

Indian Pharmaceutical Patent System Past and Current Scenario – An Over View

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ABSTRACT

A patent is the main layout of intellectual property Rights employed inside the pharmaceutical industry. Claims of Patents in India are imposed beneath the Patents Act of 1970. The goal of patent authorization is to inspire and development Within the enterprise and associated modern technology. Highbrow assets rights can help grow the financial system because of their Commercial applicability in regard to organizations within the united states in addition to exports. The Indian pharmaceutical industry, Is a highly uneven one, is inspired by using others and there have been difficulties with reference to intellectual property rights in The context of the arena change enterprise.

This overview illustrates a short outline of patent law in India because of the importance of trade-related elements of Highbrow property Rights (trips) contracts and the benefits of patentability as well as distinct types of pharmaceutical Patents are defined accordingly. Other suitable necessities related with patenting of prescription drugs like, pre and Post-alternate related components of highbrow property Rights, compulsory licensing and so on. Are also defined. The goal of this Paper is to examine the patent act of the pharmaceutical enterprise and several patents granted in India in the pharmaceutical Enterprise, aiming to offer facts in the context of pharmaceutical patenting.

Key words: Indian pharmaceutical patent, intellectual property Rights, World Trade Organization, etc...

I. 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 [1]. 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 .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].

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. 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 [4]. 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 [5]. This may similarly diminish the value on obligations.

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.

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 [6].

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[7].

Patent Law in India

Patent rights were introduced in India for the first time in 1856 and, in 1970, the Patent Act 1970 ("the Patents Act") was passed, repealing all previous legislations. India is also a signatory to the Paris Convention for the protection of industrial property, 1883, and the Patent Cooperation Treaty, 1970. The Patents Act provides that any invention that satisfies the criteria of newness, non-obviousness and usefulness can be the subject matter of a patent. Some of the non-patentable inventions under the Patents Act include methods of agriculture or horticulture, processes for the medicinal, surgical, curative, prophylactic or other treatment of human beings, animals or plants or substances obtained by a mere admixture, resulting only in the aggregation of the properties of the components, etc. With regard to pharmaceuticals, in the case of substances intended for use or capable of being used as food, drugs or medicines or substances produced by chemical processes, patents are granted only for the processes of manufacture of such substances and not for the substances themselves. Hence, pharmaceutical products are currently not granted patent protection under Indian law. India had a product patent regime for all inventions under the Patents and Designs

Act 1911. However, in 1970, the government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from eligibility for patents[8]. This exclusion was introduced to break away India's dependence on imports for bulk drugs and formulations and provide for development of a self-reliant indigenous pharmaceutical industry.

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.

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 Cooperation 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.

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].

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.

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[9].

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 [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 [11]. The different types of IPR are Patents, Trademark, Copyright, Geographical indications and Industrial designs

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:

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.

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[12].

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.

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.

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[13]. To understand the concerns of the pharmaceutical industry, it is useful to conduct a compact analysis of the primary regulation and the economics of patents6 . 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[14]. 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[15]. 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 . 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[16].

The Impact of the World Trade Organization on Pharmaceutical Patents

The establishment of the World Trade Organization (WTO) has led to a tremendous paradigm shift in world trade. The agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS) was negotiated during the Uruguay round trade negotiations of the General Agreement on Tariffs and Trade (GATT) and “one of the primary reasons for incorporating intellectual property issues into the GATT framework was the pharmaceutical industry”.⁴ India signed the GATT on 15 April 1994, thereby making it mandatory to comply with the requirements of GATT, including the agreement on TRIPS[17].

India is thereby required to meet the minimum standards under the TRIPS Agreement in relation to patents and the pharmaceutical industry. India’s patent legislation must now include provisions for availability of patents for both pharmaceutical products and processes inventions. Patents are to be granted for a minimum term of 20 years to any invention of a pharmaceutical product or process that fulfils established criteria. Compulsory licence provisions under Indian law will be required to be limited and conditional to comply with the TRIPS Agreement, and the government will grant such licences only on the merit of each case after giving the patent holder an opportunity to be heard. In addition, there will be no discrimination between imported and domestic products in the case of process patents, and the burden of proof will rest with the party that infringes. India has decided to avail itself of the full

transition period for developing countries and has until 1 January 2005 to extend patent protection to pharmaceutical products. In keeping with the TRIPS commitments⁵, India has started on a process of amending the Patents Act by providing exclusive marketing rights (EMRs) and creating a mailbox system for patent applications for a period of five years or until the patent is granted or rejected, whichever is earlier[18].

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[19]. 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[20].

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[21]. 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[22].

II. CONCLUSION

The present day sales of the Indian pharmaceutical enterprise are envisioned at US\$5 .Five billion and it is predicted to develop at a compounded annual increase fee of nineteen% and touch US\$25 billion in revenue by means of 2025.India is slowly moving into global markets and competing with worldwide excellent requirements and prices. Even though R&D is an essential component to make sure a competitive area within the global arena, the destiny of the Indian pharmaceutical industry hinges on patent protection.Indian patent regulation is an ordinary phase of the patent constitution, that is the ambition to stability the importance of each the everyday man or woman and the inventors. It isn't always in the front of the everyday person to well known intellectual property rights. An comprehensible consideration of IPR is the significance that commercial property and copyright are nicely secured on the way to enlarge the wealth of the country. Earlier than begging for a patent, the researchers have to accurately take into deliberation the principles of patentability and a consultation with a patent professional is very much required in this respect. With numerous adjustments within the Patent legal guidelines throughout the decade, India instigated a full-size evolution in the pharmaceutical trade and inside the scope of studies and development. Through the signing of the journeys agreement & arising with the product patent regimes, a first-rate sort of pharmaceutical merchandise at the side of techniques can be secured thru patents. Maintaining coordination between the advantages of each, the consumer and the inventor, the reconstituted Indian Patent Act sets a really perfect version for patent rules. But, inventors should be alert while making use of for patents.

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