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Effect of Product Patent in India with Respect to Pharmaceutical

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ABSTRACT

Pharmaceutical patents are essential for the advancement of innovative and enhanced drugs. India is an emerging market for medicines and has undertaken several initiatives in research and development to manufacture its own drugs. Before the modification to the patent statutes, only process patents were permitted for medicines in India. The implementation of product patents via the 2005 Amendment in India's pharmaceutical sector has profoundly altered the industrial environment, offering numerous advantages and concerns. Although these patents have stimulated innovation and matched India with international intellectual property rules, they have also generated concerns about medicine cost and accessibility. To reconcile patent rights with public health requirements, procedures such as compulsory licensing have been used; yet, achieving this equilibrium continues to pose a significant issue. This study examines the implication of Intellectual Property Rights in the development of novel medications. It also concentrates on the influence of TRIPs on pharmaceutical patent innovation both before and after such implementation and the impact of it on the pharma industry. The paper also highlights the legal framework that is surrounding with the grant of product patents and also about the importance of grant of compulsory licensing especially in the pharmaceutical industry. It further discusses about the effect that the introduction of product patents in the pharmaceutical sector industry has brought in along with the challenges in the implementation of the same.

***Keywords**: Pharmaceutical patents, product patents, pharmaceutical sector, compulsory license, public health.*

I. INTRODUCTION

In the contemporary world, intellectual property plays an extremely perilous role in the commercial sector. It fosters innovation, creativity, and economic expansion by offering legal safeguards to inventors and creators, enabling them to monetize their endeavours and motivating the further advancement of new goods and services, so benefitting society at large. Intellectual property promotes robust market rivalry, enabling producers, merchants, and

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proprietors to enhance their products more efficiently. The patent system is crucial for health-related development goals, serving as an incentive for innovation in the pharmaceutical sector. An effective patent system may serve as a mechanism to promote technological dissemination and access to vital pharmaceuticals. On the other hand, poorly designed systems that strike an unsuitable balance between innovation and accessibility might make it more difficult for governments to accomplish one of their main development goals, which is to protect the health of their citizens.

A patent formally grants its holder a monopoly to control the market and reap financial rewards, which is justified in contrast to the patentee disclosing their innovation to the general public.[3] WIPO mentions, "A Patent as exclusive right granted by a government for invention, which is a product or a process that provides, in general, new way of doing something, or offers a new technical solution or offers a new technical solution to problem."[4] A limited monopoly given in return for the disclosure of technological information is called a patent. The core tenet of patent law is that an invention may only be given a patent if it is both novel and practical. To put it another way, it needs to be both unique and useful.

The establishment of product patents in pharmaceuticals has led to the commercial release of several novel medications that have saved millions of lives and have also produced substantial money due to their commercial advantages. Upon the initial development of a novel medicine by a pharmaceutical firm for a specific ailment, it is marketed under a brand name, enabling doctors to prescribe it for patient usage.[5] The medication is protected by patent rights, signifying that alone the pharmaceutical business that has the patent is permitted to produce, promote, and ultimately profit from it.[6] Inventions that are novel and cannot be made by anybody else, or by a small team of individuals, are eligible for patent protection.[7] Article 27 of the TRIPs Agreement addresses patentable matter and establishes five uniform standards: (a) patents must be available for all types of inventions; (b) patents should be granted across all fields of technology, encompassing both products and processes; (c) inventions eligible for patents must meet the criteria of novelty, inventive step, and industrial applicability; (d) patent availability and rights must be non-discriminatory regarding the location of invention and field of

[3] P. NARAYANAN, PATENT LAW 1-4 (Eastern Law House, 2017).
[4] WORLD INTELLECTUAL PROPERTY ORGANIZATION, https://www.wipo.int/en/web/patents/ (last visited Feb. 6, 2025).
[5] DRUG PATENTS AND GENERIC PHARMACEUTICAL DRUGS, https://www.news-medical.net/health/Drug-Patents-and-Generics.aspx (last visited Feb. 6, 2025).
[6] Id.
[7] Dr Surana, Patent Landscaping, LIVELAW (Feb. 7, 2025, 11:40 P.M, *https://www.livelaw.in/law-firms/articles/law-firms-patent-landscaping-167378).*

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technology; and (e) patents should be granted regardless of whether products are imported or produced locally.[8]

"As of 2024, India has emerged as the world's largest supplier of generic medicines, with a 9% pharma export growth rate, nearly double the global average."[9] The Indian pharmaceutical business now leads among India's science-based sectors, exhibiting extensive skills in the intricate domain of medication manufacturing and technology. The Indian pharmaceutical business, characterized by its high level of organization, is valued at around $6 billion and is seeing an annual growth rate of over 10 percent. It stands prominently among all developing nations for technology, quality, and the extensive variety of produced pharmaceuticals. The Indian pharmaceutical business produces a wide array of medications, from basic analgesics to advanced antibiotics and intricate cardiac agents. India is among the top six global manufacturers of medicines.

II. EVOLUTION

Patent rights were first established in India in 1856, followed by the implementation of the Indian Patents and Designs Act in 1911. Following Independence, it was concluded that the Indian Patents & Designs Act of 1911 was failing to fulfil its stated objectives. Extensive patent law was considered essential owing to substantial changes in the nation's political and economic environment. The Patent Act of 1970 repealed all earlier legislation. The Patents Act states that any invention that meets the requirements of novelty, non-obviousness, and utility may qualify for patent protection.

In the past, patents were only granted for the processes of manufacturing pharmaceuticals, which are substances that are intended for use or capable of being used as food, drugs, or medications, or substances that are produced through chemical processes. The fundamental principle behind the issuance of a patent for a product preparation process is that the product may be produced using a completely novel, distinct, and inventive way. The most notable law is the Patents Act of 1970, which emerged due to the persistent domination of foreign pharmaceutical companies that held about 70% of the domestic market. This enabled India to evolve into a more efficient pharmaceutical industry globally, hence providing opportunities for local pharmaceutical businesses to penetrate the domestic market and enhance their total market

[8] INDIA AND INTERNATIONAL LAW, BIMAL N. PATEL 111 **(**Martinus Nijhoff 2005).

[9] FINANCIAL EXPRESS, https://www.financialexpress.com/business/healthcare-indian-pharma-rises-to-global-prominence-led-by-export-boom-and-better-compliance-rates-mckinsey-report-reveals-3762058/#:~:text=As%20of%202024%2C%20India%20has%20emerged%20as%20the,needs%20and%2025%25%20of%20medicines%20in%20the%20UK. (last visited Feb. 8, 2025).

share in India. The legislation barred medicines and agrochemical items from patent eligibility. This exclusion was implemented to reduce India's reliance on imports for bulk pharmaceuticals and formulations and to foster the development of a self-sufficient domestic pharmaceutical sector.

Therefore, under current patent legislation, compounds resulting from chemical reactions are non-patentable in India. The limitation, together with the prohibition on simple mixes that result in the aggregation of qualities without any synergistic effects among the components, significantly restricts the objects eligible for patenting in India. In India, "actives" produced by chemical synthesis are not patentable, regardless of their functional qualities. Similarly, typical medicinal formulations where the components function only as admixtures are not eligible for patents in India. In such instances, just the process, namely the technique of producing the product, is patentable. The lack of protection for pharmaceutical and agrochemical product patents had a major impact on the Indian pharmaceutical sector, which resulted in the development of significant expertise in reverse engineering medications that are patentable in the developed world but unprotected in India.

Recent international patent regulations have mandated the enforcement of product patents in all nations. This has incited unrest among emerging nations that have so far permitted only process patenting but nations have ultimately ratified the TRIPs agreement. In 2005, with the incorporation of the TRIPS agreement terms, product patents were safeguarded in India.

The pharmaceutical sector in India has consistently expanded as a successful high-technology business since the implementation of the Patents Act in 1970, particularly during the last thirty years. The provisions included into the Act originated from the Paris Convention for the Protection of Industrial Property of 1883 and the Patent Cooperation Treaty of 1970, to which India was a member. The Patents (Amendment) Act, 2005, established product patents for medicines, superseding the previous process-patent framework. While process patents are meant to protect the particular procedures or processes used in the production of a product, product patents are meant to protect the finished product. Under the implementation of the product patent system in India, only those goods that are novel as of the application filing date will be eligible for patent protection, excluding all others. It is believed that product patenting will stimulate research and development, hence benefiting all nations. Following the change, the replication of pharmaceuticals is now prohibited due to product patents. This indicated that novel medicinal compounds may now be patented, giving exclusive rights to developers for a duration of 20 years. The regulations guaranteed that India's pharmaceutical patent system complied with TRIPS while protecting public health, enabling

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India to maintain its position as the "pharmacy of the world" for cost-effective generics.

III. LEGAL FRAMEWORK GOVERNING PRODUCT PATENT

The amended legislation of 2005 included significant modifications that influenced the future of the pharmaceutical business, including the acknowledgment of product patents, a protection period of 20 years from the application filing date, and the provision of patents for industrial applications. The Patents (Amendment) Act, 2005, broadened the scope of product patents to encompass all fields of technology, including food, pharmaceuticals, chemicals, and microorganisms.[10] The 2005 amendment was in consonance with Article 27(1) of TRIPS which stated that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".[11]

The most significant change brought about by the amendment is the elimination of Section 5 of the Patents Act, 1970. This section had previously stated that claims involving substances that were either intended for or could be used as food, medicine, or drugs, or that were related to materials that were prepared or made through chemical processes, could not be granted a patent. The abrogation of Section 5 of the Act enables the creation of product patents for pharmaceutical and other chemical innovations. Prior to this Amendment in the Act, Product Patents were not conferred for innovations pertaining to medications, foods, and chemicals; only process patents were awarded for these inventions.[12]

The 2005 Amendment, as amended by Section 3(d), clarifies that the sheer discovery of a new form of a known substance that does not result in the enhancement of the known efficacy of the substance is not an invention and, as a result, is not patentable.[13] The case of Novartis AG and Ors. v. Union of India[14] highlighted the need to mitigate the "evergreening" of patents while affirming the importance of providing patent protection for incremental breakthroughs. After *Novartis*, Indian courts have granted interim injunctions to protect patentees' rights in pharmaceutical[9] and agrochemical inventions.[15]

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[10] Shrishti Mittal, Patent- Types & Laws related to them in India, MANUPATRA (Feb. 9, 2025 9:49 PM), https://articles.manupatra.com/article-details/Patent-Types-Laws-related-to-them-in-India

[11] NIScPR PUBLICATIONS, https://nopr.niscpr.res.in/bitstream/123456789/27796/1/JIPR%2019%282%29%2079-88.pdf (last visited Feb. 11, 2025).

[12] Tilotma Singh, A critical evaluation of the Patent (Amendment) Act,2005, LAWYERSCLUBINDIA, (Feb.17, 2025, 9:29 PM), https://www.lawyersclubindia.com/articles/a-critical-evaluation-of-the-patent-amendment-act-2005-5574.asp

[13] Id.

[14] Id.

[15] WIPO, https://www.wipo.int/patent-judicial-guide/en/full-guide/india, (last visited Feb. 16, 2025).

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IV. IMPACT

The healthcare system in India has seen significant transformation in recent decades, mostly owing to advancements in pharmaceutical research and the critical use of generic medicines. The significance of intellectual property protection is escalating due to the growing recognition of the need to secure vital expenditures in research and development (R&D). India is implementing measures to tackle the issues related to the insufficient enforcement of existing intellectual property laws, while the government advances towards the creation of a patent system that promotes technological innovation and complies with its international commitments. India has shown leadership by creatively amending pharmaceutical patent rules to meet domestic health need.

The implementation of product patents and accompanying rules resulted in substantial changes within the Indian intellectual property protection system. The shift from the Patents Act of 1970 to the revised Act of 2005 has transformed the pharmaceutical sector. The legislation substantially modified the regulatory framework for generic drugs. Prior to these revisions, Indian producers were permitted to develop generic copies of patented medications by acquiring process patents. However, the introduction of product patents has enabled several pharmaceutical businesses, particularly multinational corporations, to acquire exclusive rights for the production and sale of new medications. This has resulted in a reduction in the accessibility of generics, especially for newly developed treatments, which often have elevated costs owing to insufficient market competition.

The influence of patent law on generic medicines is beyond India's boundaries, impacting worldwide access to cost-effective drugs. The implementation of product patents will eliminate concerns around reverse engineering, enabling Indian generic manufacturers to compete with foreign corporations. With the yearly introduction of new and enhanced medications on the market, pharmaceutical patents have become more crucial, since these drugs contribute substantially to income generation for commercial advantages. The Pfizer v. Natco Pharma[16] case underscores the Indian judiciary's endeavour to reconcile the protection of inventors' rights with the facilitation of public health access. The judiciary has regularly affirmed that patents should not be awarded for minor enhancements to existing pharmaceuticals, emphasizing that equitable access to medications is a significant public policy concern.

One of the ramifications that have followed is that “Indian firms involved in Research and Development have focused on the diseases prevalent in the developed countries other than those

[16] Pfizer Inc. v. Natco Pharma, Inc., 1:21-cv-00078, (D. Del.).

specific to India."[17] Pharmaceutical businesses are now motivated to innovate and create new patentable medications, hence promoting a culture of domestic innovation and to become internationally competitive sustainable pharmaceutical business that addresses local health requirements. The new product patent policy will attract increasing foreign direct investment in India. Too far, the involvement of pharmaceutical multinationals in the Indian market has been minimal due to stringent pricing regulations and the lack of product patents.

V. COMPULSORY LICENSING

In retaliation to the difficulties presented by rigorous patent protections, India has established procedures like compulsory licensing to preserve public health interests. This clause permits the government to sanction the manufacturing of a patented medication without the patent holder's approval under certain conditions, including instances when the medication is unavailable at a reasonable cost or during a public health crisis. The granting of compulsory licenses for essential pharmaceuticals has allowed Indian producers to formulate and market inexpensive generics, therefore successfully contesting the monopolistic activities of patent holders.

The issuance of a patent grants a restricted monopoly to the patentee, excluding others from its use. Despite the fact that the law permits this, it also recognizes the possibility of abuse of the monopoly granted through a patent and, as a result, imposes specific limitations on its enjoyment. The issuance of a compulsory license is a limitation placed on the unrestricted use of a patent. A Compulsory License is considered a legal instrument designed to safeguard the "public interest" against potential monopolistic exploitation by the patent holder. Compulsory licensing is the government's permission for third parties, or itself, to use a patented idea for production and sales without the consent of the patent owners. It is a legally established license that permits certain individuals to pay a royalty and use an innovation without the patentee's consent. Section 84[18] mandates that three years post-grant of a patent, any interested party may petition the Controller of Patents for a compulsory license to exploit the patented invention, asserting that the reasonable public demand for the invention remains unmet or that the invention is not available to the public at a reasonable price.

Article 31of the TRIPs Agreement permits such use without the consent of the rights holder. Under Section 92[19] of the Patents Act, 1970 the Central Government is empowered to issue

[17] Report of Commission WHO, Intellectual Property Rights, Innovation and Public Health, WHO https://iris.who.int/bitstream/handle/10665/43460/a88438_eng.pdf?sequence=1
[18] The Patents Act, 1970.
[19] Id.

compulsory licenses under certain conditions. Section 92A[20] authorizes the Controller to provide a compulsory license for the production and export of patented pharmaceutical goods to any eligible nation, provided that a compulsory license has been issued in that country. The justification for granting a compulsory license is rooted on a utilitarian perspective that emphasizes collective benefit.

Bayer Corporation v Natco Pharma Ltd[21] is a seminal case in the years-long disputes within the Indian pharmaceutical sector about compulsory licensing. This was the first instance in India when Natco Pharma received a compulsory license for the kidney cancer medication known as 'Nexavar.' The court in this case affirmed the principles of compulsory licensing, highlighting that patent rights should be applied in a way that promotes public interest and affordability.

VI. CHALLENGES

The implementation of product patents has presented several issues in the pharmaceutical industry. The enhancement of patent regime has led to a significant increase in the cost of indispensable medicines. Multinational pharmaceutical corporations, bolstered by exclusive patent rights, sometimes establish rates that are prohibitive for a substantial segment of the Indian populace. This circumstance intensifies health disparities and presents significant obstacles for public health systems attempting to provide inexpensive treatment. There is a perception that Multi-National Companies (MNCs) would possess a superior advantage in enhancing the rewards of intellectual property in emerging nations such as India. This is due to the fact that multinational corporations possess not just financial resources but also sufficient skill in effectively managing intellectual property portfolios. This constrains the expansion of local pharmaceutical firms, undermining national self-sufficiency in medication manufacturing. Furthermore prior to the implementation of product patents, India was recognized for its robust generic pharmaceutical sector. Generic producers must await the expiration of product patents, which postpones the introduction of more affordable alternatives.

VII. CONCLUSION

India is a developing market in the pharmaceutical business, gradually entering global markets and competing with worldwide quality standards and pricing. The need for innovation in the pharmaceutical business, which is intrinsically linked to human health and life, cannot be overstated. TRIPS compliance signified a new era for India's previously underdeveloped patent system. Pharmaceutical patenting in India has been contentious owing to the opposing aims of

[20] Id.
[21] Bayer Corporation v. Natco Pharma Limited, 2014(60) PTC 277 (BOM).

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fostering innovation and ensuring cheap access to important medications. Patents incentivize pharmaceutical businesses to engage in research and development, resulting in the invention of novel and enhanced medications. Conversely, patents may impede access to vital medications, resulting in elevated costs and diminished availability, particularly in low- and middle-income nations such as India.

In conclusion, the matter of pharmaceutical patenting in India is intricate and multifaceted, necessitating a balance between fostering innovation and guaranteeing access to important medications. Despite advancements in recent years, significant efforts are still required to guarantee universal access to necessary health care.

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