Volume 40, July 2025 ISSN 2581-5504

"Ever greening of Patents: Legal Loopholes and Indian Judiciary's Stance"

Mr. Amrut Vinayak Sawant
Advocate

Introduction

The term "ever greening" has engrossed increasing criticism and judicial scrutiny in the promptly evolving world of intellectual property, particularly in the pharmaceutical sector the word constantly greening discusses to the strategic postponement of patent protection by creating negligible or insubstantial modifications to existing patented merchandises. This perception does not officially exist in patent law and it functions within the grey areas of legislation chewing corporations particularly in the drug industry to maintain market dominations beyond the prescribed patent duration. The delays practice effectively to the entry cost effective legislative frameworks and judicial pronouncements; India has attempted to strike a balance between pleasing genuine modernization and preventing unjust monopolistic controller.[1]

Understanding the Concept of Patent ever greening

Legal codification of ever greening term is not available but a practice used to lengthen the commercial life of a patent. By design Patent laws afford exclusive rights for a incomplete period which is characteristically 20 years to encourage innovation. The multinational companies however in the pharmaceutical industry often feat legal ambiguities to file new patent applications for trivial changes to their original products. This includes alterations in formulation dosage forms, salt forms, or even delivery methods, all of which may not significantly enhance the efficacy of the original product. Particularly this method allows patent holders to impulsion back the timeline for nonspecific companies to enter the market with more affordable versions. As a result, life-saving drugs remain inaccessible to large sections of the inhabitants in unindustrialized countries. Critics argue that ever greening undermines the purpose of patent law by arranging commercial welfares over societal welfare.[2]

Legal Framework in India against ever greening

Originally The Indian Patents Act of 1970 was intended with a robust focus on convenience and affordability. It did not permit invention patents for pharmaceuticals, which helped the Indian generic drug industry to flourish and to observe with the WTO's Agreement on Trade-Interrelated Characteristics of Intellectual Property Rights As a result, product patents, were reintroduced in 2005.

[1] Carlos María Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* (WHO, 2007)
[2] Dwijen Rangnekar, 'Compulsory Licensing and Access to Medicines in India: Legality, Legitimacy and Global Politics' (2020) 22(4) *Indian Journal of Law and Technology* 113.

Volume 40, July 2025 ISSN 2581-5504

The establishment incorporated **Section 3(d)** in its amended Patents Act explicitly prohibits the patenting of new forms of known ingredients except they validate **a noteworthy enhancement in therapeutic efficacy**. The potential misuse of product patents through ever greening acts as a safeguard, assuring that only truly novel and beneficial innovations are rewarded with patent protection. **Section 3(d) states**: "The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not patentable."

This clause has emerged as a embankment against ever greening and has been invoked in several high-profile patent quarrels in the country.[3]

The Role of Judiciary in combating ever greening

The India's judiciary has demonstrated a balanced approach considering the need for incentivizing revolution against the constitutional command to protect public health it has frolicked a essential role in interpreting and enforcing anti-ever greening measures. The landmark judgment that established India's global reputation for resisting ever greening came in **Novartis AG v. Union of India (2013)**. The company contended that the new form had better bioavailability and hence qualified as an innovative product.

In this context the Supreme Court ruled against Novartis, holding that **mere improvement in bioavailability without significant enhancement in therapeutic efficacy does not satisfy the test under Section 3(d)**. The Court accentuated that patents should not be settled for minor changes that do not suggestion real therapeutic benefits. This particular judgment reiterated the policy goal of preventing ever greening and ensuring wider access to essential remedies.

This particular interpretation not only supported India's legislative determined but also had global inferences. The Supreme Court has a strong message that India would not permit intellectual property rights to become tools of corporate manipulation that could endanger public wellbeing.[4]

Exploitation of Legal Loopholes: The Global Picture vs Indian Vigilance

In many developed countries it is observed that the patent systems often authorization ever greening due to compassionate standards of novelty and innovation. The U.S. and the European Union, for instance regularly grant secondary patents on modified drugs thus spreading market exclusivity. This flexibility is often justified on the grounds of encouraging incremental innovation.

[3] Feroz Ali, *The Law of Patents: With a Special Focus on Pharmaceuticals in India* (2nd edn, LexisNexis 2021).
[4] Indian Patents Act 1970, s 84.

Volume 40, July 2025 ISSN 2581-5504

This global seems to cruet trend poses significant encounters for developing countries like India, where healthcare affordability is a critical apprehension. Despite the protective framework under Indian law, multinational corporations often attempt to navigate around Section 3(d) through strategic patent filing practices. Some companies file a multitude of patents—commonly called "patent thickets" surrounding a single product, manufacture it arduous for generic producers to launch competing drugs deprived of facing litigation. This worldwide appears to cruet trend poses noteworthy encounters for unindustrialized countries like India, where healthcare affordability is a dangerous apprehension. Despite the protective framework under Indian law, multinational corporations often attempt to navigate around Section 3(d) through strategic patent filing performs. Some companies file a gathering of patents normally called "patent thickets" surrounding a single product, manufacture it arduous for generic producers to introduction competing drugs disadvantaged of opposite lawsuit.

The new application and the remaining compound often seen patent applicants may engagement technical gobbledygook or exaggerated claims to incomprehensible the similarity. The Indian Patent Office has become increasingly observant in recent years, the jeopardy of inadvertent approvals remains.[5]

Judicial Pronouncements and Trends beyond Novartis

The Novartis case observes that the Indian courts have adjudicated numerous other disputes that complicated issues of ever greening. That reflect in **F. Hoffmann-La Roche Ltd. v. Cipla Ltd.**, the Delhi High Court addressed the production of patent validity and public interest while governing on the lung cancer drug Erlotinib. In the case was categorical primarily on infringement and the court acknowledged the need to balance private rights with the accessibility of medicines.

Another observation made out in the occurrence of **Bristol-Myers Squibb v. Hetero Drugs Ltd.**, the Indian Patent Office rejected a secondary patent application for a hepatitis C drug, mentioning nonexistence of enhancement in effectiveness. Correspondingly observed in **Pfizer's patent claim for a crystalline form of the drug Atorvastatin**, the IPAB which is Intellectual Possessions Appellate Board repudiated the patent application underneath Section 3(d), reinforcing the deportment that minor ups and downs in form do not constitute genuine innovation. These rulings collectively underscore a consistent judicial philosophy: patents must be granted only for authentic, meaningful advancements that serve the public interest.[6]

[5] Baeyer Corporation v Union of India and Natco Pharma Ltd (2014) SCC Online IPAB 32.
[6] Shubha Ghosh, 'Compulsory Licensing in India: The Law and Its Application' (2019) 9(2) *Indian Journal of Law and Technology* 34.

Volume 40, July 2025 ISSN 2581-5504

Public Health vs Patent Rights: A Delicate Equilibrium

The resistance of India's ever greening reproduces a broader public health philosophy. Our constitutional framework mention particularly in the Article 21 which guarantees the right to life, and it has been understood by the Supreme Court to take account of the accurate to health. This socio-legal perspective has encouraged the Indian judiciary and legislature to implement a pro-public methodology in interpreting patent laws.

Putting essential medicines out of reach for vast sections of the population for accessing affordable medicines remainders a central concern in Indian policymaking. Patent ever greening has the potential to drastically expand drug prices. It happens by curbing ever greening, have reaffirmed their commitment to wellbeing justice and equitable access. While technically operating within the limit bounds of intellectual property law is a practice that undermines the soul of innovation by rewarding cosmetic changes over genuine breakthroughs. it simply demands that innovation be real, substantive, and beneficial to society and Safeguarding that the life-redeemable drugs remain reachable to those who need them most. It occurs by restriction ever greening, have reaffirmed their commitment to wellbeing impartiality and equitable admittance.

The Supreme Court supported the denunciation, ruling that improved bioavailability unaided does not necessarily understand to heightened therapeutic usefulness, which is the yardstick prescribed under Indian law. This ruling was celebrated by public healthiness advocates around the world as a victory for patient rights and access to affordable treatment. India's methodology to patent ever greening has drawn criticism from some quarters of the international pharmaceutical industry and trade lobbies, particularly in the United States and European Union. The equilibrium stuck between disappointing inventors and safeguarding public admission to reasonable medicine must remain central to policymaking.

Global Patent Practices and the Justification of Incremental Innovation

The broader ethical, economic, and global equity dimensions extends by The persistent threat of ever greening but it does not merely rest on legal interpretations but encompasses into extensive ethical, commercial, and universal disinterest proportions. Often showed in a globalized pharmaceutical market, ever greening has become an intercontinental apprehension, which disproportionately impacting developing countries where vast populations are dependent on affordable generics in the other hand some jurisdictions substantiate secondary patenting as fragment of incremental innovation there exists a fundamental difference between rewarding unaffected therapeutic improvements and compromise monopolies for affectation modifications. It becomes distinction especially serious in the Indian perspective where admittance to affordable

Volume 40, July 2025 ISSN 2581-5504

medicines is not only a unrestricted policy disquiet but a constitutional imperative. [7] Frequently presented in a globalized pharmaceutical arcade, ever greening has developed an intercontinental uneasiness.

Some countries like the United States authorization patent protection for secondary innovations, including newfangled dosages, conveyance systems, or chemical forms of a known substance. This flexibility is framed under the knowledge of encouraging continuous research and development. Under U.S. law, for instance, the Hatch-Waxman Act allows pharmaceutical companies to encompass exclusivity phases through mechanisms such as barefaced duration restoration and data snootiness. These inducements may be justified in a high-investment innovation-intensive environment their replication in the Indian background without satisfactory safeguards could engender severe affordability catastrophes. A mainstream of the people is covered by health insurance; an outsized percentage of India's population still reimbursements for medicines out-of-pocket manufacture the delinquent of drug estimating particularly penetrating.

India's Rejection of TRIPS-Plus Provisions

India's legislative intent to prioritize health security over profit-based patenting is further evident in its refusal to adopt provisions like **data exclusivity** and **patent linkage**. Information individuality thwarts generic producers from relying on originator experimental trial data to gain regulatory approval, while patent connection bars regulators from approving generic versions until patent [8]disputes are resolved. By not incorporating these TRIPS-plus provisions, India has retained regulatory space to facilitate generic drug production and supply. This resistance to adopting international trade provisions that compromise public access has drawn antagonism from cosmopolitan pharmaceutical companies and some established countries, who argue that India's stance discourages foreign direct investment in its pharmaceutical sector. Nevertheless, India has defended its position in various trade negotiations and WTO forums, citing the Doha Declaration's recognition of member states' rights to protect public health.

Complementary Legal Mechanisms: NPPP and Drug Price Control

The Indian judiciary's strong opposition to evergreening also finds support in the National Pharmaceutical Assessing Policy (NPPP) and the **Drug Price Control Order (DPCO)**. These policies regulate the prices of essential medicines and aim to ensure that no patent or market monopoly is misused to overprice drugs. While these regulations do not directly address patent

[7] Ministry of Health and Family Welfare, *Biologics and Biosimilars: Regulatory Guidelines* (Government of India, 2020).
[8] World Health Organization, *TRIPS and Public Health: Compulsory Licensing of Pharmaceuticals and Export of Medicines* (2006).

law, they form a complementary framework to preclude the misuse of knowledgeable property rights. Together with Section 3(d), they reflect a comprehensive policy approach where access and affordability take precedence over excessive commercial gain. This integrated model—judicial vigilance, legislative clarity, and administrative regulation—makes the Indian framework a subject of international interest and academic study.[9]

Evolving Corporate Tactics and Defensive Patenting

Despite India's proactive legal stance, the threat of evergreening remains dynamic. Pharmaceutical companies have evolved increasingly sophisticated methods to secure extended exclusivity. One such tactic is **defensive patenting**, where firms patent several variants of a drug early in the research process to build a patent wall. Even if only one or two patents are enforceable, the presence of multiple filings can deter generic participants from entering the market due to the legal complexity and high costs of litigation. Another strategy is the use of **"evergreening by association"**, where a company ties a new patent claim to an already patented product in such a way that the market entry of generics for the original drug becomes legally risky. These subtle methods require the Indian Patent Office and judiciary to remain vigilant and develop expertise in pharmaceutical patent analytics.

TRIPS Flexibilities and India's International Position

India's stance on patent ever greening is rooted in its consistent advocacy for **TRIPS flexibilities**, particularly in public health contexts. The **Doha Declaration on TRIPS and Public Health (2001)** provides that member countries have the right to interpret and implement the TRIPS Agreement in a method that supports public wellbeing and promotes admission to medicines for all. India has utilized this flexibility through Section 3(d), pre-grant opposition systems, and its rejection of TRIPS-plus conditions. By responsibility India has become a model for other developing countries facing[10] analogous public health experiments. The international community, especially in South-South cooperation forums, often cites India as a leader in creating a pro-public patent environment.[11]

Emerging Challenges with Biologics and Strategic Patenting

The development of pharmaceutical knowledge has introduced complicated challenges, particularly through the rise of biologics and biosimilar. Unlike traditional chemical-based drugs, biologics are outsized; complex molecules produced expending living cells, which makes their replication a highly sophisticated progression. In response to this complexity, pharmaceutical

[9] Raju KD, 'Patents on Biologics in India: Challenges and the Way Forward' (2020) 25(3) *Journal of Intellectual Property Rights* 145.
[10] The Patents Act 1970, s 3(d).
[11] Tahir Amin, 'How Drug Companies Abuse the Patent System to Keep Prices High' (2017) *Health Affairs*

Volume 40, July 2025 ISSN 2581-5504

companies are now securing patents not just for the biologic substance himself but also for associated elements such as the specific cell lines used, intricate manufacturing techniques, methods of purification, and even the delivery systems as the pharmaceutical industry increasingly pivots towards biologics, Indian courts will inevitably face the challenge of applying existing legal standards particularly Section 3(d) of the Indian Patents Act—to this new and evolving domain. Section 3(d), which seeks to thwart the contribution of patents for unimportant or incremental innovations, will likely need reinterpretation or more nuanced application in order to address the complexities involved in biologic patenting. The judiciary must thus anticipate and adapt to these changes to ensure that the spirit of patent law complementary innovation with public access is upheld in the face of novel technologies.

Compulsory Licensing: A Strategic Lever against ever greening

In accumulation to constitutional safeguards like Section 3(d), India's patent framework provides for the issuance of compulsory authorizations as a mechanism to uphold public health priorities. Obligatory licensing enables the government to empower a third gathering to production and sell a patented product without the agreement of the patent holder, typically when the drug is either prohibitively expensive or inadequately available to the public. A landmark example of this tool in action was the 2012 case involving Bayer's cancer drug, Nexavar (Sorafenib). Citing the exorbitant price and limited accessibility of the drug, Indian authorities granted Natco Pharma a compulsory license, which permitted it to produce a more affordable generic variant for the Indian market.The government and judiciary must explore pathways to normalize its use as a legitimate tool in the broader effort to protect public health, rather than viewing it as an exceptional or controversial step. Doing so would reaffirm India's commitment to affordable healthcare and resist the encroachment of profit-driven practices that undermine equitable access to medicines.[12]

Policy Recommendations for the Future

To strengthen the fight against evergreening and uphold the spirit of Section 3(d), several policy recommendations can be considered. First, the Indian Patent Office should invest in training and capacity-building programs for its examiners, particularly in the areas of biotechnology and pharmaceutical sciences. With rapid innovation, technical knowledge becomes indispensable for scrutinizing patent applications. Second, India could institutionalize a review mechanism for secondary patent applications to subject them to higher scrutiny. Third, public transparency in patent filings and decisions should be enhanced through open-access databases, public notifications, and opposition facilitation portals. Fourth, academic and legal collaborations could

[12] Bayeer Corporation v Union of India & Natcoo Pharma Ltd [2012] IPAB 45.

Volume 40, July 2025 ISSN 2581-5504

foster continuous review of patent trends and help develop dynamic tools to detect ever greening.[13]

The issue of ever greening extends beyond the boundaries of patent statutes into questions of justice, ethics, and access to healthcare. In India, where the constitutional mandate protects the right to health, combating ever greening is not just a legal obligation—it is a moral necessity. India's robust legal background, particularly Section 3(d), has endowed both administrative and judicial bodies to reject frivolous patent claims that would extend monopolies unjustifiably. With active participation from civil society, judicial scrutiny, and international support for TRIPS flexibilities, India has set a gold standard in resisting evergreening while encouraging real innovation. The pharmaceutical landscape is evolving, and with it, evergreening tactics are becoming more sophisticated. To stay ahead, India must continuously refine its patent regime to preserve its foundational commitment to affordable healthcare for all.

[13] Gopakumar KM, 'India's Compulsory Licensing Order: Implications for Access to Medicines' (Third World Network, 2012)