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Understanding Evergreening of Patents in the Pharmaceutical Industry

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KEYWORDS

patent, evergreening, pharmaceutical companies, intellectual property rights.

ABSTRACT: Evergreening is a strategic practice widely adopted by pharmaceutical companies to prolong market exclusivity of patented drugs, often through incremental innovations and secondary patents. This review explores the legal, regulatory, and ethical dimensions of evergreening, detailing various strategies such as formulation changes, new therapeutic indications, polymorph patents, and novel delivery systems. While proponents argue that these practices support continued innovation and help recover high R&D investments, critics highlight how evergreening delays generic drug entry, maintains elevated drug prices, and restricts access to affordable medicines—especially in developing nations. Drawing from international case studies and legal frameworks from the U.S., EU, India, Canada, Brazil, and South Africa, the article evaluates global responses to curb excessive patent extensions. It also presents policy recommendations, including stricter patentability criteria, shorter exclusivity extensions, and alternative innovation incentives. Ultimately, the paper emphasizes the urgent need for balanced patent reform to align pharmaceutical innovation incentives with global public health priorities and ensure equitable access to essential medicines.

1. INTRODUCTION

Patents play a crucial role in the pharmaceutical industry, granting drug manufacturers exclusive rights for 20 years to incentivize research and development (R&D). However, companies often adopt evergreening tactics to extend their market exclusivity, delaying the entry of lower-cost generic alternatives. These tactics include minor modifications in drug composition, repurposing existing drugs for new therapeutic indications, and patenting new delivery mechanisms. The implications of patent evergreening are profound, affecting drug pricing, healthcare costs, and global access to affordable medicines. While pharmaceutical companies argue that these strategies allow for continuous innovation and financial viability, consumer advocacy groups and public health organizations raise concerns over restricted competition and prolonged monopolies. This review seeks to explore evergreening strategies, legal frameworks across different jurisdictions, and the broader impact on healthcare accessibility and policy interventions.

2. LITERATURE REVIEW

Strategies for Evergreening Patents:-

Pharmaceutical companies employ several evergreening strategies to maintain exclusivity over their products, including:

Formulation Modifications: Companies often make slight modifications to existing drugs, such as creating extended-release versions, altering dosages, or introducing combination therapies, which are then patented as new inventions.

Polymorph Patents: Different crystalline structures of an active pharmaceutical ingredient (API) can be patented separately, effectively delaying generic competition.

New Therapeutic Indications: Obtaining new patents for previously approved drugs by demonstrating efficacy for additional diseases or medical conditions.

Combination Products: Combining existing drugs into a single formulation and patenting the new combination despite no significant improvement in therapeutic outcomes.

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Delivery Mechanism Patents: Develop new drug delivery mechanisms, such as inhalers, auto-injectors, or transdermal patches, to claim patent extensions.

Biological Variants: Introducing minor molecular or structural modifications in biological drugs and securing patents for these changes.

Impact of Evergreening on Generic Drug Availability:-

The practice of patent evergreening has a significant impact on the generic drug market, leading to:

Delayed Market Entry of Generics: Legal barriers and prolonged patent protection force generic manufacturers to wait longer before launching cost-effective alternatives.

Higher Drug Prices: Extended monopolies keep prices high, placing a financial burden on patients and healthcare systems.

Restricted Access in Developing Countries: International patent laws enforced through agreements like the Trade-Related Aspects of Intellectual Property Rights (TRIPS) prevent timely access to affordable medicines.

Increased Healthcare Expenditures: Prolonged market exclusivity contributes to rising healthcare costs for governments and insurance providers, limiting healthcare access for low-income populations.

Legal and Regulatory Frameworks Addressing Evergreening:-

Several jurisdictions have introduced legal measures to counteract the effects of patent evergreening:

United States: The Hatch-Waxman Act established an abbreviated regulatory pathway for generic drugs and permitted pharmaceutical companies to extend patents through minor modifications.

European Union: The European Medicines Agency (EMA) enforces strict regulations regarding the approval of supplementary patents, while the Supplementary Protection Certificate (SPC) sometimes extends patent life.

India: Section 3(d) of the Indian Patent Act prevents companies from patenting minor modifications of existing drugs without substantial therapeutic benefits.

Canada: The Patented Medicines Prices Review Board (PMPRB) monitors drug pricing while patent linkage regulations limit unnecessary extensions.

Brazil and South Africa: Emerging economies are refining patent laws to prevent evergreening and improve access to affordable medicines.

3. DISCUSSION

Patent evergreening presents a complex challenge that necessitates a balanced approach between pharmaceutical innovation and public health considerations. Proponents argue that extended exclusivity is necessary to sustain innovation and fund new drug development. However, critics emphasize that evergreening exploits legal loopholes to sustain monopolies at the expense of patient accessibility.

Ethical and Economic Implications:-

Financial Burden on Patients: Higher drug prices from patent extensions make essential medicines unaffordable for many patients, particularly in low-income regions.

Limited Healthcare Equity: Wealthier nations can afford brand-name drugs while developing countries suffer from restricted access due to prolonged exclusivity.

Pharmaceutical Industry vs. Public Health: The ongoing tension between maximizing profits and ensuring public welfare highlights the need for stringent patent reforms.

Potential Policy Recommendations:-

To address the negative effects of evergreening while still encouraging pharmaceutical advancements, several policy measures can be considered:

Stricter Patentability Criteria: Ensuring that only significant innovations receive patent protection, preventing the approval of trivial modifications.

Shorter Market Exclusivity Extensions: Limiting the duration of additional exclusivity granted for minor changes.

Encouraging Generic Competition: Introducing regulatory mechanisms that promote timely entry of generics into the market.

Alternative Incentives for Innovation: Exploring prize funds, public funding for research, or licensing agreements to incentivize drug development without monopolistic patent extensions.

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Global Collaboration on Patent Law Reform: Establishing international standards to regulate evergreening and enhance access to essential medicines worldwide.

4. CONCLUSION

Patent evergreening remains among the most debated pharmaceutical policy and healthcare access topics. While it supports ongoing drug innovation, it often prolongs monopolies, delaying the introduction of affordable generics and increasing healthcare costs. Addressing this challenge requires robust legal and policy interventions that balance the need for pharmaceutical advancements with the ethical obligation to provide accessible and affordable medicines. Governments, regulatory agencies, and international organizations must work together to refine patent laws, implement fair pricing mechanisms, and promote sustainable innovation without compromising public health interests.

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