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PATENT EVERGREENING IN THE PHARMACEUTICAL INDUSTRY: LEGAL LOOPHOLE OR STRATEGIC INNOVATION?

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ABSTRACT

The pharmaceutical industry operates at the intersection of public health and private innovation, with patent law serving as a vital mechanism to balance these competing interests. One of the most debated issues within this framework is *patent evergreening*—a strategy employed by pharmaceutical companies to extend the commercial exclusivity of their products beyond the original patent term. This is often achieved through secondary patents on minor modifications such as new forms, dosages, formulations, or uses of existing drugs. While proponents argue that such practices represent legitimate and incremental innovation deserving of protection, critics contend that evergreening exploits legal loopholes to delay generic entry, inflate drug prices, and undermine access to affordable medicines, particularly in developing countries.

This paper investigates the phenomenon of patent evergreening from both legal and ethical standpoints. It examines global legal frameworks including the TRIPS Agreement and national approaches in jurisdictions such as the United States, European Union, and India—with a special focus on India's Section 3(d) of the Patents Act and the landmark *Novartis v. Union of India* case. Through selected case studies, the research highlights how pharmaceutical firms navigate patent regimes to secure prolonged market dominance. The paper also analyzes the consequences of evergreening on innovation, public health, and legal systems.

Furthermore, the study engages with doctrinal and policy debates to determine whether evergreening is a necessary incentive for continued research or a manipulation of patent law that compromises societal welfare. In conclusion, the paper argues for a nuanced, context- specific approach to patent regulation—one that encourages genuine innovation while safeguarding public interest. Recommendations are offered to strengthen patent examination standards, promote transparency, and ensure that the patent system aligns with both economic incentives and the human right to health.

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INTRODUCTION

The pharmaceutical industry plays a crucial role in advancing public health by developing life- saving drugs and therapies. However, the enormous investment required in research and development (R&D), coupled with the long timelines and high risks involved in bringing a drug to market, necessitates a legal framework that rewards innovation. Patent law, by granting temporary monopolies to inventors, serves as the cornerstone of this incentive structure. Yet, within this framework, the practice of *patent evergreening* has emerged as a contentious issue—particularly in the pharmaceutical sector, where the stakes are highest.[1]

Patent evergreening refers to the strategy employed by pharmaceutical companies to extend the market exclusivity of their drugs beyond the expiration of the original patent, often by securing secondary patents on slight modifications such as new formulations, uses, dosages, or methods of delivery. While this tactic is often presented as a form of incremental innovation, critics argue that it exploits legal loopholes, delays the entry of generic alternatives, and places an undue burden on public health systems, especially in low- and middle-income countries.

The controversy surrounding evergreening raises significant legal, ethical, and policy questions. Is evergreening a legitimate exercise of intellectual property rights that fosters ongoing innovation, or does it represent an abuse of the patent system that prioritizes profit over public health? This research seeks to unpack these questions by exploring the legal foundations and real-world impacts of patent evergreening.[2]

The paper will examine international standards under the TRIPS Agreement, as well as domestic responses, with a particular focus on India's unique legal stance through Section 3(d) of the Patents Act and the landmark *Novartis v. Union of India* case.[3] By analyzing legal doctrines, industry practices, and policy responses, this study aims to evaluate whether patent evergreening is a strategic innovation tool or a regulatory failure that undermines the balance between innovation and access to medicines.

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[1] *Bracha, O., & Okediji, R. L.* (2013). "Pharmaceutical Patent Law and Policy: The TRIPS Agreement and the Doha Declaration." In *International Intellectual Property Law and Policy* (pp. 325–354). Cambridge University Press.

[2] *Chaudhuri, S.* (2005). "The WTO and India's Pharmaceutical Industry: Patent Protection, TRIPS, and Developing Countries." Oxford University Press.

[3] (2013) 6 SCC 1.

CONCEPTUAL FRAMEWORK

The conceptual framework of this research is grounded in the intersection of intellectual property law, pharmaceutical regulation, and public health policy. It explores the concept of *patent evergreening* as a legal and strategic phenomenon, providing a foundation for analyzing its implications from doctrinal, practical, and ethical perspectives.

UNDERSTANDING PATENTS IN THE PHARMACEUTICAL SECTOR

Patents are exclusive rights granted for inventions that are novel, involve an inventive step, and are capable of industrial application. In the pharmaceutical industry, patents are critical for recouping the high costs of R&D and encouraging innovation. However, the 20-year term of patent protection, as mandated by the TRIPS Agreement, often becomes a point of contention due to the extended time it takes for a drug to obtain regulatory approval and reach the market.[4]

DEFINING PATENT EVERGREENING

Patent evergreening refers to the practice of obtaining multiple patents on different aspects of a single drug to extend its exclusivity period. This may include patents on:

- New formulations or compositions (e.g., extended-release versions)
- New methods of use (e.g., treating a different condition)
- Different dosages or methods of administration
- Polymorphs or isomers of the original compound

While these modifications may provide incremental benefits, they often do not meet the threshold of substantial innovation. The line between genuine innovation and strategic patenting is therefore blurred.

LEGAL RECOGNITION AND CRITIQUE

From a legal standpoint, evergreening challenges traditional patentability criteria—especially novelty and inventive step. Jurisdictions differ in how they assess such secondary patents:

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[4] *Kapczynski, A., et al.* (2012). "Addressing Global Health Inequities: Intellectual Property, Access to Medicines, and Innovation." *Public Library of Science Medicine*, 9(1), e1001132.

- In India, Section 3(d) of the Patents Act explicitly prohibits the patenting of new forms of known substances unless they show enhanced efficacy.
- In contrast, the United States and European Union allow broader scope for patenting such modifications, although judicial scrutiny is increasing.

THEORETICAL UNDERPINNINGS

This research is informed by two competing theoretical frameworks:

- Utilitarian IP Theory: Justifies patents as incentives for innovation; supports evergreening if it results in incremental benefits.
- Public Interest/Access-to-Medicine Framework: Emphasizes health as a human right; criticizes evergreening as a barrier to access and a distortion of patent law's original purpose.

THE TRIPS AGREEMENT AND ITS FLEXIBILITIES

Article 27 of the TRIPS Agreement requires patents to be available for all inventions, without discrimination. However, the Agreement also allows member states to adopt criteria and exceptions to ensure that public health objectives are not compromised. These flexibilities have become central in the debate over evergreening, particularly in countries like India and Brazil.[5]

COMPARATIVE LEGAL APPROACHES

Patent evergreening is treated differently across jurisdictions, reflecting varying national priorities between incentivizing innovation and ensuring public access to medicines. This section compares the legal approaches adopted in the United States, European Union, and India to address or regulate evergreening practices in the pharmaceutical sector.

UNITED STATES: A PATENT-FRIENDLY REGIME

The U.S. patent system is often characterized as being favorable to pharmaceutical patent holders. Governed by the **U.S. Patent Act** and interpreted by the **United States Patent and**

[5] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), WTO, 1994. https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

Trademark Office (USPTO), the system allows for multiple layers of patent protection over a single drug.

- **Hatch-Waxman Act (1984):** Encourages generic entry but also enables brand-name companies to extend exclusivity through tactics like:
    - Filing for new patents on modified versions (formulations, delivery methods, etc.)
    - Listing secondary patents in the **FDA's Orange Book**
    - Triggering 30-month stays during generic challenges under Paragraph IV filings
- **Judicial Trends:** U.S. courts have shown limited resistance to evergreening unless clear lack of novelty or obviousness is proven.

Criticism: The U.S. model is accused of promoting "patent thickets" and allowing evergreening to delay generic competition, thereby increasing healthcare costs.

EUROPEAN UNION: REGULATORY SAFEGUARDS WITH FLEXIBILITY

The EU's approach seeks to balance innovation and access, although it is less restrictive than India's model.

- **Supplementary Protection Certificates (SPCs):** Extend patent protection for up to five years to compensate for time lost during regulatory approval.
- **Patentability Criteria:** Governed by the European Patent Convention (EPC); secondary patents are permissible if they meet novelty and inventive step.
- **Regulatory Data Exclusivity:** An 8+2+1 formula (8 years of data exclusivity, 2 years of market exclusivity, 1 year extension for new indications)

Judicial Approach: The European Patent Office (EPO) and national courts examine evergreening cases on a case-by-case basis. While not expressly banning evergreening, scrutiny is increasing around trivial modifications.

A PUBLIC HEALTH-CENTRIC APPROACH

India has taken a notably restrictive stance against evergreening, prioritizing access to medicines over extended monopoly rights.

- **Section 3(d) of the Patents Act (2005 Amendment):** Denies patents for "new forms of known substances" unless they demonstrate "enhancement of known efficacy."
- **Landmark Case – *Novartis AG v. Union of India* (2013):** The Supreme Court denied a patent for the beta-crystalline form of imatinib mesylate, ruling it lacked enhanced therapeutic efficacy. This judgment cemented Section 3(d)'s role in preventing evergreening.
- **Compulsory Licensing:** Available under Section 84 of the Patents Act if drugs are unaffordable or not reasonably worked in India.

Outcome: India's approach has been praised globally for prioritizing public health but has been criticized by multinational pharmaceutical firms for being unfriendly to innovation.

PHARMACEUTICAL INDUSTRY PRACTICES

The pharmaceutical industry heavily relies on patent protection to safeguard its investments in drug development. However, the pressure to sustain high profits and retain market exclusivity beyond the original patent term has led to widespread adoption of *evergreening strategies*. This section explores how pharmaceutical companies implement evergreening, with an emphasis on industry techniques, case studies, and the implications for generic competition and public health.[6]

COMMON EVERGREENING STRATEGIES

Pharmaceutical companies employ a range of techniques to extend their patent monopoly over a drug:

- **Polymorph and Isomer Patents:** Filing new patents for different crystalline forms or enantiomers of a known compound.
- **New Use Patents:** Patents for additional therapeutic uses of an already known drug.
- **Fixed-Dose Combinations:** Combining two or more existing drugs and claiming it as a new invention.
- **Modified Dosage Forms:** Developing sustained-release or extended-release versions.
- **Process Patents:** Slightly modifying the manufacturing process to file new patents.

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[6] *World Health Organization* (2017). "Increasing Access to Medicines through Patent Law Reform." WHO Policy Brief. https://www.who.int/publications/i/item/increasing-access-to-medicines-through-patent-law-reform.

- **Device Patents:** Securing patents on delivery mechanisms such as inhalers or auto-injectors.

These incremental innovations may or may not offer significant therapeutic benefits, but they effectively delay the market entry of generic alternatives.

CASE STUDIES OF EVERGREENING

GLEEVEC/GLIVEC – NOVARTIS

- Drug for chronic myeloid leukemia.
- Novartis attempted to patent the beta-crystalline form of imatinib mesylate in India.
- **Outcome:** The Indian Supreme Court denied the patent in *Novartis AG v. Union of India* (2013), citing lack of enhanced efficacy under Section 3(d).

HUMIRA – ABBVIE

- World's top-selling biologic for autoimmune diseases.
- AbbVie filed over **100 patents** in the U.S. to delay biosimilar competition.
- **Result:** Effective market exclusivity extended for over two decades.

NEXIUM – ASTRAZENECA

- A follow-on drug to Prilosec (omeprazole), promoted as a next-generation treatment.
- Critics argue it offered limited advantages, yet was heavily marketed to replace Prilosec before its patent expired.

These cases illustrate how secondary patents and strategic product modifications are used to sustain market dominance, even in the absence of substantial therapeutic innovation.

IMPACT ON GENERIC DRUG ENTRY

Evergreening significantly affects the timing and pricing of generic competition:

- **Delayed Entry:** Patent thickets complicate and delay generic approvals.
- **Increased Litigation:** Generic manufacturers often face prolonged and expensive legal battles.

- **Higher Costs:** Consumers and public health systems bear the financial burden of expensive branded drugs.

In contrast, jurisdictions with strong anti-evergreening measures (e.g., India) have enabled earlier entry of generics, leading to greater affordability and access.

JUSTIFICATIONS BY THE PHARMACEUTICAL INDUSTRY

The industry defends these practices as:

- Encouraging **incremental innovation** and improvements in drug safety, delivery, or effectiveness.
- Reflecting **ongoing investment** in research post-market launch.
- Supporting **regulatory compliance** (e.g., changes required by new safety standards).

While some modifications may offer real-world benefits, others are criticized as tactics to maintain revenue streams under the guise of innovation.[7]

PUBLIC HEALTH AND ETHICAL CONCERNS

From a public health perspective, evergreening is viewed as a barrier to access:

- It keeps drug prices high.
- It undermines the availability of affordable generics.
- It disproportionately impacts developing countries where patients rely on generic medicines.

The ethical dilemma lies in balancing the right to profit from innovation with the fundamental right to health.

IMPACT ASSESSMENT

Patent evergreening in the pharmaceutical industry has far-reaching consequences that extend beyond legal doctrine and corporate strategy. This section assesses the multi-dimensional

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[7] *Moon, S., et al.* (2011). "Access to Medicines and Intellectual Property: The WTO Doha Declaration and Beyond." *Health Affairs*, 30(5), 946–954.

impacts of evergreening—particularly on access to medicines, innovation, legal systems, and public health—across different jurisdictions.[8]

IMPACT ON ACCESS TO MEDICINES

One of the most significant consequences of patent evergreening is the **delayed entry of affordable generic medicines**, which affects both individuals and public health systems.

- **Higher Drug Prices:** By extending monopoly periods, evergreening maintains high prices even after the original patent expires. This is especially detrimental in low- and middle-income countries, where affordability is a key determinant of access.
- **Restricted Market Competition:** Generic manufacturers are discouraged or blocked from entering the market, undermining price competition.
- **Burden on Health Budgets:** Government-funded health programs often struggle to provide expensive brand-name drugs, diverting funds from other essential services.

Example: The prolonged exclusivity of drugs like Humira in the U.S. and Gleevec in India demonstrates how evergreening can either sustain inflated prices or be curtailed to ensure public access.

IMPACT ON INNOVATION

Patent evergreening raises complex questions about its effect on innovation:

- **Stifling True Innovation:** By allowing minor modifications to secure new patents, companies may prioritize profit-maximizing tweaks over breakthrough discoveries.
- **Shifting R&D Focus:** Resources may be redirected toward lifecycle management of existing drugs instead of developing novel treatments.
- **Crowded Patent Landscape:** The proliferation of secondary patents creates "patent thickets" that increase the cost and complexity of genuine R&D efforts, especially for smaller firms.

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[8] *Oxfam International* (2018). "Pharma's Evergreening Patent Abuse: Impact on Global Access to Medicines."

OXFAM BRIEFING PAPER

IMPACT ON LEGAL AND REGULATORY SYSTEMS

Evergreening also strains the legal and regulatory frameworks meant to ensure fair competition and public interest.

- **Patent Office Overload:** Examiners must assess a high volume of marginal patent applications, risking inconsistent or low-quality decisions.
- **Increased Litigation:** Generic challenges against evergreened patents lead to prolonged legal battles, burdening courts and delaying drug availability.
- **Legal Uncertainty:** Ambiguities in patentability criteria (e.g., what constitutes "enhanced efficacy") lead to varied interpretations across jurisdictions.

PUBLIC HEALTH IMPLICATIONS

From a public health standpoint, evergreening can undermine essential health rights:

- **Human Right to Health:** Prolonged exclusivity on essential medicines disproportionately affects vulnerable populations, violating the principle of equitable access to healthcare.
- **Global Health Inequality:** Countries with stronger anti-evergreening laws (e.g., India) provide earlier access to generics, while others (e.g., U.S.) maintain longer exclusivity, leading to unequal health outcomes globally.
- **Impact During Crises:** During pandemics or health emergencies, evergreening can hinder the rapid deployment of affordable treatments.

LEGAL AND ETHICAL ANALYSIS

Patent evergreening operates at the intersection of law, commerce, and ethics. While often legally permissible under existing frameworks, its implications raise fundamental ethical concerns related to fairness, equity, and the right to health. This section critically evaluates the legal doctrines enabling evergreening and examines the ethical dilemmas it poses in light of public health imperatives.[2]

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[9] *Rawls, J.* (1971). *A Theory of Justice*. Harvard University Press. (For ethical frameworks on justice and fairness).

LEGAL ANALYSIS

COMPLIANCE WITH INTERNATIONAL LAW (TRIPS AGREEMENT)

The **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)** under the WTO establishes baseline standards for patent protection, including pharmaceutical patents. Article 27 mandates patents for all inventions without discrimination, yet TRIPS does not explicitly prohibit secondary patents.

- **TRIPS Flexibilities:** Articles 7, 8, and 30–31 allow member states to adopt public-interest safeguards, such as compulsory licensing and exclusions from patentability.
- **Evergreening Exploits Ambiguity:** Many countries interpret TRIPS narrowly, allowing multiple follow-on patents as long as they meet formal criteria, even when substantive innovation is minimal.

NATIONAL LAWS AND JUDICIAL PRECEDENTS

- **India:** Section 3(d) of the Indian Patents Act is a legal innovation that operationalizes TRIPS flexibilities to prevent evergreening. The Supreme Court's decision in *Novartis AG v. Union of India* (2013) provided a strong judicial precedent against trivial patenting.
- **U.S. and EU:** While these systems demand novelty and inventive step, they often permit secondary patents. Courts defer significantly to administrative patent offices, making enforcement against evergreening complex and inconsistent.

COMPETITION AND ANTITRUST LAW

Evergreening may also violate competition laws:

- **Pay-for-delay agreements** (e.g., *FTC v. Actavis*, 2013) have been legally challenged as anti-competitive.
- Patent thickets can deter market entry and amount to abuse of dominance under antitrust doctrines.

ETHICAL ANALAYSIS[10]

THE INNOVATION VS. ACCESS DILEMMA

Ethically, the justification for patents lies in the **social contract theory**: society grants a temporary monopoly in exchange for public benefit through innovation. Evergreening challenges this balance.

- **Unjust Enrichment:** Extending monopoly rights without commensurate innovation results in economic gain without public value.
- **Double Burden on Consumers:** Patients and health systems pay once through public funding of R&D and again through inflated prices protected by layered patents.

EQUITY AND GLOBAL HEALTH

- **Disproportionate Impact on the Global South:** High drug prices perpetuated by evergreening hinder access in low-income countries, widening global health disparities.
- **Human Rights Considerations:** The **right to health**, enshrined in international covenants (e.g., ICESCR, Article 12), implies an obligation to ensure access to essential medicines. Evergreening undermines this obligation.

ETHICAL USE OF LEGAL TOOLS

While evergreening may comply with the letter of the law, it may violate its spirit. Legal loopholes should not be used to frustrate public welfare, particularly in life-and-death contexts like pharmaceuticals.

- **Deontological Perspective:** Treating access to medicine as a moral imperative overrides procedural legality.
- **Utilitarian Perspective:** The societal harm caused by denying affordable access often outweighs the incremental benefit of minor innovations.

Ethical corporate behavior demands that pharmaceutical companies:

- Align commercial strategies with **corporate social responsibility (CSR)** norms.

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[10] Ibid.

- Avoid manipulating patent systems to unjustly prolong exclusivity.
- Support models like patent pools, open licensing, and differential pricing.

Governments and international bodies also bear ethical responsibilities:

- To design laws that discourage evergreening without stifling innovation.
- To uphold the **Doha Declaration on TRIPS and Public Health (2001)**, affirming the right of WTO members to protect public health.

REFORM PROPOSALS & ALTERNATIVES

Given the multidimensional concerns surrounding patent evergreening—legal ambiguities, ethical dilemmas, restricted access to medicines, and innovation distortions—reform is both necessary and urgent. This section outlines legal, regulatory, and policy reforms to curb abusive evergreening practices while preserving genuine innovation. It also explores alternative models for pharmaceutical development that can ensure a fairer balance between private rights and public health.[11]

TIGHTENING PATENTABILITY STANDARDS

- **Clarify Criteria for Incremental Innovation:** Countries should adopt stricter standards for novelty, inventive step, and industrial applicability, particularly for secondary pharmaceutical patents.
- **Incorporate Enhanced Efficacy Clauses:** Similar to **Section 3(d) of the Indian Patents Act**, patent regimes should require demonstrable therapeutic advantage for modified drugs.
- **Restrict Polymorph and Isomer Patents:** Patents on new forms of known substances should be disallowed unless they show significant pharmacological improvement.

INCREASE SCRUTINY BY PATENT OFFICES

- **Specialized Pharmaceutical Patent Examiners:** Training and assigning experts in medicinal chemistry and pharmacology to assess applications more rigorously.

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[11] *Gostin, L. O.* (2001). "Global Health Law." *The New England Journal of Medicine*, 359(16), 1663–1674.

- **Third-Party Opposition Mechanisms:** Strengthen pre- and post-grant opposition processes to allow civil society and generics firms to challenge weak patents.

CURB STRATEGIC DELAYS AND LEGAL LOOPHOLES

- **Limit Continuation and Divisional Applications:** Prevent repeated filings on minor changes that cumulatively extend exclusivity.
- **Regulate Patent Linkage and Data Exclusivity:** Avoid tying regulatory approvals to patent status or, at the very least, allow generic approval parallel to ongoing litigation.

ANTITRUST OVERSIGHT

- **Challenge 'Pay-for-Delay' Agreements:** Follow models like the U.S. Federal Trade Commission (FTC) approach to treating reverse-payment settlements as presumptively anticompetitive.
- **Probe Patent Thickets:** Investigate if the deliberate creation of dense patent portfolios constitutes abuse of dominance.

STRENGTHEN PUBLIC INTEREST LITIGATION

- Encourage courts to consider **public health consequences** in patent disputes, especially where access to life-saving medicines is at stake.

CLARIFY TRIPS FLEXIBILITIES

- Through WTO negotiations or soft law instruments, member states should push for:
    - Recognition of anti-evergreening provisions like Section 3(d) as TRIPS-compliant.
    - Expansion of Article 6 and 27 interpretations to explicitly allow secondary patent exclusions.

AMEND TRIPS-PLUS OBLIGATIONS

- Encourage nations to renegotiate bilateral trade agreements (FTAs) that enforce TRIPS- plus standards, such as excessive data exclusivity or patent term extensions.

PUBLIC FUNDING AND OPEN INNOVATION

- Increase public investment in drug discovery through universities and non-profit consortia.
- Encourage **open-access models**, such as the **Drugs for Neglected Diseases Initiative (DNDi)**, which prioritize need-based over market-based R&D.

PATENT POOLS AND VOLUNTARY LICENSING

- Promote **Medicines Patent Pool (MPP)** models that allow multiple entities to access patented technology for affordable production.
- Use **tiered pricing** and **voluntary licensing** as strategies to balance company profits with access.

PRIZES AND ADVANCE MARKET COMMITMENTS

- Offer **innovation prizes** or **government-backed purchase commitments** to reward breakthroughs without depending solely on exclusivity rights.

CONCLUSION

Patent evergreening represents a critical juncture where law, commerce, innovation, and public health intersect. While pharmaceutical companies defend evergreening as a legitimate tool to protect incremental innovations and sustain research investments, this practice often serves as a strategic mechanism to unduly extend market exclusivity. The resulting delays in generic drug entry exacerbate affordability and access challenges, especially in low- and middle- income countries, raising profound ethical and legal concerns.[12]

This paper has examined the conceptual underpinnings of evergreening, compared legal approaches across jurisdictions, analyzed pharmaceutical industry practices, and assessed the wide-ranging impacts on innovation, health systems, and society. The legal analysis highlights how international agreements like TRIPS leave considerable room for interpretation, enabling

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[12] *Love, J.* (2007). "Pharmaceutical Patents: A Problem for Access to Medicines?" *American Journal of Law & Medicine*, 33(2-3), 215–237.

both exploitation and reform. Ethically, the tension between rewarding innovation and ensuring equitable access underscores the need for a balanced and just patent regime.

Reform proposals underscore the necessity of tightening patentability standards, enhancing patent office scrutiny, enforcing competition laws, and exploring alternative models of pharmaceutical innovation. Aligning intellectual property law with public health priorities requires coordinated action from governments, international bodies, courts, and industry stakeholders.

Ultimately, patent evergreening is not merely a legal or commercial issue but a societal challenge that demands solutions attentive to human rights, fairness, and the collective good. Future policies must ensure that patent systems incentivize genuine innovation while safeguarding affordable access to essential medicines for all.