with the product patent regimes, a major variety of pharmaceutical products along with processes can be secured through patents. Keeping coordination between the benefits of both, the consumer and the inventor, the reconstituted Indian Patent Act sets an ideal model for patent legislation. However, inventors must be alert while applying for patents.

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