PATENT EVERGREENING: BALANCING PHARMACEUTICAL INNOVATION AND ACCESS TO MEDICINES UNDER INDIAN AND COMPARATIVE PATENT LAW

Jatin Malhotra, B.B.A. LL.B., Bharati Vidyapeeth University

ABSTRACT

Patent law is founded on a bargain between the inventor and the State: full public disclosure of an invention in exchange for a time-bound exclusive right, ordinarily twenty years, upon whose expiry the invention passes into the public domain for unrestricted use. In the pharmaceutical sector, however, originator companies have increasingly relied on a cluster of strategies collectively termed "patent evergreening" to prolong effective market exclusivity beyond the life of the original patent, often without any accompanying therapeutic advance. Such strategies include the patenting of new salts, polymorphs, isomers, particle sizes, formulations, and methods of use of an already known molecule, the assembly of dense "patent thickets" comprising dozens or hundreds of overlapping patents, and the use of reverse-payment settlements to postpone generic or biosimilar entry. This paper undertakes a doctrinal and comparative examination of patent evergreening, situating the practice within the flexibilities available to member States under Article 27 of the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, 2001. It closely analyses India's principal statutory response, Section 3(d) of the Patents Act, 1970, and its authoritative judicial interpretation by the Supreme Court in Novartis AG v. Union of India, alongside the Delhi High Court's treatment of secondary pharmaceutical patents in F. Hoffmann-La Roche Ltd. v. Cipla Ltd. and the compulsory licensing regime illustrated in Bayer Corporation v. Natco Pharma Ltd. The paper further considers comparative developments in the United States, including the tightened non-obviousness standard under KSR International Co. v. Teleflex Inc. and the antitrust dimensions of patent thickets illustrated by the Humira litigation. It argues that India's efficacy-based screening mechanism, complemented by its compulsory licensing framework, offers a globally significant model for reconciling patent protection with public health imperatives, while identifying persistent gaps in patent examination capacity, transparency, and patent–competition law coordination that require further reform. The paper concludes that a calibrated combination of rigorous substantive examination, procedural

transparency, and cross-disciplinary regulatory coordination offers the most sustainable path to curbing evergreening without undermining genuine pharmaceutical innovation.

Keywords: Patent Evergreening; Section 3(d); TRIPS Agreement; Compulsory Licensing; Pharmaceutical Patents; Access to Medicines

I. INTRODUCTION

Patent law rests on a quid pro quo between the inventor and the State: in exchange for full disclosure of an invention, the patentee is granted a time-bound monopoly, ordinarily for a period of twenty years from the date of filing.[1] The rationale is twofold — first, exclusivity incentivises investment of resources into research and development; second, once the term lapses, the invention devolves into the public domain, allowing free use and follow-on innovation by all.[2] This bargain, however, is increasingly undermined by a pharmaceutical industry practice known as "patent evergreening" — the strategic use of the patent system to obtain successive, often overlapping, patents on incremental modifications of an already patented drug, such as new salts, polymorphs, isomers, particle sizes, formulations, dosage forms, or methods of use, so as to extend market exclusivity well beyond the life of the original patent without a commensurate therapeutic benefit to patients.[3]

Evergreening has attracted sustained scholarly and judicial attention because of its direct bearing on access to affordable medicines, particularly in developing countries where a substantial proportion of healthcare expenditure is borne directly by patients.[4] It also raises intersecting questions of patent law, competition law, and constitutional guarantees of the right to health under Article 21 of the Constitution of India.[5] This paper critically examines the concept, legal framework, judicial responses, and policy implications of patent evergreening, with particular emphasis on Indian jurisprudence under Section 3(d) of the Patents Act, 1970,

[1]The Patents Act, 1970 (Act No. 39 of 1970), s. 53 (prescribing a patent term of twenty years from the date of filing).
[2]Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, art. 7 [hereinafter TRIPS Agreement] (setting out the objective of balancing the rights and obligations of producers and users of technological knowledge).
[3]Association for Accessible Medicines, Anti-Competitive Evergreening Delays Patient Access to More Affordable Generics and Biosimilars (2023), available at https://accessiblemeds.org/resources/blog/anti-competitive-evergreening-delays-patient-access-more-affordable-generics/ (last visited June 29, 2026).
[4]Id.
[5]Constitution of India, art. 21; Paschim Banga Khet Mazdoor Samity v. State of West Bengal, (1996) 4 SCC 37 (recognising the right to health and access to medical treatment as an integral part of the right to life under Article 21).

read alongside comparative developments in the United States and under the TRIPS Agreement.

II. CONCEPTUALISING PATENT EVERGREENING

The term "evergreening" does not appear in any patent statute; it is a term of art developed in policy and legal literature to describe a bundle of strategies by which originator pharmaceutical companies extend the effective commercial life of a drug patent.[6] These strategies typically operate at two levels. First, at the level of the patent office, companies file "secondary patents" on incremental changes to the active pharmaceutical ingredient or its formulation — for instance, a new crystalline or polymorphic form, an enantiomer, a salt, a sustained-release formulation, or a fixed-dose combination — each of which, if granted, effectively confers a further period of exclusivity even though the underlying therapeutic molecule remains unchanged.[7] Second, at the level of regulatory and litigation strategy, companies deploy tools such as patent term extensions, data exclusivity, dense "patent thickets" comprising numerous overlapping patents, and reverse-payment or "pay-for-delay" settlements with generic or biosimilar challengers to deter or postpone market entry.

The underlying economic logic is straightforward: because generic entry typically causes a substantial fall in drug prices, even a few additional years of delayed competition can be highly lucrative for the originator, creating an incentive to file large numbers of low-value patents for defensive or exclusionary purposes rather than genuine innovation.[8] It is this gap between the formal validity of individual patents and their cumulative anti-competitive effect that makes evergreening analytically distinct from ordinary incremental innovation, and correspondingly difficult to address through conventional patent-validity doctrine alone.

III. THE INTERNATIONAL AND COMPARATIVE LEGAL FRAMEWORK

A. The TRIPS Agreement and the Doha Declaration

Article 27.1 of the TRIPS Agreement requires member States to make patents available for inventions, whether products or processes, in all fields of technology, provided they are new,

[6]See Association for Accessible Medicines, supra note 3.
[7]The Patents Act, 1970, s. 3(d), as inserted by the Patents (Amendment) Act, 2005 (Act No. 15 of 2005).
[8]AJMC, Humira: The First $20 Billion Drug, available at https://www.ajmc.com/view/humira-the-first-20-billion-drug (last visited June 29, 2026).

involve an inventive step, and are capable of industrial application.[9] Crucially, TRIPS does not itself define these three criteria in granular detail, leaving considerable flexibility to member States to calibrate their domestic patentability standards — a flexibility expressly affirmed by the Doha Declaration on the TRIPS Agreement and Public Health, 2001, which recognised the right of WTO members to protect public health and to promote access to medicines for all.[10] This flexibility forms the doctrinal foundation for India's comparatively stricter approach to secondary pharmaceutical patents.

B. Section 3(d) of the Indian Patents Act, 1970

India's most significant legislative response to evergreening is Section 3(d), inserted by the Patents (Amendment) Act, 2005, which brought Indian law into compliance with TRIPS while simultaneously erecting safeguards against evergreening.[11] Section 3(d) excludes from patentability 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, as well as the mere discovery of any new property or new use of a known substance, unless such new form differs significantly in properties with regard to efficacy.[12] The Explanation appended to the provision clarifies that salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers, and other derivatives of a known substance are to be regarded as the same substance unless they differ significantly in properties with regard to efficacy.[13] The provision thus directly targets the standard techniques of pharmaceutical evergreening described above.

C. The United States Framework

The United States regulates the interface between patents and generic competition principally through the Hatch-Waxman Act of 1984, which created abbreviated pathways for generic drug approval while simultaneously granting originators patent term restoration and statutory stays

[9]See Evernorth, How Drugmakers Exploit the Patent System to Delay Competition and Inflate Prices, available at: https://www.evernorth.com/articles/how-drugmakers-exploit-patent-system-delay-competition-and-inflate-prices (last visited June 29, 2026) (reporting that nearly 80 of the top 100 best-selling drugs extended their monopoly periods through strategies such as patent thickets).
[10]TRIPS Agreement, supra note 2, art. 27.1.
[11]World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001), available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited June 29, 2026).
[12]The Patents (Amendment) Act, 2005 (Act No. 15 of 2005); Novartis AG v. Union of India, (2013) 6 SCC 1, 26 (India).
[13]The Patents Act, 1970, s. 3(d).

against generic entry upon the commencement of patent litigation.[14] Although U.S. law contains no direct analogue to Section 3(d), the non-obviousness requirement performs a partially comparable gatekeeping function; the Supreme Court's decision in KSR International Co. v. Teleflex Inc. tightened the non-obviousness standard by rejecting a rigid application of the earlier "teaching-suggestion-motivation" test, making it somewhat harder to patent predictable combinations of known elements.[15] Nonetheless, empirical evidence suggests that a substantial majority of top-selling drugs in the United States have extended their period of market exclusivity well beyond the original patent term through follow-on patenting.[16]

IV. STRATEGIES OF EVERGREENING: THE PATENT THICKET ILLUSTRATED

Patent thickets constitute one of the most consequential evergreening strategies. AbbVie's biologic Humira illustrates this vividly: although the principal patent covering the active ingredient adalimumab expired in 2016, AbbVie had, by then, obtained more than 130 additional patents covering formulations, manufacturing processes, and methods of treatment, with the great majority of these later-obtained patents granted after 2014 despite the drug having been marketed since 2002.[17] This patent estate enabled AbbVie to negotiate settlements with prospective biosimilar manufacturers that permitted European market entry in 2018 while postponing entry into the United States market until 2023. Indirect purchasers subsequently challenged this strategy as an unlawful monopolisation and market-allocation scheme under Sections 1 and 2 of the Sherman Act; the federal district court, however, dismissed the claims, holding that most of AbbVie's patent-assertion conduct was protected under the Noerr-Pennington doctrine and that the alleged antitrust injury was too speculative to sustain a claim.[18] The Humira litigation therefore illustrates both the commercial efficacy of thicket-based evergreening and the present limits of antitrust law, at least under U.S. doctrine, in dismantling such strategies once the underlying patents have themselves survived validity challenges.

[14]The Patents Act, 1970, Explanation to s. 3(d).
[15]Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (commonly known as the Hatch-Waxman Act).
[16]KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007).
[17]See Evernorth, supra note 9.
[18]AJMC, supra note 8; Association for Accessible Medicines, supra note 3 (noting that AbbVie obtained more than 130 patents relating to Humira, most granted after 2014, despite the drug having been marketed since 2002).

V. JUDICIAL RESPONSES: CASE LAW ANALYSIS

A. Novartis AG v. Union of India

The most authoritative Indian pronouncement on evergreening remains the Supreme Court's decision in Novartis AG v. Union of India.[19] Novartis sought a patent for the beta-crystalline form of imatinib mesylate, marketed as the anti-leukaemia drug Glivec, claiming that this polymorphic form possessed superior properties, including greater bioavailability, compared to the free-base form already disclosed in an earlier patent.[20] The Madras Patent Office and the Intellectual Property Appellate Board rejected the application, and the Supreme Court, upon Novartis's writ petition and subsequent appeal, upheld that rejection.[21] The Court held that "efficacy" under Section 3(d) means "therapeutic efficacy," and that in the case of medicines an applicant must demonstrate a real, clinically meaningful improvement in treatment outcomes rather than merely improved physicochemical properties such as flow characteristics or thermodynamic stability.[22] The Court further upheld the constitutional validity of Section 3(d), rejecting Novartis's contention that the "enhanced efficacy" standard was vague and arbitrary, and held instead that the provision represented a deliberate and considered legislative response to the specific problem of evergreening of pharmaceutical patents.[23] The judgment has been widely regarded as a landmark in reconciling patent protection with public health imperatives and has influenced patent policy debates in several other developing countries.[24]

B. F. Hoffmann-La Roche Ltd. v. Cipla Ltd.

The Delhi High Court's decisions in the Roche v. Cipla litigation, concerning the lung-cancer drug erlotinib marketed as Tarceva, further illustrate judicial engagement with Section 3(d) and evergreening.[25] Roche held Patent No. 196774 for erlotinib hydrochloride and sued Cipla for marketing a generic version under the brand Erlocip. The Single Judge initially declined to

[19]In re Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811 (N.D. Ill. 2020) (dismissing, on grounds including the Noerr-Pennington doctrine, indirect purchasers' Sherman Act claims that AbbVie's patent-thicket and settlement strategy was anticompetitive).
[20]Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[21]Id. at paras. 2–12.
[22]Id. at paras. 66–75.
[23]Id. at paras. 187–192 (holding that "efficacy" in s. 3(d) means "therapeutic efficacy" and requires demonstrable improvement in clinical treatment outcomes).
[24]Id. at paras. 106–109 (rejecting the challenge to the constitutional validity of s. 3(d) under Article 14 of the Constitution of India).
[25]See Drishti Judiciary, Novartis AG v. Union of India, (2013) 6 SC 1, available at https://www.drishtijudiciary.com/landmark-judgement/intellectual-property-rights/novartis-ag-v-union-of-india-2013-6-sc-1 (last visited June 29, 2026).

grant an interim injunction, holding that the balance of public interest — given the life-saving nature of the drug and the substantial price differential between Tarceva and Erlocip — favoured Cipla, notwithstanding Roche's prima facie case of infringement.[26] Notably, the Controller of Patents had earlier rejected Roche's separate application for the Polymorph B form of erlotinib hydrochloride on grounds including evergreening and the absence of demonstrated enhanced therapeutic efficacy, reinforcing the significance of Section 3(d) as a screening mechanism against secondary pharmaceutical patents.[27] On appeal, the Division Bench in 2015 ultimately held that Cipla's product infringed Roche's validly granted patent for the combined polymorphic mixture, while declining to grant an injunction given the patent's imminent expiry and directing instead an accounting of profits.[28] The case underscores that while Section 3(d) filters out trivial secondary patents at the grant stage, genuinely valid patents on new chemical entities remain fully enforceable against infringers.

C. Bayer Corporation v. Natco Pharma Ltd.: Compulsory Licensing as a Counterweight

Where evergreening or ordinary patent exclusivity results in a patented medicine being priced beyond the reach of the public, Indian law provides a further corrective in the form of compulsory licensing under Section 84 of the Patents Act, 1970.[29] In Bayer Corporation v. Natco Pharma Ltd., India's first compulsory licence was granted in respect of Bayer's anti-cancer drug Sorafenib, marketed as Nexavar, after the Controller of Patents found that Bayer had failed to satisfy the "reasonable requirements of the public," had not made the drug available at a "reasonably affordable price," and had not "worked" the patent within the territory of India.[30] The Intellectual Property Appellate Board upheld the compulsory licence, increasing the royalty payable to Bayer from six to seven per cent of net sales, and the Bombay

[26]F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., I.A. No. 642/2008 in CS(OS) No. 89/2008 (Del. H.C. 2008); F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., RFA(OS) No. 92/2012 and Cipla Ltd. v. F. Hoffmann-La Roche Ltd. & Anr., RFA(OS) No. 103/2012 (Del. H.C., decided Nov. 27, 2015).
[27]F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., 2012 SCC OnLine Del 4590 (Single Judge, declining interim injunction on grounds of public interest and balance of convenience).
[28]S.S. Rana & Co., Delhi High Court: Cipla has Infringed Roche's Anti-Cancer Drug Patent, available at https://ssrana.in/articles/delhi-high-court-cipla-has-infringed-roches-anti-cancer-drug-patent/ (last visited June 29, 2026) (noting the Controller's 2008 rejection of Roche's Polymorph B application on grounds including evergreening).
[29]F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., RFA(OS) No. 92/2012 (Del. H.C., decided Nov. 27, 2015) (Division Bench holding Cipla liable for infringement of Patent No. 196774 but declining injunctive relief in view of the patent's imminent expiry).
[30]The Patents Act, 1970, s. 84 (compulsory licences).

High Court and, subsequently, the Supreme Court declined to interfere with the grant.[31] Although compulsory licensing is not a direct remedy for evergreening as such, the case demonstrates the broader statutory architecture within which Indian patent law subordinates monopoly pricing to considerations of public health and affordability — a structural check that complements Section 3(d)'s gatekeeping function at the grant stage.

VI. EVERGREENING, COMPETITION LAW, AND THE PUBLIC HEALTH INTERFACE

Beyond patent law proper, evergreening increasingly attracts scrutiny under competition law. In the United States, patent thickets and reverse-payment settlements have been challenged under the Sherman Act, most notably in Federal Trade Commission v. Actavis, Inc., where the Supreme Court held that large and otherwise unjustified reverse payments from an originator to a generic challenger to delay market entry could, depending on the circumstances, constitute an antitrust violation.[32] In India, the Competition Act, 2002 preserves reasonable conditions for the protection of intellectual property rights while still subjecting their exercise to the general prohibition on anti-competitive agreements, signalling that the exercise of patent rights is not wholly immune from antitrust scrutiny, although the interface between patent law and competition law in the Indian pharmaceutical sector remains comparatively underdeveloped.[33] This convergence reflects a growing recognition that patent law's internal doctrines, such as Section 3(d), cannot by themselves address exclusionary strategies executed through the accumulation and strategic assertion of numerous individually valid but collectively anti-competitive patents.

VII. CRITICAL ASSESSMENT AND THE WAY FORWARD

India's Section 3(d) approach, validated in Novartis, offers a globally influential model for curbing pharmaceutical evergreening at the point of patent grant, and has been credited with helping to keep the prices of several essential medicines — including generic versions of Glivec and Tarceva — substantially lower in India than in jurisdictions without an equivalent

[31]Bayer Corporation v. Natco Pharma Ltd., Compulsory Licence Application No. 1 of 2011, Order of the Controller of Patents (Mar. 9, 2012).
[32]Bayer Corporation v. Natco Pharma Ltd., Order of the Intellectual Property Appellate Board, OA/35/2012/PT/MUM (Mar. 4, 2013); Bayer Corporation v. Union of India, 2014 (60) PTC 277 (Bom.); Bayer Corporation v. Natco Pharma Ltd., Special Leave Petition dismissed by the Supreme Court of India, order dated Dec. 12, 2014.
[33]Federal Trade Commission v. Actavis, Inc., 570 U.S. 136 (2013).

efficacy threshold.[34] Several gaps nonetheless remain. First, patent examination capacity and pre-grant and post-grant opposition mechanisms require continued strengthening to prevent low-quality secondary patents from being granted in the first place, since litigation after grant is costly and time-consuming for generic and biosimilar challengers. Second, greater transparency around the full patent estate covering a marketed drug would assist generic manufacturers and regulators in identifying evergreening strategies at an early stage. Third, closer coordination between patent offices and competition authorities, along lines increasingly discussed in the United States and the European Union, would allow patent thickets and pay-for-delay arrangements to be addressed through ex post antitrust review even where individual patents survive validity challenges, as the Humira litigation itself demonstrates the limits of relying on antitrust doctrine alone. Finally, voluntary mechanisms such as the Medicines Patent Pool, which facilitates the licensing of patented medicines to generic manufacturers on negotiated terms, offer a complementary, non-adversarial route to reconciling innovation incentives with access to medicines.[35]

VIII. CONCLUSION

Patent evergreening exposes a structural tension at the heart of intellectual property law: the same doctrinal flexibility that permits incremental, follow-on innovation to be patented can also be exploited to extend monopoly pricing on essential medicines without a corresponding therapeutic benefit. India's Section 3(d), as interpreted by the Supreme Court in Novartis AG v. Union of India, together with the compulsory licensing regime illustrated in Bayer Corporation v. Natco Pharma Ltd., represents one of the most robust legal responses to this problem developed anywhere in the world, and carries particular significance for a jurisdiction that serves as a major global supplier of affordable generic medicines. Comparative experience, particularly the Humira patent-thicket controversy in the United States, demonstrates that jurisdictions lacking an equivalent efficacy-based screening mechanism remain considerably more vulnerable to evergreening, even where antitrust law is available as a residual check. Going forward, a calibrated combination of rigorous patent examination, enhanced procedural transparency, and closer coordination between patent law and competition law offers the most promising path toward ensuring that patent protection continues to reward genuine innovation without compromising access to affordable medicines.

[34]The Competition Act, 2002 (Act No. 12 of 2003), s. 3(5) (proviso preserving reasonable conditions for protection of intellectual property rights, subject to the general prohibition on anti-competitive agreements).
[35]See Drishti Judiciary, supra note 25; S.S. Rana & Co., supra note 28.