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Intellectual Property Rights in Indian Pharmaceutical Sectors- A Review



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ABSTRACT

Patent protection for pharmaceutical products and processes has become the global standard. 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. For many years prior to its membership in the World Trade Organization (WTO), India did not recognize product patents for Pharmaceuticals. For encouraging pharmaceutical R and D, the patent system is the best system. For the advancement of research, the pharmaceutical patent is essential to disclosure system. 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.

INTRODUCTION

The Indian IPR section is grossly categorized into patents, designs, trademarks, and geographical indices¹. If we see the history of Indian “IPR” section, it can be divided into three definite eras: pre-independence, post-independence (before Trade Related Aspects of Intellectual Property Rights or TRIPS), and post-independence (after TRIPS) era.

Intellectual property rights, especially patents, are highly comprehensive documents which allow inventors to register their inventions at the national and international level for a particular length of time. Patents are very important and valuable in the process of knowledge production and knowledge commercialization. Pharmaceutical patents are important for the advancement of research. Patent protection for pharmaceutical products is important as compared to other industries. Pharmaceutical Industry in Indian become globally viable 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 manufacturing².

Pre-independence era

In India, the history of IPR dates back to pre independence era. In 1856, India witnessed the first legislation regarding patent (Act VI), which was subsequently replaced in 1857 and 1859. In 1872, the act was renamed as “The Patterns and Designs Protection Act.” The 1911 act (Act II) replaced all previous acts which brought patent administration under the “controller of patents,” which was further amended in 1920, 1930, and 1945.³

Post-independence era (before TRIPS)

In the post independence era, generally, multinational companies governed Indian medicine market. The drugs were imported at a higher cost, and in terms of drug price, India ranked among the highest priced nations in the world. It was seen that the old “Indian Patents and Designs Act, 1911” was not fulfilling the requirements of the Indian population^{3, 4}. Hence, Justice (Dr.) Bakshi Tek Chand committee was constituted for a detailed evaluation of the pros and cons of the Indian patent system. The committee rightly pointed out that the patent act should contain clear recommendation to ensure Indian population's needs with regard to food, medicines, and medical devices and these should be made available to public at the

cheapest price commensurate, at the same time honoring patentee with a reasonable compensation. These recommendations are the basis of two major changes; the 1950 (Act XXXII of 1950) amendment (emphasis on working of inventions and compulsory license [CL]/revocation) and the 1953 bill (Bill No. 59 of 1953). Although this bill was introduced in the parliament in 1953, it was allowed to lapse.^{3,4}

In 1957, Government of India took two significant steps; first is the establishment of Hindustan Antibiotics Limited (As per agreement with UNICEF) and the second is appointment of Justice Rajagopala Ayyangar Committee, for revision of patent law and development of a locally sustainable market. The report of this committee (1959 report) served as the basis of the IPR revolution in India with major changes such as the “process only patent framework” and is the backbone of the “Patents Act, 1970” (brought into force since 1972) which replaced all previous patent laws (except designs). This revised act remained in place for next 24 years till the year 1994.^{3,4,5.}

History of India’s patent laws

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.²

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 filled 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 18th 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 fees⁹.



Challenges of the Current Indian Patent System

Effect of product patent on Indian pharmaceutical sector:

As Indian patent system was a “Process patent-” driven system, the transition to “product patent” system was expected to be devastating to the pharmaceutical industry, and the early reaction was full of panic¹⁰. The expected outcomes were “unexpected rise in drug price” and subsequent destruction of Indian Pharmaceuticals Industry. However, the Indian pharmaceutical sector copped up with the new regulatory changes and the indigenous R&D sector started growing.

Patent protection period of 20 years:

Granting of “patent” is a way to encourage innovation, which allows patentees to enjoy monopoly over the patented product for a period of 20 years from the date of filing. The effect of this monopoly can be very severe in pharmaceutical sector, more so in the case of lifesaving drugs.^{6, 7, 10, 11, 12, 13}

Compulsory licensing:

To counteract this monopoly-associated damage, the Patents Act, 1970, has some specific provisions to balance the situation. This act also has a provision that the patented products to be available to end users at sufficient quantity, and at the same time, the price should be in affordable range. If the patentee fails to do so, the Government of India can give CL to interested parties so that the patented product fulfills the requirement of the product. Although the first CL was issued in the year 2012 (Bayer's patented drug Nexavar to Natco Pharma Limited), the history of compulsory licensing is not new. In Section 22 of the Patents and Design Act, 1911, it is mentioned that, after the expiration of 3 years of a patent life (day 1 being the date of sealing of the patent), any interested person can apply for CL if the following grounds are not satisfied, for example, the commercial angle of the patent is not fully worked out, the Indian population demand/requirement regarding the patented property is not met adequately and the demand of the "patented product" has to be fulfilled substantially by importing it from other countries. The "Patents Act," 1970 (section 84), also kept the provision of CL if the reasonable requirements of Indian population with respect to the "patented invention" are not satisfied or the "patented invention" is not available to public at a reasonable price. In 2002, another ground was amended which states that CL can be applied if the "patented invention has not worked in territory of India." In 2005, CL covered both "manufacture and export" of pharmaceutical products (section 92A) to any country which do not have manufacturing capacity of have insufficient manufacturing capacity to address its public health issues.⁸

Although lots of controversies came after India's grant of first "CL" to NATCO and subsequent grants, the trend seems to be an unbiased one, with a critical balance between the interest of generic manufacturers, intention of the patentee, and the interest of the population⁸.^[8]

Lots of patent and no clinical translation:

Although the number of patents granted is increasing, the translational gap is quite huge in the pharmaceutical sector. Among these, lots of the patents are from academic institutions and are part of academic thesis work. Other important issues are lack of orientation toward clinical translation and deficient funding.

Evergreening:

“Evergreening,” refers to a strategy by which additional “secondary patent,” is applied by minor formulation or other changes of the parent patented molecule, of which patent period is going to expire. Indian Patent Act counteracts evergreening measures by inclusion of Section 3(d), which distinguishes between “discovery and innovation” and clearly defines which is not patentable. Although a criticism like non-agreement to TRIPS came in the NOVARTIS case with regard to GLIVEC, the Honorable Court cleared its stand on “evergreening” and discouraged such strategies.^{7,9}

Time-consuming work process: High workload compared to patent office of other countries and less workforce are implicated in the delay in the patent process.²

CONCLUSION AND FUTURE DIRECTION

Although lots of patent applications are from pharmaceutical sector, their clinical translation is very less. Rationally, right now Indian Pharmaceutical Market is dominated by the generic market and invention has a very little share in its expansion. The main reason behind this seems to be separate work in each field, lack of proper multidisciplinary work between the preclinical and clinical scientists, deficient funding, and heterogeneous interests of the involved sectors, lack of systematic training of workforce, and lack of visionary. Industry-academia collaboration and establishment of quality control bodies can be valuable in this regard.¹⁴

So far, the Indian Patent System is balancing the delicate balance between the interest of the patentee and Indian population. There are several stories such as imatinib (Novartis), tadalafil (Eli Lilly), rosiglitazone (GlaxoSmithKline), fenofibrate (Abbott), sorafenib (Bayer) regarding the product patent, EMR, off-patent products, and how the inventor company tries to save their inventions from generic marketing. Effective lessons learned from these events allowed us to understand the limitations of current IPR system and subsequently to make the system more strong.

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