

## INTELLECTUAL PROPERTY RIGHTS AND ITS APPLICATION TOWARD PHARMACEUTICAL INDUSTRY WITH SPECIAL REFERENCE IN INDIA

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### ABSTRACT

Patents are a form of intellectual property rights providing exclusive rights over an invention to the inventor. The owner of a patent has the right to exclude making, using, or selling the new invention for a limited period, subject to a number of exceptions. For encouraging pharmaceutical R and D, the patent system is the best mechanism. Patent protection for pharmaceutical products and processes has become the global norm. For the advancement of research, the pharmaceutical patent is essential to disclosure system. The pharmaceutical industry in Indian has been growing in the post-trade-related aspects of intellectual property rights period. On the other hand, there are still concerns that the new patent act might reduce generic drug supplies and lower access to medicines in India. Since India is the major manufacturer as well supplier for generic drugs, the issue of access to medicines is crucial not only for India but also for other poor developing countries. Thus, the Government of India should seek an appropriate balance between the development of the pharmaceutical industry in Indian and the improvement of public health. The aim of this article is to gather some information from various sources and provides the fundamental knowledge of pharmaceutical patent to the public and pharmaceutical professionals toward the patent.

**Keywords:** Pharmaceutical intellectual property, Generic drugs, Public health.

### INTRODUCTION

Intellectual property rights, especially patents, are highly detailed documents which allow inventors to register their inventions at the national and international level for a specified length of time. Patents are very important and valuable in the process of knowledge production and knowledge commercialization. Pharmaceutical patents are essential for the advancement of research. Patent protection for pharmaceutical products is important as compared to other industries. Pharmaceutical Industry in Indian become globally competitive through the world in present scenario because of their manufacturing capabilities with quality and cost-efficiency of production capacity and up gradation of research and development capabilities for new drugs and associated activities such as clinical trials and contract manufacturing.

After independence when India wanted to develop the pharmaceutical industry, the multinational corporations (MNCs) were invited to come to India to help develop the industry. Before 1972, the MNCs themselves were not very keen on manufacturing in India; they used their patent rights to prevent Indian companies from manufacturing. As a result, on the one hand, the industry remained underdeveloped and on the other hand, the monopolies led to high prices. After 1972, the monopoly power of the MNCs was eliminated, the industry experienced rapid growth and India emerged as a major player in the global pharmaceutical industry receiving worldwide recognition as a low-cost producer of high quality. In accordance with the trade-related aspects of intellectual property rights (TRIPS) agreement, drug product patent protection has been reintroduced in India since 1 January 2005 [1]. India became self-reliant in drugs. After expiry of the patent, the MNCs are interested not only in the patented markets but also they are trying to grow aggressively in the generic segments as well [2]. Traditionally, MNCs have relied for their growth on patented drugs and focused mainly on developed country markets. When product patents were abolished in India in 1972, the MNCs did not stop their business in India. All the major MNCs decided to stay back. Considering the role that abolition of product patent protection played in the pharmaceutical industry in India, reintroduction of product patent protection since 2005 has crucial significance. It was decided that, though product patents have

been introduced from 1 January 2005, a mailbox facility was put in place to receive and hold product patent applications. As per the TRIPS agreement, these applications are being processed since 1 January 2005 for grant of patents, thus to understand the impact on the market structure and prices. Indian generic companies are no longer permitted to manufacture and market new drugs, for which patents have been granted in India. All new drugs are patentable in India, Under Article 70(3) of TRIPS, a WTO member country has no obligation to provide patent protection for any subject matter which had fallen into the "public domain" before WTO came into being, i.e., before 1 January 1995. Thus, any drug product patented abroad before 1995 can continue to be manufactured and sold in India after 1995 even though these may be under patent protection in other countries [3]. The aim of the present study is to focus on patents toward the pharmaceutical field. The paper provides an overview of the pharmaceutical industry toward patent.

### History of India's patent laws

The patent is a kind of intellectual property rights. The patent can be defined as a monopoly right conferred to the inventor who has invented a new product or process through his/her intellectual efforts capable of industrial application [4]. Patent law was passed first in India, in 1856, during British colonial rule. That time, the law was followed the British Patent Law, which was passed in 1852, that law was provided privileges to inventors for a period of 14-year. India was beginning to industrialize accordingly the patent law in the pharmaceutical industry at that time. At the time of independence, India's patent regime was governed by the patents and Designs Act, 1911, which had provisions both for product and process patents. After that, it was felt that there was a need to change in the existing patent law since it had not helped in the promotion of scientific research and industrialization in the country. Immediately after independence, a Committee was constituted, and the Committee was headed by Justice (Dr.) Bakshi Tek Chand, a retired judge of the Lahore High Court, to undertake a comprehensive review of the working of the 1911 Act. The Committee submitted its interim report on August 4, 1949, and the final report, in 1950, making recommendations for prevention of misuse or abuse of patent rights in India. The Committee recounted the patent act and advised that it should contain a clear indication that food and medicine and surgical and curative devices were to be made available

to the public at the lowest price while giving reasonable compensation to the patentee. Based on the Committee recommendations, some amendments were made in the Patents and Designs Act, 1911. In 1952, compulsory licenses were provided for food and medicines, insecticide, germicide, or fungicide and for the process for producing substance or any invention relating to surgical or curative devices. Subsequent to that, one more Committee was constituted under Justice Ayyanger in 1957. The objective of that Committee is to specially decide (a) patents for chemical inventions and (b) patents for inventions relating to food and medicine. After examining thoroughly the contemporary law of patents governing inventions on chemical substances of different countries, the Ayyanger Committee recommended that only process claims be allowed. For foods and medicines, the Committee recommended that inventions related to foods and medicines including insecticides and fungicides should not be patentable as such and processes for their productions should alone be patentable. On the basis of these reports, the Patents Act 1970 was enacted and came into force from 1972. The Patents Act 1970 allowed process patents for drugs, foods, and products of chemical reactions, but no product patents were allowed for inventions related to such substances. Indian pharmaceutical industry is a successful, high-technology-based industry that has witnessed consistent growth over the past three decades. The current industry players comprise several privately owned. During the period 1970-1994, the Indian pharmaceutical industry became nearly self-sufficient and one of the largest exporters of generic medicines. A large number of developing countries depend on the supply of cheaper generic medicines from India.

#### TRIPS agreement and Indian pharmaceutical industry

According to the TRIPS Agreement, pharmaceutical product patents represented one of the most divisive issues, being opposed by developing countries because of concerns that stronger patent protection would hinder access to drugs and prevent the development of a domestic pharmaceutical industry. The TRIPS agreement forced developing country members of the WTO to grant patents with a statutory lifetime of 20-years from the patent application also to pharmaceutical compounds [5]. Despite the strengthening of intellectual property rights brought by TRIPS, some developing countries continue to apply more restrictive approach than developed countries to the granting of pharmaceutical patents. TRIPS requires the availability of patent protection for the processes as well as products in "all fields of technology" the agreement provides countries with substantial freedom to define the standards of patentability. Developing countries, like India (India's Patents Act of 2005 (Amended)), have used this freedom to restrict the granting of so-called secondary pharmaceutical patents. As opposed to primary patents which protect an active ingredient directly, secondary patents protect a range of chemicals related to an active ingredient (such as crystalline forms of the original compound), methods of use, formulations, dosages, etc. For pharmaceuticals, data exclusivity provides protection to the clinical data generated by innovator companies to prove the safety and efficacy of their products. Pharmaceutical companies that are innovators for any product are required to submit clinical test data relating to safety and efficacy to national regulatory authorities to obtain market approval for new drugs. Pharmaceutical companies that are manufacturing generic products, i.e. generic companies are not required to conduct their own clinical testing and submit their own test data to gain market approval.

#### Brief summary on patents

Drugs patented after 1 January 1995 can be classified into the following categories:

1. New chemical entities (NCEs) or new molecular entities, and new biological entities (NBEs) patented after 1995
2. NCEs/NBEs developed before 1995 but with patents after 1995 and satisfy
  - a. New formulations and compositions
  - b. New combinations
  - c. New chemical derivatives (salts, esters, etc.,).

The government has granted patent, which is an exclusive right, given to the applicant for an invention. The patent can be applied by

the inventor or any other person/company assigned by the inventor. Patentee includes to provide rights to license others for the purpose of making, using, or selling the patented invention. The 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. Patenting provides a strategy for protecting inventions without keeping the invention secret. For the technical problem of a patent, patent offers provide technical solution. Inventions which satisfies certain conditions known as criteria of patentability. Patent is granted only to that inventor. Patents have a limited term of 20 years counted from the date of filing the patent application. The patent is a territorial right; thus, it can be enforced only in the country where it is granted. Patent cooperation treaty (PCT) provides a route to file an international patent application through which 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.

Patents are distinguished as primary patent and secondary patent.

**Primary patent:** Patents, those are usually filed already during the research phase in the development of a new drug, in the pharmaceutical industry are called primary patents. In that primary patent, patents give on the active ingredients. These early patents are filed to protect potential active ingredients that form the basis of the new drug. Since the early stages of drug development are characterized by an enormous amount of uncertainty that 1 in 5,000-10,000 test active ingredients results in a successful drug, early patent filings in this, in that case, many of these filings will either not be pursued, or if granted, will never be related to a marketed drug.

**Secondary patents:** After drug development, patents are filed on other aspects of active ingredients such as different dosage forms, formulations, and production methods [6,7].

#### Criteria of patentability

Some requirements should be full filled during patent application, to achieve the status of a patent. Broadly, the invention itself has to meet three main requirements: (i) Novelty, (ii) inventive step, and (iii) industrial applicability (needless to say that deadlines and fees might apply). The first requirement, novelty, means that only new inventions can be patented. If an invention is publicly disclosed before a patent application is filed, it will not be able of protection. This previous disclosure is known as either prior art or state of the art of the technological field. The second requirement by definition is reached whenever an invention is not obvious to someone with a good knowledge and experience in the corresponding technical field. Finally, the requirement of industrial applicability implies the invention to be possible to be carried out in practice.

The invention lies in one of the following categories: (i) Products, (ii) processes or methods, and (iii) machines. Although a machine can also be a product if a firm makes machines for sale, it is better to keep them in different categories because of their characteristics in terms of enforcement [8]. For product, if a company invents a product, it is likely that it will attempt to profit from it, and therefore, that product will be available in the market soon. If the invention is the machine, however, it does not necessarily mean that it will be launched on the market, especially if selling machines is not a firm's core business. A company can keep in secrecy the apparatus to make a product since it is unlikely that competitors will have access to it and then copy it. It also means that a machine patent tends to be more difficult to prove infringement than a product patent because the latter can be found easily in the marketplace. Processes or methods would be procedures responsible for making a product. Alike machines, processes may never be accessed by competitors. It means that process patents tend to be more difficult to enforce. In general, product patents are the most valuable followed by process and machines patents. The scope of a patent is basically described by its claims, which are sentences at the end of each patent

that describe the invention. They may pose a threshold to others keen on performing the invention. A patent application may be filed in a national patent office or supra-national patent offices, such as the world intellectual property organization (WIPO). The date when a patent application is first filed is labeled the priority date. An applicant may file for patent in as per his own choice; once a patent application is filed it will be either examined or registered. Latter case implies that a patent will automatically be granted, and its validity will only be tested in the court. The patent office, where the applicant applies for patent, will request to deposit the fee to be paid on filing. Within 12 months, the applicant must request and pay the corresponding fee for the preliminary examination - to check whether the application is able to proceed - and search - to look for any relevant documents which may invalidate or restrict what is claimed in a patent application. There is no need to wait 12 months to request preliminary examination and search; it can be done on filing since the priority date is the one taken into account to determine prior art. Unless the one who applied for a patent (applicant) withdraws his/her application, or simply abandon it, the invention will be disclosed soon. An invention is kept secret until the 18<sup>th</sup> month from the priority date, and then the patent application is published. From that point, the disclosed invention also becomes prior art against any application filed later. From that point, the disclosed invention also becomes prior art against any application filed later. The date when a patent application is first filed with a patent office (priority date) is of crucial importance for the subsequent prosecution of the application. It is the date, which is used to give priority to an invention. It means that if more than one institution, or individual, seek protection for the same invention, a patent might be granted for the one who applied first. Patent systems operate at single country levels (e.g., the UK and US) and at supra-national levels (e.g., European Patent Office and WIPO), but there is no such a thing as an international patent covering all countries in the world. Even if a company chooses to use one of those supra-national systems, it has to designate all countries of interest (as long as the chosen countries have signed any treaty agreeing with the rules of the system) and pay the corresponding fees [9].

### Description

Patents play an integral role in pharmaceutical research and development of developed and developing countries. An invention is any new or useful process, machine, article of manufacture, or composition of matter. An improvement on any of these items also can be an invention. Patent rights are territorial in nature and exist only in the national jurisdictions in which the patentee has applied for and received recognition of his property rights. The presence of strong patent protection combined with the concurrent ability to assure a profitable return on investment means that commercial pharmaceutical research and development is being overwhelmingly directed at producing drugs which will meet patient needs in these developed as well as developing countries. Patent protection for pharmaceutical products in the developing country can help to encourage the development of new medicines for diseases that affect these countries, by providing protection for the investments that need to be made by the pharmaceutical companies. Pharmaceutical companies often maintain that patent protection for drugs ensures that they are able to invest billions of dollars into the development of new products, by making sure that they will be able to take advantage of the sales. A patent claim

relating to a pharmaceutical product may relate to an active ingredient as such independently of or jointly with formulations, salts, prodrugs, and isomers, or cover any of these subject matters separately. It may also solely cover a manufacturing process or include both a process and a product. In some countries, as noted below, use-related claims are admissible [10]. The Indian pharmaceutical industry has achieved self-sufficiency in pharmaceutical production and emerged as one of the largest drug exporters in the world. India is one of the major drug-producing countries. The industry has become one of the major drug exporters since the late 1980s and showed promise of its global competitiveness. The Indian pharmaceutical industry continues to expand its presence across the world.

### CONCLUSIONS

A patent is considered a major incentive for technological development, both for being an official document that grants legal protection to the invention and for being the greatest source of information on technological innovation in the world. Since pharmaceutical industry based on products and processes, have now assumed an increasing importance in the global economy, there is a definite need to globally harmonize policies and procedure in respect of protection of intellectual property rights in view of the fact that enterprises engaged in research will make investment only if strong legal protection is available for the result of their research. India has begun to see some positive results as awareness of the need for greater IP protection has increased. Educating all the pharma professionals from manufacturer to innovators to industry players is vital for achieving the benefits of IP regime as well as for standing strong among global competing players.

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