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PHARMACEUTICAL PATENTING IN INDIA: AN ANALYSIS[1]

ABSTRACT

In the pharmaceutical sector, a patent is one of the most common forms of intellectual property. The Patents Act of 1970 governs the issuance of patents in India. After India adopted the TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement in 1995, significant modifications to the Indian patent system, such as the grant of product patents, were made. This research paper offers a brief outline of how India's pharmaceutical patent system have evolved as a result of the TRIPS agreement. Eligibility criteria to get a patent, the various classes of pharmaceutical patents that are presently being issued in India, importance and benefits of patents are outlined in order to get a thorough understanding of pharmaceutical patent system.Other regulations pertaining to pharmaceutical patenting, such as section 3(d), compulsory licensingare addressed.This paper also gives an overview on how public health sector is being affected by pharmaceutical patenting and various solutions in place to overcome this issue.

1. INTRODUCTION AND BACKGROUND

Many countries have made a concerted effort to harmonize intellectual property laws in past times which has not been without controversy, specifically when it comes to pharmaceutical patent regulations. This is due to the continuous conflict among giant, multinational pharmaceutical companies and emerging economies that lack the facilities and funding to construct self-sustaining pharmaceutical sectors.The Patents and Designs Act 1911 established a product patent framework for all innovations in India. In 1970, however, the government passed the new Patents Act, that made pharmaceuticals products ineligible for patent protection.India only acknowledged process patents and not product patents for pharmaceuticals for several years before joining WTO. Without product patents to deal with, Indian pharmaceutical corporations were able to produce high number of generic medicines, positioning India as one of the world's biggest generic drug producers. The price level of

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generic medications opposed to their patented versions has allowed India to not only provide reasonable medicines to its own citizens, but also to operate as a pharmacy for so many underdeveloped nations.This exemption was enacted to reduce India's reliance on imported bulk medications and compositions and to encourage implementation of a self-sufficient domestic pharmaceutical sector.India seems to have become a frontrunner in the developing world in endeavoring to reform pharmaceutical patent regulations to cater to domestic healthcare needs, concentrating much more on requirements of an average man and therefore pushing ahead with its advancement. However, a substantial segment of the population live in extreme poverty, and healthcare costs paid out of pocket, implying that there is still a major health problem in India, with deficiency in terms of healthcare as well as the convenience, cost, and availability of medicines. Nevertheless, India was required to alter its legislation in 2005 to extend product patent protection to pharmaceuticals as a result of its responsibilities under the TRIPS agreement. In order to meet the multiple demands for low-cost medicines and efficient intellectual property protection, the Indian parliament implemented a legislation that limited pharmaceutical protection to those that were either completely new chemical compounds or improved the therapeutic efficacy of existing ones. Sections 2(1)(j), 2(1)(ja), and S.3, notably Sections 3(d), 3(e), and 3(i) of the Patents Act, 1970, are used to decipher the patentability of pharmaceutical innovations. Section 3(d) is an exclusive provision which strikes a good compromise between the objective of the Agreements on Trade Related Aspects of International Trade (TRIPS) and the protection of impoverished people's access to medicine. As a result, India has become a global leader in the pharmaceutical industry.

2. DRUG PATENTS AND REQUIREMENTS TO GET A PATENT

In the pharmaceutical sector, a patent is an intellectual property right issued by the state to the innovator to safeguard his creation, which could be a medicine or a manufacturing technique. It's worth noting that while the patent can solve a wide range of technical difficulties, the innovations must meet patentability requirements in order to be protected.According to Indian patent act, an innovation can be patented if it involves a novel product or process that fits the set of criteria.[2]

Novelty- The topic area must be original, meaning this should not have been disclosed in any documentation or utilized anywhere around the market before even the filing deadline.

Inventive step- This necessitates the creation of an innovative product or process. It's not a method that a manufacturer could think of. Even competent people should not be able to figure

[2] The Patent (Amendment) Act 2005
http://ipindia.gov.in/writereaddata/images/pdf/oatent-office-procedures.pdf (last accessed 8th Nov 2021)

out what the invention is about. This should, for example, expand current understanding in terms of technology or have economic advantages, or even both.

Industrial Application- The invention must be able to accommodate into the appropriate industry. In the view that it should have a beneficial or functional use, industrial applicability implies that the asserted invention could be created and used in any industry.

3. CLASSIFICATION OF PHARMACEUTICAL PATENTS IN INDIA

The pharmaceutical industry is among the most competent industries. Pharmaceutical research is both expensive and uncertain. The studies can lead to the development of a novel, innovative, and helpful product or process. In this dynamic industry, it is critical for pharmaceutical firms to access patent claims over their developed products or processes in order to safeguard their discoveries from unlawful commercial utilization. The following are the several classes of pharmaceutical patents in India.

Process Patents- A process patent is a type of patent that provides protection to inventors for a specific method of making or producing a product. To put it another way, a process patent grants rights to a specific manufacturing process rather than the product directly. An identical product can be made using a different process or by modifying the method's characteristics. The main advantage of a process patent system is that it gives the government authority over the monopolies of powerful multinational corporations, allowing it to protect the welfare of the community.

Technology Patents- These patents cover methods such as stabilization, increased manageability, taste masking, and others that are utilized to resolve complex technology-based concerns. The innovators can prevent others from employing similar methods by claiming the taste-masked composition.

Polymorph Patents- Polymorphs are various crystal configurations or components of a substance which is already recognized. Companies make them to improve the durability of their current substances or to remove contaminants. Patents of this type enable pioneering companies to protect enhanced versions of their founding medicines.

Drug Compound Patents- These are patents that assert the chemical composition of a medicinal molecule. These are meant to provide the most comprehensive protection to a drug's developer, and they restrict other firms from developing a similar drug. Until about the approved patent lapses, nobody is authorized to manufacture or commercialize any formulation containing this medication.

Synergistic Patents- Whenever two or even more medicines combine in such a way that their effects are magnified or enhanced, this is known as drug synergy. According to Indian patents act, the innovator can seek protection for innovative synergistic medicinal compositions.

Biotechnology Patents- The use of living creatures or natural elements in the creation of pharmaceutical drugs is referred to as biotechnology. A vast range of diagnostic, medicinal, and immunological items are covered under biotechnological patents.

4. IMPORTANCE AND ADVANTAGES OF GETTING DRUG PATENTED IN PHARMACEUTICAL SECTOR

The pharmaceutical industry has progressed over time, resulting in the introduction of various drugs that have preserved a million lives. These medications also brought in a sizable sum of money for their commercial supporters. For many years, patent-protected pharmaceuticals are free of price controls and competition, granting the patent holder marketing authorization. In a perfect world, everyone would have access to medical care. However, someone must spend in research to continue to develop new and better drugs. Some pharmaceutical corporations just wouldn't fund the research if patents were not available, preferring to wait for some other company to develop and license the medicine.These corporations then would sell the medicine at a reduced price than their competitors. In perspective of a positive externality, this results in market inefficiency. In addition, other companies can benefit from one company's work despite needing to pay for that too.It is essential to gain patent protection in terms of protecting the pharmaceutical company's creative methods. Patents limit encroachment by making it difficult for competitors to replicate the production of any drug or therapy. Because creating and marketing a new drug is so expensive, patents in the pharmaceutical sector aid in reimbursing the expenditures invested during the process of being developed. Drug patents contribute to

enhance investment capital, which improves the overall economic advancement of companies in this industry.

5. INTERPRETATION OF SECTION 3(D) OF THE PATENT (AMENDMENT) ACT, 2005

The Indian Patents Act of 1970 introduced Section 3(d) under the category "What are not inventions."[3] Just after the early 1970s did Indian enterprises start producing bulk medications. As a result, India swiftly established itself as a key provider of low-cost medicines to a variety of emerging and developing countries; yet, the lack of product patent manufacturing in the pharmaceutical industry stifled invention. In 2005, the Indian Parliament updated (amendment) section 3(d) to ensure that it not only adhered with TRIPS and also did not damage health of the public.The Patents (Amendment) Act of 2005 has the principal goal of prohibiting ever-greening of patented drugs and allowing patents on just those chemical compounds that demonstrate major improvements in treatment response.In most cases, an invention could only be patented for 20 years. A product's patent is effective for this duration after it is granted by a pharmaceutical company. After the time limit has passed, other companies are able to create these items at a far reduced cost. Normally, pharmaceutical corporations strive to keep their patents alive by making minor changes to the existing drug, but Indian law has a stricter standard.Section 3(d) doesn't at all serve as a deterrent to the patentable subject matter of pharmaceutical developments. In the case of ***Novartis V. Union of India***[4], the Supreme Court of India highlighted the positive development of Section 3(d) in the patentability of pharmaceutical drugs as a qualifying benchmarks for pharmaceutical goods so that the real and true creations are protected while also preventing attempts at recurring patenting or patent period extensions on flimsy pretexts.

6. JUDICIAL PRONOUNCEMENTS GIVEN ON SECTION 3(D)

Novartis V. Union of India[5]

Glivec, a drug manufactured by Novartis, is used to treat Leukemia, which is one of the most frequent blood cancers in Europe. The SC rejected the patent application for 'Glivec' on the premises of Section 3(d), which seeks to constrain ever-greening and patent rights of new uses or new forms of original drug products without even any remarkable improvement in

[3]Indian Patents Act of 1970, S.3(d).
[4]Novartis AG vs. Union of India and Ors. [Civil Appeal Nos. 2706-2716 of 2013 (Arising out of SLP (C) Nos. 20539-20549 of 2009)]
[5]Ibid

efficacy. Furthermore, there is no definition of efficacy given under the Indian Patent Act and its amendments, therefore there are no recommendations available for businesses like Novartis pursuing second-generation patents. This is a landmark decision since the court saw through the technicalities to the reality that such corporations were attempting to 'evergreen' their patents, rendering them unreachable at trivial costs, it also raises questions about IP protection and accessibility to medications.

ABRAXANE DRUG BY ABRAXIS BIOSCIENCES[6]

Abraxene is a medication used to treat breast cancer, lung cancer, and pancreatic cancer. Abraxis filed for a patent in India. NATCO submitted a pre-grant objection claiming a lack of originality because the claimed medication comprised a mix of new forms of a recognized compound. The applicant claims that his innovation reduces the associated adverse of the proposed composition. However, in light of the given substance, the specifications neither suggested any increased effects nor established any importance of such advantages in terms of therapeutic efficacy.As a result, the application was denied under section 3(d), due to the lack of medicinal efficacy of the compound as stated. It prepared the way for generic manufacturers to enter the domestic industry with more cheaper products.

7. CONCEPT OF COMPULSORY LICENSING OF DRUGS PRODUCED BY PHARMACEUTICAL COMPANIES

Pharmaceutical products in India can now be compulsorily licensed. A compulsory license is a license granted by a country's government to someone that allows him to utilize an innovation even without approval of the patent holder.[7] This normally occurs whenever the patent holder is not employing or effectively using the innovation, or if the innovation is for the benefit of the public but is not readily available to the general public.Under section 84 of the Patents Act, 1970, a compulsory license may be provided on the reasons stated-[8]

(i) the general public's requirements have not been met,

(ii) the patented invention is not accessible to the public at a decent cost,

(iii) the entire product is not being used in the Indian territory.

Compulsory licenses, on the other hand, can only be awarded after a three-year period has passed since the patent was issued.

The compulsory licensing of patented medicines was met with protest from inventors and patent

[6] https://www.financialexpress.com/industry/relief-for-natco-pharma-as-chennai-patent-office-rejects-us-firms-application-for-cancer-drug/80962/ (last accessed 8th Nov 2021)

[7] https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm(last accessed 8th Nov 2021)

[8] Indian Patent Act 1970, S.84.

holders. Below mentioned are some concerns that have been raised regarding compulsory licensing.

Low-quality drugs - when a pharmaceutical corporation owns both a process and a product patent on a drug, a third party could be granted permission to manufacture another drug that use the same technique as the patented medicine. Low-quality medications could be accessible to the general populace, causing harm rather than the betterment of humankind for which they were intended.

Gray Markets- A big issue occurs when a generic business that has been granted compulsory licensing to sell a patented medicine to a specific country also sells the medication to other countries. This puts an end to the original patent owner's sales territory.

Violation of the rights of manufacturers- The patentee's rights are guaranteed by Section 48 of the Patents Act of 1970. They lose all rights to distribute when compulsory licensing is granted, and when generic medications of the same product are permitted, they also lose the right to make the medication with the same element solely.

In the landmark case of ***Natco Pharma Ltd. India V. Bayer Corporation, USA***[9], the Controller of Patents signed a decree granting India's first compulsory patent license. Natco Pharma Ltd was granted a compulsory license. This patent covers a medicine manufactured by Bayer and marketed under the name Nexavar. Natco is now authorized to develop and market a generic form of Nexavar after obtaining this compulsory license. This judgement was justified on the basis outlined in section 84 for granting a compulsory license. The public's reasonable criteria for the patented invention was not met, according to the controller. The Controller ruled that the patented invention could not be bought by the wider populace at a reasonable cost.Because Bayer did not manufacture the product in India and instead imported it from elsewhere, the patented invention could not be used in India. Hence, the compulsory license was issued to Natco.

8. ISSUES ARISING IN PUBLIC'S ACCESSIBILITY TO HEALTHCARE AND SOLUTIONS TO TACKLE THE SITUATION

People in India who have the highest need for healthcare have had the most difficulty receiving quality healthcare and are therefore the significantly less likely to have their healthcare requirements satisfied. Patent monopolies are frequently abused by drug corporations, as there

[9]C.L.A. No.1 of 2011, http://docs.manupatra.in/newsline/articles/Upload/93092AEC-D7C8-4C1E-9219-3B4CB5DAE8F9.pdf (last accessed 8th Nov 2021)

is excessively high pricing for patented drugs. Drug access has been hampered by the advent of product patents. In India, a massive proportion of generic drugs, notably vaccines, are patented, finding it challenging for the sector to create life-saving medications. Outrageously high medical costs prevent regular people from obtaining medicines, which goes against the government's stated goal of protecting individuals' healthcare. Particularly in a place like India, in which a big segment of the population lives below the poverty line and health care system prices are excessive, there seems to be an apparent medical issue with inadequacy in relation to the health and the price, ease of access, and availability of medications. An already existing solution to tackle the issue is compulsory licensing. Nevertheless, compulsory licensing should be done in such a way that neither the legislation nor the regulations are overly stringent, causing problems with drug regulation, nor are they too lax, allowing people to abuse the system. Compulsory licensing's principal goal is to enhance easy accessibility to patented, costly medications. This also enhances competitive market and lowers the price of patented pharmaceuticals, because market dominance can contribute to higher prices and, as a consequence, patent infringement. This could safeguard the public's right to health and availability of drugs. As a result, nations should make compulsory licensing an important part of their public health programs. Also, as a resolution to this dilemma, price reduction of drugs could be done achieve a good balance.

CONCLUSION

The Indian patent law is an excellent example of patent law that strives to consider the interests of both ordinary people and innovators. A broad range of pharmaceuticals can now be protected in India due to the implementation of the product patent system. There are numerous problems in the Indian healthcare sector. The government must strike the balance between creativity and affordability. There are also issues with the current system. In India, Section 3(d) is neglected. The Novartis guidelines are frequently misconstrued. To avoid this, the state must clearly state the rules and make them available to authorities.The authorities must likewise make good use of Section 84. As a result, even if patents are issued incorrectly, the state can guarantee low-cost access even before patent has expired. Eventually, a reliable infrastructure should be implemented. Only by taking these actions can the impoverished have access to cheaper medications.

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