RESEARCH ARTICLE

INTELLECTUAL PROPERTY RIGHTS: EXCEPTIONS AND COMPARATIVE PATENT SYSTEM STUDY

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Abstract:
Intellectual Property Rights (IPR) play a vital role in pharmaceutical drug discovery, providing legal protection for innovations while balancing public health concerns. Patents serve as the primary mechanism for safeguarding pharmaceutical inventions, granting exclusive rights for a specified period, typically 20 years. These protections help companies recover significant research investments, which can range from $300 million to $1 billion per new drug. However, IPR also raises ethical concerns regarding medicine accessibility, particularly in developing countries. Beyond patents, pharmaceutical companies navigate trademarks, copyrights, trade secrets, and data protection mechanisms to maintain market competitiveness. The emergence of artificial intelligence (AI) in drug discovery introduces new legal challenges, necessitating a focus on human contributions for patent eligibility. As the legal landscape evolves, the pharmaceutical industry must strategically manage intellectual property, ensuring both innovation and equitable access to essential medicines.

Keywords: Intellectual Property Rights (IPR), Pharmaceutical Patents, Drug Discovery, Artificial Intelligence (AI), Medicine Accessibility.

Introduction:

Intellectual Property Rights (IPR) play a critical role in the pharmaceutical drug discovery industry, serving as a complex framework of legal mechanisms to protect and incentivize scientific innovation providing exclusive rights for a specific period. The fundamental purpose of IPR in pharmaceuticals is to balance innovation and public health needs, simultaneously raising ethical concerns about medicine accessibility. The pharmaceutical industry relies heavily on these legal protection rights by IPR to safeguard their creations and substantial investments in research and development and maintain a competitive edge in the market. In the context of pharmaceutical research, these rights are particularly significant due to the immense costs and risks associated with drug development, which can range from $300 million to $1 billion per new drug.

Patents represent the primary mechanism of IP protection for new drugs, granting inventors exclusive rights to their innovations to manufacture and sell a novel pharmaceutical compound for a specified period (typically offering 20 years). While patent protections enable companies to recoup expensive research

costs, protecting innovative research while supporting continued investment in developing life-saving medications, they can also create barriers to affordable medicine, particularly in developing countries. This tension underscores the nuanced role of intellectual property rights in drug discovery and global healthcare. The pharmaceutical industry must navigate a complex landscape of intellectual property law, which includes not just patents, but also trademarks, copyrights, trade secrets and data protection mechanisms.

The complexity of IPR in the pharmaceutical industry faces an ongoing debate about how IPR impacts global health contexts, where balancing innovation with access to medicines remains a critical challenge. As such, the complexity of drug discovery has recently been compounded by the emergence of artificial intelligence (AI) in research processes. It has introduced some novel legal challenges in recent developments and has highlighted the intricate challenges surrounding AI's role in invention. However, legal guidance from the USPTO emphasizes that while AI-assisted inventions are not categorically unpatentable, focusing on human contributions remains crucial for patent eligibility. As technology evolves, particularly with AI's increasing involvement in drug discovery, the legal framework surrounding intellectual property rights continues to adapt, ensuring that human ingenuity remains at the core of pharmaceutical innovation. Thus, the pharmaceutical industry must carefully manage intellectual property, treating it as a core corporate activity.

Comparison of Patent System of India, US and China

Among the leading global economies, India, China, and the United States have developed contrasting patent systems influenced by their unique legal traditions and innovation strategies. India follows a judicial-based enforcement model, China has a dual enforcement system with strong administrative action, and the U.S. relies on federal courts and the Patent Trial and Appeal Board (PTAB) for dispute resolution. The comparative analysis of the patent systems in these three countries, focusing on key aspects such as patent enforcement, litigation processes, examination procedures, and compulsory licensing provisions. Understanding these differences is crucial for businesses, innovators, and policymakers navigating the complex landscape of international intellectual property rights.

Patent enforcement in India relies exclusively on judicial intervention, as there is no administrative body dedicated to handling patent disputes. Patent infringement cases must be pursued in civil courts, leading to long and costly legal battles. In contrast, China follows a dual enforcement model, where both administrative and judicial mechanisms are available for patent holders. The China National Intellectual Property Administration (CNIPA) and local IP offices can handle administrative enforcement, allowing seizures, fines, and injunctions against infringers, making enforcement faster. Meanwhile, the U.S. has the strongest enforcement system, with disputes handled by federal courts and the Patent Trial and Appeal Board (PTAB), ensuring high damages and strict penalties against infringers.

In terms of the litigation process, India lacks specialized IP courts, meaning patent disputes are heard in High Courts or District Courts, which results in delayed proceedings (3-5 years on average) and high burdens of proof on patent holders. China has specialized IP courts in Beijing, Shanghai, and Guangzhou, allowing for faster resolution of patent disputes (6-12 months), though foreign companies sometimes face biases in favor of local firms. In the U.S., federal courts handle patent litigation, with cases often lasting 1-3 years, but with significant financial stakes, as

damages can reach millions of dollars. Additionally, the Court of Appeals for the Federal Circuit (CAFC) provides a specialized forum for patent appeals, ensuring consistency in rulings.

The examination process also varies between the three countries. In India, a patent application requires a separate request for examination, which must be filed within 48 months of submission, often resulting in delays of 3-5 years before a patent is granted. China follows an automatic substantive examination system, ensuring a faster patent review process (2-3 years), with priority examination available for strategic industries like AI and pharmaceuticals. Similarly, in the U.S., applicants must request examination within 3 years, and patents are typically granted within 2-3 years, with an expedited Track One option for faster review.

Regarding compulsory licensing, India has the strongest provisions among the three, allowing compulsory licenses under public health concerns, affordability issues, and national emergencies. A notable example is the Natco vs. Bayer case, where India issued a compulsory license for an anti-cancer drug to ensure affordability. China also allows compulsory licensing, but it is rarely granted and mainly used in cases of public interest or national security. In the U.S., compulsory licensing is uncommon, though the Bayh-Dole Act provides a mechanism for government intervention in cases involving publicly funded research.

Finally, the availability of injunctions and damages differs significantly. In India, injunctions are available but difficult to obtain, and damage awards are generally lower compared to China and the U.S. China provides stronger protection, with injunctions easier to secure and damages gradually increasing due to legal reforms. However, the U.S. remains the most patent-holder-friendly jurisdiction, with high-value damages (often millions of dollars) and stronger injunctive relief than India or China. Overall, India's system is slower and more favorable to public interest protections, China's system is efficient but sometimes biased toward local firms, and the U.S. provides the strongest, yet most expensive, patent protection. [3][4][5]

IPR laws and their exceptions

Intellectual Property Rights (IPR) laws in India are designed to protect creators' rights while balancing public interest through specific exceptions. These exceptions ensure that the enforcement of IPR does not hinder scientific progress, access to essential goods, or the preservation of cultural heritage. Below is an overview of key IPR laws and their notable exceptions, along with recent references for further reading.

Patent Law and Its Exceptions

The Indian Patents Act, 1970, grants patent holders exclusive rights over their inventions.

However, certain exceptions limit these rights:

- **Private and Non-Commercial Use**: Individuals can use a patented invention privately and non-commercially without infringing on the patent.
- **Experimental Use**: Using a patented invention for research or experimental purposes is permitted, fostering scientific advancement.
- **Regulatory Use (Bolar Exception)**: Generic manufacturers can use a patented invention to obtain regulatory approval before the patent expires, ensuring timely public access to generic medicines.
- **Compulsory Licensing**: The government can authorize third parties to produce a patented product without the consent of the patent holder, especially in cases of public health emergencies.

Generic Drugs

Once a patient expires generic drugs can enter the market, these drugs are medication created to be

the same as an existing and approved brand name drug, the dosage form, safety, strength, route of administration, quality, and performance characteristics of these drugs remain similar to the branded drugs, patients may take a generic drug as an equal substitute for the branded drug.

Generic medications are generally cheaper and more affordable which makes them extremely important as an alternative in third world countries that are unable to afford branded drugs which are very expensive. Some countries do not have a generic drug policy which can make it difficult to acquire medications at an affordable price. Implementation of a generic drug policy can make healthcare more accessible in these countries.

Case Studies on IPR

1. Intellectual Capital and Property Rights (IPR) as The Key Asset of a Family Firm: A Case Study with an Evaluation Approach

The case study examines the role of Intellectual Property Rights (IPR) as critical assets in a family-owned music production business in Finland, highlighting the significant challenges in their valuation, especially in financial negotiations. The study focuses on information asymmetry between the business owner, Eric, and his primary financier, referred to as the "Fund." While Eric sees his company's IPR assets—such as copyrights, artist popularity, brand value, and distribution networks—as core drivers of business value, the financial institution underestimates these intangible assets, leading to difficulties in securing loans and financial support. The financiers primarily assess tangible assets like equipment, physical inventory, and property, disregarding the long-term revenue potential of copyrights, artist goodwill, and market presence. This undervaluation forces Eric to rely heavily on personal assets, including mortgaging his family home, to sustain business operations. The study applies two theoretical frameworks—Intellectual Capital Theory and Information Asymmetry Theory—to explain the gap in understanding between business owners and financial institutions. It finds that the lack of recognition of IPR as a valuable business asset has severe implications, not only for individual business growth but also for loan negotiations, credit ratings, taxation, and family business succession. Despite Eric's efforts to educate the Fund about his company's financial potential, provide transparency in performance data, and showcase market success through national awards and artist signings, the financiers remain unconvinced. This disconnect has resulted in limited financial support, stagnated business expansion, and a halt to internationalization efforts. The study suggests that financiers should develop new frameworks for evaluating IPR assets and that government policies should facilitate better access to funding for creative industries, where intangible assets often hold the most value. Without such reforms, family businesses in industries reliant on intellectual capital risk financial instability, hindering their ability to compete with larger multinational corporations. The findings underscore the pressing need for a shift in financial evaluation practices to ensure that businesses in creative fields receive adequate support based on the true value of their intellectual assets.

2. A Case Study on IPR Infringement: Kellogg's Company V/S National Biscuit Company

The case study explores the Intellectual Property Rights (IPR) infringement dispute between Kellogg's Company and National Biscuit Company (Nabisco) over the use of the term "Shredded Wheat" and the shape of their cereal biscuits. Nabisco, after acquiring the Shredded Wheat Company, claimed that Kellogg's was engaging in unfair competition by using the same

product name, a similar pillow-shaped cereal biscuit, and packaging that featured two shredded wheat biscuits submerged in milk, arguing that these elements misled consumers into believing that Kellogg's product was associated with or originated from Nabisco. The legal battle revolved around trademark laws and the concept of "passing off," where a company attempts to make its product look like another brand's. However, the U.S. Supreme Court ruled in favor of Kellogg's, stating that the term "Shredded Wheat" was generic and could not be trademarked, as it described the nature of the product rather than serving as a distinct brand identifier. Additionally, the court ruled that the pillow-shaped biscuit design was functional and therefore not eligible for trademark protection, as allowing such a monopoly would unfairly restrict competition in the marketplace after the expiration of Perky's original patents. Regarding Nabisco's claim that Kellogg's packaging misled consumers, the court determined that Kellogg's branding was prominent on its cartons, reducing the likelihood of confusion, and thus, no fraudulent "passing off" had occurred. This case set a significant legal precedent in intellectual property law, particularly in relation to generic trademarks and trade dress protection. The ruling reinforced the doctrine of genericide, which states that once a term becomes widely recognized as the common name for a product, it loses its trademark protection. Furthermore, the case clarified that functional product designs cannot be protected under trademark or unfair competition laws once a patent expires, as this would prevent fair market competition. The decision had lasting implications, shaping future intellectual property cases and influencing how courts assess trade dress, functional designs, and generic terms in trademark disputes. It highlighted the importance of companies securing distinct brand elements rather than attempting to extend expired patent protections through trademark claims, ensuring that fair competition is maintained in the marketplace.

Conclusion:

Intellectual Property Rights (IPR) play a crucial role in fostering innovation while ensuring a balance between corporate interests and public health. In the pharmaceutical industry, patents and other IPR mechanisms serve as essential tools for incentivizing research and development, allowing companies to recover substantial investments. However, they also raise concerns regarding affordability and accessibility, particularly in developing nations. The comparison of patent systems in India, China, and the U.S. highlights the diverse approaches to IPR enforcement, litigation, and regulatory exceptions. While the U.S. has a robust and well-established patent protection system, India's framework prioritizes public health through compulsory licensing, and China's evolving system seeks to strengthen enforcement while fostering local innovation. The rise of artificial intelligence (AI) in drug discovery presents new challenges in IPR, particularly in determining patent eligibility for AI-generated inventions. As technology advances, legal frameworks must adapt to ensure that innovation continues to thrive without compromising ethical considerations and equitable access to medicines. Ultimately, the future of IPR in pharmaceuticals will depend on striking a balance between protecting intellectual property and ensuring that life-saving medicines remain accessible to those in need. Collaborative efforts between policymakers, industries, and international organizations will be essential in shaping a fair and sustainable IPR system that benefits both innovators and society at large.

References:

1. Barbosa, D. B., & Grau-Kuntz, K. (2011). Exclusions from Patentable Subject Matter and Exceptions and Limitations to the

Rights - Biotechnology. SSRN Electronic Journal. https://doi.org/10.2139/ssrn.1734286

2. Al-Worafi, Y. M. (2020). *Drug safety in developing countries: Achievements and Challenges*. Academic Press.
3. Feng L, Yu X. The Fourth Amendment of Chinese Patent Law and Discussion on its Practical Effects. *European Review*. 2023;31(2):196-211. doi:10.1017/S1062798722000278
4. Lafond, F., Kim, D. Long-run dynamics of the U.S. patent classification system. *J Evol Econ* 29, 631–664 (2019). https://doi.org/10.1007/s00191-018-0603-3
5. Dash, D., Vaiswade, R., & Gupta, G. (2023). A Review on the Indian Patent System and Its Implication on the Pharmaceutical Industry. *Journal of Health Science and Medical Research, 41*(3), e2023926. doi:http://dx.doi.org/10.31584/jhsmr.2023926
6. 22.Kartal M. (2021). Intellectual property protection in the natural product drug discovery, traditional herbal medicine and herbal medicinal products. Phytother Res.
7. Bently L, Sherman B. (2022). Oxford: Oxford University Press. Intellectual property law.
8. Saha CN, Bhattacharya S. Intellectual property rights: An overview and implications in pharmaceutical industry. J Adv Pharm Technol Res. 2011 Apr;2(2):88-93. doi: 10.4103/2231-4040.82952. https://pmc.ncbi.nlm.nih.gov/articles/PMC3217699
9. Lalit Jajpura, Bhupinder Singha and Rajkishore Nayakb et, Faculty of Engineering and Technology, BPS Mahila Vishwavidyalaya, Khanpur Kalan, Sonipat - 131 305, India, Journal of Intellectual Property Rights, Vol 22, January 2017, pp 32-41.
10. https://docs.manupatra.in/newsline/articles/Upload/41C26FED-7AFE-40EA-8736-4E6C5 16917AE.pdf