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Protecting Lives or Profiting?: India's battle against Evergreening and Public Health

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ABSTRACT

This article explores the intricate connection between public health access to necessary medications in developing nations and intellectual property rights (IPRs), with a particular emphasis on India. It looks at the problems with "evergreening" patents—many pharmaceutical corporations make little changes to already-approved medications in order to prolong their patent life and keep them at high prices. The study makes the case that restricting evergreening is essential to guaranteeing poor countries' access to reasonably priced medications and advancing public health. The analysis also encompasses the latest modifications implemented to the Indian patent legislation and their possible implications for harmonizing the concerns of public health and innovation. Finally, the study emphasizes how important it is that future judicial rulings and interpretations clarify the meaning of the "efficacy" criterion in order to promote real innovation and knowledge exchange while protecting the public health.

Keywords: *Evergreening, efficacy, pharmaceutical, healthcare, innovation*

I. INTRODUCTION

To put it simply, evergreening is the act of "tweaking" a base material to create an upgraded version of the base material. The patent holders seek this approach to improve their inventions and increase the duration of their patent protection which is said to expire in 20 years. Pharmaceutical firms mostly adopt this tactic of extending the patent protection period to safeguard their drugs and other pharmaceutical items. This unethical practice is mostly carried out to preserve the drug's monopoly, preventing generic manufacturers from producing the same.

India amended the Patent Act in 2005, with a particular focus on the pharmaceutical sector, to fortify its patent framework and bring it into compliance with the TRIPs agreement. India provided only minimal protection against evergreening before 2005[2]. In key sectors, only process patents were in place, and evergreening persisted with minor adjustments. Clarity

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[2] Akanksha Saha, *Evergreening of Patents with reference to the Novartis Case*, LEGAL SERVICE INDIA - LAW, LAWYERS AND LEGAL RESOURCES (2021), https://www.legalserviceindia.com/legal/article-5825-evergreening-of-patents-with-reference-to-the-novartis-case.html.

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concerning "inventive step" and "mere modifications," as well as transparency regarding clinical data and pre-grant opposition, were lacking under the Patents Act. These shortcomings were rectified in the 2005 amendment, which greatly enhanced protection against evergreening by introducing product patents, data exclusivity, pre-grant opposition, and more precise definitions.

According to the definition of the "inventive step" given in **Section 2(1)(ja) of the Patents Act 1970**, this precise definition entails the need for a technological advancement or economic importance that is not obvious to a person with ordinary skill in the art.

A key provision that concerns the prevention of evergreening is **Section 3(d) of the Patents Act of 1970**. Patents for inventions with small modifications are denied unless the modifications have some efficacy.

II. IMPACT ON PHARMACEUTICAL INDUSTRIES

Since its inception, evergreening has undoubtedly had a favorable effect on the pharmaceutical industry, helping smaller businesses by increasing profitability, fostering R&D, and providing prolonged market exclusivity. However, there has been more harm than good.

Evergreening has resulted in increased drug costs, making it more challenging for patients to buy the necessary medications. In the pharmaceutical sector, innovation has lagged due to the ease with which patents can be granted with minor modifications. Evergreening has also had the effect of discouraging the production of generic versions of medications. Thus, evergreening refers to a purposeful strategy employed by patent holders to increase the duration of their patent monopoly without considering patient accessibility or affordability.

According to a **2003 WHO report**[3], almost 50% of people in Asia and Africa lacked access to necessary medications. This issue of restricted access is caused by multiple factors. If large corporations have the correct incentives, including patent protection for incremental pharmaceutical innovations in developing countries, they can solve one of the main issues, which may be insufficient manufacturing and inadaptability to the unique local conditions. One aspect of the problem is the high cost of drugs, although it can be addressed with different approaches like compulsory licensing.

Compulsory licensing has also had both positive and negative impacts in addressing evergreening. It lowers costs and improves access to medications, but it can also stifle

[3] Akshay Anurag, *Pharmaceutical Patents And Healthcare: A Legal Conundrum | SCC Blog*, SCC BLOG (Sept. 3, 2019), https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/.

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innovation and erode intellectual property rights. Its efficacy is dependent upon several elements, such as specific circumstances like the three year time period before granting it for a patent[4], legislative structures, and governmental competence. Its potential is demonstrated by recent examples such as the COVID-19 vaccinations, but it is still a complicated matter that calls for careful talks.

NOVARTIS V. UNION OF INDIA

Novartis, a Swiss pharmaceutical company, sought a patent in India for the **Beta crystalline form of imatinib mesylate**, a drug used to treat cancer. This application fell under Section 3(d) of the Indian Patents Act, which aims to prevent evergreening, the practice of extending patent protection by making minor modifications to existing drugs.

The base substance of Novartis's drug was a known substance, imatinib mesylate. They essentially tweaked it to create a new form, the Beta crystalline form. However, the patent office in Madras rejected their application on two grounds:

1. **Lack of novelty:** The base substance and its use in cancer treatment were already known due to prior art, meaning Novartis's invention lacked novelty.
2. **Non-obviousness:** Novartis failed to demonstrate that the Beta crystalline form offered any significant therapeutic benefits compared to the known substance. Section 3(d) specifically prevents patents for inventions that are mere modifications of known substances unless they exhibit enhanced efficacy.

Novartis challenged this decision in the Madras High Court on two grounds:

1) **Section 3(d)** violated their **right to equality(Article 14)** by being arbitrary and vague.
2) The Patent Office's decision was incorrect.

The High Court dismissed both arguments, upholding the Patent Office's decision. Novartis then appealed to the Supreme Court.

The Supreme Court focused on interpreting the term "efficacy" in Section 3(d). They concluded that it specifically referred to **"therapeutic efficacy",** meaning a tangible benefit for patients undergoing treatment. Novartis claimed three enhancements in their new form:

I. Beneficial flow of properties

[4] Shri Hari Mangalam & Pritish Raj, *COVID-19 and the Shortage of Drugs: A Case for Compulsory Licensing – The Leaflet*, THE LEAFLET – AN INDEPENDENT PLATFORM FOR CUTTING-EDGE, PROGRESSIVE, LEGAL, AND POLITICAL OPINION. (May 29, 2021), https://theleaflet.in/covid-19-and-the-shortage-of-drugs-a-case-for-compulsory-licensing/.

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II. Thermodynamic stability

III. Lower Hygroscopicity

However, the Supreme Court ruled that these enhancements did not constitute therapeutic efficacy. They did not translate into direct benefits for patients in their treatment. Therefore, Novartis's patent application was rejected.

This case highlighted the importance of Section 3(d) in preventing evergreening and ensuring that only truly innovative inventions with significant therapeutic benefits are granted patents. While Novartis argued for a broader interpretation of "efficacy," the Supreme Court prioritized the protection of public health and access to affordable medicines.

III. CRITICISMS FACED BY SECTION 3(D)

Section 3(d) of the Indian Patents Act, 1970, has undergone various criticisms, which includes[5]:

a. There has been a contention that Section 3(d) breaches the TRIPs Agreement by subjecting pharmaceutical inventions to more stringent requirements for patent eligibility than other inventions. This may result in the Indian pharmaceutical industry seeing a decline in innovation and international investment.

b. It has also been said that the Supreme Court's view of "efficacy" as "therapeutic efficacy" is too limited and ignores other possible advantages of novel inventions.

c. The section has been considered to be vague and ambiguous in its interpretation and application by the patent office and the courts.

d. Additionally, there is worry that generic medicine makers may misuse Section 3(d) by challenging patents for newly developed drugs, which would delay the products' release onto the market and prevent patients from receiving new treatments.

IV. LATEST DEVELOPMENTS

The Indian Patent Office recently denied an application by the major pharmaceutical company **Johnson & Johnson (J&J)** to keep its patent on the vital anti-tuberculosis medication **Bedaquiline** until July 2023, marking a significant ruling. The availability of cost-effective therapy for individuals suffering from **multidrug-resistant tuberculosis (MDR-TB)**, a serious public health issue, would be greatly impacted by this decision.

In its patent application, J&J aimed to safeguard a particular process for producing bedaquiline

[5] Intepat Interns, *Evergreening Of Patents - An Analysis and International Approach*, INTEPAT IP (Nov. 18, 2022), https://www.intepat.com/blog/evergreening-of-patents/.

pills. However, according to the Patent Office, this method did not exhibit enough originality to qualify for patent protection under Indian law, nor did it have an "inventive step." They further contended that the application merely repackaged preexisting knowledge without making any significant advances, largely relying on J&J's current patent.

This ruling is significant because it keeps the Bedaquiline patent from evergreening. The Patent Office has allowed generic manufacturers in India to begin producing their versions of bedaquiline after July 2023 by turning down this attempt.

This will significantly affect the drug's pricing, which is now covered by J&J's patent and is estimated to be about $400 per person. Experts predict that the introduction of generic versions may result in up to 80% price reductions, greatly increasing bedaquiline's affordability for patients in India. This is especially crucial in light of the nation's high rate of MDR-TB, a disease that necessitates more extensive and costly treatment plans[6].

The Indian government will be able to increase access to this life-saving drug through its tuberculosis programmes by lowering the cost of bedaquiline. In the end, this will help MDR-TB patients receive better treatment outcomes and support the worldwide effort to combat tuberculosis.

The ruling by the Indian Patent Office is a triumph for vital drug access and public health. It makes it abundantly evident that evergreening practices will not be accepted, guaranteeing that innovation advances the public interest and that everyone has access to necessary medications[7].

ROLE OF INDIAN PATENT OFFICE

Evergreening has increased drug monopolies and reduced access to and cost of medications, endangering public health in a major way. With the help of its many initiatives, the Indian Patent Office is vital to the fight against this problem.

Strengthening Patent Examination: This entails introducing more stringent requirements for patent eligibility, enhancing examiner expertise through training and capacity-building initiatives, and boosting examination efficiency by utilizing advanced technology and data analysis tools.

Encouraging transparency and disclosure: Overseeing the release of clinical trial data and other pertinent data during the patent application procedure and raising stakeholder knowledge

[6] Admin, *Evergreening of Patent*, DRISHTI IAS (Mar. 27, 2023), https://www.drishtiias.com/daily-updates/daily-news-analysis/evergreening-of-patent.
[7] ClearIAS Team, *Evergreening of Patents*, CLEARIAS (Oct. 6, 2023), https://www.clearias.com/evergreening-of-patent/.

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of evergreening practices.

PUBLIC HEALTH AND EVERGREENING

The process of creating new medications involves a large financial expenditure, costly clinical trials, and extensive long-term research. The exclusive rights to their inventions are awarded to patent holders as an incentive for this innovation. However, particularly in developing nations, this may result in conflict between the interests of public health and intellectual property rights.

The TRIPS Agreement seeks to preserve intellectual property rights while advancing access to necessary medications in order to resolve this balance. Pharmaceutical businesses are incentivized by this system to allocate resources towards research and development, which in turn propels global healthcare advancements[8].

It's important to keep in mind, nevertheless, that the ultimate objectives of medication research are public health improvement and life preservation rather than profit maximization. Profit should not be seen as the ultimate goal in and of itself, but rather as a means to these ends. Ensuring adequate healthcare for the world's population becomes a more feasible goal when this idea is given priority.

V. CONCLUSION

Many people in India lack basic access to healthcare due to systemic shortcomings, which raises questions about social fairness and abuses of fundamental rights. The way the pharmaceutical industry reacts to the TRIPS agreement will have a significant impact on India's public health future. Generic alternatives from different companies join the market when patents expire, promoting competition and lowering prices. Nevertheless, monopolies are maintained and this natural price drop is hindered by "evergreening" tactics, in which businesses extend patent protection by little adjustments. Reducing evergreening has several advantages for developing countries such as India in lower costs, easier public access to necessary pharmaceuticals, and protection of public health through the provision of reasonably priced treatments.

The amendments made to India's patent legislation are intended to strike a careful balance between safeguarding the inventive and generic industries, promoting ongoing research and development while guaranteeing the availability of reasonably priced alternatives, and giving the populace access to necessary medications priority. Future legal interpretations and rulings pertaining to the "efficacy" criterion will be critical in distinguishing real innovations from

[8] Rashi, *Patents and Public Health*, LEGAL SERVICE INDIA - LAW, LAWYERS AND LEGAL RESOURCES, https://www.legalserviceindia.com/legal/article-3717-patents-and-public-health.html.

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trivial inventions, advancing scientific progress by guaranteeing that intellectual property rights are reserved for genuine breakthroughs, and facilitating the exchange of knowledge and information, collaboration, and knowledge transfer, all of which will encourage further innovation[9].

India's future depends on achieving a balanced stance on access to public health care and intellectual property rights. India can create a more robust healthcare system that benefits the whole country by giving access and innovation equal priority.

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[9] Prachi Bhardwaj, *Evergreening of Patents in India*, ARTICLES MANUPATRA (June 10, 2023), https://articles.manupatra.com/article-details/Ever-Greening-Of-Patents-Of-India.

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