ROLE OF INTELLECTUAL PROPERTY IN THE PHARMACEUTICAL INDUSTRY OF INDIA

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ABSTRACT

The pharmaceutical industry is driven by innovation and the development of new drugs and therapies to improve human health. Intellectual Property (IP) is critical in this sector because it provides legal protection for the unique ideas, inventions, and discoveries that serve as the foundation for pharmaceutical developments.

Patents, trademarks, copyrights, and trade secrets are the most common types of intellectual property in the pharmaceutical sector. These types of intellectual property protection allow pharmaceutical companies to protect their R&D investments, promote innovation, and assure fair market competition. The most valuable asset of a pharmaceutical or biotech firm is intellectual property (IP), which is critical for the sector's future development. Intellectual property is a critical component in the safe development of innovative medications and therapies. This paper attempts to study the different types of Intellectual property rights and their role in the pharmaceutical Industry. The author focuses on the importance of interconnectedness between the pharmaceutical sector of India and Intellectual property rights.

Keywords: *Drugs, Innovation, Intellectual property, Inventions and Pharmaceutical.*

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1. INTRODUCTION

As time goes on and technology advances, people who come up with new things are getting the recognition and special rights they deserve because of the worldwide recognition and growth of intellectual property rights. Intellectual property is defined as intangible property with no physical value, and it includes innovations, literary works, artistic works, designs, symbols, and trade names. A notable comment respecting intellectual property rights was delivered in a British judgement: "What is worth copying is prima facie worth protecting." The phrase "intellectual property rights" (IPR) refers to the legal rights provided to the author or inventor to protect their work for a set length of time. In recent decades, the Indian pharmaceutical business has expanded dramatically, both in terms of market share and impact on our country's GDP. As the market expands and significant industry participants invest, the necessity for firms to preserve their intellectual property rights develops. The pharmaceutical sector should have a solid intellectual property strategy in place to ensure strong patent protection while also maximising profits on investment[1]. The key to discovering new pharmaceuticals is to foster creativity, and IPR can help you acquire a competitive advantage. The author attempted to investigate the relationship between intellectual property rights and the pharmaceutical industry in this research.

2. INTELLECTUAL PROPERTY: CONCEPT AND TYPES

2.1 Meaning

The collection of legal rights granted to a creator or owner of intellectual property is referred to as "intellectual property rights" (IPR). These are the rights that an individual has over his or her intellectual works. By rewarding the creators for their mental labour and preserving their ownership rights over their works, IP rights intend to preserve their interests. Thus, innovators and creators are permitted to profit from their innovations. The legal rights that control the use of intellectual property are known as IP rights.

[1] Amitav Singh, *Intellectual Property Rights in Pharmaceuticals*, ACADEMIKE (Aug 7, 2023, 5:00 PM), https://www.lawctopus.com/academike/intellectual-property-rights-in-pharmaceuticals/

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2.2 Why there is a need to provide legal safeguards to Intellectual property?

- **Boosting Inventions and Creations:** These laws encourage people to come up with new works and inventions that help society grow. By giving creators exclusive rights, they can earn money from their work, which motivates them to keep inventing and creating.
- **Keeping Creations Safe:** These laws provide a legal shield for creative things. This means that the law stands up for the people who make things like art, music, inventions, and more.
- **Stopping Others from Using Your Stuff:** These laws stop other people from using someone else's creative work without permission. This way, creators get to enjoy the benefits of their own hard work.
- **Making Trading Fair:** These laws help make sure trading and business dealings are done fairly. Nobody can just take someone else's work and use them without permission.
- **Boosting Creativity and Sharing:** These laws encourage people to be creative and then share their creations.
- **Recognizing Effort:** These laws give credit to the people who put in the effort to create something new. It's like a pat on the back for their hard work.
- **Stopping Unauthorized Use:** These laws prevent others from using someone's creation without permission.
- **Encouraging Investment:** These laws make it a good idea for people to invest their time, skills, money, and other resources into coming up with new and innovative things. This benefits everyone in society.

2.3 Types of Intellectual Property Rights:

2.3.1 Copyright

"*Copyright protects the rights of authors, i.e., creators of intellectual property in the form of literary, musical, dramatic and artistic works and cinematograph films and sound recordings*"[2].

Copyright is a type of protection for people who create original things like books, plays, music, art, movies, recordings, computer programs, graphs, and more. It even covers things like computer databases that can be written down, coded, or shown in other ways.

Copyright rules don't protect just ideas, but they do protect how those ideas are turned into something real. This could be a story, a play, a song, a painting, a movie, or even a recording of sound. These protections are explained in Section 13 of the Copyright Act of 1957[3].

In sections 14 and 57 of the Copyright Act, it is stated that the person who made something creative and artistic, like music, art, computer programs, and more, gets to have both economic rights[4] (like making money from it) and moral rights[5] (like being recognized as the creator).

2.3.2 Trademark

Simply said, consider a trademark to be a type of "source identifier." It's similar to a useful label that not only identifies the source of goods or services but also distinguishes them from competing goods and services. The Trademark Act, 1999 governs trademarks in India[6]. A trademark is anything that can be used to identify a business, a product, or another entity, including a symbol, logo, phrase, term, or tagline that, among other things, identifies a specific product. According to the Act, a trademark is a symbol that can distinguish one person's goods or services from those of another in the course of commerce and can be graphically represented.

2.3.3 Patent

[2] *A Handbook of Copyright Law*, GOVERNMENT OF INDIA (Aug 9, 2023, 6:00 PM), https://copyright.gov.in/documents/handbook.html#:~:text=Copyright%20protects%20the%20rights%20of,cinematograph%20films%20and%20sound%20recordings

[3] Copyright Act, 1957, § 13, No. 14, Acts of Parliament, 1957 (India).

[4] Copyright Act, 1957, § 14, No. 14, Acts of Parliament, 1957 (India).

[5] Copyright Act, 1957, § 57, No. 14, Acts of Parliament, 1957 (India).

[6] Trademark Act, 1999, No. 47, Acts of Parliament, 1999 (India).

A patent is an exclusive right given for an invention that offers a new technical approach to a problem or presents an innovative means of doing something. This innovation can be a product, a method, or a process. For inventions with economic and industrial value, a patent is given. In exchange for disclosing the innovation, you are given the sole right to produce the novel product using the inventive technique for a set amount of time (often 20 years from the application filing date). An owner of a patent may sell it or grant another party a licence to use it.

Patentability criteria:

1. It must be original.
2. It must be non-obvious
3. It must be suitable for industrial use.

A thorough process for getting a patent, from application submission to patent issuance, is laid out in the Patent Act of 1970[7].

2.3.4 Industrial Design

Industrial design refers to the ornamental or visually appealing elements of a product. It could include two-dimensional elements like lines, patterns, or colour, as well as three-dimensional elements like the shape of an object. Industrial design is merely aesthetic, utilitarian, and non-functional. To prevent others from imitating an industrial design, its creative originality must be given legal protection. By allowing the owner of a registered industrial design a limited-time monopoly right to use that design, the Designs Act of 2000 aims to balance competing interests and encourage the development of fresh, original designs[8].

2.3.5 Geographical Indications

Products with a particular geographic origin are identified using a geographical indication (GI). These signs indicate the quality, reputation, or additional attributes of these commodities that are primarily related to their place of origin. GIs are typically utilised for food, agriculture, wine, industrial goods, and handicrafts. GI products include things like Basmati rice and Darjeeling

[7] Patent Act, 1970, No. 39, Acts of Parliament, 1970 (India).
[8] Designs Act, 2000, No. 16, Acts of Parliament, 2000 (India).

tea. The Geographical Indications of Goods (Registration and Protection) Act, 1999 enables the registration of geographical indications relating to goods and enhances their protection[9].

2.3.6 Trade Secrets

Trade secrets are intellectual property rights on private knowledge that can be licenced or sold. Any proprietary business information, such as plans, blueprints, drawings, company strategies, R & D-related data, etc., is referred to as a trade secret. The information must be helpful in a trade or company, be known only to a small number of persons, and be subject to reasonable measures taken by the legitimate owner of the information to keep it hidden in order to be considered a trade secret.

3. PHARMACEUTICAL INDUSTRY AND IPR

3.1 Pharmaceutical Sector: Origin and Development

The pharmaceutical industry, which dates back centuries, has experienced significant modernization. Herbal treatments and early medical practices were pioneered by ancient cultures. The contemporary pharmaceutical industry, on the other hand, evolved in the nineteenth century, propelled by developments in chemistry and synthetic drug manufacture. This industry has evolved tremendously since then. Scientific advances, technological improvements, and regulatory changes have rocketed it to new heights. The emphasis changed from simple treatments to complex, tailored medicines. Pharmacology, genetics, and biotechnology are now driving drug discovery, enabling for personalised precision treatment. Globalisation and connectedness have accelerated knowledge interchange, fostered collaborative research and international corporations, accelerated medicine development, and improved access.

Nonetheless, these advancements are accompanied by problems. High research expenses, lengthy regulations, affordability, and equitable drug access continue to be issues. Patent

[9] Geographical Indications of Goods (Registration and Protection) Act, 1999, No. 48, Acts of Parliament, 1999 (India).

protection, pricing, and the profit-public health trade-off are all topics of ethical controversy. In conclusion, the pharmaceutical industry's historical path from ancient cures to current achievements represents an astounding evolution. While progress has improved well-being and lengthened life, continued attempts to address complicated issues of research, access, and ethics in this essential subject remain critical.

3.2 Nexus between IPR and the Pharmaceutical Industry

The pharmaceutical industry invests significant resources, time, and capital in research and development (R&D) to discover and develop new medicines. Intellectual property rights play a crucial role in providing incentives for these investments. Patents, in particular, grant exclusive rights to the inventor for a limited period, typically 20 years, during which they can recoup their investment and gain a competitive advantage. This exclusivity encourages companies to undertake risky and costly R&D endeavours, fueling the innovation necessary for breakthrough treatments and medical advancements[10].

Intellectual Property Rights (IPR) play a crucial role in protecting the pharmaceutical industry in several ways:

- Eliminating Unauthorised Use or Reproduction: Pharmaceutical companies' intellectual property rights safeguard them from unauthorised use or reproduction of their patented products. Patent infringement rules allow patent holders to sue companies or individuals that create or distribute unauthorised counterfeit or generic copies of their patented drugs. This safeguard ensures that pharmaceutical companies retain control over the manufacture, distribution, and sale of their unique products, preventing revenue loss and preserving market integrity.

- Ensure Patient Safety as well as Quality Control: In the pharmaceutical sector, intellectual property rights such as trademarks and copyrights play a role in guaranteeing

[10] Vedant Kuchhal and Dhannjay Singh Pundir, *An Overview of the Pharmaceutical Industry and Its Implications in Terms of IP Laws*, 6 INT'L J. L. MGMT & HUMAN. (2023)

patient safety and maintaining quality control. Trademarks assist consumers in identifying and trusting certain pharmaceutical items, ensuring genuine and safe treatments. Copyright protects the original expression of product labels, packaging inserts, and promotional materials, ensuring that healthcare professionals and patients receive accurate and reliable information.

- Incentives for Innovation: Intellectual property rights, particularly patents, provide a legal framework for safeguarding new drug discoveries and technologies. To create new pharmaceuticals, pharmaceutical companies invest enormous resources, time, and skill in research and development. Patents provide these corporations exclusive rights, allowing them to recoup their investments and incentivize additional innovation. This safeguard encourages pharmaceutical companies to take risks and invest in the discovery of new and improved treatments, hence advancing healthcare forward[11].

- Commercial Exclusivity: IPR grants pharmaceutical corporations market exclusivity for a set period of time, usually 20 years. This exclusivity precludes competitors from producing, using, or selling the same medicine without the consent of the patent holder. Pharmaceutical businesses can gain a competitive edge, recoup their investments, and create revenue by obtaining market exclusivity. It also allows businesses to recoup the costs of research, clinical trials, and regulatory processes required for drug development.

- Encouraging Collaboration and Technology Transfer: Intellectual property rights (IPR) encourage collaboration and technology transfer in the pharmaceutical sector. Pharmaceutical businesses can share their knowledge, skills, and technologies with other entities through licensing agreements and collaborations. This relationship boosts creativity, speeds up medication development procedures, and encourages the sharing of ideas and technologies. IPR protection ensures that shared intellectual property is not misappropriated or utilised without permission, fostering trust and cooperation among industry participants.

[11] Chandra Nath Saha and Sanjib Bhattacharya, *Intellectual property rights: An overview and implications in pharmaceutical industry*, 2 J ADV. PHARM. TECH. RES. (2011)

- Keeping Trade Secrets and Confidential Information Safe: In the pharmaceutical sector, trade secrets are another type of intellectual property protection. Pharmaceutical businesses engage in R&D and production processes, which frequently contain proprietary information that gives them a competitive advantage. Trade secret protection ensures that this proprietary information is kept private and is not used by competitors. It enables pharmaceutical businesses to keep their competitive edge and safeguard their investments in intellectual knowledge and know-how.

5. THE ROAD AHEAD

The Indian pharmaceutical industry's future appears positive, with various elements contributing to its growth and development. Here are some significant indicators of a bright future for the industry:

- The Indian pharmaceutical business is rapidly moving its emphasis from being largely a generic medicine maker to investing in R&D. To develop novel treatments and technology, several Indian businesses are investing in R&D, innovation centres, and partnerships with international pharmaceutical organisations.[12] This shift towards innovation will boost the industry's competitiveness and allow it to satisfy unmet medical requirements.

- Indian pharmaceutical firms are extending their foothold in worldwide markets, particularly in developed countries. Indian companies are well-positioned to acquire a larger portion of the global pharmaceutical market due to their competence in low-cost manufacturing and compliance with globally recognised quality standards. Strategic alliances, acquisitions, and cooperation with multinational players expand their global footprint.

[12] Amitav Singh, *Intellectual Property Rights in Pharmaceuticals*, ACADEMIKE (Aug 10, 2023, 5:00 PM), https://www.lawctopus.com/academike/intellectual-property-rights-in-pharmaceuticals/

- The Indian pharmaceutical sector is also progressing in the discovery and production of biopharmaceuticals and biosimilars. Because of rising demand and improved profit margins, these advanced pharmaceuticals, which include biologics and biosimilar medications, have substantial growth potential. Indian firms are investing in biotechnology and biosimilar manufacturing skills in order to capitalise on this expanding market segment.

- India has proven its position as an international leader in generic medication production. Indian pharmaceutical businesses have been able to deliver affordable pharmaceuticals to both domestic and international markets thanks to the country's cost-effective production capabilities and solid regulatory structure. The growing global demand for generic medications creates substantial prospects for the Indian pharmaceutical industry to increase its market share[13].

- Pharmaceutical product demand is predicted to expand in India and internationally as a result of a variety of causes such as an ageing population, more healthcare awareness, and the incidence of chronic diseases[14]. As a result, the Indian pharmaceutical industry is poised to benefit from rising demand for low-cost, high-quality pharmaceuticals.

- The healthcare industry is being transformed by the introduction of digital technologies such as artificial intelligence, big data analytics, and telemedicine. The Indian pharmaceutical sector is adopting these technologies to improve R&D, production processes, and supply chain management. The industry's expansion and competitiveness will be driven by digital transformation, which will increase efficiency, expedite drug discovery, and enable personalised treatment.

Still, obstacles such as rising competitiveness, demanding regulatory requirements, and the need for ongoing innovation continue to exist. To sustain growth and remain competitive, the industry

[13] Vedant Kuchhal and Dhannjay Singh Pundir, *An Overview of the Pharmaceutical Industry and Its Implications in Terms of IP Laws*, 6 INT'L J. L. MGMT & HUMAN. (2023)
[14] Ibid

must invest in R&D, modernise manufacturing capacities, and adapt to changing market conditions. Ultimately, the Indian pharmaceutical industry's future looks bright, thanks to rising demand, an emphasis on inventiveness, regulatory reforms, and the use of digital technology. The industry has the ability to sustain its growth trajectory and contribute considerably to global healthcare developments with the correct strategy and investments.

6. CONCLUSION

In the world of medicine, intellectual property rights are super important. To stimulate innovation, fuel R&D investments, and bring breakthrough medications to market, the pharmaceutical sector significantly relies on intellectual property rights. Intellectual property protection is essential for regulatory affairs professionals since it provides a framework for ensuring compliance, protecting data, and protecting public health[15]. The interconnectedness of intellectual property and regulatory affairs ensures that pharmaceutical companies protect their creative contributions while adhering to stringent regulatory criteria. This harmonious teamwork not only accelerates research and development but also fosters a culture of mindful intellectual property management, supporting the effective advancement, authorization, and launch of ground-breaking discoveries in medicine. As the pharmaceutical landscape evolves, the seamless incorporation of intellectual property principles into regulatory structures remains critical to ensuring the continued blooming of inventiveness, the prioritisation of patient welfare, and the broader societal harvest of benefits resulting from ground-breaking medicinal advancements.

[15] Chandra Nath Saha and Sanjib Bhattacharya, *Intellectual property rights: An overview and implications in pharmaceutical industry*, 2 J ADV. PHARM. TECH. RES. (2011)