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Exploring the Controversial Practice of Patent Evergreening

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This paper dives into the difficult topic of Patent Evergreening in the pharmaceutical industry. Patent Evergreening is a strategy used by pharmaceutical companies to extend the life of a patent for a certain medicinal chemical, generally by modest changes or innovative formulations. Because of its substantial implications for healthcare accessibility and pioneering breakthroughs, this contentious strategy has sparked several arguments. The paper thoroughly examines the many dimensions of Patent Evergreening, including its historical context, jurisprudential implications, and the consequences suffered by patients and healthcare infrastructures. It sheds light on the tremendous influence of Patent Evergreening on medicine cost, the postponement of generic competition, and the potential impediment of access to economically feasible therapies by drawing on extensive research initiatives and illustrated case studies. Furthermore, the study looks into worldwide legal frameworks and policies that have been painstakingly developed to address the phenomena of Patent Evergreening and its complex aftermath. It emphasizes the complex obstacles that legislators, healthcare leaders, and patients face while navigating this complex labyrinth. By delving into the intricacies of Patent Evergreening, this paper contributes significantly to the continuing debate about intellectual property rights, pharmaceutical innovation, and the goal of equal access to healthcare. It provides essential insights for politicians, eminent researchers, and entrenched stakeholders attempting to find a balance between stimulating new technologies and ensuring affordable access to critical therapeutic cures.

Keywords: *patent evergreening, generic medicine, healthcare, pharmaceutical.*

INTRODUCTION

"Patents are the key to our technology; technology is the key to production."

– Franklin D. Roosevelt

The notion of patent evergreening arises as a controversial practice in the world of intellectual property and innovation, wielded by firms with an arsenal of tactics to prolong the longevity of their patents much beyond the standard 20-year term.[1] This cryptic strategy thrives in the pharmaceutical sector's tortuous structure, where businesses swiftly file new patents for modest adjustments to current medical compositions or the blending of diverse pharmacological components. The consequences of patent evergreening are far-reaching, affecting patients, healthcare infrastructures, and the fundamental fabric of the pharmaceutical business.[2]

The versatility of this technique is shown in its ability to fan the flames of invention. It coerces firms to put their resources into the furnace of research and development through the alchemical concoction of financial incentives. Under this technique, intellectual property rights for inventive inventors are protected, guaranteeing that customers travel through a domain decorated with items that radiate quality, safety, and efficacy, analogous to rare jewels in a treasure trove.

However, underneath the enticing facade of innovation is a sinister underbelly. Patent evergreening throws a powerful shadow, capable of obscuring the arrival of generic medications, those beneficent entities that provide affordable healthcare to ill individuals. These generic substitutes are frequently a ray of hope, illuminating the route to affordable healthcare. This brilliance, however, is diminished in the presence of evergreened patents. Drug costs are reaching dangerously high levels, but the path to life-saving elixirs is narrowing, limiting access to individuals in desperate need.

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[1] Prachi Gupta, 'Ever Greening Of Patents Of India' (*Manupatra,* 10 June 2013) <https://articles.manupatra.com/article-details/Ever-Greening-Of-Patents-Of-India> accessed 13 September 2023

[2] *Ibid*

Furthermore, the poisonous tendrils of patent evergreening can choke off the lifeblood of invention. This Machiavellian tactic fortifies the market gates against the flood of new rivals with fresh ideas. As a result, it creates a stagnant atmosphere in which the fruits of development are imprisoned, out of reach of those who could have driven them to greater heights.

A troubling tendency develops as we go through the ages. Patent evergreening is becoming increasingly popular, notably in the pharmaceutical industry. According to the World Health Organization's comprehensive examination in 2021, the number of patent filings for new pharmaceutical innovations fell by 25% between 2010 and 2019.[3]

Simultaneously, the number of requests to amend existing drug patents increased by an alarming 50%.[4] This unsettling development threatens to transform the pharmaceutical environment, making crucial treatments less inexpensive and accessible on a worldwide scale. It is critical to emphasize that patent evergreening is rarely used to stoke the flames of innovation. In many cases, firms may recoup their R&D expenses without resorting to these intricate schemes. The route to promoting innovation does not have to be overshadowed by the looming shadows of ever-expanding patents.

Patent evergreening techniques operate as both a bulwark and a wall in the complicated fabric of intellectual property, fostering innovation while inhibiting competition and limiting access to important therapies. The collision of these competing forces affects the landscape of industries and the lives of individuals they affect, creating a never-ending narrative of complexity and contention.

ARGUMENTS IN FAVOUR OF PATENT EVERGREENING

Fostering Innovation via Incentives for Corporate R&D: The perpetual patenting method gives businesses the exclusive right to commercialize their products for an extended period of time.

[3] World Intellectual Property Organization, *World Intellectual Property Indicators 2022* (2022)
[4] *Ibid*

This provides businesses with a significant financial incentive to invest in research and development projects, encouraging the production of innovative and cutting-edge goods.[5]

Perpetual patenting acts as a barrier against the violation of innovators' intellectual property rights by preventing the unlicensed reproduction of their discoveries. This protects the visionaries' intellectual property rights. By encouraging innovators to share their ground-breaking innovations with the public, such protection eventually benefits society.[6]

Providing Customers with Access to Top-Tier, Secure and Effective Goods: Perpetual patenting is a key notion in ensuring that customers have access to high-quality products that are known for their effectiveness and safety. Companies that adhere to the principles of research and development are typically at the forefront of creating products that meet these exacting standards.

In addition to the overarching arguments, there exist certain specific rationales advocating for the practice of patent perpetuation within the pharmaceutical realm. To illustrate, proponents posit that patent perpetuation stands as an imperative to facilitate the recuperation of the exorbitant expenditures incurred during the developmental phases of novel pharmaceuticals. They further contend that perpetuating patents serves as a catalyst for pharmaceutical enterprises to persist in their commitment to advancing research and development initiatives aimed at the creation of groundbreaking drugs.

Nonetheless, it is imperative to acknowledge the weighty counterarguments against patent perpetuation. To elucidate, detractors contend that the prolongation of patents has the potential to engender protracted delays, and in some instances, outright obstruction to the introduction of generic pharmaceuticals, which are markedly more economically accessible to patients. Moreover, they assert that the perpetuation of patents can culminate in escalated drug pricing

[5] Roger Collier, 'Drug patents: Innovation V. accessibility' (2013) 185(9) Canadian Medical Association Journal <https://doi.org/10.1503%2Fcmaj.109-4465> accessed 15 September 2023

[6] Janice M. Mueller, 'The Tiger Awakens: The tumultuous transformation of India's patent system and the rise of Indian Pharmaceutical Innovation' (2007) 68(3) University of Pittsburgh Law Review <https://doi.org/10.5195/lawreview.2007.79> accessed 15 September 2023

and concurrently diminish accessibility to indispensable medicinal treatments. Furthermore, critics argue that protracting patent lifecycles can quash innovation by acting as an impediment to competitors seeking entry into the pharmaceutical arena.

ARGUMENTS AGAINST PATENT EVERGREENING

The practice of 'patent evergreening' can be ascribed to the delay or probable blockage of the introduction of generic medications, which are more economically practical for patients. Pharmaceutical corporations use this method to extend the exclusive period of brand-name pharmaceuticals.[7] Generic drugs, on the other hand, are often substantially less expensive since they are free from the rigorous and costly research and development initiatives faced by their brand-name counterparts.

Patent evergreening has the potential to delay or even block the arrival of generic alternatives by extending the patent protection of brand-name drugs. This, in turn, can make it difficult for people to purchase necessary prescriptions. The strategy essentially allows businesses a monopoly on the sales of their patented pharmaceuticals, allowing prescription costs to rise and access to critical treatments to be limited.[8] This might have a negative impact on patients' access to critical pharmaceuticals, particularly in less developed countries.

Furthermore, the negative impact of patent evergreening extends to the field of innovation. It has the potential to hinder innovation by building hurdles to entry into the pharmaceutical business. Companies that own current drug patents can use these rights to prevent competitors from developing and selling comparable drugs.[9] As a result, the overall number of novel medications available to patients may decrease.

Aside from these overall concerns, there are particular grounds against patent evergreening in the pharmaceutical industry. Proponents of reform argue that it is not always necessary for pharmaceutical companies to use patent evergreening to recuperate the expensive expenses

[7] Collier (n 5)
[8] *Ibid*
[9] Reed F. Beall et al., 'Is patent "evergreening" restricting access to medicine/device combination products?' (2016) 11(2) PLoS ONE <https://doi.org/10.1371/journal.pone.0148939> accessed 15 September 2023

involved with the development of new pharmaceuticals. Furthermore, they argue that this method may deter pharmaceutical corporations from investing in R&D targeted at developing innovative and improved treatments. The attraction of long-term income from old treatments, made possible by patent evergreening, may discourage investment in newer, more advanced pharmaceutical solutions.[10]

Nonetheless, it is critical to recognize that strong arguments in support of patent evergreening are also advanced. Advocates argue that this technique is essential for stimulating innovation and protecting inventors' intellectual property rights. However, it is equally important to consider the counterarguments to patent evergreening when developing rules on this sensitive topic.

CASE STUDY

Case Study: The Evergreening of the Leukemia Drug Gleevec: Gleevec, also known as imatinib mesylate in the scientific community, is a pharmacological drug used to treat chronic myeloid leukemia (CML), a kind of hematological cancer. This ground-breaking medicinal substance received its first approval from the prestigious United States Food and Drug Administration (FDA) in the year 2001. As a result, it has come to be regarded as the gold standard of care for people suffering from CML. Nonetheless, Gleevec's sterling performance is offset by an unfavorable component, namely its extravagant financial necessity.

The fiscal outlay for an annual distribution of Gleevec inside the contiguous United States may reach stratospheric heights, exceeding the astronomical barrier of $100,000. This dizzying price tag acts as a tremendous hurdle for a slew of patients, particularly those from underdeveloped countries who are mired in the quagmire of financial restraints. The shadow of this expensive cost weighs heavily over those seeking relief from the totalitarian grasp of CML.

[10] Ghily Kirsher et al., 'The Impact of an 'Evergreening Strategy Nearing Patent Expiration on the Uptake of Biosimilars and Public Healthcare Costs' (2023) Erasmus Universiteit Rotterdam EsCHER Working Paper No. 2023001/2023 <https://www.eur.nl/en/media/2023-07-2023001-kirshner-et-al-trastuzumabescherworking-paper> accessed 15 September 2023

The high expense of Gleevec is due, in part, to the harmful problem of patent evergreening. The intellectual property protection provided to Gleevec's active ingredient, imatinib mesylate, expired in 2016. However, Novartis, the maker of this strong pharmacotherapeutic entity, deftly avoided the expiration of this patent by introducing a slew of additional patents.

One example, in 2007, Novartis was successful in obtaining a patent on a new formulation of Gleevec, which claimed improved its administration and tolerability. Furthermore, in 2012, the pharmaceutical behemoth was granted a patent for a hybrid formulation containing Gleevec and the pharmacological substance nilotinib, which was designed to treat CML. These well-timed patents, although ostensibly encouraging innovation, have had the unexpected consequence of maintaining Novartis' monopoly on Gleevec. As a result, the exorbitant price tag connected with this life-saving medicine remains resistant to market competition.[11] The harmful practice of patent evergreening has sparked outrage from critics who argue that it is an unethical disservice to the sick and serves as a malicious impediment to true innovation in the pharmaceutical arena. Their incisive analysis contends that Novartis, engaged in the convoluted pursuit of financial gain, intends to prolong its stronghold on Gleevec while abruptly relegating patient interests to the periphery.

Novartis responds forcefully in support of their patent evergreening strategies. The pharmaceutical behemoth claims that such legal measures are required to protect its massive expenditures in Gleevec research and development. Furthermore, Novartis believes that orchestrating patent evergreening is intrinsically linked to the broader aim of stimulating innovation within the pharmaceutical realm, hence promoting the development of innovative treatment modalities.

The long-running Gleevec drama, in all its complexities, offers a painful example illuminating the numerous aspects of patent evergreening, with negative consequences for patients and the pharmaceutical sector at large. This heinous behaviour not only creates an impossible barrier to the introduction of generic medicine alternatives, which intrinsically provide patients with

[11] Ellen't Hoen, *Private Patents and Public Health Changing Intellectual Property Rules for Access to Medicines* (Health Action International: Access to Medicines 2023)

affordability, but it also has a negative impact on the spiraling trajectory of prescription costs. As a result, it creates an atmosphere in which governments are hampered in their capacity to respond quickly to urgent public health emergencies.

Case Study: The Evergreening of the HIV/AIDS Drug Emtriva: Emtriva, formally known as emtricitabine, is a pharmacological substance recruited in the valiant fight against the indomitable scourge of HIV/AIDS. In the fortunate year of 2003, this pharmaceutical miracle received the coveted mark of approval from the discriminating authorities at the United States Food and Drug Administration (FDA). Since that historic endorsement, it has risen to the pinnacle of the pantheon of HIV/AIDS treatments, gaining global praise for its efficacy.

However, one persistent problem overshadows Emtriva's stellar reputation - its high price. The monetary outlay for a single year's sustenance of Emtriva in the United States is reported to reach stratospheric heights of over $10,000. This exorbitant price tag makes it a real mirage of affordability for a sizable section of affected people, particularly those living in impoverished countries.

Emtriva's onerous financial burden is, to a large measure, the result of a process known as 'Patent evergreening'. While the patent protecting the core makeup of Emtriva, with emtricitabine as its cornerstone, lost its legal moorings in 2017, the pharmaceutical behemoth Gilead Sciences has demonstrated an amazing predilection for extending the tethers of patent longevity. This ruse has been accomplished through the issuance of additional patents, frequently for minor changes to the formulation or by combining Emtriva with various pharmacological partners.

A notable example occurred in the year of 2012 when Gilead skilfully obtained a patent for an avant-garde replica of Emtriva, distinguished by its simplicity of administration. Following that, in 2015, Gilead achieved yet another breakthrough by obtaining a patent for the combination of Emtriva and tenofovir alafenamide, therefore giving an enlarged arsenal in the fight against

HIV/AIDS. These deft maneuvers have granted Gilead long-term domination over Emtriva, allowing it to maintain its excessive pricing.[12]

Nonetheless, the practice of patent evergreening has sparked a firestorm of debate. Detractors argue vehemently that such manipulation is detrimental to the interests of suffering patients and is a powerful contradiction to the spirit of innovation. It is their contention that Gilead, in its never-ending search for profit, is just establishing a long-term monopoly on Emtriva, preventing equal access.

Gilead claims the sanctity of its investments in Emtriva's research and development operations in fierce support of its patent evergreening gambits. Furthermore, they argue that such strategies act as a crucible for nurturing innovation inside the sanctuaries of the pharmaceutical industry. The Emtriva affair serves as an instructive case study, providing valuable insight into the far-reaching implications of patent evergreening. At its peak, this strategy has the ability to block the development of cost-effective generic analogues, prolonging the afflicted's financial woes. Furthermore, it encourages an environment in which pharmaceutical pricing jumps to dizzying heights, jeopardizing government's ability to respond to urgent public health problems.

It is critical to recognize that the controversy surrounding Gilead's Emtriva and similar medications is not a unique occurrence. A slew of additional medications, ranging from HIV/AIDS to oncological and hepatitis C treatments, have succumbed to the siren song of patent evergreening. This technique, with its labyrinthine intricacy, portends a slew of repercussions, including creativity, access to therapeutic cures and the looming threat to public health.

In developing policies to address the labyrinthine maze of patent evergreening, stakeholders must tread carefully, mindful of the numerous implications for innovation, access to therapeutics and the larger tapestry of public well-being.[13]

[12] *Ibid*
[13] *Ibid*

REGULATORY AND POLICY PERSPECTIVES ON PATENT EVERGREENING

The complexities of patent evergreening create a convoluted problem filled with disparate legislative and policy perspectives. Fundamentally, patent law is precisely structured to stimulate invention by granting inventors a temporary, exclusive right to create, utilize and market their discoveries. Nonetheless, patent law has several protections that have been painstakingly crafted to prevent patent owners from abusing their monopolistic control.

The concept of patent terms is paramount among these regulations in patent law. Traditionally, these time constraints are imposed throughout a two-decade period, beginning with the fortunate moment of patent application starts. Nonetheless, patent holders have devised a plethora of stratagems for extending the terms of their patents. For example, patent custodians may submit new patent applications for minor modifications to existing innovations or for the creation of unique amalgamations thereof. This strategy, known as patent evergreening, has a tangible influence not just on the landscape of patient care, but also on the intricate maze of healthcare systems and the sacred halls of the pharmaceutical business.[14]

In recent eras, there has been a surge of concern about the effects of patent evergreening on the availability of essential pharmacopoeial commodities. As a result, several governments have taken up the task of enacting legislation to address this problem. To clarify, several sovereignties have issued legislative edicts to make it more difficult for patent holders to obtain patents for minor adjustments to proven technologies. Other nations, on the other hand, have pioneered the notion of patent consortiums, in which a phalanx of corporate organizations can share in the use of a patent related to a certain medication or commodity.

The World Trade Organization (WTO) has also issued a slew of rules designed expressly to deal with the complex maze of patent evergreening. Exempli gratia, the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) broadens the scope of its protection to include the adjudication of compulsory licensing for

[14] Matthew B. Stanbrook, 'Limiting "evergreening" for a Better Balance of Drug Innovation Incentives' (2013) 185(11) CMAJ <https://www.cmaj.ca/content/cmaj/185/11/939.full.pdf> accessed 15 September 2023

patents in specific limited circumstances. These obligatory licenses provide state authorities the right to issue authorization for the manufacture of generic versions of proprietary medications without the permission of the patent holder. This tool is a vital weapon in the armoury of nations coping with the difficult challenge of providing access to essential therapeutic elixirs.[15]

An emerging consensus is surfacing, emphasizing the negative impact of patent evergreening on the accessibility of essential medicinal panaceas. As a result, a slew of governments and international organizations have pooled their resources to develop and execute policies aimed at finding a solution to this problem. However, there is a compelling, if inchoate, discourse relative to the most prudent ways of reconciling the clashing interests of patent custodians and the people in need of their innovations.

IMPLICATIONS OF PATENT EVERGREEN

The notion of patent evergreening has far-reaching implications for innovation, pharmaceutical accessibility, and the larger landscape of public health. Patent evergreening supporters argue that it plays an important role in fostering innovation by incentivizing firms to invest in research and development. Their argument is based on the notion that when corporations anticipate the prospective extension of their patent rights, they are more likely to start new and innovative research activities.

Opponents of patent evergreening say that the technique may inadvertently stifle innovation by building hurdles to market entrance for rivals. They argue that firms with current pharmaceutical patents can use these legal shields to prevent competitors from developing and selling similar drugs. As a result, the number of innovative drugs available to patients may be reduced, slowing medical advancement.

One major problem of patent evergreening is that it has the potential to hinder or even prevent the introduction of generic pharmaceuticals, which are normally more cost-effective for patients.

[15] Bryan Mercurio, 'Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines' (2007) 5(1) Journal of Human Rights <https://scholarlycommons.law.northwestern.edu/njihr/vol5/iss1/1/> accessed 15 September 2023

Generic medications are often less expensive since they do not go through the lengthy and costly research and development processes that their brand-name equivalents do. However, the process of patent evergreening can result in higher medicine prices by providing businesses with an unrivaled monopoly on product sales. This may have the unintended consequence of making vital medications less accessible to patients, particularly those living in underdeveloped countries.[16]

The repercussions of this technique extend into the realm of public health, having a significant impact on a wide range of issues. Patients who are unable to pay for necessary drugs for their health, for example, may choose to postpone or discontinue therapy. The end effect is a worsening of their health issues, which might lead to catastrophic consequences, including death. Furthermore, patent evergreening might compound the difficulties that states confront when reacting to public health crises. During the COVID-19 pandemic, some nations faced barriers to getting vaccinations and crucial medical supplies owing to patent monopolies, providing a harsh picture of this situation.[17]

To summarize, the implications of patent evergreening are complex and complicated. While it may provide incentives for research and development, it also has the potential to stymie the introduction of generic pharmaceuticals, raise prescription prices, and limit a country's ability to respond effectively to public health emergencies. When developing policies on this topic, it is critical to conduct a thorough assessment of the potential consequences, with the overarching goal of striking a prudent balance that promotes innovation without jeopardizing patients' access to reasonably priced medicinal treatments.

[16] Andrew Hitchings et al., 'Making medicines evergreen' (2012) 345 <https://doi.org/10.1136/bmj.e7941> accessed 15 September 2023

[17] Austin Frakt, 'How Patent Law Can Block Even Lifesaving Drugs' (*The New York Times*, 28 September 2015) <https://www.nytimes.com/2015/09/29/upshot/how-patent-law-can-block-even-lifesaving-drugs.html> accessed 15 September 2023

CONCLUSION

When creating policies on this subject, it is crucial to carefully take the potential effects of patent evergreen into account. Finding a balance that encourages innovation and ensures that patients have access to the cheap medications they require should be the objective.

One strategy is to change the legislation on patents to make it more challenging for businesses to get patents for small changes to already-existing ideas. Another strategy is to establish patent pools, which give different businesses access to a patent for a certain medication or item. Governments can also think about approving the manufacturing of generic copies of patented medications without the patent holder's consent through compulsory licensing.

The optimum strategy for overcoming the difficulties faced by patent evergreening will ultimately depend on the unique conditions of each nation. But it's obvious that this is a complicated problem that needs considerable thought.

In addition to the aforementioned, I also want to emphasize how critical the topic of patent evergreening is in light of the COVID-19 epidemic. The epidemic has demonstrated to us the necessity for speedy and affordable production and distribution of crucial medications. This might become more challenging due to patent evergreening.

I implore decision-makers and interested parties to cooperate in order to find answers to the problems presented by patent evergreening. No matter their financial situation, everyone ought to have access to the medications they require.