A Study on Intellectual Property Rights and Its Significance for Pharmaceutical Industry in India

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Abstract: **Intellectual property right (IPR) is the property right that are granted to an author or creator of a new invention, which include both tangibles and intangibles. The concept of intellectual property emerged in the 18th century in the United States of America, with the first federal patent statute enacted in 1790. Intellectual property rights are legal protections granted to those who have invented something new or created something original that can be reproduced or transmitted. The scope of intellectual property rights varies by country, but in principle, any form of expression that falls within copyright or patent law is protected as intellectual property (refer Sec 20(1)(b) of the Copyright Act 1957). In pharmaceutical industry there has been surge of copying the name of medicines and reproducing it under their fake identity. Now a days, the pharmaceutical industry sees the surge in IPR litigation due to unauthorized use of brand name, style, design etc. by other parties. In order to protect the interest of inventor or creator of goods or services the IPR Act needs to have stricter provisions.**

Key words: **Drug, Intellectual property rights, Pharmaceuticals, Medicines, Legal protection, Patent, Trademark, Copyright**

INTRODUCTION

The phrase intellectual property (IP) refers to the exclusive rights to creative works. Intellectual property law protects intangible assets such as innovations, literary and artistic works, phrases, designs, symbols, and images. Patents, trademarks, designs, and copyright enable this protection. These rights enable their owners to profit financially or receive acclaim for their innovations or creations.

Intellectual Property Rights (IPRs) are crucial in fostering innovation, ensuring competitive advantage, and protecting the interests of inventors. For the pharmaceutical industry, IPRs play a pivotal role due to the high costs and risks associated with drug research and development (R&D). This study explores the importance of IPRs for the Indian pharmaceutical sector and evaluates their impact on growth, innovation, and global competitiveness.

The pharmaceutical industry is dedicated to the research, development, production, and distribution of medications to prevent, diagnose, and treat diseases. Its key functions include: Research and Development (R&D) - identifying and developing new drugs, treatments and therapies, conducting clinical trials to ensure safety and efficacy; Manufacturing - producing high-quality medicines, including generics, branded drugs, and biosimilars, adhering to stringent regulatory standards for safety and quality; Quality Assurance - ensuring products meet regulatory and safety standards through rigorous testing; Marketing and Sales - promoting medicines to healthcare professionals and patients, conducting market analysis to identify healthcare needs; Distribution - ensuring medicines reach pharmacies, hospitals, and healthcare providers globally; Regulatory Compliance - meeting the requirements of global health authorities such as the FDA, EMA, and WHO; Public Health Initiatives - collaborating with governments and organizations to address health challenges. In India some of the top pharmaceutical companies are Sun Pharmaceutical Industries, Cipla, Dr. Reddy's Laboratories, Lupin, Aurobindo Pharma, Zydus Lifesciences (formerly Cadila Healthcare), Torrent Pharmaceuticals, Biocon, Glenmark Pharmaceuticals, Alkem Laboratories, Dabur, Patanjali, Baidyanath, Himalaya, Charak Pharma, Zandu Pharmaceuticals, Kerala Ayurveda Ltd., SBL (Schwabe India), Dr. Willmar Schwabe India Pvt. Ltd., and Bakson Homeopathy etc.

LITERATURE REVIEW

Scherer and Watal (2001) emphasize that strong patent protections incentivize R&D investments, especially in high-risk sectors like pharmaceuticals.

Lanjouw and Cockburn (2000) argue that patents allow companies to recover significant upfront costs in drug discovery and clinical trials.

Chaudhuri (2005) explores the relationship between IPR enforcement and market expansion, suggesting that robust IPR frameworks boost exports and enhance international credibility.

Maskus (2000) notes that strong IPR regimes attract foreign direct investment (FDI) in emerging economies, fostering technological advancement.

The seminal case of Novartis vs. Union of India (2013) is often cited to illustrate the tension between patent protections and public health priorities.

Pogge (2008) and Basheer (2012) discuss the role of compulsory licensing in ensuring affordable access to life-saving drugs while maintaining incentives for innovation.

The TRIPS agreement's impact on India's transition from process patents to product patents has been extensively studied (Chaudhuri, Goldberg, & Jia, 2006). Studies highlight persistent challenges, including bureaucratic delays, patent disputes, and high litigation costs (Gopakumar, 2009).

Kumar and Pradhan (2003) highlight India's dominance in the global generics market, which has been fueled by a historical emphasis on process innovation under soft patent rules. The change to a product-patent regime has glinted debate about how to strike a balance between generic production and innovative incentives.

Kesan and Gallo (2009) observe that strategic alliances and license agreements are becoming increasingly important for innovation, notably in biotechnology and specialty pharmaceuticals. Partnerships between foreign corporations and Indian businesses combine local production capabilities with global R&D knowledge. This research emphasizes IPRs' multidimensional impact on the pharmaceutical business, particularly their role in promoting innovation, economic growth, and resolving public health issues.

Dr. Arjun Gaikwad (2020). This paper discusses the history, aims, and various types of intellectual property rights. Intellectual property rights (IPR) refer to ideas, innovations, and creative expressions that the public is willing to confer the status of property upon. IPR grant certain exclusive rights to the property's inventors or developers so that they can earn commercially from their creative activities or reputation.

Punam Kumari (2018). Intellectual property rights (IPR) refer to ideas, innovations, and creative expressions for which the public wishes to bestow property status. IPR grants specific exclusive rights to the creators, innovators or developers of that property so that they can make profits from their creative endeavours or reputation. Intellectual property protection can take various forms, including trademarks, copyrights, and patents and designs.

Sreeragi R.G. (2021). To get privilege over innovations, a request for grant of rights must be filed in line with local law. The current study looks at the different categories of intellectual property and how long registered inventions will be legally protected.

Lalit Jajpura, Bhupinder Singh, and Rajkishore Nayak (2016). The current paper addresses a variety of intellectual property rights concepts, such as patents, trademarks, industrial designs, geographic indications, copyright, and so on, as well as the rules, regulations, needs, and functions that accompany them, specifically in the context of India. There is also a brief review on India's current involvement in IPR-related activities around the world.

Ming Yang (2018). In order to prepare for the arrival of the big data era, this article examines a number of major issues of intellectual property protection in the e-commerce array and gives recommendations for developing an e-commerce intellectual property protection supervision system.

Andriamirado Rakoto (2018). E-commerce is now extremely important to the global economy. In fact, whether growing or established, the majority of the world's nations have an internet-based infrastructure for performing electronic transactions. This study attempts to highlight some key features of intellectual property rights protection in online trade.

Dian Retnaningdiah, Siti Resmi, Indah Kurniawati, and Beni Suhendra Winarso(2020). The goal of this study is to look at how Small Business Enterprises (SMEs) use their supply chains to boost their competitiveness by leveraging e-commerce and intellectual property rights (IPR). This study adopts an experimental methodology, with respondents given a choice.

Ravi Kiran (2016). In this article, the author analyzes how the pharmaceutical sector has culturally adapted to IPR tactics, and how this has influenced the company's local and international growth. The research conducted for this article establishes the state of IPR in specific businesses, and the findings indicate a clear upward trend while simultaneously emphasizing the need for more industry-wide awareness and IPR implementation.

Rindu Rika Gamayuni, (2015). The author of this paper offers a path analysis of the inter-connection between intangible assets, financial policies, and financial performance to company value at Indonesian going-public companies between 2007 and 2009. Intangible assets have limited influence on financial policy, despite their significant beneficial impact on financial performance, ROA, and business value.

Sagar Kishor Saval, Varsha Kishor Savale (2018). This application is critical for safeguarding the inventor's invention while also maintaining the inventor's high standards of quality and performance. IPR objectives, types of IPR (patents, trademarks, copyrights and implied rights, GI tags, industrial designs, trade secrets, layout designs for integrated circuits, protection of new plant varieties), duration of IPR, and concept-related patents (patent types, tangible-intangible property, originality, non-obviousness, utility and expectancy).

SIGNIFICANCE OF THE STUDY

Most global businesses now value their intellectual property (IP) more than their physical assets. This is because IP laws protect them from unfair competition and the disclosure of trade secrets. The main purpose of IP law is to encourage or inspire the creation of various intellectual goods and services. It achieves this by granting individuals and organizations ownership rights over their intellectual creations for a limited time, providing an economic incentive for their development. These incentives, which vary depending on the level of protection offered, are intended to stimulate innovation and technological advancement within countries.

In today's economy, the importance of intellectual property rights (IPR) is particularly evident in the pharmaceutical industry. By safeguarding creators' work, IPR regulations and procedures have fostered innovation. These laws prevent unauthorized use of IP for personal gain without compensating the original inventors for their efforts and creativity. This study specifically focuses on the significance of IPR within the pharmaceutical industry.

OBJECTIVES OF THE STUDY

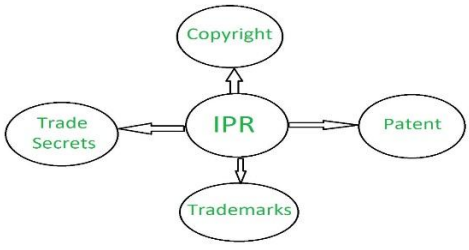
- To understand the history and background of intellectual property rights.
- To examine the role of intellectual property rights in the pharmaceutical industry.
- To explore the different types of intellectual property rights.

RESEARCH METHODOLOGY

In order to achieve the pre mentioned objectives data is collected from the secondary sources freely available in the public domain. Various kind of reports, scholarly papers, subject matter expert case studies regarding role of intellectual property right were referred to, apart from numerous journals and articles. The logical analysis of various literature had helped the authors to frame the idea about intellectual property rights and its significance for pharmaceutical industry. This research paper is descriptive in nature and conceptual in approach. It is descriptive in the sense that it attempts to identify various features of research objectives and it is conceptual because it observes literature review of historical studies conducted in these arenas.

DISCUSSION

There are four main types of IPR: Patents, Copyrights and Trademark. In this discussion only Patent, copyright and trademark are being discussed.



Source: Intellectual Property Rights – Geeks for Geeks

HISTORY OF INTELLECTUAL PROPERTY RIGHTS

Background of Patents

The beginning of trademark law in India may be traced back to the British colonial era. Before any

specific legislation, trademark protection in India relied on common law principles of "passing off" and equity, similar to the system in England before their first Registration Act of 1875. "Passing off" is a legal action to prevent someone from distorting their goods or services as those of another. The next breakthrough in the year 1940 by the Trade Marks Act, 1940. This was the first statutory law related to trademarks in India. It was largely based on the UK Trade Marks Act, 1938, reflecting the influence of British law during that period. This Act provided a framework for the registration and statutory protection of trademarks in India. The third breakthrough was the Trade and Merchandise Marks Act, 1958 which replaced the 1940 Act. It aimed to consolidate trademark-related provisions from various other statutes, such as the Indian Penal Code, Criminal Procedure Code, and the Sea Customs Act. This was a significant step in developing a more comprehensive trademark law in independent India.
Currently the Trade Marks Act, 1999 is the governing law for trademarks in India. A key reason for this new Act was India's entry into the World Trade Organization (WTO) in 1995. As a WTO member, India was obligated to align its trademark laws with the common agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The 1999 Act introduced several important changes, including:

- Registration of service marks and collective marks.
- Enhanced protection for well-known marks.
- Establishment of the Intellectual Property Appellate Board (IPAB) for faster resolution of appeals.

In 2023, India filed 90,300 patents, which is 17% higher than 2022. India is now the sixth-largest country in the world for the number of patents filed. Patents offer significant advantages to researchers and inventors pharmaceutical businesses and other business as well. They facilitate licensing, outsourcing, and strategic partnerships. Beyond simply capturing new ideas, patents enhance product sales by conferring unique attributes that differentiate them from competitors in the online marketplace.

A patent is a crucial form of intellectual property (IP). It's a government-granted right that provides exclusive control over an invention for a specific period, preventing others from making, using, or selling it. Inventors or organizations seek patent protection by submitting a detailed description of their invention to the patent office and paying the required fees. This effectively establishes legal ownership of their innovation.

Background of Copyright

The evolution of copyright law in India reflects the country’s colonial history and its adaptation to international norms.

1. Early Development (1847): The 1st copyright law in India was enacted in 1847, during the East India Company era. This ordinance granted copyright protection for 42 years, plus an extra 7 years after the author's death. Copyright registration was mandatory in order to enforce rights under the law. The statute also allowed the government to issue a forced license for publishing if a copyright holder refused to publish a work after death.
2. An important change occurred in 1914, with the implementation of a new copyright legislation that largely resembled the United Kingdom's Copyright Act of 1911. While broadly identical to UK law, India's version includes sections 7–12 that specified criminal sanctions for copyright infringement.
3. Post-Independence (1957): Following independence, India passed the Copyright Act of 1957, which replaced previous British-influenced rules. This statute was drafted to be consistent with international standards, particularly the Berne Convention, ensuring protection for both Indian and foreign works.
4. Modern Amendments: The Copyright Act of 1957 has been revised multiple times to reflect developing technologies and changing demands. The most recent revision, made in 2012, included provisions for digital rights management, fair use for educational purposes, and tighter protections for authors and creators.

Today, the Copyright Act of 1957 controls copyright law in India, protecting original literary, theatrical, musical, and creative works, as well as cinematographic films and sound recordings, while maintaining adherence to worldwide intellectual property standards.

Copyright is crucial in protecting creative content and information, particularly in the rapidly expanding digital world. As digitization accelerates, copyright holders increasingly rely on legal protections to prevent unauthorized use, copying, or distribution of their works online. Additionally,

technologies such as encryption and watermarking are widely used to safeguard the intellectual property of digital businesses.

Copyright provides exclusive rights to creators, including authors, artists, musicians, and performers, for their original works. It also extends to broadcasters and performers for their related rights. Like patents, copyright laws grant monopolistic rights, allowing creators to control the reproduction, distribution, and commercialization of their works.
This legal protection applies to a wide range of creative expressions, such as literary, musical, dramatic, artistic, and architectural works. By empowering creators with control over their creations, copyright ensures they can reap the benefits of their efforts while maintaining the integrity and value of their work in the digital environment.

Background of Trademark

Pre-independent India adapted trademark regulation from the British Trademark Act 1938 in the form of the Trademark Act of 1940. This is considered as the first milestone in the history trademark-related law in India. Later on, as the current scenario was changing in India to cater to the needs of industry, The Trade & Merchandise Act, 1958 was also mandated. Number of changes were introduced until December 30, 1999, when the Trade Mark Act, 1999, which is currently in effect in India, was established.

The two main objectives/goals achieved by this act are to: a) protect the owner from competitor mark's duplication.
b) protect the name and goodwill that the trademark owner has built up through deep vision and investment of time and money.

Health sector trademarks account for 21.9% of India's total trademarks sector of IPR. Trademarks play a crucial role in the country in general and in the pharmaceutical industry in particular. Trademarks assist shoulders in building brand identity and facilitating the growth or sale of goods and services. A registered trademark provides legal advantages, making it easier to take legal action against companies that infringe on intellectual property rights in any possible form.

A trademark is a distinctive symbol that helps consumers identify the source of specific goods or services. It can consist of text, words, numbers, phrases, symbols, designs, colors, smells, shapes, sounds, packaging, textures, or a combination and permutation of these elements. The primary goal of a trademark is to establish a unique association between the mark and the producer of a product or service provider.

Trademarks not only help businesses stand out but also assure customers of the quality and consistency of the products or services they represent. By creating a strong connection between the trademark and its source, businesses can foster trust and loyalty among their consumers.

Intellectual Property Rights in the backdrop of Pharmaceutical Industries

Developing a new drug is an incredibly expensive and risky endeavour. A 2020 study estimated the median cost at $985 million and the average cost at $1.3 billion (1,125 Lac Crores approx.). Given these enormous costs and the high risk of failure during development, pharmaceutical companies prioritize protecting their intellectual property (IP). This is a sound and essential business strategy. Managing IP—including its creation, acquisition, protection, and administration—must be a core corporate function, on par with financial management and resource allocation. The anticipated knowledge revolution will elevate the importance of IP, demanding its careful consideration in all strategic decisions.

In the highly competitive global pharmaceutical market, scientific knowledge and innovation are paramount, surpassing the importance of manufacturing expertise. A company's success hinges largely on its research and development (R&D) efforts. Consequently, pharmaceutical companies invest substantial portions of their revenue in R&D, sometimes as much as 15% of total sales. A central challenge in this industry is balancing the inherent risks of innovation with the pursuit of a competitive advantage. The potential for failure in pharmaceutical R&D carries a significant financial burden. Many promising drug candidates fail to meet rigorous safety standards and are terminated, often after years of substantial investment. Even for drugs that successfully navigate the complex development process, the journey from initial compound synthesis to market launch typically takes 8-10 years.

With product patents serving as the primary mechanism for IP protection, drug companies are shifting their R&D focus. They are moving away from developing new manufacturing processes for existing drugs and increasingly concentrating on the discovery and development of entirely new drug molecules and new chemical entities (NCEs). This shift has been further influenced by changing disease patterns. During the 1980s, after successfully addressing many short-term illnesses, the industry's R&D focus transitioned towards chronic diseases requiring long-term treatment.

Navigating the global market requires adherence to diverse and often stringent regulatory requirements. The documentation required for regulatory submissions has nearly tripled in the past decade. Furthermore, regulatory agencies are taking longer to approve new drugs. This extended review process effectively shortens the period of patent protection, forcing companies to maximize profitability within a compressed timeframe. This challenge is particularly acute for drugs developed through biotechnology, especially those involving gene therapies, due to the complexity and novelty of these treatments.
In response to these pressures, industrialized nations may advocate for extended patent protection periods for pharmaceuticals. Simultaneously, governments may increasingly implement price controls on medications to address public health and affordability concerns. These opposing forces create a complex dynamic. On one hand, there is a strong need to reduce the costs associated with development, production and sales & marketing of drugs. On the other hand, companies must plan for potentially lower margins of profit and longer periods payback period.

The pharmaceutical industry, therefore, operates within a complex web of conflicting demands. Over the past 10-15 years, various strategies have emerged to address cost containment and maintain a competitive edge. These strategies include outsourcing R&D activities to specialized companies, forming collaborative R&D partnerships with other organizations, and establishing strategic alliances to share resources and expertise. These collaborative approaches can help mitigate risk, accelerate development timelines, and share the substantial financial burden of bringing new drugs to market.

Nature of Pharmaceutical Industry

The race to decode the human genome has significantly advanced scientific and technical knowledge and, transforming the scenario of drug development. The future likely holds personalized medicine, with individuals' genomes mapped and stored, allowing doctors to tailor treatments accordingly. This raises important IP concerns regarding the protection of personal genetic databases.

Biotechnologically developed drugs are increasingly entering the market, requiring different protection procedures compared to conventional drugs. Patent documents for drugs or vaccines developed using microbial strains must specify those strains. Known strains are easily addressed, but newly discovered and developed strains are deposited with international depository authorities as per the Budapest Treaty, whose databases must be consulted during novelty searches. Companies typically avoid publishing research before filing patent applications to protect their inventions.

For microbiological inventions, depositing the strain with a recognized depository (and obtaining a registration number for the patent specification) is crucial, avoiding complex written descriptions of living organisms. While depositing strains incurs costs (less so for non-cell lines), inventions involving genes, gene expression, DNA, and RNA require sequence descriptions in the patent specification.

R&D alliances can serve various purposes, including sharing expertise, facilities, marketing networks, and production capabilities. Formal agreements are essential for R&D alliances, covering IP ownership, cost sharing, revenue distribution, trade secret protection, pre-existing IP, and dispute resolution. A stronger IP portfolio is advantageous in such alliances. Drug companies are increasingly using contract research with academic institutions, private R&D agencies, and government R&D institutions, requiring strict confidentiality.

The current state of the pharmaceutical industry suggests potential over-strengthening and abuse of IPR, potentially harming competition. A perceived lack of risk-taking and innovation may indicate an imbalance detrimental to public good. This issue may require not only legislative reform but also antitrust intervention. While antitrust laws have addressed certain pharmaceutical practices (e.g., mergers, non-compete agreements), other areas like patents on

minor drug modifications, reformulations for new patents, and brand name marketing to hinder generic entry also warrant scrutiny.

Traditional medicine using natural botanical products is significant in many developing and developed countries, leading to a global market of around US$60 billion with 5-15% annual growth. While purely traditional knowledge is generally not patentable, some claim patents after minor modifications. The rapid increase in herbal medicine patent applications reflects this trend. Patent applications for natural products, traditional herbal medicine, and herbal medicinal products are handled under each country's IPR policies for food, pharmaceuticals, and cosmetics. Medicinal herbs, plants and other related products are key targets for patent claims due to their importance to the international herbal drug and beauty industries.

Patent specification writing requires scientific, technological, and legal expertise. Patent claims are crucial for securing legal proprietary rights. Discovering a new product in a known material is not patentable unless it has a practical application. A new use for a known substance, or a combination of known substances with a new result, may be patentable. If a new molecule's structure is unknown, its description, properties, and production method are crucial. Combining known substances into useful products may be patentable if they have a working relationship, but this offers limited protection. Methods of treatment for humans and animals are generally not patentable (with the US as an exception). Claims for new pharmaceutical uses of known substances must avoid implying a method of treatment. Approximately 62% of patent applications belong to medicine, including herbal drugs, with fewer applications in engineering, electronics, and chemicals.

CONCLUSIONS

Managing intellectual property (IP) and intellectual property rights (IPR) is a complex, multifaceted undertaking requiring diverse actions and strategies carefully aligned with national laws, international treaties, and established practices. This is no longer a purely national concern; IP and its related rights are significantly shaped by market demands, market reactions, the financial investments required to commercialize IP, and other trade and commerce considerations. Effective IPR management, therefore, is deeply intertwined with economic realities.

Different forms of IPR (patents, trademarks, copyrights, designs, etc.) necessitate distinct handling, planning, and strategic approaches. This requires engaging professionals with diverse expertise spanning various domains, including science, engineering, medicine, law, finance, marketing, and economics. Each industry, based on its specific area of operation, should develop tailored IP policies, management styles, and strategies. The pharmaceutical industry, for instance, is currently navigating an evolving IP landscape, adapting its strategies to the unique challenges and opportunities it faces. The pharmaceutical industry invests heavily in research and development, with drug development often taking a decade or more and costing billions of dollars. This necessitates robust IP protection to recoup investments and incentivize further innovation. Pharmaceutical products are subject to rigorous regulatory scrutiny, requiring extensive testing and approval processes before they can be marketed. This further extends development timelines and adds to costs, making IP protection even more critical. Once patent protection expires, generic drug manufacturers can enter the market, often at significantly lower prices. This creates a strong incentive for pharmaceutical companies to maximize their returns during the patent protection period. Some pharmaceutical companies have been accused of "evergreening" their patents by making minor modifications to existing drugs to extend their patent protection. This practice has raised concerns about hindering competition and delaying the availability of affordable generic medications.

Given the increased possibility of invalid IPR being asserted, antitrust law plays a crucial role in preventing the unlawful use of such rights to establish and maintain illegitimate, even if limited, monopolies within the pharmaceutical sector. This is important to ensure fair competition and prevent artificial inflation of drug prices. Antitrust enforcement can address issues such as: Patent Thickets: The accumulation of overlapping patents that can create barriers to entry for competitors, Pay-for-Delay Agreements: Agreements between brand-name and generic drug manufacturers to delay the entry of generic drugs into the market, Abuse of Regulatory Processes: Using regulatory processes to delay or hinder the approval of generic drugs.

Despite the importance of these legal safeguards, many challenges remain in balancing the need to incentivize innovation with the need to ensure affordable access to essential medicines. Ongoing dialogue and adjustments to legal frameworks are needed to address these complexities effectively. For India, the interplay between IP law, antitrust law, and public health policy will continue to be a crucial area of focus in the pharmaceutical industry. The role of Indian judiciary becomes very important here. Timely decisions without error in judgements in all litigations in pharmaceutical sector is the need of the hour.

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