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PATENT EVERGREENING IN PHARMACEUTICALS: IMPACT AND ETHICAL CONSIDERATIONS

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ABSTRACT

Patent evergreening, the practice of extending patent protection on existing drugs through minor modifications, is a growing concern in the pharmaceutical industry. This strategy prolongs the exclusivity of brand-name drugs, impedes the market entry of generics, and raises the cost of medicines worldwide. This paper investigates the practice of patent evergreening through contemporary case studies, real-time data, and its impact on drug affordability, accessibility, and innovation. Focusing on notable examples, such as Glivec, Humira, and Revlimid, this journal critiques the ethical and economic consequences and suggests regulatory changes to address the growing challenge of patent manipulation in global healthcare systems.

Keywords: Patent Evergreening, Pharmaceutical Industry, Generic Drugs, Biosimilars, Patent Manipulation Drug Affordability, Intellectual Property, Innovation vs. Incrementalism, Public Health, and Regulatory Reform.

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1. Introduction

Patent evergreening, the act of extending the market exclusivity of a drug through the modification of existing formulations or patents, poses a significant challenge to global drug access, affordability, and the encouragement of true innovation. While the primary intent of patents is to incentivize innovation by protecting intellectual property for a defined period (usually 20 years), pharmaceutical companies have found ways to manipulate the patent system to extend monopolistic control over products far beyond the typical patent period. These tactics may not always yield significant medical advancements but allow companies to retain high prices and delay the entry of generic alternatives, thereby limiting access to life-saving

treatments. In this paper, we analyze key real-time data and case studies to explore the effects of patent evergreening and its long-term consequences on public health.

2. The Mechanisms of Patent Evergreening.

Patent evergreening refers to the strategic manipulation of the patent system by pharmaceutical companies to extend their exclusivity over a product for longer than the original 20-year patent term. This often involves making incremental or trivial modifications to a drug, which do not significantly improve its therapeutic value but allow the company to secure new patents. These minor changes can block generics or biosimilars from entering the market, thereby maintaining high prices and controlling market share.

The main mechanisms of patent evergreening are:

- **New Formulations.**

Pharmaceutical companies often make slight modifications to the drug's delivery system or formulation to extend the patent protection. These modifications can include changes to the drug's dosage form or its method of administration. While these changes may not improve the drug's clinical efficacy, they allow companies to secure new patents.

Examples:

- Extended-Release (ER) Formulations: Changing a drug's formulation from an immediate-release (IR) tablet to an extended-release (ER) or controlled-release version can secure a new patent. The ER version may allow for fewer doses throughout the day, providing convenience to patients, but it doesn't always provide substantial new therapeutic benefits. However, it can be marketed as an "improvement" and given a fresh patent.
    - *Example*: OxyContin (oxycodone) had its original patent extended by Purdue Pharma when it developed an extended-release version. While the ER version improved dosing convenience, the active ingredient (oxycodone) and its primary effect were unchanged.
- Transdermal Patches: Some drugs are reformulated into transdermal patches, which allow the drug to be absorbed through the skin, offering a new method of administration but not necessarily improving the drug's clinical effects.
    - *Example*: Fentanyl patches provide a slow release of the opioid medication, making it more convenient for chronic pain patients but without offering significant therapeutic advancements over the oral version.

These changes can prevent generic alternatives from entering the market, as the new formulations are protected by separate patents. Even though they may not offer significant therapeutic benefits over the original drug, they prolong market exclusivity and keep prices high.

- **New Dosage Strengths.**

Pharmaceutical companies can file new patents based on different strengths or dosages of an already marketed drug. This allows them to extend patent protection, even when the active ingredient and its formulation remain unchanged. This tactic can be used to create additional monopolies on variations of the drug, such as a higher or lower dose, without providing meaningful innovation in terms of the drug's clinical benefits.

Examples: A company may patent a higher or lower dose of a drug, such as a 100 mg version of a drug after the original 50 mg patent expires. The patent extension on this new dose may delay the availability of generics of the original strength.

- *Example*: Prozac (Fluoxetine), the antidepressant drug, had its exclusivity extended by patenting new doses of the same compound, making it harder for generic versions of the original Prozac to enter the market.
- *Example*: Celebrex (Celecoxib), a painkiller, had patents filed for new dosing strengths, prolonging the exclusivity of the drug and delaying generic versions.

These types of patents are often considered "evergreen patents" because they are based on minor adjustments rather than true innovation, allowing companies to block generic competition while offering no significant improvement in efficacy or safety. This has a direct impact on drug affordability, as generics, which are typically much cheaper, are not allowed to enter the market.

3. Ethical Considerations and Innovation vs. Incrementalism.

Patent evergreening raises critical ethical questions regarding the balance between rewarding innovation and ensuring that essential medications are accessible to those who need them most. While patents are intended to incentivize genuine innovation, evergreening distorts the system by providing monopolies for minimal or no new therapeutic advancements.

The pharmaceutical industry faces an ethical dilemma: Should incremental changes be rewarded with extended patent protection, or should the focus shift to ensuring broad access to medicines? The abuse of the patent system through evergreening practices undermines public trust in the pharmaceutical industry and could ultimately lead to reduced incentives for companies to pursue true innovation.

4. Policy Recommendations and Solutions.

To effectively address the challenges posed by patent evergreening, several key strategies must be implemented across various levels of the pharmaceutical industry, regulatory bodies, and international institutions. These strategies aim to strike a balance between encouraging innovation and ensuring that patients have access to affordable, life-saving medications. Below are detailed descriptions of each strategy that can curb the impact of patent evergreening:

1. Reform patent standards.

One of the primary ways to curb patent evergreening is to implement stricter patent standards. Patent offices around the world should require a higher bar for granting patents, ensuring that only truly innovative and novel inventions receive patent protection. Currently, many patents are granted based on incremental changes to existing drugs that do not significantly improve their therapeutic efficacy or safety. These incremental innovations, which are often the basis of evergreening, should not be granted patent protection unless they meet a stricter criterion for novelty and utility.

Proposed Reforms:

- Enhanced Criteria for Novelty and Utility: Patent offices should scrutinize claims more rigorously, ensuring that only substantial innovations, such as entirely new formulations or methods of action, are patentable.
- Secondary Patents Scrutiny: When a new patent is filed based on a minor modification, such as a new dosage form or a combination of existing drugs, the novelty of the innovation should be carefully assessed to ensure it offers genuine clinical benefits beyond convenience.
- Public Health Impact: In cases where a modification does not provide significant clinical improvement, such as in the case of formulation changes that do not improve efficacy,

the patent office should consider the potential harm to public health in delaying generic entry and reducing drug affordability.

By enforcing stricter patent standards, patent offices can reduce the frequency of evergreening practices, ensuring that patents are only granted for genuine, groundbreaking innovations. This would make it harder for pharmaceutical companies to extend exclusivity unjustifiably and pave the way for generics and biosimilars to enter the market sooner, enhancing drug affordability and access.

2. Increase generic and biosimilar accessibility.

Governments can adopt stronger policies to facilitate the entry of generics and biosimilars into the market, reducing the opportunities for patent evergreening to block competition. Generic drugs are critical for reducing the cost of medications once the original drug's patent expires. Similarly, biosimilars—biological products that are highly similar to an already-approved reference product—can offer affordable alternatives to costly biologic treatments. Encouraging these alternatives can reduce the monopolistic power of brand-name drug makers and increase access to essential medications.

Proposed Policies:

- Compulsory Licensing: Governments should have the ability to issue compulsory licenses in cases of public health emergencies, which would allow for the production of generic versions of patented drugs without the patent holder's consent. This could be especially important during global health crises, such as pandemics, where timely access to medications is crucial.
- Faster Approval Pathways for Generics and Biosimilars: Regulatory bodies should streamline the approval process for generics and biosimilars to ensure they enter the market as soon as the original drug's patent expires, preventing patent evergreening from extending drug monopolies.
- Patent Opposition Mechanisms: Countries can establish systems where third parties, including generic manufacturers and public health organizations, can formally challenge patents at the time of filing, particularly when those patents are based on minor or non-innovative changes.

By removing barriers to generic and biosimilar market entry, governments can make essential medicines more affordable and accessible. This would diminish the ability of pharmaceutical companies to use evergreening tactics to delay the introduction of more affordable alternatives, improving overall public health outcomes.

6. Conclusion.

Patent evergreening remains a significant challenge to global healthcare systems, leading to high drug prices and limited access to essential treatments. The cases of Glivec, Humira, and Revlimid highlight how pharmaceutical companies manipulate patent laws to maintain market exclusivity at the expense of patients. By reforming patent standards, increasing generic and biosimilar accessibility, and encouraging innovation that truly benefits public health, it is possible to combat patent evergreening and create a more equitable and efficient healthcare system for all.

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