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IPR's Significance in the Pharma Sector

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Any rights connected to intangible assets that are owned by a person or business and are safeguarded against unauthorized use collectively constitute intellectual property rights. IPR gives the creators or developers of that property certain exclusive rights that allow them to make money commercially off of their creative endeavours or reputation. There are various ways to safeguard intellectual property, including patents, copyright, and trademarks. A patent is granted to an invention that satisfies the standards of all-encompassing novelty, non-obviousness, and industrial use. Improved innovation or creative work identification, planning, promotion, and protection are all dependent on IPR. A greater emphasis and plan will be required in the future as the pharmaceutical industry's IPR approach is currently changing.

Keywords: *drug, intellectual property, license, patent, pharmaceutical.*

INTRODUCTION

Regarding market share and its contribution to our nation's Gross Domestic Product, the Indian pharmaceutical business has experienced a phenomenal expansion in recent decades. The domestic pharmaceutical market in India is anticipated to reach USD 41 billion in 2021, USD 65 billion by 2024, and USD 120–130 billion by 2030. Given the bright future of the pharmaceutical sector, the Indian government is actively working to promote this sector by adopting and

implementing laws that are on par with international norms. The need for enterprises to secure their intellectual property rights grows as a result of market expansion and investment from key industry participants.

IPRs are known to have two main effects on the pharmaceutical industry. First, there is the topic of pricing and access, where the connection between IPRs (especially patent rights), the exclusion of rivals, and the accessibility and cost of new medications is discussed. Second, there is the problem of R&D incentives, or more specifically, the function of IPRs in motivating the discovery, development, and marketing of novel medicines, as well as the impact of IPRs on R&D spending and its distribution among diseases, nations, and organizations.[1] These two problems are strongly correlated, and their interaction poses several extremely challenging economic problems and policy dilemmas. One of the world's most resilient sectors is the pharmaceutical one. Whatever occurs, whether the economy is showing its most stable behaviour or is in a state of recession. Anyone can get sick or need their supplements medication at any time. In essence, the things are in use constantly. The following IPR categories apply to the pharmaceutical industry:

- Patents
- Industrial designs
- Trademarks
- Copyright
- Trade Secrets

IMPORTANCE OF IP IN THE PHARMACEUTICAL INDUSTRY

The pharmaceutical business places the biggest value on intellectual property because it is necessary for the continuous development of new medications, as seen in the points below:

[1] Iain M. Cockburn, 'INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICALS: CHALLENGES AND OPPORTUNITIES FOR ECONOMIC RESEARCH' (*WIPO*) <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1012-chapter5> accessed 20 November 2022

Medical Invention Protection: Once a person or business has created a novel drug or medical procedure, they must either file a patent application for it or keep it a trade secret to protect it. Contrarily, a patent provides far more robust protection because a drug cannot be reverse-engineered in the case of trade secrets, which could result in the innovation being stolen.[2]

Ensures Competitiveness and Economic Growth: Intellectual property enables pharmaceutical businesses to expand their economies significantly by giving the sole intellectual property rights to the originator of medicine or cure The exclusive owner of the invention's marketing rights, with the ability to sell or license it, is the inventor.[3]

Consumer and Family Protection: The public's safety is the primary concern of intellectual property in the pharmaceutical sector since it enables customers to make informed decisions when choosing medical products. By guaranteeing quality, intellectual property rights aid in ensuring a standard, which further builds a dependable and efficient public health infrastructure.

Generates responses to Global Problems: Innovation promotion is crucial, but finance is also required to make it happen. Intellectual property rights in the pharmaceutical sector encourage the development of medicines and vaccines for the new diseases that are being found constantly. They offer incentives for developing novel concepts into potential new medicines.[4]

Protection from Possible Infringers: Pharmaceutical companies can take tough action against fake pharmaceuticals, thanks to intellectual property rights. Without these rights, nations all over the world would struggle to guarantee the security of their medical inventions.[5]

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[2] Ashish Arora et al., 'Markets for Technology and Corporate Strategy' in Ove Granstrand (ed), *Economics, Law and Intellectual Property* (Springer New York 2003)
[3] Iain M. Cockburn (n 1)
[4] R.M. Gadbaw et al., *Intellectual Property Rights: Global Consensus or Global Conflict?* (Avalon Publishing 1988)
[5] Bruce Rasmussen, 'Aspects of the Pharmaceutical Business Model: Implications for Australia' (*Centre for Strategic Economic Studies Victoria University of Technology*, August 2003) <https://kipdf.com/aspects-of-the-pharmaceutical-business-model-implications-for-australia_5b0dfca07f8b9a3c9b8b457d.html> accessed 20 November 2022

THE ROLE OF THE PATENT COOPERATION TREATY

The International Patent Cooperation Treaty (PCT) went into effect in 1978. An inventor from a member country contracting state of PCT can simultaneously obtain priority for his or her invention in all or any of the member countries by designating the countries of interest in the PCT application, without having to submit a separate application in each of the countries of interest The Geneva-based World Intellectual Property Organization (WIPO) oversees the coordination of all PCT-related operations.[6]

It is necessary to submit a separate patent application in every country of interest to get priority in these nations and protect ideas there. In some situations, this must be done within a certain amount of time. This would require a significant financial outlay within a short period to cover costs for filing fees, translation, attorney fees, etc. Additionally, it is believed that the decision regarding whether or not to file a patent application in a particular nation may not be properly justified due to the limited time available for doing so. On the other hand, inventors of PCT participating states can simultaneously get priority for their discoveries without needing to submit separate applications in the countries of interest, saving the initial costs for filing fees, translation, and other related expenses. Additionally, the method offers much more time for member countries to file patent applications.[7]

According to the Paris Convention, you have 12 months from the date of your initial filing to obtain priority in other nations. The time allotted under the PCT could range between 20 and 31 months in length. The search report created under the PCT procedure also helps an inventor to confirm if the claimed invention is new. To be doubly certain that the invention qualifies for patent protection, the inventor may choose to have a preliminary examination performed before filing in other nations.

[6] *WIPO Intellectual Property Handbook* (first published 2004, WIPO Publication 2008)
[7] M Angell, 'The pharmaceutical industry--to whom is it accountable?' (2000) The New England Journal of Medicine <https://www.nejm.org/doi/full/10.1056/NEJM200006223422509> accessed 20 November 2022

THE INDIAN PHARMACEUTICAL INDUSTRY'S USE OF PATENT LAW

The Patent Act of 1970 contains the legislation that governs patents in India. The Paris Convention of 1883 and the Patent Cooperation Treaty (PCT) of 1970 both have India as a signatory. The Patents Act outlines the requirements for a patent that must be met for it to be protected:

- It must be novel.
- It should not be immediately obvious.
- It must be helpful to qualify as patentable material.

According to the Act, some inventions are not patentable, such as:

- Agricultural or horticultural techniques.
- Processes of surgical, curative, or prophylactic procedures or,
- Treatment methods for people, animals, plants, and other substances that are simply the outcome of mixing, which aggregates the properties of the constituent parts, include surgical, curative, preventative, and other treatments.

Chemical processes are used to create the chemicals that are intended for use or capable of being used as food compounds, drug compounds, or even medicines or products, and these processes are protected in Indian pharmaceuticals. Patents are not granted for the full compound product but rather for the processes or procedures used to produce such chemical process products. Patents are not issued for the entire compound product itself but rather for the techniques or methods of manufacturing such products of chemical processes. Therefore, due to the following reasons, pharmaceutical "products" are now protected by a patent under Indian law:

- Strong reliance on the importation system.
- Bulk imports are expensive and put profitable businesses in a better position.
- Since branded pharmaceuticals have a higher reputation on the market, local brands are not encouraged to produce these products.
- The prices will rise if the products are protected.

- Only consumers in upper economic strata will be able to purchase it, and cost inflation will make it less affordable and make the consumer base more susceptible to sickness.
- The local brands' research and development efforts will suffer in the country.[8]

MANDATORY LICENCING IN INDIA FOR PHARMACEUTICALS WITH PATENTS

According to laws regarding compulsory licensing in the Patents Act, anybody who is interested in working on a patented innovation may request a compulsory license for the development of that specific drug after three years have elapsed after the patented medicine was sealed. The controller of patents has the authority to order the drug's patent holder to award the license in question on the conditions it sees proper, which must take into account not only the patent holder's satisfaction with the drug but also whether or not the reasonable pricing criteria have been met. This aids in keeping the consumer base satisfied and prevents a monopoly in the market.

LAW OF TRADEMARKS AND THE PHARMACEUTICAL SECTOR

Drugs from various pharmaceutical businesses are greatly protected by trademark registration, which also significantly increases the value of the drug's brand name in the marketplace. The pharmaceutical business especially accounts for the bulk of trademark registrations in India as compared to any other industry.

Drugs are protected as trademarks:

The protection of pharmaceutical trademarks is more challenging than that of other trademarks. The Trademark Act of 1999's Section 9(a) prohibits the registration of trademarks that are descriptive or lack any distinctiveness, i.e., are unable to distinguish between the goods or services from one source from another and are of a type to deceive the public or cause confusion. Such trademarks are also prohibited from being used in advertising. But after lengthy usage and market familiarity, the trademark has acquired a secondary meaning or a distinctive character.

[8] Amit Aggarwal et al., 'Intellectual Property and the Indian Pharmaceutical Industry' (*DRUG* DISCOVERY & DEVELOPMENT, 10 February 2016) <https://www.drugdiscoverytrends.com/intellectual-property-and-the-indian-pharmaceutical-industry/#:~:text=Intellectual%20Property%20Rights> accessed 20 November 2022

Because the brand name or drug name is frequently taken from the treatment that the drug offers, the salt composition of the drug, or any other associated medical word, pharmaceutical trademarks in particular lack an intrinsic distinctive quality. However, for a mark to be considered a trademark, it must be "distinctive."

Additionally, a trademark cannot be confusingly similar to an earlier property, as defined by Section 11 of the Trade Marks Act, 1999. To prevent or minimize errors when purchasing pharmaceutical goods or drugs, customers should be able to quickly distinguish between goods based on a brand name, drug name, and trade dress. As a result, it is more challenging to protect a brand name or drug name, and evidence about the secondary meaning or acquired distinctive character is the factor used to ascertain distinctiveness.

ALTERNATIVE TRADEMARK PROTECTION

Pharmaceutical businesses have started to use cutting-edge and creative strategies to help set their products apart from those of their rivals in the market today. Therefore, rather than only using the brand name or drug name to protect their products, pharmaceutical businesses are turning to non-traditional methods. This underlines the trademark's distinctiveness and aids in preventing customer confusion and deceit.

In the pharmaceutical sector, in particular, non-traditional or unconventional marks include trade dress, drug colour combinations, and drug shapes. It's interesting to note that pharmaceutical firms have registered sound markings in India, such as the Japanese company Hisamitsu Pharmaceutical Co. Inc.'s "HI-SA-MI-TSU" sound mark. As registered colour trademarks, "The Purple Pill" from AstraZeneca's Nexium and "Red and White" from SK&F's Dyazide have helped the companies establish their respective brand identities. In the case of Cadila Health Care Ltd v Cadila Pharmaceuticals Ltd. [2], the Supreme Court of India established a list of criteria for deciding whether two pharmaceutical trademarks are deceptively similar, including:

- Whether the marks are word, label, or compound marks, or their nature;
- The degree of likeness, or similarity of idea or sound, between the markings;

- The makeup of the goods;
- The type of consumers, their level of education and intelligence, and the level of caution they are likely to exercise when buying and/or using the goods;
- The method of purchasing the goods or placing orders for the goods; and
- Any other environmental factors that may be relevant in determining how dissimilar the competing marks are from one another.

PATENT LAW AND THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry has always required significant investments and relied heavily on knowledge. Compared to other sectors or businesses, the pharmaceutical industry requires significantly more time to develop products before they achieve a successful conclusion. Therefore, it becomes crucial for pharmaceutical businesses to get patent rights to protect their inventions[9]. In addition to protecting the capital made in research and development, patents foster innovation by encouraging inventors to pursue new ideas. However, due to legal issues, the patentability of pharmaceutical ideas has always been hotly contested, especially in India. In addition to meeting the criteria for universal patentabilities, such as novelty, inventive step, and industrial usefulness, pharmaceutical discoveries and those connected to them must also pass the litmus test outlined in Section 3 of the Patents Act of 1970. The Patents Act of 1970 specifies the number of inventions that are not patentable subject matter, even though they meet the criteria for patentability. Pharmaceutical inventions are covered by Section 3(d) of the Patents Act of 1970, which reads as follows:

"The mere discovery of any new property or use for any known substance; the mere use of any known substance in a new form that does not increase the known efficacy of that substance; or the mere use of any known process, machine, or apparatus, unless such use produces a new product or uses at least one new reactant. Explanation: For this clause, the same substance includes salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers,

[9] C.T. Taylor & Z.A. Silberston, *The Economic Impact of the Patent System* (Cambridge University Press 1973)

mixtures of isomers, complexes, combinations, and other derivatives of known substances, unless their properties significantly differ in terms of efficacy.[10]

It is significant to note here that the Indian Patent Office offers the chance to submit supplementary documents or experimental investigations to support the "therapeutic efficacy" of the invention, which was not specified in the specifications at the time the application was filed. About the patenting of combination inventions in the fields of chemical and biotechnological sciences, Section 3(e) of the Patents Act, 1970, states A process for producing such a substance or a substance obtained by a simple admixture that only aggregates the properties of its components are not patentable.

The simple combination of two or more materials that perform the same purpose without the employment of any innovative faculties is not patentable, according to a key concept of the Indian Patent Laws. If the interactions between these elements provide novel or enhanced outcomes, the subject matter is regarded as patentable It has been observed that the technique of treatment claims is frequently made in the context of composition claims in the field of medicine. It is crucial to remember that any claim about treatment is not a patentable invention in India. However, medical, therapeutic, or diagnostic devices or equipment may be eligible for a patent.

CONCLUSION

Pharmaceutical businesses must ultimately allocate marketing, legal fees, and research and development funds. To compete with generic manufacturers, pharmaceutical businesses must make use of the advantages of patent protection and data exclusivity. But above all, pharmaceutical firms need to have a strong patent protection program and an efficient intellectual property strategy that will maximize returns on investment. Managing IP and IPR requires a variety of activities and techniques, all of which must comply with local laws as well

[10] A. Subramanian, 'Putting Some Numbers on the Pharmaceutical Debate' (1994) International Journal of Technology Management

as international conventions and standards. It is no longer solely influenced by a national viewpoint.

The market's demands, reaction, the expense of converting IP into a business enterprise, and other factors significantly impact IP and its related rights. In other words, the administration of IPR must take into account issues relating to trade and commerce. Diverse IPR forms necessitate various management, planning, and strategy approaches, as well as the participation of experts in a range of fields, including science, engineering, medicine, law, finance, marketing, and economics. Antitrust law must step in to prevent the improper claim of invalid rights to establish and sustain illegitimate, albeit temporary, monopolies within the pharmaceutical industry, given the greater likelihood that some IPRs are invalid. In this context, many issues still need to be handled.