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Patent law and its impact on generic pharmaceuticals: A case study of the Indian healthcare system

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Abstract

This research paper examines the impact of patent law on generic pharmaceuticals in India, focusing on the historical evolution from the Patents Act of 1970 to the amendments introduced in 2005. It explores key concepts such as patents, generic drugs, and compulsory licensing, highlighting their implications for public health and access to essential medicines. The paper analyzes the challenges faced by generic pharmaceutical manufacturers in navigating the patent landscape and the role of compulsory licensing in enhancing drug accessibility during public health emergencies. Additionally, it discusses the broader public health implications of patent law, including its effect on disease burden and economic considerations within the healthcare system. Finally, the paper offers policy recommendations aimed at strengthening the link between patent law and public health, emphasizing the need for a balanced approach that prioritizes both innovation and accessibility. Through this analysis, the study aims to contribute to the ongoing discourse on intellectual property rights and their implications for healthcare in India.

Keywords: Patent law, generic pharmaceuticals, compulsory licensing, public health, access to medicines, India

Introduction

The healthcare landscape in India has undergone significant transformation over the past few decades, largely driven by advancements in pharmaceutical research and the vital role of generic drugs. With a burgeoning population and increasing demand for affordable medications, the Indian healthcare system faces the challenge of balancing innovation and accessibility. Central to this dynamic is patent law, which governs the protection of pharmaceutical inventions while simultaneously influencing the availability of generic alternatives. Patent law serves as a double-edged sword in the pharmaceutical industry. On one hand, it incentivizes innovation by granting inventors exclusive rights to their creations, encouraging research and development of new drugs. On the other hand, the extension of patent protections can lead to monopolistic practices, stifling competition and resulting in exorbitant prices for essential medications. This is particularly concerning in India, where a significant portion of the population relies on generic drugs for their healthcare needs.

The Indian Patent Act of 1970 marked a pivotal moment in the country's approach to intellectual property rights, allowing for the production of generic drugs that have been crucial in addressing public health challenges. This legislation not only facilitated the growth of a robust generic pharmaceutical industry but also positioned India as a leading supplier of affordable medicines to developing countries. However, recent amendments and international trade agreements have raised questions about the future of generic pharmaceuticals in India, as they may impose stricter patent regulations that could hinder access to life-saving medications.

This paper aims to critically analyze the impact of patent law on generic pharmaceuticals within the Indian healthcare system. Through a comprehensive examination of relevant legislation, case studies, and empirical data, this research will explore the delicate balance between protecting intellectual property and ensuring access to affordable healthcare. Ultimately, this study seeks to provide insights into the complexities of patent law and its implications for public health in India, contributing to the broader discourse on healthcare accessibility and equity.

Background: The evolution of patent law in India has been shaped by a unique confluence of historical, economic, and social factors, significantly influencing the pharmaceutical landscape in the country.

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The Patents Act of 1970 marked a crucial turning point, emphasizing the need to protect domestic industries while making affordable medicines accessible to the population. Under this act, India adopted a system of process patents rather than product patents, allowing local manufacturers to produce generic versions of patented drugs. This legislation was instrumental in fostering a robust generic pharmaceutical industry, which emerged as a global supplier of affordable medications, particularly for developing nations.

However, with India's accession to the World Trade Organization (WTO) in 1995 and the subsequent implementation of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the framework governing patents underwent significant changes. TRIPS mandated member countries to adhere to higher standards of intellectual property protection, including the introduction of product patents in the pharmaceutical sector. This shift necessitated a comprehensive overhaul of India's patent laws, leading to the enactment of the Patent (Amendment) Act of 2005. This amendment not only introduced product patents but also aligned Indian laws with international norms, reflecting the global commitment to protect intellectual property rights.

The implications of these changes have been profound. While the 2005 amendments aimed to foster innovation and attract foreign investment, they also sparked concerns over access to essential medicines. The introduction of product patents allowed multinational pharmaceutical companies to exercise exclusive rights over new drugs, often resulting in steep prices that limited access for the average Indian consumer. As a consequence, the availability of life-saving medications became a pressing public health issue, particularly for marginalized communities who rely on affordable generic alternatives.

To address the challenges posed by stringent patent protections, India has incorporated the concept of compulsory licensing into its legal framework. Compulsory licensing allows the government to permit the production of a patented drug without the consent of the patent holder, under specific conditions, such as public health emergencies or when the patented drug is not accessible at a reasonable price. This provision has been utilized in several high-profile cases, including the issuance of compulsory licenses for antiretroviral medications, which played a critical role in ensuring that affordable treatments were available to those affected by HIV/AIDS in India.

Key concepts underpinning this discussion include patents, generic drugs, and compulsory licensing. A patent is a legal right granted to an inventor, providing exclusive control over the production, use, and sale of an invention for a specified period, typically 20 years. Generic drugs, on the other hand, are medications that are chemically identical to their branded counterparts but are sold at lower prices once the original patent expires or is overridden. Compulsory licensing serves as a critical mechanism that balances patent rights with public health needs, enabling governments to intervene when necessary to protect the health and welfare of their citizens.

Understanding these concepts and their historical context is essential for analyzing the impact of patent law on generic pharmaceuticals in India. As the country grapples with the ongoing tensions between innovation and accessibility, it is crucial to explore how legal frameworks can adapt to meet

the healthcare needs of its diverse population while fostering an environment conducive to pharmaceutical innovation.

Impact of patent law on generic pharmaceuticals

The interplay between patent law and the generic pharmaceutical industry in India has profound implications for public health, accessibility, and innovation. The transition from the Patents Act of 1970 to the amended Act of 2005 has reshaped the pharmaceutical landscape, presenting both opportunities and challenges for the production and availability of generic drugs.

1. Reduction in generic drug availability

The introduction of product patents in India under the 2005 Patent (Amendment) Act significantly altered the regulatory environment for generic pharmaceuticals. Before these amendments, Indian manufacturers could produce generic versions of patented drugs by obtaining process patents, enabling widespread access to affordable medicines. With the advent of product patents, however, many pharmaceutical companies, especially multinational corporations, have gained exclusive rights to manufacture and sell new drugs. This has led to a decrease in the availability of generics, particularly for innovative treatments, which often come with high price tags due to the lack of competition in the market.

2. Increased prices for essential medications

As patent protections have strengthened, the cost of essential medications has risen sharply. Multinational pharmaceutical companies, empowered by exclusive patent rights, have often set prices that are unaffordable for a significant portion of the Indian population. For instance, life-saving drugs for conditions like cancer, diabetes, and HIV/AIDS can become prohibitively expensive, thereby limiting access for those who need them most. This situation exacerbates health inequities and poses serious challenges for public health systems striving to provide affordable care.

3. Role of compulsory licensing

In response to the challenges posed by stringent patent protections, India has implemented mechanisms such as compulsory licensing to safeguard public health interests. This provision allows the government to authorize the production of a patented drug without the patent holder's consent under specific circumstances, such as when the drug is not available at an affordable price or in a public health emergency. The issuance of compulsory licenses for critical medications has enabled Indian manufacturers to produce and sell affordable generics, effectively challenging the monopolistic practices of patent holders. For example, the landmark case in 2012, where the Indian Patent Office granted a compulsory license for the cancer drug Nexavar, showcased the potential of this mechanism to enhance access to life-saving treatments.

4. Encouragement of domestic innovation

While the introduction of product patents has posed challenges for the generic pharmaceutical sector, it has also led to increased focus on research and development within India. Pharmaceutical companies are now incentivized to innovate and develop new drugs that can be patented, thus fostering a culture of domestic innovation. This shift is

crucial for building a sustainable pharmaceutical industry that can compete globally while addressing local health needs.

5. Global implications and trade agreements

The impact of patent law on generic pharmaceuticals extends beyond India's borders, affecting global access to affordable medications. India has long been known as the "pharmacy of the developing world," supplying generics to many countries with limited access to expensive patented drugs. However, international trade agreements and pressure from developed nations to strengthen intellectual property protections threaten to undermine this role. Stricter patent laws could hinder the production of generics, affecting not only Indian consumers but also millions of patients worldwide who rely on affordable medications.

The role of compulsory licensing

Compulsory licensing is a critical mechanism in the context of patent law, particularly in ensuring access to affordable medications in India. It allows the government to permit the production and sale of a patented drug without the consent of the patent holder under specific circumstances. This provision is designed to balance the rights of patent owners with the public health needs of the population, particularly in a country like India, where access to essential medicines is a significant concern.

1. Legal framework and provisions

The legal basis for compulsory licensing in India is enshrined in Section 84 of the Indian Patents Act, 1970, which allows the government to grant a compulsory license if:

- The patented invention is not available to the public at a reasonably affordable price.
- The patented invention is not working in the territory of India.
- The patented invention is not accessible to the public in sufficient quantity or quality.

Additionally, Section 92 provides provisions for issuing compulsory licenses in cases of national emergency or extreme urgency, such as public health crises.

2. Enhancing access to medicines

The primary purpose of compulsory licensing is to ensure that life-saving medications are accessible to those who need them. In a country where a significant proportion of the population relies on affordable generics, compulsory licensing acts as a safety net against monopolistic practices by patent holders. By allowing domestic manufacturers to produce generic versions of patented drugs, the government can significantly reduce prices, making essential medications available to low-income and marginalized communities.

For example, in 2012, India issued its first compulsory license for the cancer drug Nexavar, manufactured by Bayer. The patent for Nexavar was held by Bayer, which had set the price at approximately INR 2.8 lakhs for a month's supply, making it unaffordable for most patients. The Indian Patent Office granted a compulsory license to Natco Pharma, allowing it to manufacture and sell the generic version at a significantly reduced price of INR 8,800 for a month's supply. This landmark decision underscored

the potential of compulsory licensing to enhance access to essential medications in critical situations.

3. Facilitating public health response

Compulsory licensing plays a vital role in responding to public health emergencies. During outbreaks of diseases such as HIV/AIDS, tuberculosis, and hepatitis C, the ability to issue compulsory licenses has enabled governments to ensure the rapid availability of affordable treatments. By circumventing patent protections, countries can mobilize resources to address public health crises effectively, providing essential drugs to those in need without the constraints imposed by patent monopolies.

4. Fostering innovation and competition

While compulsory licensing primarily aims to enhance access to medications, it can also stimulate competition and innovation within the pharmaceutical sector. By enabling generic manufacturers to produce patented drugs, the market becomes more competitive, which can lead to lower prices and increased availability. Additionally, the presence of generics in the market can encourage patent holders to reduce their prices voluntarily to remain competitive, thus benefiting consumers.

Moreover, the pressure from compulsory licensing can motivate pharmaceutical companies to invest in research and development for new, innovative drugs rather than relying solely on existing patents. This shift is crucial for fostering a sustainable and dynamic pharmaceutical industry that can respond to the evolving healthcare needs of the population.

5. Challenges and Criticisms

Despite its potential benefits, the implementation of compulsory licensing is not without challenges. Patent holders often resist compulsory licensing, viewing it as a threat to their intellectual property rights and investments. Additionally, the process of obtaining a compulsory license can be complex and time-consuming, deterring governments from utilizing this mechanism fully.

Moreover, there are concerns that excessive reliance on compulsory licensing could discourage foreign investment in the pharmaceutical sector, as companies may be less inclined to invest in research and development in an environment where their patents are vulnerable to government intervention. Striking a balance between safeguarding public health and protecting the rights of patent holders remains a contentious issue.

Challenges faced by generic pharmaceutical manufacturers

While generic pharmaceutical manufacturers in India play a crucial role in providing affordable medications, they face several challenges that can hinder their operations and impact their ability to meet public health needs. These challenges stem from a complex interplay of regulatory, economic, and market dynamics.

1. Regulatory hurdles

The regulatory environment for generic pharmaceuticals in India can be complex and burdensome. Manufacturers must navigate a labyrinth of regulations imposed by various governmental bodies, including the Drug Controller General of India (DCGI) and the Central Drugs Standard Control

Organization (CDSCO). Obtaining approvals for new generics often requires extensive clinical trials and documentation, which can be time-consuming and expensive. This bureaucratic process can delay the entry of generics into the market, limiting their availability to patients who need them.

Moreover, the compliance with Good Manufacturing Practices (GMP) standards is mandatory for generic manufacturers. While these standards ensure the quality and safety of drugs, the costs associated with maintaining compliance can be particularly burdensome for smaller companies, potentially stifling innovation and competition within the industry.

2. Intellectual property challenges

The introduction of product patents in India through the Patent (Amendment) Act of 2005 has intensified competition and litigation in the generic pharmaceutical sector. As multinational corporations seek to enforce their patent rights, generic manufacturers often find themselves embroiled in legal battles over patent infringements. These disputes can result in costly litigation, diverting resources away from research and development and potentially delaying the launch of generics.

Additionally, the uncertainty surrounding patent status can pose significant challenges. Generic manufacturers must conduct thorough patent searches and analyses to avoid infringing on existing patents. However, the intricacies of patent law can make it difficult to ascertain the validity of a patent or its expiration date, increasing the risk of unintentional violations.

3. Market competition and pricing pressures

The generic pharmaceutical market in India is characterized by intense competition, with numerous players vying for market share. While competition generally benefits consumers through lower prices, it can also lead to price wars that erode profit margins for manufacturers. Many generic drugs are sold at minimal profit, making it difficult for manufacturers to sustain their operations while investing in research and development.

The pressure to keep prices low can also impact the quality of generics produced. In a race to the bottom, some manufacturers may cut corners, potentially compromising quality and safety standards. This practice not only endangers public health but can also damage the reputation of the entire generic pharmaceutical industry.

4. Supply chain issues

Generic manufacturers often face challenges related to supply chain management, which can affect their ability to produce and distribute medications efficiently. Fluctuations in raw material costs, transportation delays, and disruptions in the supply chain can all hinder production schedules and lead to shortages of essential medications. Moreover, the reliance on global supply chains for raw materials exposes manufacturers to geopolitical risks and trade barriers, further complicating their operations.

5. Research and development limitations

Although the generic pharmaceutical industry primarily focuses on producing copies of existing drugs, innovation in the form of developing new formulations or delivery methods is essential for staying competitive. However, the investment required for research and development is often

significant, and many generic manufacturers may lack the financial resources to undertake such initiatives. This limitation can restrict their ability to introduce novel generics that meet evolving patient needs.

6. Public perception and trust issues

Despite their critical role in providing affordable medications, generic drugs often face public skepticism regarding their efficacy and safety. Misinformation and misconceptions about generics can impact patient trust and acceptance. Generic manufacturers must invest in education and awareness campaigns to ensure that healthcare providers and patients understand the quality and benefits of generic drugs compared to their branded counterparts.

Public health implications

The relationship between patent law and the generic pharmaceutical industry has profound public health implications, particularly in a country like India, where a significant portion of the population relies on affordable medications. The dynamics of patent law not only affect the availability and pricing of drugs but also influence overall health outcomes and access to essential treatments. This section explores the various public health implications arising from the intersection of patent law and the generic pharmaceutical market.

1. Access to essential medicines

One of the most critical public health implications of patent law is its direct impact on access to essential medicines. The introduction of product patents in India has led to increased prices for new drugs, as patent holders are granted exclusive rights to manufacture and sell these medications. As a result, many life-saving drugs become unaffordable for low- and middle-income patients, leading to disparities in healthcare access.

For instance, treatments for chronic diseases such as diabetes, hypertension, and cancer can be prohibitively expensive when they are under patent protection. This situation forces patients to forgo necessary treatments or to seek alternatives, often with adverse health consequences. The availability of affordable generic alternatives through mechanisms like compulsory licensing is crucial for ensuring that all patients, regardless of their economic status, can access essential medications.

2. Public health emergencies

The ability to issue compulsory licenses in response to public health emergencies is another significant public health implication of patent law. During health crises, such as the COVID-19 pandemic, the capacity to rapidly produce generic versions of vaccines and treatments becomes vital. Compulsory licensing allows governments to intervene and authorize the production of necessary medications, ensuring timely access to life-saving therapies.

For example, during the HIV/AIDS epidemic, India's use of compulsory licensing enabled the production of affordable antiretroviral drugs, significantly improving access for millions of patients. Such measures can effectively address public health emergencies by ensuring that critical medications are available when they are needed most.

3. Impact on disease burden

The accessibility of affordable generic medications can have a substantial impact on the overall disease burden within a

population. When patients can access necessary treatments without financial strain, it leads to better adherence to medication regimens and improved health outcomes. This is particularly important in managing chronic diseases, where consistent treatment is essential for controlling symptoms and preventing complications.

Conversely, when patients are unable to afford medications due to patent protections, the result can be an increase in morbidity and mortality rates. This not only affects individual patients but also places a burden on the healthcare system, as untreated conditions can lead to more severe health complications and increased healthcare costs.

4. Economic implications

The economic implications of patent law and its impact on generic pharmaceuticals extend beyond individual health outcomes to the broader public health system. High drug prices can strain public health budgets, limiting the resources available for other essential services. When a significant portion of healthcare expenditures is directed toward high-priced patented drugs, it can detract from funding for preventive care, infrastructure, and public health initiatives.

Moreover, when individuals cannot afford necessary medications, they may rely more heavily on public health facilities, which can become overwhelmed and under-resourced. This can lead to a vicious cycle of poor health outcomes and increased healthcare costs, exacerbating public health challenges.

5. Encouragement of innovation and local manufacturing

The generic pharmaceutical industry not only addresses immediate health needs but also plays a role in fostering local manufacturing and innovation. A robust generic market can stimulate competition, encouraging both domestic and international pharmaceutical companies to invest in research and development of new drugs. This, in turn, can lead to the development of innovative treatments that cater to the unique health needs of the Indian population.

By supporting the growth of the generic pharmaceutical sector, patent law can create an environment conducive to local innovation, ultimately contributing to the long-term sustainability of the healthcare system.

Policy Recommendations

To ensure that patent law effectively promotes public health while fostering the growth of the generic pharmaceutical industry in India, several policy recommendations can be implemented. These recommendations aim to strike a balance between protecting intellectual property rights and ensuring access to affordable medications for all citizens.

1. Strengthening compulsory licensing mechanisms

The Indian government should enhance the clarity and efficiency of the compulsory licensing process. Streamlining the application and approval procedures can encourage the use of compulsory licensing in situations where public health is at stake. Establishing clear guidelines and criteria for when and how compulsory licenses can be issued will provide certainty for both patent holders and generic manufacturers. This clarity can foster an environment where

public health needs are prioritized without compromising the rights of patent holders.

2. Promoting local manufacturing and innovation

To bolster the domestic pharmaceutical industry, the government should incentivize local manufacturing and innovation through grants, subsidies, and tax benefits. Establishing public-private partnerships can facilitate research and development initiatives, particularly for diseases that disproportionately affect low-income populations. By supporting local manufacturers in developing new formulations and delivery methods for existing drugs, India can enhance its capacity to produce affordable generics while also fostering innovation.

3. Increasing transparency in patent filings

Implementing policies that promote transparency in patent filings can help generic manufacturers navigate the patent landscape more effectively. The establishment of a publicly accessible patent database that includes detailed information about patent status, expiration dates, and licensing agreements will empower generic manufacturers to make informed decisions. This transparency can reduce the risk of patent infringement and encourage competition in the generic market.

4. Expanding access to health insurance

Expanding access to health insurance can mitigate the financial burden of medications on patients, ensuring that they can afford essential treatments regardless of patent protections. Policymakers should consider implementing universal health coverage or enhancing existing schemes to include comprehensive pharmaceutical coverage. This approach will help ensure that patients are not forced to choose between financial stability and access to necessary medications.

5. Enhancing public awareness and education

Public awareness campaigns aimed at educating healthcare professionals and consumers about the efficacy and safety of generic medications are essential. The government and industry stakeholders should collaborate on initiatives to dispel myths surrounding generics and promote their benefits. By fostering trust in generic drugs, these efforts can encourage healthcare providers to prescribe generics and patients to choose them, ultimately improving access to affordable medications.

6. Implementing stronger regulatory oversight

Strengthening regulatory oversight of both patented and generic pharmaceuticals can ensure that quality standards are maintained across the board. The government should invest in capacity-building initiatives for regulatory bodies to enhance their ability to monitor compliance with quality and safety standards. Ensuring that generics meet rigorous standards will build public trust and enhance the reputation of the Indian pharmaceutical industry globally.

7. Engaging in international dialogues

India should actively engage in international dialogues regarding intellectual property rights and public health. Participating in discussions at the World Trade Organization (WTO) and other global forums can help India advocate for policies that balance patent protections with public health

needs. By collaborating with other nations facing similar challenges, India can promote a more equitable global framework for access to medications.

Conclusion

The intricate relationship between patent law and the generic pharmaceutical industry in India is critical in shaping the landscape of healthcare accessibility and affordability. The evolution of patent law in India, particularly with the shift from the Patents Act of 1970 to the amendments introduced in 2005, reflects a significant paradigm shift in the country's approach to intellectual property. While the intention behind these changes was to foster innovation and attract foreign investment, the resulting landscape poses substantial challenges for public health, particularly in terms of access to essential medications. The introduction of product patents has resulted in heightened protection for pharmaceutical companies, allowing them to set prices that are often prohibitive for large segments of the Indian population. This situation is particularly concerning in a country where many citizens rely on generic drugs as a means to afford necessary treatments. The contrast between high prices for patented drugs and the significantly lower costs of generics underscores the critical role that generic manufacturers play in enhancing healthcare access. Without these affordable alternatives, the healthcare system could face insurmountable barriers, leading to increased morbidity and mortality rates from treatable conditions.

Compulsory licensing stands out as a vital mechanism to mitigate these issues. By permitting the government to allow third parties to produce patented drugs without the consent of the patent holder, compulsory licensing can be instrumental during public health emergencies or when patented drugs are priced beyond the reach of average citizens. The successful application of this provision, as demonstrated in the landmark case involving the cancer drug Nexavar, highlights its potential to facilitate access to essential medicines in times of need. Such mechanisms not only support individual health but also contribute to the broader goal of public health equity, particularly in a nation where healthcare disparities remain a significant concern. However, the challenges facing generic pharmaceutical manufacturers in India are multifaceted. Regulatory hurdles, complicated by stringent compliance requirements and lengthy approval processes, often impede the timely introduction of generics into the market. Furthermore, the threat of litigation from patent holders can create a chilling effect, discouraging manufacturers from pursuing potentially profitable generic versions of patented drugs. This environment of uncertainty and risk can stifle innovation and limit the growth of the generic sector, ultimately undermining the very objectives of patent law.

In light of these challenges, it is imperative for policymakers to implement strategies that strengthen the relationship between patent law and public health. This paper recommends a series of targeted policy measures aimed at enhancing the efficacy of patent law while promoting the interests of public health. Key among these recommendations is the need to streamline the compulsory licensing process, making it more transparent and accessible. Establishing clear guidelines will encourage its use in situations where public health is at stake, ensuring that life-saving medications are accessible to those in need.

Moreover, fostering local manufacturing and innovation through financial incentives, public-private partnerships, and research grants can invigorate the generic pharmaceutical industry. By empowering local manufacturers to develop new formulations and delivery systems, India can create a more resilient and responsive healthcare system. This approach not only addresses immediate public health needs but also cultivates a culture of innovation within the domestic pharmaceutical sector.

In addition, enhancing public awareness about the efficacy and safety of generic medications is crucial in building trust among healthcare providers and patients alike. Public health campaigns can play a pivotal role in dispelling myths and misconceptions surrounding generics, encouraging their adoption in clinical practice. Ensuring that patients understand the value of generics can lead to greater acceptance and increased demand, further driving competition and affordability. Lastly, engaging in international dialogues on patent law and public health will position India as a proactive participant in shaping global policies. By advocating for a balanced approach that prioritizes public health without compromising intellectual property rights, India can influence discussions that have far-reaching implications for healthcare access worldwide.

In conclusion, the future of India's pharmaceutical landscape hinges on the ability to navigate the complexities of patent law while ensuring equitable access to medications. By prioritizing public health in the formulation and implementation of patent policies, India can build a more inclusive healthcare system that safeguards the rights of all citizens to access essential treatments. The challenges are formidable, but with concerted efforts from policymakers, industry stakeholders, and civil society, India can emerge as a leader in the global effort to balance innovation with healthcare accessibility, ultimately improving health outcomes for millions of people.

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