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When Patents Outlive Patients: Evergreening And The Crisis Of Drug Affordability

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Abstract

Evergreening refers to extending pharmaceutical patent monopolies by formulating slight changes to current drugs and has become a notable impediment to accessible healthcare around the world. The objective of patent protection is to boost innovation; however, evergreening is the strategic abuse of extending monopolies, delaying the entry of generics, and keeping high prices on medicines. This paper seeks to review the methods and consequences of evergreening, focusing on its effect on public health, the health budget of a nation, and the availability of medicines globally. This is illustrated by Novartis's Gleevec, AbbVie's Humira, and Warner Chilcott's Doryx, which reflects the rising cost of treatment due to the adverse influence on competition and the rising inequity between rich and poor nations. The paper also critiques policy and legal responses, which includes India's Section 3(d), competition law interventions and the WTO and WHO international legal frameworks, and suggests reforms on patent examination, competition law, and international collaboration. This paper ultimately insists that evergreening must be curtailed to offer a better equilibrium concerning the right to health and the incentivizing of innovation. This is to advocate for the provision of affordable, life-saving medicines.

Keywords - Access to Medicines, Evergreening, Generic Drugs, Patent Law, Right to health.

I. INTRODUCTION

It is claimed that the most significant source of economic creation of value is a society's ability to develop, take advantage of, and distribute technological breakthroughs. Pharmaceutical corporations use a variety of strategies to gain undeserved patents. One way to get unfair monopoly rights is to evergreen pharmaceutical patents. The WHO Commission on Intellectual Property, Innovation, and Public Health defined evergreening as a term popularly used to describe when patent holders employ different tactics to prolong their exclusivity beyond the regular 20-year patent period in the absence of any evident further therapeutic benefits.[176] The phrase patent evergreening can refer to methods that prolong a patent holder's exclusive ownership by seeking minor enhancements or changes to a drug.[177]

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[176] World Health Organization (2006) Public Health Innovation and Intellectual Property Rights. World Health Organization 131.

[177] Lisa P. Lukose, "Patent Evergreening: Law and Ethics," in Proceedings of the 7th *Int'l Conf. on Info. L. & Ethics* (ICIL 2016) 1 (2016).

A patent is defined in the Indian Patents Act, 1970 as *a grant or the ability to prohibit others from producing, utilising, or marketing one's invention, as well as the ability to grant others permission to do so*.[178] This privilege is granted exclusively for a set tenure of years. Once the time period has completed, they lose this right, and the technology or product becomes widely accessible in the open market, and he may no longer capitalize on his own invention. Several innovator firms have recently extended the patent life of their novel compounds in order to safeguard their market supremacy.

According to global rankings, the Indian pharmaceuticals industry ranks fifteenth in terms of value and third in terms of volume. It is one of seventeen emerging pharmaceuticals markets, also referred to as pharmacy countries along with China, Brazil, and Russia. By 2013, it is anticipated to account for around half of the pharmaceutical industry's yearly increase.[179] India's capacity to generate large quantities of medications at affordable prices has led many to refer to it as the Pharmacy of the Developing World. It has established itself as a key provider of generic medications in several underdeveloped countries.[180] In particular, India's manufacture of HIV/AIDS drugs has assisted cut the expenditure of medical care substantially, from up to USD $10,000 annually in 2000 to USD $150 per year now.[181]

Over the past few decades, innovation and creativity have advanced in many ways. In 2005, India agreed to completing its commitments under the Agreement on Trade Related Aspects of Intellectual Property Rights, often known as the TRIPS Agreement. The Novartis case was founded on Section 3(d) of the Indian Patents Act[182], which was revised in 2005 as a result of the need for India to evaluate its patent legislation.

Patent evergreening is a misleading patent protection strategy. [183] In addition to having little effect on raising the standard of care[184], the practice of patent evergreening also hinders and delays the release of generic medications. [185] It has been suggested that secondary patents are frequently of poorer kind than main patents and that they effectively limit competition even if they might not have compelling claims of originality and non-obviousness[186]. Given that the cost of medications is one of the main obstacles to citizens' access to necessary medical care, developing nations are especially vulnerable to denying their citizens this access because of the growing monopoly and consortium of pharmaceutical companies and a dearth of production and transportation infrastructure features for generic versions.[187] By creating private monopolies that take advantage of the patent system, it restricts access to essential medications, disproportionately affecting vulnerable populations.

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[178] Indian Patents Act, No. 39 of 1970, § 2(1)(m), Sec. 48, India Code (1970).
[179] IMS Health, http://www.imshealth.com/portal/site/ims (last visited July 13, 2025).
[180] Kapczynski, Amy, "Engineered in India — Patent Law *2.0"*, 369 *New Eng. J. Med*. 497 (2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3884017 (last visited July 13, 2025).
[181] Id.
[182] The Patents Act, No. 39 of 1970, § 3(d), India Code (1970).
[183]G. Dwivedi, S. Hallihosur & L. Rangan, "Evergreening: A Deceptive Device in Patent Rights", 32 *Tech. Soc'y* 324, 330 (2010).
[184] Reed F. Beall et al., "Is Patent Evergreening Restricting Access to Medicine/Device Combination Products?", 11 *PLOS ONE* e0148939, 8 (2016), https://doi.org/10.1371/journal.pone.0148939.
[185] Singh & Assocs., The Wrongs of Evergreening, (2008) at 101.
[186] ibid 693.
[187] Roger Magnusson, "Advancing the Right to Health: The Vital Role of Law – Chapter 15: Access to Essential Medicines, TRIPS and the Patent System*"* 240 (World Health Org., 2017).

Another method of evergreening is Product hopping, sometimes called product switching, is the practice of releasing slightly modified medicine versions at the end of the original patent to prevent generic competition. For example, a new extended-release tablet may be introduced in place of an expiring immediate release version.[188,189] Notably, product hopping in drugs like glatiramer acetate (Copaxone) has cost consumers approximately USD 4.3-6.5 billion before courts invalidated the tactic.[190]

II. THE MECHANICS OF EVERGREENING AND PRODUCT HOPPING

Evergreening pharmaceutical patents undermines the patent system's rationality by excluding reasonable inputs from patent applications. Though some evergreening tactics adhere to national patent regulations in some jurisdictions[191], they are a misappropriation of pharmaceutical patents and contradict the fundamental principles of the patent system. Advancement are done by making the medicine more adaptable and decreasing negative consequences. [192] A considerable proportion of freshly authorised medications are simply advanced versions of current drugs. The expenditure and labour needed in suggesting reformulations are far lower than the expense of inventing and introducing a novel medicine.[193]

Major corporations frequently apply for an array of life-cycle management techniques on purpose.[194] Using life-cycle tactics to extend the term of exclusivity for more profitable pharmaceuticals might be viewed as a tool-box for originator corporations to employ with the goal to obtain gain from their drugs.[195] This method of creating a new utility of an existing patented drug is also regarded as drug repositioning.[196] For example, AbbVie created a vast "patent thicket" around Humira, deploying over 130 patents to push its exclusivity window to 2034.[197]

Another commonly used method is Extended- Release Formulations in which a drug's composition is changed from immediate-release (IR) tablet to extended-release (ER) or controlled-release version can result in a new patent. The ER version allows for fewer dosages throughout the day, which is convenient for patients, but it does not necessarily deliver significant

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[188] Michael A. Carrier & Steve D. Shadowen, "Product Hopping: A New Framework", 92 *Notre Dame L. Rev.* 167 (2016).

[189] Michael A. Carrier & Steve D. Shadowen, "Product Hopping: A New Framework", 92 *Notre Dame L. Rev.* 167 (2016).

[190] Knox, Ryan and Curfman, Gregory, "The Humira Patent Thicket, the Noerr-Pennington Doctrine, and Antitrust's Patent Problem" (September 11, 2022). Available at SSRN: https://ssrn.com/abstract=4215822 or http://dx.doi.org/10.2139/ssrn.4215822

[191] G. Dwivedi, S. Hallihosur & L. Rangan, Evergreening: A Deceptive Device in Patent Rights (2010).

[192] E. Kappe, "Pharmaceutical Lifecycle Extension Strategies", in *Innovation and Marketing in the Pharmaceutical Industry* 225, 254 (Springer 2014).

[193] M.Z. Abbas, "Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System*"*, 15 *J. Generic Meds.* 53 (2019), https://doi.org/10.1177/1741134319848797.

[194] H. Löfgren & P. Sarangi eds., "The Politics and Culture of Globalisation: India and Australia" 124 (Berghahn 2009).

[195] B. Sampat, "Institutional Innovation or Institutional Imitation? The Impacts of TRIPs on India's Patent Law and Practice" (2010), https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_6_10/wipo_ip_econ_ge_6_10_inf_1.pdf.

[196] Supra n.19.

[197] Michael Bluhm, "The Role of Monopoly in America's Prescription Drug Crisis", *Open Markets Institute White Paper*, Dec. 9, 2019.

new therapeutic benefits[198]. Purdue Pharma, for example, extended the initial patent for OxyContin (oxycodone) by developing an extended-release version. While the ER version made administration more convenient, the active ingredient (oxycodone) and its fundamental impact remained unaltered.[199]

One frequently used anti-competitive tactic by pharmaceutical companies is entering into an Agreement in which generic companies are paid to extend the release of their generic versions of similar drugs. In this arrangement, the innovator and the generic entities enter into a settlement arrangement in which the generic company agrees not to launch its variant of the drug for a specified period[200]. In the 2003 case of re Cardizem CD Antitrust Litigation[201], a U.S. appellate court declared that these kinds of agreements between generic and brand-name corporations are illegal. Nevertheless, since 2005, a number of judgements have misconstrued antitrust rules and declared that these kinds of agreements are acceptable[202], enabling these big pharmaceutical group to take favor of both patent rights and consumers. The European Commission fined Johnson & Johnson and Novartis a total of €16 million for preventing cheaper generic medications from entering Netherlands. [203]

The pharmaceuticals company file for patents in other jurisdictions like US, since it's easy to get it approved. An example of extensive evergreening is Sanofi's medication, Lantus. The drug's exclusivity has been extended for a further 37 years due to 74 patents, most of which were filed after it had been authorized for usage in 2000.[204] The American patent system is seriously ruptured, since Sanofi filed 1.5 times as many patents in the US than it did at the European Patent Office (EPO). [205] The main patent for Lantus expired in 2015, providing Sanofi at least 15 years of commercial exclusivity following FDA regulatory approval in 2000. [206]

Dolutegravir, an antiviral medication used to cure HIV/AIDS, had its patent application denied by the Controller of Patents in Kolkata in November 2024 because it was only marketed as a novel formulation and did not pass the patentability criteria. The Controller of Patents, Kolkata, determined that the advanced form of the medication did not show any improved "therapeutic efficacy" over the original formulation, despite this application seeking patent protection for a more recent version of the treatment. [207] Granting the patent would have limited competition,

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[198] Nerella Srinivas, "Patent evergreening in Pharmaceuticals : Impact and Ethical Considerations", *Int'l J. Intell. Prop. Rts.,* Vol. 14, No. 2, pp. 33–37 (July–Dec. 2024), https://doi.org/10.34218/IJIPR_14_02_003.

[199] Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy", 99 *Am. J. Pub. Health* 221 (2009), https://doi.org/10.2105/AJPH.2007.131714.

[200] Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, (2010), available at: https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drugcompany-pay-offs-cost-consumers-billions-federal-trade-commission-staffstudy/100112payfordelayrpt.pdf.

[201] Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003).

[202] Id.

[203] Brussels, EU Fines Johnson & Johnson, Novartis $22mn, *Business Standard*, Dec. 11, 2013, https://www.business-standard.com/article/international/eu-fines-johnson-johnsonnovartis-22-mn-113121100052_1.html.

[204] I-MAK, Overpatented, Overpriced Special Edition: Lantus (Insulin Glargine) 2018. https://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf.

[205] ibid.

[206] Supra n.31.

[207] Shilpi Bose & Ishan Dhyani, "Evergreening of Patents: Bridging the Gap Between Intellectual Property Rights and Healthcare Law", 7 *Int'l J. L. Mgmt. & Hum*. (2024). https://3fdef50c-add3-4615-a675-a91741bcb5c0.usrfiles.com/ugd/3fdef5_1b828d8e1529490e8adefadb47023706.pdf.

raised prices, and made the treatment unaffordable for many people who rely on affordable prescriptions.

III. LEGAL AND REGULATORY FRAMEWORK

INDIA

A distinctive clause in the Indian Patents Act, *Section 3(d)*[208], establishes a high standard for patentability in the context of medical inventions, this amendment came in the year 2005 in response to the Trade Related Aspects of Intellectual Property Rights (TRIPS), mainly to be compliant globally. The standards for patentability were made clearer with the adoption of Section 3(d), particularly for the pharmaceutical sector. India's spot as a major supplier of reasonably priced drugs has been maintained in large part because to this section. The importance of this clause was reinforced in the historic *Novartis AG v. Union of India* [209] case in 2013, in which the Supreme Court rejected a patent application for the cancer medication Glivec, concluding that the drug's alterations did not provide appreciable therapeutic benefits.

Table 1: Key Case Studies of Evergreening / Its Rejection & Impact

Case / Drug / Company	What Happened (Evergreening Attempt or Patent Review)	Outcome & Impact on Access / Affordability
Glivec (Imatinib) – Novartis[210]	Novartis sought a patent in India (late 1990s / 2000s) for a "new form" of imatinib (beta-crystalline form / mesylate salt) a classic "evergreening" bid.	The application was denied by the Indian Patent Office under health-safeguard clause Section 3(d) of the Indian Patents Act (that disallows patents for new forms of known substances unless efficacy is enhanced) The rejection was upheld by appellate authority and finalised by the Supreme Court of India in 2013.
Bedaquiline (TB drug) – Johnson & Johnson / Janssen	J&J filed for a secondary patent (fumarate-salt form, formulation) for bedaquiline to extend exclusivity beyond its primary patent expiry — essentially an evergreening attempt.	In March 2023, the Indian Patent Office (IPO) denied the application, citing the claims lacked inventive step / novelty as per Section 3(d) / 3(e), thus disallowing the evergreening attempt.
General "Secondary Patents" / Pharma-	Over the years, multiple multinational companies have	Thanks to the safeguard under Section 3(d) of the

[208] The Patents (Amendment) Act, No. 15 of 2005, § 3(d), India Code (1970).
[209] (2013) 6 SCC 1.
[210] Gabble, R., Kohler, J.C. "To patent or not to patent? the case of Novartis' cancer drug Glivec in India". *Global Health* 10, 3 (2014). https://doi.org/10.1186/1744-8603-10-3

Evergreening Attempts in India (multiple drugs)[211]	attempted to seek patents on "new forms," salts, formulations, or dosage changes for existing drugs essentially using incremental changes to extend monopolies.	Patents Act interpreted strictly by Indian courts / IPO many such applications have either been rejected or severely restricted.

Why These Cases Matter: What They Show About Evergreening & Access

- The Glivec case shows that legal safeguards (like Section 3(d)) + rigorous examination can prevent "evergreening," ensuring that patents are given only for legitimate innovations thus preserving generic competition.
- The cost difference with generics being many times cheaper than what a patented/evergreened drug would cost demonstrates how rejecting incremental patents can translate to real savings for patients and health systems**.**
- The bedaquiline example highlights how these laws remain relevant even today not just for "old" drugs but for new critical therapies (e.g., against TB). By rejecting secondary-patent claims, India made it possible for generics to enter, improving affordability and access especially important in a high-burden, lower-income context.
- The cumulative effect: through a consistent stance against evergreening, India preserves its role as a global "pharmacy for developing countries," enabling widespread access to essential, low-cost generics benefiting both domestic and international patients dependent on affordable medicines.

Limitations & Context

- Even where evergreening is prevented, price reductions vary depending on the drug, manufacturing costs, competition, regulatory approvals, etc. A rejected patent does **not** automatically guarantee a steep price drop to rock-bottom generic prices.
- Generic uptake depends on manufacturing capacity, quality standards (regulation / WHO pre-qualification), supply chains, distribution infrastructure, and demand. Patent rejection is necessary but not sufficient for equitable access.
- For globally distributed drugs: even if generics are available in India, secondary patents may still exist in other countries which can limit export or access in those geographies. For instance, in the bedaquiline case, although India's IPO rejected secondary patents, J&J reportedly held patents in several other high-TB-burden countries.[212]

What This Means for Policy & Public Health (Especially for India / LMICs)

- Strong patent-law safeguards against evergreening (like India's Section 3(d)) are crucial tools for balancing innovation incentives and public health requirements.
- Maintaining a robust generic industry supported by transparent patent examination helps ensure critical medicines remain affordable and widely accessible.
- Rejecting frivolous "incremental" patents frees up the market for generics, which can significantly reduce drug costs and broaden access particularly for life-saving drugs for cancer, TB, chronic diseases.

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[211] Raj GM. From "Glivec®" to "Prevnar 13®": How strong is the Indian drug patenting system? *Perspect Clin Res.* 2018 Oct-Dec;9(4):187-188. doi: 10.4103/picr.PICR_102_18. PMID: 30319951; PMCID: PMC6176695.

[212] European AIDS Treatment Group, India rejects Johnson & Johnson's attempt to extend monopoly on lifesaving TB drug, *EATG*, Apr. 3, 2023 available at https://www.eatg.org/hiv-news/india-rejects-johnson-johnsons-attempt-to-extend-monopoly-on-lifesaving-tb-drug/.

- For global public health: countries like India, by enforcing strict patent standards, help make low-cost generics available not just domestically but also for many other developing countries that rely on imported generics.

TRIPS

Section 5 of Part II [213]of the agreement discusses patents, and pharmaceutical innovators are given strong patent rights under Articles 27 and 28. The qualifications for patentability are limited by *Article 27*, which stipulates that patents must be granted for any inventions... in all fields of technology, provided they are new, inventive, and capable of industrial application. [214] However, these terms are not defined, giving autonomy to the TRIPS members to make obtaining pharmaceutical patents more difficult. [215] Secondly, Article 27 allows for patentability exclusions when crucial to safeguard public order or integrity. Excluding an innovation from commercialization only because it is restricted by a state's law is insufficient. A comprehensive restriction on commercialization is necessary.

A patented invention cannot be "manufactured, used, offered for sale, sold, or imported" by third parties without the patent holder's consent, according to *Article 28*[216], which outlines the rights granted by a patent. Therefore, it stops generic medication manufacturers from infringing on pharmaceutical product patents. Moreover, *Article 31 of TRIPS* allows member states to undertake compulsory patent licensing programs under certain conditions[217], limiting the applicability of Article 28. It allows TRIPS signatories to provide generic drug firms a license to use the product patents of branded medication manufacturers without the former's consent, for example, in cases of high sickness prevalence or poverty. Signatories must, however, provide patent holders with "appropriate compensation" when they participate in such licencing techniques.[218] The limitations-imposed show that TRIPS members have array of options to reduce the market exclusivity of pharmaceutical companies.

USA

Patents granted by the United States Patent and Trademark Office (USPTO) generally remain legal for 20 years following the date of application[219]. Evergreening is made possible in the United States by the Patent Term Extension (PTE) provision of the Drug Price Competition and Patent

[213] 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, 33 I.L.M. 1197, Part II, § 5.
[214] TRIPS Agreement art. 27.
[215] U.N. Conference on Trade & Dev. & Int'l Ctr. for Trade & Sustainable Dev., *Resource Book on TRIPS and Development* 359–61 (Cambridge Univ. Press 2005).
[216] TRIPS Agreement art. 28.
[217] TRIPS Agreement art. 31.
[218] Contemporary Stance of Compulsory Licensing in Indian Pharmaceutical Industry, 30 *J. Intell. Prop. Rts.* 361 (2025), https://doi.org/10.56042/jipr.v30i3.9402.
[219] 35 U.S.C. § 154(a)(2) (2018).

Term Restoration Act of 1984[220], ordinarily referred to as the Hatch-Waxman Act. The act allows a patent period to be prolonged by up to five years to make up for time lost during the FDA clearance process.[221]

A patent may be obtained under 35 U.S. Code § 101 to anyone who invents or discovers a new and useful technique, machine, manufacture, composition of matter, or any new and useful improvement thereof, subject to the terms and requirements of this section.[222] It is also patentable to come up with new applications for existing products.[223]

Regulatory Authorities

- ***Abuse of Dominant Position under Indian Competition Act, 2002***

Abuse of dominant position is barred by ***Section 4 of the Indian Competition Act, 2002***[224], which also covers exploitative or exclusionary practices that limit market competition, including evergreening strategies based on patents. Anti-competitive agreements, licensing contracts, and other entry obstacles put in place by powerful companies are all investigated by the Competition Commission of India (CCI). As evident from the case of Roche group wherein it attempted to stop generic drug producers from accessing the market by influencing medical professionals and regulatory bodies. However, the CCI through their order on April 21, 2017, regarded there practices as anti-competitive.[225] In October 2018, the CCI came up with the policy note named Making Markets Work for Affordable Healthcare, that flagged the expansion of branded generics, lack of transparency, and vertical arrangements as significant threats. Pharmaceutical companies and trade associations have been fined by CCI for engaging in anticompetitive practices, like price fixing along with market allocation. [226]

The Indian Competition and Regulation Report 2023, particularly addresses that consumer choices have been restricted due to the industry practices that choke competition and limit the affordable accessibility to essential medications[227].

- ***US Anti-Trust Laws***

The FTC (Federal Trade Commission) formally disclosed the analysis of generic drug competition in 2000 in response to anti-competitive practices by pharmaceutical companies abusing the Hatch-Waxman Act, such as the pay for delay technique or planning to extend the 180-day exclusivity for first-filing generic drug application and then prolong its access into the market.[228] According

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[220] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417.
[221] 35 U.S.C. § 156 (2018).
[222] 35 U.S.C. § 101 (2018).
[223] Dennis B. Worthen, American Pharmaceutical Patents from a Historical Perspective, 7 *Int'l J. Pharm. Compounding* 38 (2003).
[224] The Competition Act, No. 12 of 2003, § 4, India Code (2003).
[225] Comp. Comm'n of India, Biocon Ltd. & Ors. v. F. Hoffmann-La Roche Ag & Ors., C-68/2016 (Comp. Comm'n Ind. Apr. 21, 2017).
[226] Competition Commission of India, "Making Markets Work for Affordable Healthcare," policy note, October 2018; CUTS Institute for Regulation & Competition, *Competition and Regulation in India, 2023: Regulatory Deficit in Access to Equitable Healthcare* (2023), ch. 3.
[227] Mehta, Pradeep S., and Ujjwal Kumar, eds. *"*Competition and Regulation in India, 2023: Regulatory Deficit in Access to Equitable Healthcare*." CUTS International*, 2023. https://circ.in/pdf/Report-ICRR2023.pdf.
[228] J. Eng & N. Liu, "Different Routes, the Same Destination: A Comparative Study of Antitrust Regulation for the Pharmaceutical Industry in the United States and China", 16 *Front. Pharmacology*, no. 1557876 (2025), https://doi.org/10.3389/fphar.2025.1557876.

to the FTC, these transactions cost American taxpayers billions of dollars each year. [229]As a result of its lawsuit and policy advocacy, significant court rulings have been made, including *FTC v. Actavis*[230], which made it clear that reverse payment settlements may be illegal under antitrust law.

- ***EU***

The European Medicines Agency (EMA) and the European Commission (EC) both act against evergreening by examining data exclusivity plans, supplemental protection certificates, and patent settlements.[231] The two main provisions of EU competition law are set out in Article 101 and Article 102 TFEU. Article 101 TFEU forbids anticompetitive agreements between undertakings [232] while Article 102 TFEU deals with the strategy of undertakings with big market power, prohibiting an abuse of a dominant power on the internal market.[233] The AstraZeneca was one of the first cases where the EU had to determine whether there was violation of Article 102 of TFEU to engage in evergreening of pharmaceutical products.[234] AstraZeneca was fined EUR 52.5 million for two abuses of dominant position after the European Court of Justice (ECJ) affirmed the GC's decision in December 2012.[235]

Table 2: Global Case Studies on Evergreening & Their Impact on Affordable Medicines

Country	Drug / Disease Area	Company	Evergreening Strategy	Outcome	Impact on Access & Prices
Brazil	Efavirenz (HIV/AIDS)	Merck	Sought new patent for crystalline form of existing ARV to extend monopoly	Patent rejected by INPI for lack of inventive step	Government switched to generics → millions in savings, major price reduction, strengthened universal HIV program
South Africa	Tenofovir (HIV)	Gilead Sciences	Multiple secondary patents + settlement strategies to	Activist challenge → key patents withdrawn;	Generic price fell >80%; enabled world's

[229] Robin C. Feldman, "The Price Tag of Pay-for-Delay", 23 *Colum. Sci. & Tech. L. Rev*. 1 (2022), https://repository.uclawsf.edu/faculty_scholarship/1866.
[230] *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).
[231] Josette Sciberras, Raymond Zammit & Patricia Vella Bonanno, "The European Framework for Intellectual Property Rights for Biological Medicines", 28 *J. Generic Meds.* 123 (2021).
[232] Consolidated Version of the Treaty on the Functioning of the European Union art. 101, Oct. 26, 2012, 2012 O.J. (C 326) 47.
[233] TFEU art. 102.
[234] Josef Drexl, "AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law*"*, *Max Planck Inst. for Intell. Prop. & Competition L*., Research Paper No. 12-10, at 2 (2012).
[235] *Case C-457/10 P, AstraZeneca AB v. Eur. Comm'n*, ECLI:EU:C:2012:770, ¶¶ 165–67 (Dec. 6, 2012).

			delay generics	later voluntary licenses	largest HIV program to scale treatment
Thailand	Kaletra (Lopinavir/Ritonavir) (HIV)	AbbVie	Filed incremental patents for formulation & heat-stable versions	Thailand issued compulsory license (CL)	Price dropped from ~US$2200 → <US$700 per patient/year; thousands received treatment
EU / UK	Omeprazole (Prilosec)	AstraZeneca	"Isomer evergreening" → Esomeprazole (Nexium) + formulation tweaks + extensions	Courts rejected parts; generics approved earlier in EU	After generic entry → price fell 90%+; classic example of lifecycle manipulation
USA	Humira (Adalimumab)	AbbVie	Over 130 secondary patents on formulations, dosing, delivery devices, manufacturing	Biosimilars delayed until 2023 (US), earlier in EU	EU saw 50–80% price cuts; US prices stayed high for years due to evergreening
Colombia	Imatinib (Glivec) (Cancer)	Novartis	Filed secondary patent similar to India attempt	Colombia rejected the patent & later imposed price controls	Access improved; price dropped ~44%, reducing cancer-treatment burden
Argentina	Ritonavir (HIV)	AbbVie	Multiple incremental patents on formulations and combinations	Strict patentability → many patents refused	Strong generics supply kept prices low; maintained HIV

					treatment affordability

IV. CONSEQUENCES ON ACCESS TO AFFORDABLE MEDICINES

The patent evergreening phenomenon is becoming one of the most vital issues in the field of global pharmaceuticals. While the intention of patents is to incentivize innovation and reward the considerable investment made in the making of new drugs, the practice of evergreening acquiring secondary patents for inconsequential changes to existing drugs allows monopolies to be extended well past the legitimate time. The consequences of this for patients, governments, and entire health systems is enormous. This chapter addresses the consequences of evergreening on the proliferation of affordable medicines, taking into consideration inflation of costs, late introduction of generics, public healthcare budget deficits, inequity of burden among countries, and the burden of evergreening with real-world examples of drugs.

Price Inflation and Delayed Entry of Generics

The existence of generic competition in the marketplace is the most effective way to bring drug costs down. When a generic competitor is offered, the price of the original formulation typically drops by 60-80% within the first few years. Unfortunately, price competition is often delayed by evergreening practices such as product hopping, new formulation patents, and trivial patent changes through minor chemical patenting.[236]

Pharmaceutical companies take benefit of the way outs in governing systems by acquiring secondary patents for modified release mechanisms, new crystalline forms, or combination therapies even when these lack significant therapeutic value. Such actions extend the entry of generics and expand exclusivity for the companies.[237]

The delay directly translates into exorbitant prices and patients paying monopoly prices for medications long after the primary patent should have lapsed. For instance, in the United States, the yearly cost of delayed generic entry is several billion dollars to the patients and insurers. The economic burden is exacerbated by issues of patient compliance and survival in the case of life-threatening diseases such as certain cancers and auto-immune disorders.

Public Health Budgets and Insurance Schemes

The impact of price inflation due to patent evergreening is primarily borne by health budgets and insurance schemes. Countries with universal health coverage have to spend excessive resources in the form of public health expenditures to cover the medicines for the longer periods of exclusivity, while lower- and middle-income countries (LMICs) have to face impossible choices, often involving severe economic compromises to provide essential medicines.

The negative impacts on the economy take on several forms:

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[236] Rachel Goode and Bernard Chao, "Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem," *Journal of Law and the Biosciences* 9, no. 1 (2022): lsac022, https://doi.org/10.1093/jlb/lsac022.

[237] Novartis AG v. Union of India & Others, AIR 2013 SC 1311 (India), Supreme Court of India, April 1, 2013, https://globalhealth.harvard.edu/novartis-v-union-of-india-supreme-court-decision-2013/.

- Increasing expenditure on drugs: Health services take on the costs of patented high-priced drugs. This limits the ability of services to provide care in other areas of the healthcare system.
- Strain on insurers: In the U.S. market, private insurers shift costs to patients by increasing premiums and co-payments, adding pressure on the system.
- Opportunity costs: High costs mean governments must ration or delay the adoption of innovative subsidized treatments, and this impacts the patient outcome directly.

Detrimental health outcomes create and reinforce inequities in health access. For instance, expensive oncology drugs subject to evergreening take a disproportionate share of oncology budgets, resulting in the delayed access to new treatments, and reduced access for other diseases.

Inequity in Access Between High and Low-Income Countries

High-income countries, despite their strained healthcare budgets, provide subsidized or reimbursed access to expensive drugs. In lower-income countries, evergreening placed healthcare even more strained budgets, making it even more impossible to provide basic access. International trade agreements, including the TRIPS Agreement and later bilateral treaties, often require LMICs to recognize and enforce pharmaceutical patents, including secondary patents derived from evergreening, increasing the risk of LMICs becoming legally obligated to restrict the manufacturing or import of cheap generics or becoming legally obligated to import more expensive generics, receiving no sanction for doing so. Consequently, LMIC patients often face:

- No or finite access to critical drugs for the duration of the patents.
- Catastrophic and out-of-pocket expenditures while trying to access affordable treatment, mostly affecting already impoverished families.
- Uncontrolled morbidity and mortality, particularly with chronic and fatal diseases.

This inequity is highlighted by the fact that while patients from high-income countries deal with high medicine costs, patients from low-income countries are completely left without the life-saving medicines. This is a clear violation of fundamental international and global health principles and the WHO's goal of essential medicines for all.

Case Study 1: Gleevec (Imatinib)

Gleevec, a novel treatment for chronic myeloid leukemia (CML) by Novartis, is frequently described as the poster child for evergreening. Gleevec became available for use in 2001 and was highly praised for the high price of effective treatment, becoming the first line treatment for the chronic myeloid leukemia. However, the price of treatment was high, often exceeding $70,000 a year in the United States, and the treatment was highly effective by the standard of treatments available at the time. Novartis filed several secondary patents trying to protect exclusivity for imatinib for a little longer. In an Indian patent case regarding a beta-crystalline imatinib patent, Novartis's patenting efforts were recognized as patent evergreening. In 2013, the Supreme Court of India recognized the case as evergreening, and patenting beta-crystalline forms for imatinib was rejected.[238]

[238] G. Mudur, Court Dismisses Novartis Challenge to Indian Patent Law, *BMJ* 346 (2013): f2296, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3620026/.

This case represents a critical point at which Bollywood for Gleevec and its imatinib generics spread like wildfire, especially in LMICs, Gleevec was unattainable for many before the generics flooded the market. It was a lifesaving drug to many.[239] Gleevec in its branded form was being sold for thousands of dollars, while the generics sold for a couple hundred if not less. Novartis was able to charge monopoly prices for Gleevec in branded form after the generics were launched, and in countries where patent protection for imatinib was not as weak, they were able to charge monopoly prices.

Case Study 2: AbbVie's Humira

Focusing specifically on Humira, we see an example of evergreening at its most aggressive. It was first approved for sale in 2002, and, marketed by AbbVie for autoimmune diseases like Crohn's and Rheumatoid Arthritis, was the first drug to reach a sales figure of 20 billion dollars.[240] AbbVie constructed a "patent thicket" of over 200 patents that covered everything from formulations to manufacturing processes to delivery methods.[241] As a result, AbbVie was able to ward off competition from biosimilars in the U.S. until 2023, long after the initial patent expired. In the meantime, AbbVie enjoyed a 20-year monopoly, which negatively affected both patients and the insurance system.

U.S. patients continued to enjoy AbbVie's Humira monopoly while U.S. insurance companies suffered. Annual treatment costs skyrocketed, totalling over $80,000. This was in stark contrast to the 80% price reductions that U.S. patients could have enjoyed if they were able to access the biosimilars launched in Europe in 2018. U.S. patients continued to be held captive with exorbitant prices for AbbVie's Humira monopoly, which illustrates that the strategic patenting of inventions can be just as damaging as a core monopoly in the global medicine market.[242]

Case Study 3: Doryx and Product Hopping in the U.S.

Doryx, an antibiotic (doxycycline hyclate), was poorly managed with respect to product hopping and offers a valuable lesson. This is when companies try to move patients from one version of the medicine to another just before the generic is set to be released. Warner Chilcott, the drug's manufacturer, continuously reformulated Doryx into new dosage forms.

Every change had predatory marketing campaigns to switch patients to the new formulation, all while old versions were pulled from the market. This essentially locked generic manufacturers out of the market, as their equivalents were no longer substitutable at pharmacies.[243]

As the therapeutic benefit of these reformulations was practically zero, the tactic was very successful in extending Doryx's monopoly period. Patients and insurers incurred unnecessary

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[239] Naresh Asuri, Proper Interpretation of Section 3(d) of the Indian Patent Act Could Save Incremental Innovations, *IPWatchdog*, July 7, 2020, https://ipwatchdog.com/2020/07/07/proper-interpretation-section-3d-indian-patent-act-save-incremental-innovations/id=122929/.

[240] Judge Holds AbbVie Did Not Violate Antitrust Laws With Humira Patent Thicket, *Big Molecule Watch*, June 9, 2020, https://www.bigmoleculewatch.com/2020/06/09/judge-holds-abbvie-did-not-violate-antitrust-laws-with-humira-patent-thicket/.

[241] *Mayor and City Council of Baltimore v. AbbVie Inc.*, No. 20-2402 (7th Cir. Aug. 1, 2022), opinion available at https://casetext.com/case/mayor-city-council-of-baltimore-v-abbvie-inc.

[242] AbbVie Wins First Round in Humira Antitrust Lawsuit, *Petrie-Flom Center, Harvard Law School*, June 10, 2020, https://blog.petrieflom.law.harvard.edu/2020/06/10/abbvie-humira-antitrust-lawsuit/.

[243] Federal Trade Commission, Product Hopping in the Pharmaceutical Industry: A Review of the Evidence, FTC Report, 2015, https://www.ftc.gov/reports/product-hopping-pharmaceutical-industry-review-evidence.

costs, which was later described by the U.S. Federal Trade Commission (FTC) as product-hopping, an anti-competitive behavior that targets generic competition.

Broader Public Health Consequences

When multiple drugs implement evergreening practices, the result includes some negative consequences for public health, such as:

• Reduced adherence to treatment: Patients will leave out doses, split pills, or disregard treatment altogether when the expense of drugs is too high.

• Health inequity exacerbation: Vulnerable populations, especially those uninsured or underinsured, are more likely to be affected.

• Global treatment innovations remain stagnate: Defending or contesting patents stifles genuine innovations and improvements to broad access.

Also, the lack of generics and reduced competition from GSK and the patent holders will result in stagnation and control by a few large corporations in the market.

The evergreening of patents is a public health and social justice issue, in addition to the legal and economic implications. It violates the basic right of access to essential medicines by increasing the cost of drugs, delaying generics, and widening the void between poor and rich nations.

The Gleevec, Humira and Doryx case studies show the scope of impact these strategies have on patients and the health systems of multiple countries. Absent stronger patent examination, regulatory vigilance, and international collaboration, the negative impacts of evergreening will remain a barrier to access and equity in healthcare.

V. REFORM, REMEDIES, AND THE WAY FORWARD

One of the most direct answers to the evergreening problem is to revise down the legal and institutional adjustments to patentability. Many of the secondary patents are granted for marginal changes with no great therapeutic gain. Clearer and more systematic adjustments will need to be made on the side of legislature and patent offices to the legal and institutional systems so that real innovation may be patented and only those granted patents.

One oft-cited example is India's Section 3(d) of the Patents Act. In the 2013 case of Novartis AG v. Union of India, the Indian Supreme Court upheld the decision of the lower court, establishing that incremental innovations without enhanced efficacy should not qualify for patent protection, and therefore, patent protection should be denied for a new crystalline form of imatinib.[244] This case illustrates the value of tailored legal standards that can adequately filter out attempts at patent evergreening and simultaneously reward genuine innovations.

Other jurisdictions can learn from this by requiring patent applicants to include some form of clinical or therapeutic evidence of the proposed innovation's enhanced efficacy. Patent offices could also do more to assist examiners in evaluating the proposed innovation by providing more patent examination guidelines and patent transparency in the evaluation of secondary applications to minimize the risks of inadvertent allowance of patents that could be regarded as a frivolous patent.

Proactive Monitoring of Secondary Patent Filings

[244] *Novartis AG v. Union of India & Others*, AIR 2013 SC 1311 (India), Supreme Court of India, April 1, 2013, https://globalhealth.harvard.edu/novartis-v-union-of-india-supreme-court-decision-2013/.

Patent authorities can use proactive policies to monitor inter-related secondary filings to identify potential patterns. This could include publishing patent packs of inter-related patents that are easily searchable or providing a patent family database. With this information, the public and the courts can get a better realization of the contextual value of overlapping extensions of patent rights and assist in the identification of abusive or frivolous filings.[245]

In addition, patent linkage systems which connect regulatory approval of generics to the patent status of the originator drug need to be designed to avoid abusive practices. The systems currently in use in the United States and some other jurisdictions grant originator companies the power to trigger automatic stays of generic approvals simply by filing patent infringement lawsuits.[246] Reforming this type of regulatory system to require proof of infringement at some reasonable level would reduce litigation-driven generic approval delays to a more tolerable level.

Incorporating a Public Interest Check

A third option, legally speaking, is to include public interest considerations at the level of patents and regulatory approvals. Patent agencies and drug regulators could require public health impact assessments, at least in a limited form, especially in cases of secondary patents, considering the potential public health impact of the innovation claimed by the applicant. Some authors even proposed incorporating cost-effectiveness assessments similar to those performed by national health technology assessment (HTA) bodies into the patent system.[247]

While this would definitely increase the administrative burden of patenting, the potential public health value of drugs justifies this approach. The proposed public interest assessment could also be a justification for extreme cases of compulsory licensing. These would be cases of patent abuse aimed at maintaining market power and, therefore, access to the drug.

Role of Competition Authorities

Proactive Enforcement

Competition authorities are essential in targeted enforcement of anticompetitive practices related to evergreening. This includes product hopping, pay-for-delay deals, or patent thickets. For instance, the U.S. Federal Trade Commission (FTC) has acted on several product hopping cases, such as Warner Chilcott's manipulation of Doryx formulations to undermine generics. [248]Courts are increasingly seeing these practices as violative of antitrust laws as they serve no commercially reasonable purpose other than delaying competition.[249]

To improve enforcement actions, competition authorities need to take the initiative rather than just respond to complaints. Regulatory agencies should actively survey the pharmaceutical industry for suspicious reformulation, settlement, or patent clustering behaviors. The European

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[245] Carlos M. Correa, Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective, ICTSD/UNCTAD/WHO, 2007, https://www.who.int/phi/publications/guidelines/en/.

[246] Robin Feldman, "May Your Drug Price Be Evergreen", *Journal of Law and the Biosciences* 5, no. 3 (2018): 590–647, https://doi.org/10.1093/jlb/lsy022.

[247] Ellen 't Hoen, "Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines", *Health Action International*, 2016, https://haiweb.org/what-we-do/access-to-medicines/.

[248] Federal Trade Commission, Product Hopping in the Pharmaceutical Industry: A Review of the Evidence, FTC Report, 2015, https://www.ftc.gov/reports/product-hopping-pharmaceutical-industry-review-evidence.

[249] Michael A. Carrier, "Product Hopping: A New Framework", *Notre Dame Law Review* 92, no. 1 (2016): 167–225, https://scholarship.law.nd.edu/ndlr/vol92/iss1/3/.

Commission has already begun to take steps in this direction by fining firms for collusive behavior and anticompetitive practices in the pharmaceutical industry. [250]

Monitoring Mergers and Abuse Cases

Mergers and acquisitions is another area of competition law that remains largely unexplored. The merger of pharmaceutical firms not only diminishes competition but also substantially increases patent thicket and evergreening strategy deployment by patent monopolists. By conditioning or blocking mergers that undermine generic competition, competition authorities can reduce long-term monopolistic control.

Moreover, cases of abuse of dominance should cover firms that continuously apply evergreening strategies to monopolize exclusionary practices. Such an approach provides an excellent opportunity to prioritize competitive access to medicines within competition law instead of remaining at the policy fringe.[251]

The Role of the Courts and Public Interest Litigation

Courts address evergreening through the interpretation and enforcement of the laws on patents and provides public interest litigation avenues. This form of litigation is powerful in jurisdictions where civil society organizations defend patients on the right to challenge illegitimate patents. The Novartis case in India is, one of, the best such instances where organized patient advocacy and NGOs challenged the secondary patents.[252]

In jurisdictions where there are less developed patent opposition systems, weak patents may only be reviewed and nullified by the courts, which would then be the only meaningful venue to serve such a purpose. Broader public interest standing, in the form of litigation, that is intended to govern patenting practices, should also include consumer groups and civil society organizations to capture surplus judicial activism in governance of the public patent regime.

Patents that are cores of innovation are most likely to be undermined by lack of competition and entry of generics. Courts should understand that innovation is likely to be exploitative when there is a robust incentive to draw competitive access to the medicine.[253] Such a balance is most desirable and public health centered. Courts should, therefore, align patent laws and public health.

Global Coordination

Collaboration from the WTO, WHO, and UN Human Rights Council

Given the interconnection of pharmaceutical markets and the cross-border implications of patents, evergreening is not just a domestic challenge, but a worldwide one. International bodies can help in standard-setting and facilitating access.

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[250] European Commission, Pharmaceutical Sector Inquiry: Final Report, July 8, 2009, https://competition-policy.ec.europa.eu/public-consultations/2008-pharma-inquiry_en.

[251] OECD, Excessive Pricing in Pharmaceutical Markets, OECD Competition Committee Report, 2018, https://www.oecd.org/daf/competition/excessive-pricing-in-pharmaceutical-markets.htm.

[252] G. Mudur, "Court Dismisses Novartis Challenge to Indian Patent Law", *BMJ* 346 (2013): f2296, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3620026/.

[253] Amir Attaran and Lee Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" *JAMA* 286, no. 15 (2001): 1886–1892, https://jamanetwork.com/journals/jama/fullarticle/194627.

Universal health coverage must include the availability of affordable medications, as advocated by the World Health Organization (WHO). The Model List of Essential Medicines should shape global access priorities and provide the raw materials for the assessment of evergreened drugs.[254] The World Trade Organization (WTO) also plays an important role, particularly in administering the TRIPS Agreement. Countries still need to abuse patents as TRIPS flexibilities, such as compulsory licensing, provide a vital way for countries to still address patent abuse. Unfortunately, such TRIPS flexibilities are under pressure from bilateral and regional trade agreements. Refreshing the global focus on these clauses might give developing countries the power needed to counter evergreening.[255]

Access to medicines is also a part of the right to health, as acknowledged by the UN HRC. The Council has documented such calls and passed resolutions encouraging member states to ensure that access to affordable medicines is not obstructed by legislative frameworks on intellectual property. The involvement of human rights institutions would strengthen the case for these reforms by stating them as human rights obligations instead of discretionary policies.

VI. CONCLUSION

Rethinking the doctrine and practice of evergreening requires different approaches. Defensive weak patents can be limited through stricter patentability criteria, transparent watching of secondary filings, and public interest checks. Merger reviews and the challenger's role on anticompetitive behavior should be more proactive. The courts and public interest litigation should coordinate so that the former interprets and enforces the law's limits on patents.[256] Ultimately, the WHO, WTO, and the human rights institutions will need to collaborate to harmonize and stabilize the protective reforms.

Challenging the status quo is essential, and will be complicated. The right to access medicine is integral to one’s dignity, and thus the right to health requires the reform of patent law and practice to stop evergreening.

[254] World Health Organization, WHO Model List of Essential Medicines – 22nd List, September 2021, https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02.

[255] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, November 14, 2001, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[256] United Nations Human Rights Council, Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, A/HRC/RES/23/14, June 13, 2013, https://digitallibrary.un.org/record/755819.