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"Intellectual Property Rights and the Pharmaceutical Industry in India: Evolving Strategies in a Globalized Market"

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Abstract

As a result of globalization, being ahead of the trends in terms of creativity and invention is crucial for thriving in the face of intense economic and technological competitiveness. In several technical domains, including software engineering, missile technology, and missions to the Moon or Jupiter, India's brilliance has been widely acknowledged. The number of registered patents, industrial designs, trademarks, etc., is one indicator of India's intellectual property asset creation gap. India ranked 29th out of 30 nations in the world for intellectual property (IP), according to a recent assessment by the US Chamber of Commerce.

Both for policymakers and the country at large, this is a highly concerning situation. An effective framework for IPR is crucial to any society's progress. The innovation death spiral, high infringement risk, economic loss, and intellectual era decline in the nation were all caused by a lack of intellectual property rights knowledge. In order to encourage more domestic research and technological advancements, it is essential to disseminate knowledge on intellectual property rights relating to pharmaceutical sector.

This study traces the evolution of intellectual property rights from global origins to India's legal framework, emphasizing their impact on innovation in the pharmaceutical sector. It examines patent protection, trade secrets, and landmark judicial decisions, highlighting how India balances international compliance, industry competitiveness, and public welfare in managing IPR.

Keywords- globalization, intellectual property rights, innovation, pharmaceutical, technological and etc.

1. INTRODUCTION

The term "intellectual property rights" (IPR) refers to the legal protections afforded to works of creative expression, including ideas, inventions, and literary works, that the general public is prepared to treat as private property. The purpose of IPR is to allow the people who created something to profit from their work and build a name for themselves. Copyright, trademark, patent, and other forms of intellectual property protection exist. An innovation that meets the requirements of worldwide originality, non-obviousness, and industrial use may be recognized with a patent. Proprietary rights are necessary for the proper discovery, development, marketing, and protection of creative works. Different industries should develop unique intellectual property rules, management philosophies, tactics, etc., based on their own fields of expertise. There is a

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need for a more targeted and efficient approach in the pharmaceutical industry's expanding intellectual property strategy in the next age.[1]

1.1 Research Questions

1. How has the evolution of global intellectual property frameworks influenced the development of India's IPR laws and policies?
2. What role do intellectual property rights play in fostering innovation and competitiveness in the Indian pharmaceutical industry?
3. How can India's IPR regime balance innovation incentives with public health and equitable access to medicines?

1.2 Research Methodology

The methodology used in the paper is doctrinal in nature. The researcher has gathered information from both primary and secondary sources like statutes, case laws, commentaries, reports, books, journal articles and websites.

2. TRACING THE JOURNEY OF INTELLECTUAL PROPERTY RIGHTS: FROM GLOBAL ORIGINS TO THE INDIAN FRAMEWORK

2.1 Evolution and Development of Intellectual Property Laws

European countries are the cradle of IPR legislation and administrative processes. It was in the fourteenth century when patents first began to be popular. England used to entice craftsmen from other nations on favorable conditions since it was technologically sophisticated compared to other European countries in several subjects. Italy was the birthplace of the first copyrights. Due to the concentration of intellectual property (IP) law and policymaking in Venice, the city-state may be said to have been the birthplace of IP as we know it today. The Indian Patent Act is about 150 years old. The first of these measures, the 1856 Act, established a fourteen-year patent term modeled after the British patent system; subsequent acts and revisions built upon this foundation.

Any innovation that meets the requirements of being both innovative and non-obvious as well as having potential for use in a commercial or industrial setting may be granted a patent. Products and methods are both eligible for patent protection. A patent in India would typically be valid for 14 years from the filing date, according to the Indian Patent Act of 1970. However, for methods used to make food or pharmaceuticals, the patent would be valid for either 7 years from the filing date or 5 years from the patent's effective date, whichever came first. Medications and foodstuffs did not get any patents. There is no need to register a copyright that is created in a nation that is a member of the Berne Convention; all member countries will automatically protect it. India has

[1] Yaeko Mitsumori, *The Indian Pharmaceutical Industry: Impact of Changes in the IPR Regime* 125-131 (Springer 2018).

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excellent copyright laws on par with any other nation, and the country is a party to the Berne Convention. But in nations that aren't signatories to the Berne Convention, copyright protection won't be accessible immediately. Consequently, copyright may not be a territorial right in the literal sense. Ownership rights to intellectual property may be donated, sold, or transferred just like any other kind of property.[2]

The legal regime governing Intellectual Property Rights (IPR) in India has evolved significantly over time, aligning domestic laws with international standards set by the World Trade Organization (WTO) and the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights). The principal legislations governing IPR in India include:

- The Patents Act, 1970 (as amended in 2005) – governing inventions and ensuring product patent protection in compliance with TRIPS.
- The Copyright Act, 1957 (as amended in 2012) – protecting literary, artistic, and musical works.
- The Trade Marks Act, 1999 – safeguarding brand identity and preventing deceptive use of marks.
- The Designs Act, 2000 – protecting industrial designs.
- The Geographical Indications of Goods (Registration and Protection) Act, 1999, and
- The Semiconductor Integrated Circuits Layout-Design Act, 2000, among others.

India is also a signatory to several international conventions such as the Paris Convention (1883), Berne Convention (1886), and the WIPO Convention (1967), reflecting its commitment to global IP protection standards.

2.2 Protection of Undisclosed Information and Trade Secrets

While corporations, R&D institutions, and other organizations working with IPR may not give it much thought, protecting confidential information is one of the most critical forms of protection. Any formula, pattern, compilation, program, device, method, technique, or process that is not publicly revealed is considered confidential or a trade secret. The practice of keeping essential information under wraps, usually by sharing it exclusively within close family, is not new to mankind; in fact, it has been around for as long as there have been humans. Although India has laws in place to protect many types of intellectual property, none of them specifically address the protection of concealed knowledge, trade secrets, or sensitive data.[3]

[2] Bindusha HC, 'Intellectual Property Rights Issues in Indian Pharmaceutical Industry' (2021) 33(38B) Journal of Pharmaceutical Research International 281–286.
[3] Dinesh Thakur and Prashant Reddy Thikkavarapu, *The Truth Pill: The Myth of Drug Regulation in India* 89 (Simon & Schuster India 2022).

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From the 1950s through the 1980s, when globalization and internationalization were not pressing concerns, many nations, India included, were able to get by without a robust system of intellectual property rights. Research and development (R&D) budgets have ballooned due to globalization's push from the chemical, pharmaceutical, electrical, and information technology (IT) sectors. Reduced product cycle time and increased vulnerability to reverse engineering by rivals are hallmarks of this technique. It became clear to businesses that trade secrets weren't enough to secure a technology. Without standardized regulations and laws governing copyright, patents, trademarks, etc., it was difficult to capitalize on breakthroughs. That is how IPR became a vital part of the WTO.

3. IPR AND INNOVATION IN THE PHARMACEUTICAL INDUSTRY

The pharmaceutical and drug-related technical sectors most closely fit the profile of globalization and the need of a robust IP system. Because of the high potential costs and dangers involved in developing and releasing a new medicine to the public, no business is willing to take the chance that its intellectual property may become public domain without sufficient compensation. Intellectual property (IP) creation, acquisition, protection, and management should be considered a core business function alongside capital raising. A unique position for intellectual property and treatment inside the decision-making process will be necessary in the knowledge revolution that we are certain to see.[4]

The pharmaceutical sector is highly competitive on a worldwide scale, and companies rely on scientific understanding and research and development (R&D) more than manufacturing know-how to succeed. As a result, the pharmaceutical sector pours a substantial amount of money into research and development (R&D), with estimates putting the figure at 15% of revenues. Managing creative risks in pursuit of a competitive edge is a major challenge for businesses operating in this sector. In pharmaceutical research and development, there is a significant cost associated with the risk of failure, which may lead to the termination of prospective medications that fail to fulfill the rigorous safety criteria, even after years of investment.

From the date of chemical synthesis all the way to the date of drug approval, the development process may take anywhere from eight to ten years. As product patents become the primary means of IP protection, pharmaceutical firms will need to reorient their research and development efforts away from creating novel methods for manufacturing existing pharmaceuticals and toward creating novel drug molecules and NCEs. Following an era of effective treatment of several short-term disorders, the emphasis of research and development moved to long-term (chronic) diseases in the 1980s. Finding success in the global market necessitates adhering to the rules set down by various regulatory bodies.

[4] Tare Harshal, 'Challenges Faced by Indian Pharmaceutical Companies in Protecting Various Forms of Intellectual Property Rights' (2022) 6(S6) International Journal of Health Sciences 6167–6175.

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It is well-known that the number of documentation required by regulatory bodies has almost quadrupled during the last decade. Furthermore, the time it takes for regulatory bodies to approve a new medication has significantly increased. As a consequence, you'll have to work harder to get enough money since the patent protection term is shorter. Medications created using biotechnology, particularly those that use genes, may be in an even more precarious position. The developed world will probably start lobbying for medicine patent extensions shortly.[5]

More and more price controls might be implemented by numerous countries in order to achieve public objectives. Efforts to cut the cost of medication research, manufacture, and marketing should be prioritized. Simultaneously, lower profit margins should be planned for in order to amortize expenses over an extended time. Therefore, it is clear that the pharmaceutical sector must navigate several competing demands. Over the past ten to fifteen years, a plethora of tactics for achieving cost reduction and trade advantage have emerged. Research and development (R&D) outsourcing, R&D partnership formation, and strategic alliance establishment are a few examples.

Managing IPR is clearly a complex undertaking requiring a wide range of approaches, all of which must be in harmony with applicable domestic legislation as well as international treaties and norms. The interests of the country are no longer its exclusive motivator. The demands of the market, the reaction of the market, the expense of turning IP into a business enterprise, and other factors have a significant impact on IP and the rights attached to it. Which is to say, when it comes to managing intellectual property rights, trade and commerce factors play a significant role.

IPR come in many forms and need experts in fields as diverse as economics, engineering, medical, law, finance, marketing, and research to properly manage, develop, and implement plans. The IP policies, management philosophies, tactics, etc. of any given industry should develop independently of those of any other. An IP strategy is now being developed by the pharmaceutical sector. Since there is a greater chance that certain intellectual property rights are not legal, antitrust law must intervene to prevent the pharmaceutical sector from establishing and maintaining illegitimate, but limited, monopolies via the unlawful assertion of defective rights. In this context, there are still many unanswered questions. Having a solid grasp of science, technology, and the law is essential when crafting patent specifications; this is a talent that takes time and practice to master. A patent's claims are its "heart" and the source of any legal claim to exclusive information. While the ability of a known substance to endure mechanical stress may not be patentable, the use of same substance as a train sleeper may be. Even if a material isn't novel, its novel quality may have led to its discovery. If it shows a novel effect when combined with other known chemicals, it might be patented. This is due to the fact that no one has ever utilized this particular combination to create a medication, fertilizer, or pesticide before. A new molecule may have been developed,

[5] Gomase VS, 'Intellectual Property Rights Effects on India's Pharmaceutical Industry' (2025) Bentham Open Access Journal 1–10.

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but its exact structure remains a mystery. In this situation, it will be crucial to describe the chemical, its qualities, and the process used to make it.

Landmark judicial decisions have further shaped India's IPR jurisprudence. In "*Novartis AG v. Union of India*"[6], the Supreme Court denied a patent for the cancer drug Glivec, reinforcing Section 3(d) of the Patents Act to prevent "evergreening" of patents and ensure affordable access to medicines. In "*Bayer Corporation v. Union of India*"[7], the Bombay High Court upheld the first compulsory license granted in India, emphasizing public health over monopolistic control. In "*Eastern Book Company v. D.B. Modak*"[8], the Supreme Court defined the originality standard for copyright protection in compilations.

Thus, India's IPR regime seeks to balance innovation incentives with public welfare, ensuring equitable access while promoting research and creativity.

4. CONCLUSION AND SUGGESTIONS

Everything that is novel and created by humans, whether it be works of art, literature, technology, or science, is considered intellectual property (IP). Legal protections granted to an inventor or creator to use and profit from his work for a certain amount of time are known as IPR. During the duration of these legal protections, the inventor or his assignee will have the only right to make full use of the innovation. There can be no doubt about the importance of intellectual property in today's economy.

Also, it's a done deal that the innovation's accompanying intellectual effort deserves serious consideration so that the public benefit may be realized.Research and development (R&D) expenses, along with the corresponding increases in capital needed to bring a new technology to market, have seen a quantum leap.

Technology developers today have a lot riding on their work, therefore it's more important than ever to keep their expertise safe from prying eyes. This is necessary, at least temporarily, to recoup the expenses of research and development (and everything else related to it) and make enough money to keep investing in R&D. IPR are a powerful instrument for safeguarding the financial, time, and effort put in by an IP's author or inventor by granting them a temporary monopoly on the use of their work. With the promotion of healthy competition and the encouragement of industrial development and economic progress, IPR therefore contribute to a country's economic development.

[6] (2013) 6 SCC 1.
[7] (2014) 60 PTC 277 (Bom.).
[8] (2008) 1 SCC 1.

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Suggestions

- Strengthening patent examination processes to ensure faster and more transparent approvals.
- Encouraging compulsory licensing to balance public health needs with innovation incentives.
- Promoting public-private R&D collaborations to reduce costs and accelerate drug development.
- Enhancing IP awareness and training for professionals in law, research, and pharmaceuticals.
- Harmonizing domestic and international IP policies to improve competitiveness while safeguarding access to medicines.

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