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Patent Evergreening and Its Impact on Affordable Medicines in Developing Countries

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Abstract
Patent evergreening, the practice of extending drug monopolies through minor modifications, has become a significant barrier to affordable medicines in developing countries. While intended to reward innovation, this strategy often delays generic competition and keeps drug prices high, undermining access to essential treatments. This article examines the mechanisms and impacts of evergreening, especially in the context of international trade rules like TRIPS and TRIPS-plus agreements. It also explores legal and ethical responses, with a focus on India's model, and calls for a more balanced approach that supports both innovation and the right to health.

Keywords: Patent Evergreening, Access to Medicines, Developing Countries, Intellectual Property Rights (IPR), Pharmaceutical Ethics.

Introduction

Access to affordable, life-saving medicines remains one of the most pressing public health challenges in the developing world. While significant advancements have been made in medical science and pharmaceutical innovation, millions of people in low- and middle-income countries continue to suffer and die from treatable conditions due to the high cost of essential drugs. At the heart of this issue lies the global intellectual property regime, particularly the role of patents in determining the availability and pricing of medicines.

Patents are intended to reward innovation by granting pharmaceutical companies a temporary monopoly, typically 20 years, to recover research and development (R&D) costs and earn profits. However, in recent decades, a growing concern has emerged over the practice of patent evergreening, where pharmaceutical companies exploit legal and regulatory loopholes to extend their patent protection well beyond the original expiration date. This is often done through minor modifications to existing drugs, such as changing formulations, delivery methods, or dosages, or by securing patents for new but non-innovative uses. While such strategies may offer some incremental benefits, they rarely justify additional years of exclusivity.

The impact of patent evergreening is particularly severe in developing countries, where health systems are underfunded, generic competition is crucial for drug affordability, and populations are more vulnerable to high medicine costs. By delaying the entry of generic alternatives, evergreening keeps drug prices artificially high, putting essential medicines out of reach for large segments of the population. This not only undermines public health efforts but also raises ethical and human rights concerns, as it directly challenges the right to access affordable healthcare.

Compounding the problem is the influence of international trade agreements, such as the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which mandates stronger patent protections globally. While TRIPS includes certain flexibilities to protect public health, like compulsory licensing and strict patentability criteria, many developing countries face political, economic, or legal pressure that limits their ability to use these provisions effectively.

As the global health community grapples with pandemics, rising chronic diseases, and increasing healthcare costs, the debate over patent evergreening has become more urgent. This article explores the mechanisms and consequences of patent evergreening, with a focus on its impact on access to affordable medicines in developing countries. It also examines legal responses, policy options, and ethical dimensions surrounding this practice, aiming to propose a more balanced approach that respects both innovation and the right to health.

Understanding Patent Evergreening

Patent evergreening refers to the strategy employed by pharmaceutical companies to extend the commercial life of a drug beyond the original patent term, usually by making minor or insignificant modifications to the existing product. These modifications may include changes in dosage forms, methods of administration, formulation, crystalline structures, or discovering new uses of the same compound, none of which necessarily constitute genuine innovation or enhanced therapeutic efficacy.[1]

This practice is particularly prevalent in the pharmaceutical industry, where the expiration of a drug's primary patent opens the door for generic manufacturers to enter the market with more affordable versions. By filing successive secondary patents, companies effectively delay generic competition, thereby maintaining monopoly pricing and market exclusivity for longer periods than originally intended by patent law.

For instance, a company may obtain a patent for a slightly altered formulation of an existing drug, such as a sustained-release version, and claim it as a new invention. Even though the original compound may have already been protected and nearing patent expiry, this new patent can prolong the company's exclusivity for years.[2] In some cases, the original drug remains off-patent, but the surrounding legal and regulatory barriers erected through evergreening discourage or delay the entry of generics.

Patent evergreening is a contested issue in global health and intellectual property law. Critics argue that it undermines the balance between incentivising innovation and ensuring public access to essential medicines.[3] It allows pharmaceutical firms to monopolise drug markets without meaningful innovation, thereby impeding access to affordable treatment, especially in resource-constrained developing countries.[4]

Courts and legislators in several countries have responded by tightening patentability criteria. For example, India's Patent Act, 1970, under Section 3(d),[5] explicitly prohibits the patenting of new forms of known substances unless they show a significant enhancement in efficacy, thus aiming to curb evergreening practices.

[1] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, Zed Books, London, 2000, p. 76.

[2] World Health Organisation, *Public Health, Innovation and Intellectual Property Rights*, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, WHO, 2006, p. 80.

[3] Shamnad Basheer, "India's Tryst with TRIPS: The Patents (Amendment) Act, 2005", (2005) 1 Indian Journal of Law and Technology 15, at p. 20.

[4] Thomas Pogge, "Human Rights and Global Health: A Research Program," (2005).

[5] Section 3(d), The Patents Act, 1970 (India) – "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.

The Role of Patents in the Pharmaceutical Industry

Patents play a crucial role in the pharmaceutical industry by serving as a legal tool to protect innovations and incentivize the development of new drugs. A patent grants the inventor an exclusive right to manufacture, use, sell, and license an invention for a fixed period, typically 20 years from the filing date, during which competitors are legally barred from making or selling the same product without authorisation. This monopoly allows pharmaceutical companies to recoup the substantial investments involved in research, clinical trials, and regulatory approvals.[6]

Drug development is a high-risk, capital-intensive process that often spans over a decade, with billions of dollars spent on R&D, most of which do not lead to marketable products.[7] Patents ensure that when a company successfully brings a drug to market, it has a limited period of exclusivity to earn profits and fund further innovation. Without such protection, generic manufacturers could replicate and sell the same drug at lower costs, undercutting the original innovator and disincentivizing future R&D efforts.[8]

However, the system of patent protection is a double-edged sword. While it encourages innovation, it also creates monopolies that can lead to exorbitant drug prices, limiting access, especially in low- and middle-income countries. The patent holder may charge high prices without competition, which can place a heavy burden on public health systems and out-of-pocket consumers in developing regions.

Moreover, the balance between innovation and public health becomes skewed when companies use patents not to protect genuine innovations, but to block competition through strategic legal mechanisms like patent evergreening. This misuse of patent rights can undermine the original intent of the patent system and exacerbate global health inequities.

International agreements, such as the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), have harmonised patent standards across WTO member countries, including many developing nations. While TRIPS obligates members to grant patent protection for pharmaceutical products, it also includes flexibilities intended to protect public health, though these are often underutilised or contested due to political and economic pressures.[9]

The challenge is clear: we must design and enforce an effective patent system that not only rewards genuine pharmaceutical innovation but also guarantees affordable access to essential medicines for all.

Impact of Patent Evergreening on Drug Prices

Patent evergreening has a significant and direct impact on the affordability of medicines by delaying the entry of generic drugs into the market, thereby allowing originator pharmaceutical companies to maintain high prices even after the expiry of the original patent. This extension of monopoly control over drug production and pricing prevents healthy market competition and sustains inflated prices for medicines that would otherwise be substantially cheaper if generics were available.[10]

[6] Rebecca S. Eisenberg, "The Role of the FDA in Innovation Policy," (2007) 13 Mich. Telecomm. & Tech. L. Rev. 345, at p. 348.
[7] Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," (2016) 47 J. Health Econ. 20, at p. 25.
[8] Margaret Llewelyn and Mike Adcock, *European Patents and Access to Medicines: Voluntary Licensing and Public-Private Partnerships*, Edward Elgar Publishing, 2016, p. 12.
[9] World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1994, Arts. 27–34.
[10] Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, Health Action International, Amsterdam, 2016.

Generic medicines typically cost 30% to 90% less than their branded counterparts.[11] They become available when the patent on a drug expires, allowing multiple manufacturers to produce and sell the drug, leading to competitive pricing. However, through evergreening strategies, companies obtain secondary patents on marginally modified versions of the original drug, such as new salts, crystalline forms, or delivery mechanisms, which effectively create a legal barrier to generic entry. Even when the original patent has lapsed, these secondary patents can result in litigation or regulatory delays for generic manufacturers.

A striking example of this is the case of Imatinib Mesylate (Gleevec), an anti-cancer drug originally patented by Novartis. In India, Novartis sought a patent for a beta-crystalline form of imatinib, but the application was rejected under Section 3(d) of the Indian Patents Act, which prohibits patenting of new forms of known substances unless they significantly enhance efficacy. The rejection helped pave the way for affordable generic versions of the drug in India and other developing countries.[12] Without such legal safeguards, the cost of life-saving medications remains prohibitively high for many patients.

In the absence of generics, originator companies can maintain monopoly prices. For instance, second-line antiretroviral therapies (ARTs) for HIV were priced at over US$5,000 per patient per year before generic versions became available; prices dropped to a few hundred dollars per year after generics entered the market.[13] Patent evergreening postpones such affordability, prolonging the financial burden on patients and public healthcare systems in resource-poor countries.

Moreover, the economic strain caused by high drug prices is compounded in developing countries by weak insurance coverage and limited government healthcare spending. Patients often pay out-of-pocket, which leads to increased levels of medical debt, treatment abandonment, and preventable mortality.[14]

Patent evergreening decisively prioritises commercial interests at the expense of public health, obstructing timely access to affordable therapies and exacerbating health equity disparities between developed and developing nations.

Developing Countries and Access to Medicines

Access to essential medicines remains a critical issue in developing countries, where a large portion of the population struggles to obtain timely and affordable treatment for common and life-threatening illnesses. Despite advancements in pharmaceutical innovation, the benefits of medical progress are unevenly distributed due to socio-economic disparities, weak healthcare infrastructure, and restrictive intellectual property regimes.[15]

In many developing countries, healthcare systems are underfunded, public procurement is limited, and health insurance coverage is minimal or non-existent. As a result, individuals often bear the full cost of medicines out of pocket, making high-priced branded drugs unaffordable for the majority.[16] Patent

[11] World Health Organization, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, WHO/WIPO/WTO, 2013.
[12] Novartis AG v. Union of India, (2013) 6 SCC 1.
[13] Médecins Sans Frontières (MSF), *Untangling the Web of Antiretroviral Price Reductions*, 16th Ed., MSF Access Campaign, 2013, pp. 10–12.
[14] Oxfam International, *Patents versus Patients: Five Years after the Doha Declaration*, Oxfam Briefing Paper No. 95, 2007, Available at: https://policy-practice.oxfam.org/resources/patents-versus-patients-five-years-after-the-doha-declaration-114562/ (Last Visited on 25 May 2025)
[15] UNDP, *Access to Medicines, Intellectual Property, and Human Rights*, Human Development Report 2001 Background Paper, UNDP, New York, 2001, p. 7.
[16] World Health Organization, *World Medicines Situation Report 2011*, WHO, Geneva, 2011, p. 17.

protection further exacerbates this situation by restricting the production and availability of low-cost generic alternatives, which are crucial for expanding access to treatment in low-resource settings.

The World Health Organisation (WHO) has estimated that more than one-third of the global population lacks access to essential medicines, a proportion that is significantly higher in Sub-Saharan Africa and South Asia. In such regions, the affordability of medicines is often determined by the presence or absence of patent barriers. While generic medicines have played a pivotal role in increasing access to drugs for diseases like HIV/AIDS, tuberculosis, and malaria, the practice of patent evergreening delays the introduction of these affordable versions, perpetuating healthcare inequality.[17]

For example, the introduction of first-line antiretroviral therapies (ARVs) for HIV in developing countries was made possible largely due to the availability of generics produced in countries like India. When patents on key drugs were not enforced or expired, local manufacturers were able to offer dramatically lower prices, enabling international organizations and governments to scale up treatment. However, as newer patented drugs for drug-resistant strains and second-line therapies became necessary, evergreening practices once again raised barriers to affordability.[18]

Moreover, developing countries often face political and economic pressure when attempting to use TRIPS flexibilities such as compulsory licensing or strict patentability standards. Multinational pharmaceutical corporations and their home governments may challenge such measures through diplomatic means or trade sanctions.[19] As a result, many countries hesitate to adopt strong public health safeguards in their patent laws, fearing international backlash or loss of investment.

In this context, India's approach to patent law, particularly Section 3(d) of the Patents Act, has been hailed as a model for balancing innovation and public health. It allows patents only for genuine innovations and not for trivial modifications, thereby preventing evergreening and facilitating generic competition.[20] However, such legislation remains rare in other developing countries, which often lack the legal expertise or political will to implement similar reforms.

Developing countries are facing significant legal, economic, and geopolitical challenges in their efforts to ensure equitable access to medicines. Patent evergreening is a critical issue that extends monopolies and drives up drug prices, substantially widening the access gap and jeopardising the health and lives of millions. It's essential to address these challenges to secure a fairer system for all.

Legal and Policy Responses

The global response to patent evergreening has involved a mix of legal reforms, judicial interpretations, and policy-level interventions aimed at striking a balance between promoting innovation and ensuring public health. Many countries, especially developing nations, have recognized that unchecked patent protection can hinder access to affordable medicines and have thus introduced safeguards against abusive patenting practices.

[17] Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, Health Action International, Amsterdam, 2016, p. 54.
[18] Médecins Sans Frontières (MSF), *Untangling the Web of Antiretroviral Price Reductions*, 16th Ed., MSF Access Campaign, 2013, p. 8.
[19] Oxfam International, *All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines*, Oxfam Briefing Paper No. 102, 2007, p. 5. Available at https://policy-practice.oxfam.org/resources/all-costs-no-benefits-how-trips-plus-intellectual-property-rules-in-the-us-jord-114080/ (Last Visited on 27 May 2025)
[20] Novartis AG v. Union of India, (2013) 6 SCC 1.

One of the most significant legal responses to patenting practices arises from India, a leading global supplier of generic medicines. The Indian Patents Act of 1970, especially following its 2005 amendment to align with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, contains a powerful provision, Section 3(d), designed to effectively prevent evergreening. This provision unequivocally prohibits the patenting of new forms of known substances unless they demonstrate a significant improvement in therapeutic efficacy.[21] As such, this clause stands as a benchmark for patent legislation that prioritises public health.[22]

India's approach was upheld and clarified in the landmark case of Novartis AG v. Union of India (2013), where the Supreme Court rejected Novartis's patent claim for a modified form of the cancer drug Imatinib Mesylate, stating that the modification did not meet the efficacy threshold under Section 3(d).[23] The judgment affirmed the legislative intent to discourage evergreening and protect access to life-saving medicines by encouraging generic competition. It also set a precedent for other countries grappling with similar issues.

Other developing countries such as Brazil, South Africa, and Thailand have also adopted or considered similar provisions, such as stricter patentability criteria and increased scrutiny of secondary patent applications.[24] For instance, Brazil's health regulatory agency, ANVISA, was granted the authority to review pharmaceutical patent applications from a public health perspective, although this has been contested by the patent office.[25]

At the international level, the Doha Declaration on the TRIPS Agreement and Public Health (2001) reaffirmed the right of WTO member states to use TRIPS flexibilities to protect public health. This includes the right to grant compulsory licenses, define patentability standards, and prioritise generic production in the interest of public welfare. However, the implementation of these flexibilities often faces resistance from developed nations and pharmaceutical corporations, sometimes backed by trade and diplomatic pressure.

To counteract these challenges, several civil society organisations, legal scholars, and global health agencies have called for increased technical assistance and legal capacity-building in developing countries, so they can craft IP laws that are TRIPS-compliant yet public health-oriented.[26]

Legal and policy responses to patent evergreening may vary across jurisdictions, but India exemplifies how national patent law can effectively protect public health while meeting international obligations. The path forward is clear: we must replicate these successful models, stand firm against external pressures, and ensure that intellectual property law promotes equitable access to healthcare for all.

Ethical and Public Health Implications

Patent evergreening raises critical ethical and public health concerns, particularly in the context of devel-

[21] Section 3(d), The Patents Act, 1970 (India), inserted via Patents (Amendment) Act, 2005.
[22] Shamnad Basheer, "India's Tryst with TRIPS: The Patents (Amendment) Act, 2005," (2005) 1 Indian Journal of Law and Technology 15, at p. 20.
[23] Novartis AG v. Union of India, (2013) 6 SCC 1.
[24] Carlos M. Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective*, WHO/ICTSD/UNCTAD, Geneva, 2007, p. 32.
[25] Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, Health Action International, Amsterdam, 2016, p. 65.
[26] Frederick M. Abbott and Jerome H. Reichman, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions," (2007) 10 Journal of International Economic Law 921, at p. 926.

oping countries where access to life-saving medicines is already limited. While the patent system is designed to reward innovation, the strategic extension of patent monopolies through evergreening reflects a misalignment between commercial interests and the right to health.[27]

From an ethical perspective, denying access to affordable medicines to protect corporate profits contradicts the core principles of medical ethics, including beneficence, justice, and non-maleficence.[28] The Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights both recognise access to healthcare as a fundamental human right.[29] When pharmaceutical companies use legal loopholes to maintain high prices through secondary patents, it impedes this right and prioritises market exclusivity over human welfare.

The consequences of evergreening are particularly devastating for vulnerable populations in low- and middle-income countries, where healthcare systems are often under-resourced. Patients may be forced to choose between basic necessities and essential medicines, leading to delayed treatment, worsened health outcomes, and, in many cases, preventable deaths.[30] Public health emergencies such as HIV/AIDS, tuberculosis, and cancer further illustrate the need for affordable access to medicines, yet evergreening continues to pose a systemic barrier to achieving this goal.

In addition, the practice undermines trust in the pharmaceutical industry, which is increasingly seen as exploiting the patent system not for innovation, but for profit-maximisation at the expense of human lives. Critics argue that truly innovative companies should not fear generic competition once a reasonable period of exclusivity has expired.[31] Evergreening, therefore, not only skews market competition but also undermines ethical pharmaceutical development, where the goal should be public benefit, not indefinite monopoly.

From a public health standpoint, evergreening leads to higher drug expenditures for governments, NGOs, and international health agencies. This diverts resources from other critical areas such as vaccination programs, diagnostics, or maternal health services. Furthermore, delayed access to generics impedes the scaling up of treatment programs and hinders the achievement of global health targets, such as those outlined in the Sustainable Development Goals (SDG 3), which call for "universal access to safe, effective, quality, and affordable essential medicines and vaccines."[32]

Patent evergreening underscores a critical conflict between the ethics of healthcare as a public good and the principles of intellectual property as a private right. We need a more balanced system that not only rewards true innovation but also effectively prevents legal tactics that block affordable access to medicines and threaten public health. This approach is essential for ensuring that healthcare serves the broader community rather than just private interests.

Conclusion

To effectively combat the detrimental effects of patent evergreening, especially in resource-limited settings, we must adopt a decisive and multifaceted approach that includes robust legislative action, stra-

[27] Thomas Pogge, "Human Rights and Global Health: A Research Program," (2005) 36 Metaphilosophy 182, at p. 183.
[28] World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013 Nov 27;310(20):2191-4. DOI: 10.1001/jama.2013.281053. PMID: 24141714.
[29] United Nations, *International Covenant on Economic, Social and Cultural Rights*, 1966, Article 12.
[30] Oxfam International, *Patents versus Patients: Five Years after the Doha Declaration*, Oxfam Briefing Paper No. 95, 2007, p. 9.
[31] Love, James, "Paying for Public Goods," (2007) Knowledge Ecology International, at p. 4.
[32] United Nations, *Sustainable Development Goals*, Goal 3: Ensure healthy lives and promote well-being for all at all ages.

tegic policy changes, and strong international collaboration.

First and foremost, countries need to implement strict patentability criteria, akin to India's Section 3(d) of the Patents Act, which rightfully prevents the patenting of minor modifications unless they deliver significant improvements in efficacy. Governments must assert their authority to interpret the TRIPS Agreement in a manner that prioritizes public health and stand firm against pressures to weaken these vital provisions.

Second, it is imperative to enhance the legal and technical capacity of patent offices. This will enable examiners to effectively identify and reject evergreening patent applications. Moreover, establishing independent pre-grant opposition mechanisms is essential to empower health advocates and civil society organizations to challenge weak patents.

Third, countries should actively leverage compulsory licensing and parallel importation for costly patented drugs, particularly during public health emergencies. Utilisation of these TRIPS-compliant measures is not just advisable; it is necessary to ensure access to life-saving medications. International organizations like the WHO, UNDP, and WTO play a crucial role in providing the guidance and support needed to make the most of these flexibilities.

Fourth, developing countries must be discerning when entering Free Trade Agreements (FTAs) that include TRIPS-plus intellectual property provisions. By forming regional alliances, such as the African Union (AU) or ASEAN, they can negotiate unified positions that resist the imposition of high IP standards threatening access to essential medicines.

Finally, a comprehensive global rethink of innovation incentives is overdue. Approaches like delinkage, which decouple research and development (R&D) costs from drug prices, and open-source pharmaceutical innovation offer ethical and sustainable alternatives to the profit-driven patent system.

By confidently promoting equity, transparency, and health justice, the global community can decisively move away from evergreening and establish an intellectual property framework that truly serves humanity.