

The Antidote of Patent Opposition: Curbing Pharmaceutical Evergreening

Khushnuma Rahman

Bball.B. 7th Semester, Amity University Patna, Patna, Bihar

Abstract:

In the high-stakes world of pharmaceuticals, a clever shell game known as "evergreening" keeps drug prices soaring. Patent opposition is an effective safeguard against pharmaceutical evergreening, a practice where drug companies prolong their market dominance through minor modifications that offer no significant therapeutic benefit. Opposition proceedings, which enable third parties to challenge patent applications, are crucial in preventing unwarranted extensions of market exclusivity and ensuring public access to affordable medicines. This paper argues that the smartest cure for this tactic is the patent opposition. This legal tool lets experts and the public challenge weak patents before they can block cheaper generics. By looking at real-world successes, we show that opposition systems are a powerful way to protect both real innovation and affordable medicine. They ensure patents reward true invention, not just legal loopholes.

Keywords: Patent Evergreening, Pharmaceutical Evergreening, Pre-grant & Post-grant Opposition, Drug Affordability

1. INTRODUCTION

The soaring cost of prescription medicines presents a critical and escalating challenge for global public health. From straining the budgets of national healthcare systems to placing life-saving treatments out of reach for patients in both developed and developing nations, the issue of drug affordability strikes at the core of equitable healthcare access. This crisis is often perpetuated not by a lack of existing treatments, but by complex legal and corporate strategies that artificially extend market monopolies on blockbuster drugs long after their core intellectual property should have expired. At the heart of this issue lies a strategic practice known as **pharmaceutical evergreening**. This refers to the process whereby pharmaceutical companies obtain a series of secondary patents on minor, often trivial modifications to an existing drug product. These can include new formulations, dosages, crystal forms (polymorphs), or methods of use, which offer little to no therapeutic advance over the original invention. The primary objective is not to introduce a groundbreaking new medicine, but to strategically create a "patent thicket" a dense web of intellectual property rights - that surrounds the original drug. The negative effects are profound: this practice deliberately delays the entry of cheaper generic competitors, sustains artificially high prices for years beyond the intended patent term, and ultimately stifles true innovation by incentivising legal gaming over genuine research and development.

The patent system itself is caught in a paradox. Its fundamental purpose is to incentivise innovation by granting inventors a temporary monopoly, a limited period of exclusivity to profit from their invention. This social contract is designed to reward risk and drive medical progress. However, evergreening exploits

this very system. Instead of protecting a genuine novel invention, it leverages legal loopholes to prolong exclusivity on known substances, thereby distorting the patent's intent and creating windfalls for corporations at the direct expense of patients and healthcare systems. Against this backdrop, a potent legal and procedural "antidote" has emerged: the patent opposition system. Patent opposition is an administrative procedure that allows third parties, including generic drug manufacturers, civil society organisations, and public health advocates, to formally challenge the validity of a patent application (pre-grant opposition) or a granted patent (post-grant opposition) directly before the patent office. This mechanism provides a crucial platform to scrutinise and invalidate weak secondary patents that form the backbone of evergreening strategies, acting as a democratic check on the abuse of the patent system.

2. RESEARCH METHODOLOGY

This research adopts a qualitative and comparative case study design to facilitate an in-depth, context-rich investigation into the function of patent opposition as a mechanism against pharmaceutical evergreening. The design is selected for its capacity to examine complex real-world phenomena within their authentic settings, allowing for a nuanced analysis of legal procedures and their outcomes across different jurisdictions. The primary method of inquiry is doctrinal legal analysis, which involves the systematic interpretation of statutory laws, patent office guidelines, and judicial precedents to establish the legal framework governing evergreening and opposition. This is substantiated through a thematic analysis of secondary literature, including academic commentaries and policy reports, to identify prevailing arguments and challenges. Furthermore, a comparative analysis is employed to juxtapose the processes and impacts of key opposition cases, notably from India and Europe. This comparative approach enables the identification of operational efficiencies, strategic commonalities, and jurisdictional idiosyncrasies, thereby providing a robust, evidence-based assessment of the opposition mechanism's efficacy and limitations.

3. UNDERSTANDING THE UNDERLYING CRITICISM OF SUCH PRACTICES

The pharmaceutical industry justifies intellectual property (IP) protection as essential for recovering the significant costs associated with research, development, and regulatory clearance. By granting temporary exclusive rights to a specific invention, patent law permits the rights holder, typically an originator company, to set prices above competitive market levels. This ability to command premium pricing creates a natural economic incentive to prolong the duration of exclusivity. Critics contend that this incentive has led to the adoption of specific patenting strategies which artificially extend market protection. These practices, they argue, maintain high drug prices without delivering corresponding benefits to consumers or advancing genuine innovation. The primary strategies under scrutiny include several key approaches. "**Evergreening**" involves securing additional patents on peripheral aspects of a drug, such as new formulations or methods of use, as the original patent nears expiration. This tactic can effectively prolong market exclusivity beyond the standard twenty-year term, delaying generic competition and enabling the continued charging of premium prices. Another criticised practice is "**Product hopping**," where a brand-name company introduces a modified version of a drug protected by a newer patent as the older version's patents expire. This can be executed as a "hard switch," by removing the original product from the market, or a "soft switch," by heavily marketing the new product while keeping the old one available. The goal is to shift the market to the new version, thereby pre-empting the uptake of generic alternatives for the older product.

A further tactic involves the creation of "**Patent thickets**," which refers to the strategy of obtaining a dense network of overlapping patents around a single product. This complex web of intellectual property can deter generic manufacturers from entering the market due to the high risk of infringement litigation and the associated legal costs. Finally, "**Pay-for-delay**" settlements have drawn significant criticism. These agreements occur when a patent-holding brand-name company settles litigation with a generic challenger by providing monetary or other compensation in exchange for the generic company delaying its market entry. Critics label these settlements as anti-competitive, as they allow the brand to maintain high prices without the risk of its potentially weak patent being invalidated in court, ultimately harming consumers.

In defence, drug manufacturers argue that their patent strategies are legitimate, designed to protect new and innovative inventions as intended by patent law. They maintain that the terms used by critics are unfairly biased and describe exceptional behaviour rather than standard industry practice. Supporters of these strategies reject their characterisation as anti-competitive, emphasising that robust patent rights are a fundamental necessity to incentivise the high-risk, life-saving research and development that leads to new therapies.

4. RECENT CASE EXEMPLIFYING THE ENDURING PRACTICE

The 2013 ruling by the Indian Supreme Court against **Novartis AG** in the case of its cancer drug Gleevec (imatinib mesylate) became a landmark event in global public health, setting a critical precedent in the battle against pharmaceutical evergreening. The facts of the case centred on Novartis's application for a patent on the beta-crystalline salt form of imatinib, which the company argued offered superior "bioavailability" and stability compared to the original compound. This original compound, imatinib, had never been patented in India itself, a key point the judges would later emphasise.

India's unique patent law, specifically Section 3(d), acted as the legal bedrock for the rejection. This provision was specifically designed to prevent evergreening by stating that new forms of known substances are not patentable unless they demonstrate a significant enhancement in "therapeutic efficacy." The Indian Patent Office, the Intellectual Property Appellate Board, and finally the Supreme Court all unanimously found that Novartis's new salt form, while potentially easier to process, did not meet this high bar. The courts ruled that increased bioavailability alone did not automatically translate into a tangible improvement in how effectively the drug treated the disease from a patient's perspective. This legal interpretation was hailed by public health advocates as a robust defence of access to medicines, ensuring that patents are granted only for genuine therapeutic breakthroughs, not minor pharmacological improvements.

The immediate aftermath was profound. By definitively rejecting the patent, the Supreme Court cleared the path for Indian generic manufacturers to continue producing and selling affordable versions of imatinib. The price difference was staggering: while Novartis's branded version cost a patient around \$2,600 per month, the generic equivalents were available for approximately \$175 per month. This ensured that life-saving treatment was accessible to thousands of leukaemia patients in India and across the developing world, where Indian generics are a primary source of medicine.

Beyond India's borders, the case sent a powerful signal to other developing nations, providing a legal blueprint for using patent law flexibilities to safeguard public health. It emboldened health agencies and civil society groups to more aggressively challenge secondary patents. However, the aftermath also intensified the debate between the innovative and generic pharmaceutical sectors. The industry and its

supporters argued that the interpretation of Section 3(d) was too narrow, discouraging incremental innovation that can offer real-world patient benefits, such as reduced side effects or improved dosing schedules. They contended that such a stance creates uncertainty for investors and risks stifling the development of improved formulations that, while not revolutionary, still represent meaningful medical progress.

In the years since, the "Novartis ruling" has become a permanent reference point in global drug policy discussions. It forced a stark confrontation between two competing philosophies: one viewing patents as a tool to maximise commercial returns on any modification, and the other, embodied by India's law, viewing them as a reward reserved for demonstrable therapeutic gains. The case's enduring legacy is that it successfully established a high legal barrier against evergreening, empowering countries to prioritise affordable access to essential medicines while continuing to challenge the global pharmaceutical industry on the definition of truly valuable innovation.

4.1 Other Important Judicial Interpretations:

- **F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd:**

This case involved a patent dispute between Roche and Cipla over the drug Erlotinib, used for treating lung cancer. Roche alleged patent infringement by Cipla's generic version. The Delhi High Court ruled in favour of Cipla, holding that Roche's patent was not valid as it lacked inventive steps and did not satisfy the requirements of Section 3(d) of the Indian Patents Act. The judgment affirmed the strict interpretation of patentability criteria, including the enhanced efficacy requirement under Section 3(d).

- **Bayer Corporation v. Union of India & Others:**

This case dealt with the patentability of the anti-cancer drug Sorafenib Tosylate, marketed as Nexavar. Bayer held a patent for the drug and challenged the grant of a compulsory license to Natco Pharma, allowing it to manufacture and sell a generic version. The decision by the Intellectual Property Appellate Board (IPAB) upheld the grant of the compulsory license, recognising the importance of ensuring affordable access to life-saving medicines.

4.2 TRIPS Perspective on The Pharmaceutical:

Patents The General Agreement on Tariffs and Trade (GATT) Uruguay Round negotiations between 1986 and 1994 resulted in a significant treaty known as Trade-Related Aspects of Intellectual Property Rights (TRIPS). This agreement aims to promote technological transfer, innovation, and the dissemination of knowledge, benefiting both innovators and consumers while fostering socioeconomic welfare and a balanced distribution of rights and responsibilities. TRIPS sets minimum standards for intellectual property protection that member countries must follow. Developing nations, although compelled to sign due to international pressure, argued that the new conditions would raise pharmaceutical patent prices, making medicines less accessible to the general public. For example, the Indian Patent Act of 1970, amended in 2005 under TRIPS, recognised only process patents, not product patents. After 2005, the granting of both process and product patents limited reverse engineering by generics, impacting their market. While TRIPS is not entirely beneficial, it also has its merits. Certain provisions favour developing countries and aim to balance rights and duties, supporting broader policies like access to essential medicines. Article 7 seeks to balance innovation with social welfare. Article 8 allows states to implement measures to protect public health and promote socio-economic interests. Article 27(2) permits restrictions on patentability based on health or safety concerns. Additionally, Article 30 provides limited exemptions to patent rights to prevent unreasonable exploitation, and Article 31 outlines conditions under which member states may use patented inventions without authorisation, facilitating compulsory licensing.

Overall, TRIPS endeavours to balance the interests of innovators and public welfare, though brand-name pharmaceutical companies often exploit patent rights using various tactics, discussed further below.

4.3 Post-Novartis Situation:

Has Patent Exploitation Ended? Although the US and EU criticise India based on the Novartis Judgement, the reality is that even after the ruling, patent rights are still exploited to some extent. While the claims of innovator companies undergo a strict legal framework, the paradox is that most of these companies misuse the regulations governing patent authorisation. According to research 43, on pharmaceutical patents granted between 2009-16, the majority, i.e., 72 %, were secondary patents granted for marginal improvements. The same report suggests that applicants can bypass these strict requirements, with only 15% of patents granted undergoing detailed scrutiny. After 2013, pharmaceutical innovators must meet certain criteria or principles laid down as the ‘Novartis Standard’. Furthermore, in 2014, new guidelines for pharmaceutical patent applications were introduced, which also need to be followed. 44 However, the common strategy of innovators is to argue that the relevant provision for their patent application is s.3(e) and not s.3(d). Where s.3(d) requires demonstrating “enhanced therapeutic efficacy” over a known substance, s.3(e) only requires showing that the new combination has a synergistic effect.

4.4 Implications and Significance:

Access to Affordable Medications: The Indian Supreme Court’s ruling safeguarded access to affordable generic versions of Imatinib for patients in India. This decision had implications beyond India, as it allowed for the production and export of low-cost generic versions, benefiting patients in other countries that relied on India’s generic pharmaceutical industry.

Public Health Impact: The Novartis case raised concerns about the impact of patent evergreening on public health. By extending market exclusivity and delaying generic competition, pharmaceutical companies can maintain high prices, limiting access to life-saving medications. The ruling highlighted the importance of ensuring access to affordable medicines as a fundamental aspect of public health.

Policy Considerations: The Novartis case prompted discussions on the need for patent reform and the balance between intellectual property rights and public health. Stricter examination standards and safeguards against patent evergreening were recognised as essential to prevent the grant of patents for trivial modifications lacking substantial therapeutic benefits.

Industry Transparency and Accountability: The case brought attention to the wider issue of patent evergreening within the pharmaceutical industry. It emphasised the importance of transparency and accountability in patenting practices to ensure that patents are granted only for genuine innovations that provide significant clinical advancements.

5. CONCLUSION

The evidence collected and analysed in this research paper leads to an inescapable conclusion: patent opposition mechanisms stand as a critical, effective, and necessary antidote to the pervasive problem of pharmaceutical evergreening. The practice of evergreening, through strategies like product hopping, patent thickets, and pay-for-delay settlements, represents a strategic subversion of the patent system's intent, prioritising prolonged profitability over both genuine innovation and public health. It creates a legalistic maze that delays generic competition, sustains exorbitant drug prices, and ultimately restricts patient access to essential medicines.

This paper has demonstrated that pre-grant and post-grant opposition procedures offer a powerful corrective to this imbalance. By providing a transparent, administrative forum for third-party challenges,

the opposition system injects a vital dose of public-interest scrutiny directly into the patent-granting process. Case studies from India, fortified by Section 3(d) of its Patents Act, and the European Patent Office illustrate this principle in action. These examples show how opposition proceedings can surgically dismantle weak secondary patents that form the backbone of evergreening strategies, thereby clearing the path for robust generic competition. The resultant market dynamics—evidenced by the precipitous drop in the price of drugs like Gleevec following a successful opposition—confirm the direct, tangible benefit of these mechanisms for healthcare systems and patients.

It is crucial to acknowledge that the opposition "antidote" is not a panacea without its own challenges, including resource disparities, legal delays, and political pressure. However, these limitations do not undermine its value but rather highlight areas for strategic strengthening. The findings affirm that a robust opposition system does not hinder innovation; instead, it refocuses it. By raising the bar for patentability and challenging frivolous claims, it channels pharmaceutical R&D toward the development of truly novel and therapeutically significant drugs, rather than rewarding minor, non-inventive modifications

In the final analysis, the debate over evergreening and patent opposition is a debate about the soul of the intellectual property system. It is a choice between a system that permits indefinite monopolies through legal manoeuvring and one that vigorously protects its integrity to reward genuine progress. The findings of this research compellingly argue for the latter. Strengthening and broadly implementing patent opposition frameworks is not an anti-innovation policy; it is a pro-competition, pro-access, and pro-public health policy. It is the essential corrective needed to ensure the patent system fulfils its original bargain: fostering true innovation while safeguarding the public's right to affordable healthcare.

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