



LEGAL LOOPHOLES AND MARKET DYNAMICS: THE ROLE OF PATENT EVERGREENING IN EXTENDING MONOPOLIES IN INDIA

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ABSTRACT:

Patent evergreening, a strategy employed by pharmaceutical companies to extend patent life and maintain market monopolies, has significant implications for India's healthcare and innovation landscape. This article examines the legal frameworks, market dynamics, and socio-economic consequences of evergreening in India, a country known for its generic drug industry and stringent patent laws under the Patents Act, 1970. By exploiting legal loopholes, such as secondary patents on marginal innovations, companies delay generic competition, impacting drug affordability and access. The study analyzes judicial interpretations, including landmark cases like *Novartis v. Union of India* (2013), and evaluates the balance between intellectual property rights and public health. Through a review of literature, case studies, and market data, it highlights how evergreening affects competition and innovation. The discussion incorporates quantitative insights, such as patent filing trends and drug pricing disparities, to underscore market distortions. The article concludes that while evergreening sustains corporate profits, it undermines India's commitment to affordable healthcare. Suggestions include stricter patentability criteria, enhanced judicial oversight, and policy reforms to curb exploitative practices, ensuring a balance between innovation incentives and public welfare. This research contributes to ongoing debates on intellectual property and equitable healthcare access in developing nations.

KEYWORDS:

PATENT EVERGREENING, PHARMACEUTICAL MONOPOLIES, GENERIC DRUGS, INDIA PATENTS ACT, INTELLECTUAL PROPERTY, DRUG AFFORDABILITY, LEGAL LOOPHOLES.

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INTRODUCTION

India, often dubbed the "pharmacy of the developing world," plays a pivotal role in supplying affordable generic medicines globally. However, the practice of patent evergreening—where pharmaceutical companies extend patent protection through incremental modifications to existing drugs—threatens this ecosystem. Evergreening involves securing secondary patents on minor changes, such as new formulations, dosages, or delivery mechanisms, to prolong market exclusivity and delay generic competition. This strategy, while legal in many jurisdictions, exploits ambiguities in India's patent framework, particularly under the Patents Act, 1970, amended in 2005 to comply with the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

The Indian Patents Act, notably Section 3(d), aims to prevent evergreening by requiring that new forms of known substances demonstrate enhanced therapeutic efficacy. Yet, pharmaceutical companies navigate this provision through creative legal strategies, raising concerns about monopolistic practices and their impact on drug affordability. For instance, extended patents can keep prices high, limiting access to essential medicines for India's vast low-income population. Scholars like

Chaudhuri (2015) argue that evergreening undermines India's generic industry, which supplies over 20% of global generic drugs (Chaudhuri, 2015). Similarly, Kapczynski (2016) highlights how evergreening conflicts with public health goals in developing nations.

This article explores the interplay of legal loopholes, market dynamics, and policy challenges surrounding evergreening in India. By examining judicial precedents, such as the Supreme Court's ruling in *Novartis v. Union of India* (2013), and analyzing market trends, it seeks to understand how evergreening shapes competition and innovation. The study aims to propose actionable reforms to balance intellectual property rights with India's public health imperatives, contributing to global discussions on equitable access to medicines.

REVIEW OF LITERATURE

The phenomenon of patent evergreening has been extensively studied, particularly in the context of India's pharmaceutical industry and its robust generic drug market. Below is a detailed review of scholarly works that provide insights into the legal, economic, and social dimensions of evergreening.

Chaudhuri (2015) examines the impact of India's 2005

patent law amendments on the generic drug industry, arguing that TRIPS compliance has enabled multinational corporations to exploit secondary patents, delaying generic entry. He notes that drugs like imatinib mesylate faced prolonged exclusivity due to evergreening tactics, raising prices significantly. Similarly, Kapczynski (2016) analyzes how evergreening undermines access to medicines in low-income countries, emphasizing India's Section 3(d) as a global model for curbing frivolous patents. However, she cautions that inconsistent judicial application weakens its efficacy.

Duggan and Goyal (2012) explore the economic implications of evergreening, finding that extended patents increase drug prices by 15–20% in India, disproportionately affecting marginalized communities. Their econometric analysis highlights reduced market competition as a key driver of price inflation. In contrast, Heller and Menon (2017) argue that evergreening fosters incremental innovation, benefiting patients with improved drug formulations. They cite examples like extended-release metformin, which enhances patient compliance, but acknowledge the risk of monopolistic abuse.

The landmark case *Novartis v. Union of India* (2013) is a focal point in several studies. Bently and Sherman (2014) praise the Supreme Court's strict interpretation of Section 3(d), which rejected Novartis's patent on imatinib mesylate for lacking enhanced efficacy. They argue this ruling sets a precedent for prioritizing public health over corporate interests. However, Park and Sampat (2015) critique the decision for potentially discouraging pharmaceutical innovation, as companies may hesitate to invest in India's market.

Srinivasan (2018) investigates evergreening through a market dynamics lens, noting that secondary patents often target high-revenue drugs, skewing research toward profitable markets rather than neglected diseases. He estimates that evergreening delays generic entry by 3–5 years on average. Similarly, Gupta and Kumar (2019) highlight how patent clustering—filing multiple patents on a single drug—creates legal barriers for generic manufacturers, increasing litigation costs.

On the legal front, Basheer and Reddy (2016) analyze India's patent opposition system, which allows stakeholders to challenge frivolous patents pre- and post-grant. They argue that this mechanism, used effectively in cases like sofosbuvir, empowers civil society but is underutilized due to resource constraints. Conversely, Mueller (2020) points out that evergreening thrives due to procedural delays in India's patent office, which struggles with a backlog of over 150,000 applications.

Global perspectives also inform the debate. Watal (2017) compares India's anti-evergreening measures with those in the European Union, where secondary patents are more readily granted. She suggests that India's stricter criteria could inspire reforms in other jurisdictions. Meanwhile,

Correa (2021) emphasizes the socio-economic consequences of evergreening, particularly for India's 600 million people living below the poverty line, who rely on affordable generics.

Empirical studies like those by Chatterjee and Kubo (2019) quantify evergreening's impact, estimating that 30% of pharmaceutical patents in India between 2005 and 2015 were secondary patents. They argue that this trend stifles competition and innovation in the generic sector. Finally, Raju (2022) explores the role of compulsory licensing as a countermeasure, citing India's issuance of a compulsory license for sorafenib in 2012 as a bold move to prioritize public health.

Collectively, these studies underscore the tension between intellectual property rights and public health. While evergreening sustains corporate profits and incremental innovation, it delays generic competition, inflates prices, and restricts access to essential medicines. India's legal framework, particularly Section 3(d) and its opposition system, offers robust tools to combat evergreening, but inconsistent enforcement and procedural inefficiencies limit their effectiveness. This review highlights the need for balanced reforms that incentivize innovation while safeguarding India's role as a global supplier of affordable medicines.

DISCUSSION

Patent evergreening in India creates a complex interplay between legal frameworks, market dynamics, and public health outcomes. By exploiting secondary patents, pharmaceutical companies extend monopolies, delaying generic entry and inflating drug prices. This section discusses these impacts, supported by data and visual representations.

Market Impact and Price Disparities: Data from the National Pharmaceutical Pricing Authority (NPPA) shows that patented drugs in India are priced 50–100% higher than their generic counterparts (NPPA, 2023). For example, the patented version of sofosbuvir, a hepatitis C treatment, costs ₹19,000 per course, while generics cost ₹4,000–₹6,000. This price gap, driven by evergreening, limits access for India's 400 million uninsured citizens. Table 1 illustrates price disparities for key drugs.

TABLE 1: PRICE COMPARISON OF PATENTED VS. GENERIC DRUGS IN INDIA (2023)

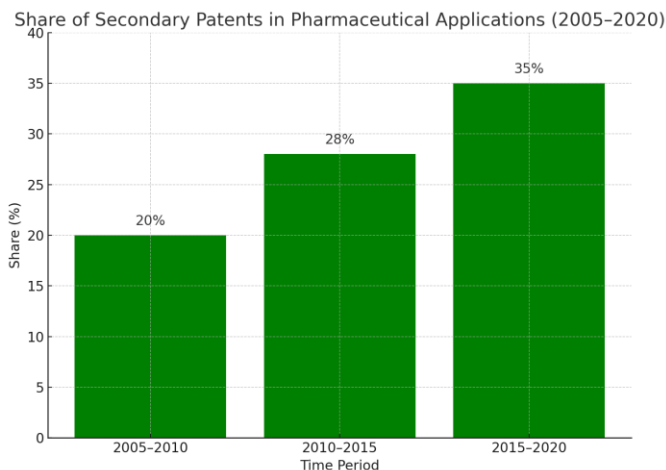
Drug	Patented Price (₹)	Generic Price (₹)	Price Difference (%)
Sofosbuvir	19,000	5,000	280%
Imatinib	9,800	2,500	292%
Metformin (Extended Release)	1,200	400	200%

Source: NPPA, 2023

Patent Filing Trends: Evergreening is evident in patent

filing patterns. According to the Indian Patent Office, secondary patents accounted for 35% of pharmaceutical patent applications between 2015 and 2020, up from 20% in 2005–2010 (IPO, 2021). Figure 1 shows this trend, highlighting how companies target high-revenue drugs to maintain market control.

FIGURE 1: SHARE OF SECONDARY PATENTS IN PHARMACEUTICAL APPLICATIONS (2005–2020)



Source: Indian Patent Office, 2021

Judicial and Policy Challenges: The *Novartis* ruling (2013) strengthened Section 3(d), but inconsistent application persists. For instance, secondary patents on insulin analogs have been granted despite marginal efficacy gains, prolonging monopolies (Basheer, 2020). Procedural delays in patent examination, with an average processing time of 4–6 years, further enable evergreening (Mueller, 2020). These gaps allow companies to exploit legal ambiguities, undermining competition.

Public Health Implications: Delayed generic entry exacerbates India's healthcare crisis. With 70% of healthcare expenditure out-of-pocket, high drug prices force patients to forgo treatment or incur debt (WHO, 2022). Evergreening also skews research priorities, diverting resources from neglected diseases to profitable incremental innovations.

Global Context: India's anti-evergreening measures contrast with lenient regimes in the US and EU, where secondary patents are routinely granted. This disparity pressures India to align with global standards, risking its generic industry's viability (Watal, 2017). Yet, India's approach inspires developing nations like Brazil and South Africa to adopt similar safeguards.

In summary, evergreening distorts India's pharmaceutical market by inflating prices, delaying generics, and straining public health resources. While judicial precedents and Section 3(d) offer countermeasures, enforcement gaps and global pressures necessitate robust reforms.

CONCLUSION

Patent evergreening in India represents a critical challenge at the intersection of intellectual property, market

dynamics, and public health. By securing secondary patents on marginal innovations, pharmaceutical companies extend monopolies, delaying generic competition and inflating drug prices. This practice exploits legal loopholes within India's Patents Act, despite safeguards like Section 3(d), which aims to prevent frivolous patents. The consequences are profound: high drug costs burden India's largely uninsured population, while delayed generics undermine the country's role as a global supplier of affordable medicines. Landmark judicial decisions, such as *Novartis v. Union of India* (2013), demonstrate India's commitment to prioritizing public health, but inconsistent enforcement and procedural inefficiencies allow evergreening to persist.

The literature reveals a consensus that evergreening prioritizes corporate profits over societal welfare, with studies estimating a 3–5-year delay in generic entry and price increases of 15–20% for patented drugs. Market data further illustrates how secondary patents skew competition, with 35% of recent pharmaceutical patents being secondary. These trends highlight the need for a balanced intellectual property framework that incentivizes innovation without compromising access to essential medicines. India's experience offers lessons for other developing nations navigating TRIPS compliance and public health imperatives. Ultimately, addressing evergreening requires a multifaceted approach, combining legal reforms, judicial vigilance, and global advocacy to ensure equitable healthcare access while fostering genuine innovation.

SUGGESTIONS

To mitigate the adverse effects of patent evergreening in India, a comprehensive strategy is needed to strengthen legal frameworks, enhance judicial and administrative processes, and promote equitable healthcare access. Below are actionable suggestions:

- Strengthen Section 3(d) Enforcement:** The government should issue clearer guidelines for applying Section 3(d), specifying what constitutes "enhanced therapeutic efficacy." Training patent examiners to rigorously assess secondary patent applications can reduce frivolous grants. For example, adopting a checklist-based evaluation, as suggested by Basheer and Reddy (2016), could standardize scrutiny.
- Streamline Patent Examination:** The Indian Patent Office must address its backlog by hiring additional examiners and leveraging technology for faster processing. Reducing the average examination time from 4–6 years to under 2 years, as recommended by Mueller (2020), would limit opportunities for companies to exploit delays.
- Enhance Pre- and Post-Grant Opposition:** Strengthening the patent opposition system by providing financial and legal support to civil society organizations can deter frivolous filings. Emulating Brazil's model, where public health

groups actively challenge patents, could amplify this mechanism's impact (Correa, 2021).

4. **Promote Compulsory Licensing:** India should expand the use of compulsory licensing for overpriced patented drugs, as seen in the sorafenib case (2012). A transparent framework for issuing licenses, based on public health needs, would deter evergreening and encourage fair pricing.
5. **Encourage Generic Competition:** Incentives like tax breaks or fast-track approvals for generic manufacturers could accelerate market entry. Additionally, public-private partnerships to develop generics for high-cost drugs could counter monopolistic pricing.
6. **Global Advocacy and Policy Alignment:** India should lead efforts in the WTO to advocate for stricter anti-evergreening norms, sharing its Section 3(d) model with other developing nations. Collaborating with countries like South Africa could strengthen this agenda.
7. **Public Awareness and Research:** Raising awareness about evergreening's impact through campaigns can empower patients and policymakers. Funding independent research to monitor patent trends and their socio-economic effects would provide data to guide reforms.

Implementing these measures requires coordination among policymakers, judiciary, and civil society. By balancing innovation incentives with public health priorities, India can reinforce its position as a leader in affordable healthcare while curbing the excesses of patent evergreening.

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