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India's Stance against Evergreening: A Patent War

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ABSTRACT

Evergreening under patents has emerged as a controversial strategy used by the pharmaceutical giants to extend monopoly rights beyond the standard patent term. The impact of Evergreening on the entry of generics poses a threat to public health and access to medicines as it can drastically increase the price of a drug. There are several instances where the companies have have used different mechanisms to extend their monopoly rights , one such instance is the case of insulin, where companies like Eli Lilly, Novo Nordisk and others have established their monopoly through the biosimilars of insulin and kept the prices high in the USA for more than 100 years. This practice has raised critical questions regarding access to affordable medicines and innovation in the pharmaceutical sector. Despite India's stringent stance on patent evergreening through section 3(d) of the Patents Act, 1970, there are certain loopholes while balancing innovation and public health. This paper discusses all the facets of patent evergreening by analyzing the legal and regulatory responses to it. Further this paper highlights the implications of India's stand for global access to medicines and suggests potential reforms to address the underlying challenges related to it.

Keywords*: Patent, Evergreening, pharmaceutical, Innovation, Public health.*

I. INTRODUCTION

Is being healthy a privilege only for the wealthy? The question may seem cliché, but the reality is that access to essential medicines is increasingly controlled by pharmaceutical monopolies. The big pharmaceutical companies tend to employ every possible method to increase the patent term and extend their exclusive patent monopolies and one such method is patent evergreening.[3]

Patent evergreening is a technique to prevent access to generic medicines by delaying the patent cliff through slight modifications to the existing patented drug, delaying the generic drug's entry[4]. This practice allows pharmaceutical giants to extend the standard patent term beyond 20

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[3] Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & Biosciences 590 (2018).
[4] R. Collier, *Drug Patents: The Evergreening Problem*, 185 CMAJ E385 (2013), https://doi.org/10.1503/cmaj.109-4466.

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years, preventing generic or the affordable alternatives from reaching the market.

The Indian patent law has always been subjected to criticism by big pharmaceutical companies and international investors, as it allegedly provides a rigid and narrow protection to Patents in India. While India complies with TRIPS provisions by granting 20-year patent exclusivity, pharmaceutical companies contend that the lengthy and expensive R&D process justifies broader patent protections.

India's legal framework prioritizes public health over patent monopolies. Under Section 3(d), companies seeking new patents on modified versions of existing drugs must prove enhanced "therapeutic efficacy". The Supreme Court of India, in cases like Novartis v. Union of India (2013), has reinforced this restrictive interpretation to prevent evergreening. Yet, this raises critical questions :

- Whether the explanation of the term 'Enhanced Efficacy' is restricted as it does not cover all medical advantages?
- Whether such restrictions discourage pharmaceutical innovation?
- Whether India should make flexible laws to provide a balance between innovation and Public health?

The absence of reliable mechanisms to track how frequently big pharma companies extend their patent terms and the methods they employ further complicates this issue. Despite these challenges, this research critically examines the realities of patent evergreening, using available online data, books, and legal analysis to uncover the hidden dynamics of intellectual property law.

II. INSIGHTS OF PATENT EVERGREENING

With the amount of data and content available on the trends of patent evergreening in India and the behavior of big pharma companies regarding the extension of patent term, the authors have recorded certain observations that are as follows:

The research and development of a new drug is both expensive and risky, as only one out of a thousand potential drugs successfully reaches the market. Given this high failure rate drives pharmaceutical companies to adopt aggressive strategies to extend their patent terms.

A notable trend in the pharmaceutical industry as correctly pointed out by Robin Feldman in her Paper *'May your drug price be Evergreen'* is that the number of new drugs that are being patented are less than the patents of the drugs that are recycled and repurposed by the

pharmaceutical companies.[5] The companies practice strategic patent filings to prolong the exclusivity and most of these big pharmaceutical companies employ more than one protections to delay patent cliff and use mechanisms such as patent thickets, patent evergreening, secondary patents of same drugs etc.

This practice not only prolongs monopolies but also increases unnecessary litigations in the pharmaceutical sector, the rise in litigation within the pharmaceutical industry places a significant burden on generic companies, ultimately leading to an increase in drug prices In result it affects the accessibility and affordability in developing countries which highly depends on generic companies for their healthcare.

India's stance against evergreening is strict with Section 3 (d) of the Indian Patents Act, 1970 requiring companies to demonstrate enhanced therapeutic efficacy before granting patents on modified drugs. However, grey areas remain – such as interpretation of the term 'enhanced efficacy', scope of data exclusivity, barrier towards innovation, etc., which continue to be debated.

While **evergreening is not a viable solution to incentivize innovation**, the concerns of pharmaceutical companies regarding **R&D costs and risks** cannot be ignored. Instead there are other solutions that a country can adopt to incentivize innovation and balance innovation and public health.

The above observations are being discussed in detail in this paper, as this paper tries to incorporate every aspect of Evergreening that can help to shape a perspective on what is Evergreening and what amounts to actual innovation that shall be incentivized.

III. MECHANISMS OF EVERGREENING

As Robin Feldman's research shows that 78% of new patents are for existing drugs, which do not contain a new molecule.[6] It highlights that the trend of patent evergreening is increasing at a great pace. While Professor Feldman's study is based on a comprehensive U.S. database, the growing number of patent litigations related to evergreening in India further supports the relevance and applicability of her findings to the Indian context. She also claims that these Pharma companies employ many mechanisms to delay the patent cliff , hence before delving into the case studies and the interpretations of Evergreening in India, let us look into the mechanisms that are engaged by the big pharmaceutical companies:

[5] Feldman, supra note 1, at 597.
[6] Id. at 507.

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1. **Patent Thickets:** Patent Thickets is a strategy used by the big pharmaceutical companies, where they file multiple overlapping patents to create legal barriers for the entry of generic drugs. A very well recognized example for patent Thickets is the case of **AbbVie's blockbuster drug Humira,** which had more than 100 patents in USA and blocking biosimilars for years, where the patent for Humira should have been expired by 2016 but through the technique of patent Thicket the company managed to extend it's monopoly by 2023 in USA.[7]

However, In India the biosimilars for Humira were available as early as 2014 because of the presence of section 3(d) of India's patent law, 1970. Several Indian pharmaceutical companies, including **Zydus Cadila and Torrent Pharmaceuticals**, successfully introduced biosimilars of Adalimumab bypassing AbbVie's patent thicket.[8]

Another significant case from India's Delhi High court to prevent patent Thicket **F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd**[9]Roshe filed several secondary patents for a modified version of Trastuzumab (Herceptin), a lifesaving breast cancer drug, in order to extend its monopoly. The **Delhi High Court** ruled against Roche, allowing generic manufacturers **Biocon and Mylan** to launch **cheaper biosimilars**, reinforcing India's strict stance against patent thickets. Hence , it can be well established that India's strict stance under section 3(d) has played a crucial role in preventing patent thickets, Nonetheless, large pharmaceutical corporations still use this tactic, which makes it a recurring problem in the sector.

2. **Combination drugs:** When pharmaceutical companies modify their existing product by combining one or more molecules in order to extend the term of the patent it is called as Evergreening through combination drugs. [10]It is a controversial practice as it leads to delay the entry of the generics beyond the legally permitted period.

One such case of combination drugs is regarding Boehringer Ingelheim's **Telmisartan (also known as Micardis)** Which is an Angiotensin II receptor blocker (ARB) that is primarily used for **hypertension** which was patented in the USA earlier. Then boehringer filed a secondary patent for **Telmisartan + Peroxisome Proliferator-Activated Receptor Gamma (PPAR-γ) agonists** that can be further used for Type-2 diabetes treatment, The Delhi High Court

[7] Michael A. Carrier & S. Sean Tu, Why Pharmaceutical Patent Thickets Are Unique, 32 TEX. INTELL. PROP. L.J. 79 (2024).
[8] Adalimumab Similar Biologic Launched in India, GENERICS AND BIOSIMILARS INITIATIVE (Dec. 2014), https://gabionline.net/biosimilars/news/Adalimumab-similar-biologic-launched-in-India.
[9] F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., 2017 SCC OnLine Del 9360 (Del. H.C. 2017).
[10] R.F. Beall et al., Patent "Evergreening" of Medicine-Device Combination Products: A Global Perspective, 18 HEALTHCARE POL'Y 14 (2022), https://doi.org/10.12927/hcpol.2022.26973.

considered matters pertaining to patent applications for combinations incorporating Telmisartan in the case of **Boehringer Ingelheim International GmbH vs. The Controller of Patents & Anr,** where the court held that the secondary patent cannot be granted as falling under section 3(d) and does not involve any therapeutic efficacy, rather it is merely combination drugs.[11]

India's strong opposition to secondary patents made it possible for more people to get telmisartan-based therapies for diabetes and high blood pressure.

3. **Polymorph patents:** It is a practice where the companies sought patents for different crystalline forms of known drug substances.[12] Polymorphs provide variations in the properties like stability and solubility, but the pharmaceutical companies use the polymorphs patenting as a strategy to extend the period of the original drug, which further results in Evergreening. Novartis's famous drug Gleevec is a notable example where a patent was sought in India for the β-crystalline form of Imatinib, known as Imatinib Mesylate; this case has been examined in detail in this paper. Another case of polymorph patents is **Pfizer's Lipitor (Atorvastatin Calcium)**, where Pfizer obtained multiple patents on different polymorphic forms of Atorvastatin calcium in order to delay the generic competition.[13]There are several other such examples where the companies sought the mechanisms like polymorph patents in order to extend the exclusivity, however the courts as well as other regulatory institutions assess the validity of such patents based on the efficacy and Novelty.

4. **Data exclusivity:** The Aim of the Intellectual property law is to protect those things that arise out of 'intellect' and to exclude others from using such a thing, In today's world data is often referred as 'the oil of the digital era, making it the most precious asset for the company**,** Recognizing the importance of proprietary data, Article 39.3 of the TRIPS Agreement mandates the protection of undisclosed test data submitted for regulatory approvals, particularly in the pharmaceutical and agrochemical industries. This protection, known as data exclusivity, prevents competitors—especially generic manufacturers—from relying on the original test data for a certain period[14] .

Despite the protection of data against unfair use under Article 39.3 of the TRIPS agreement,

[11] Boehringer Ingelheim Int'l GmbH v. Controller of Patents & Anr., C.A. (COMM.IPD-PAT) 295/2022 (Del. H.C. July 12, 2022).
[12] R. Tandon, N. Tandon & R.K. Thapar, Patenting of Polymorphs, 7 PHARM. PAT. ANALYST 59 (2018), https://doi.org/10.4155/ppa-2017-0039.
[13] Id.
[14]Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39.3, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm *(last visited Jan. 29, 2025).*

Data exclusivity arises from legal loopholes in many jurisdictions rather than from some explicit statutory provisions. Since TRIPS does not grant exclusive rights over data but merely prevents unfair use, companies exploit this ambiguity based on their own whims and fancies, sometimes leading to evergreening. Several nations such as USA China and European union recognize data exclusivity and provides with a fixed data exclusivity period but India holds a different approach because of its pro-public health stance, way back in 2007, Satwant Reddy Committee Report examined whether India should adopt data exclusivity , it concluded that it could increase drug prices and delay generic competition.[15] Various big pharma lobbies advocates for stricter data exclusivity measures in India, often alleging that the India's rigid stance violates the provisions of TRIPS, However they fail to consider the fact that as per Article 39.3,Countries must protect this data from unfair commercial use but have flexibility in how they implement this protection, hence India's present scenario does not violates any provision of TRIPS, India protects the data from unfair use through trade secret protection rather than data exclusivity.

India's position endorses public health interests, although certain changes, such as more precise regulatory requirements, could improve accessibility and conformity to global standards.

IV. CASE STUDIES

Through various judicial precedents and case studies we can understand various aspects of patent evergreening and its position in India, one of the landmark judgments that cleared India's policies regarding patent evergreening is Novartis v. Union of India in which the supreme court of India clarified that mere tweaking an old molecule and providing a new use of it does not qualify the criterias of patent in India. India does not in any way promote evergreening as it results against public policy and access to medicines. In this segment, the authors have compiled various case studies including the landmark cases to look between the lines and understand India's stand on patent evergreening.

(A) Novartis v. Union of India:[16]

- **Background of the case:**

Swiss based company: Novartis, a pharmaceutical giant, filed a patent for its blockbuster drug - Glivec, which is used for treatment of blood cancer and soft tissue tumors like Gist. The company filed a patent for Glivec in 1993 worldwide but not in India as till then India did not

[15]Dep't of Chemicals & Petrochemicals, Gov't of India, Report on Steps to be Taken by Government of India: Committee Report on Data Exclusivity (2007), https://chemicals.gov.in/sites/default/files/Reports/DPBooklet%5B1%5D.pdf *(last visited Jan. 30, 2025).*
[16] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).

provide any product patent. This drug was patented across 35 countries. In 1995 when India became a party to TRIPS as a developing country, India had the transition period of 10 years to come up with its own indigenous product patent law i.,e, till 2025. Till that time India came up with Exclusive Marketing Rights (EMR) and mailbox provisions to provide monopolies during the transition period.

Jürg Zimmermann invented the β-crystalline form of imatinib i.e., Imatinib mesylate for which Novartis claimed to have enhanced bioavailability than the original drug, i.e., it absorbs more than 30% in the blood. It has a beta crystalline form of imatinib i.e., Imatinib mesylate. This drug got a patent in the USA (Zimmermann patent No. 5,521,184'), This time Novartis filed a patent in India under the 'mailbox provisions under chapter IV-A of Indian patents act, 1970. But as by now the generic companies were already selling the drug at 10% price lower than the branded drug, Novartis imposed pressure on the Indian government to grant exclusive marketing rights and as India granted EMR to Novartis for Gleevec.

In 2005 India came up with the amendment in patent act,1970 and under section 3(d) that provided that the new forms of new substance are not patentable unless they show significant enhanced efficacy. Hence in 2006 Indian patent office rejected Novartis patent application for Imatinib Mesylate.

Further Novartis appealed against the decision of the patent office which was rejected by both Madras high court and the Intellectual Property Appellate Tribunal. Then in 2013 Novartis went to the Supreme Court against the previous decisions.

- **Issues:**

The issues to be decided by the supreme court in the case of Novartis v. Union of India were:

  - Whether the beta crystalline form Imatinib Mesylate demonstrates the 'enhanced therapeutic efficacy' to be qualified under the exception of section 3(d) of patents act, 1970.
  - Whether India's commitments under the TRIPS Agreement were infringed by rejecting Novartis's patent under Section 3(d) of the Indian Patents Act, 1970.

- **Judgement:**

Firstly the supreme court clarified that under Indian law both 'inventions' and 'patents' are two distinct concepts as for a grant of a patent the twin test has to be qualified where something which qualifies as invention shall also be patentable. Simply qualifying as an invention does

not automatically make it patentable under the Act.[17]

The court further clarified that the three criterias to grant patent in India i.e., Novelty[18], Inventive step[19] and Industrial application[20] has to be read along with section 3(d) of the patents act,1970, as it cannot be expected in the pharmaceutical industry to come up with an entirely unfamiliar or strange new product but in order to determine the patentability of a drug it's enhanced efficacy has to be determined under section 3(d) along with its explanation under patents act,1970 whose purpose is to prevent Evergreening..

The court held that a 'manipulative step' may or may not be an 'Inventive step' and based on the records, the supreme court of India held that the β-crystalline form of imatinib i.e., Imatinib mesylate does not qualify as an 'Invention And held it to be a new form of known substance under section 3(d)..

Further, just increased bioavailability of ß-crystalline-Imatinib Mesylate, as compared to Imatinib-in-free-base-form, alone may not necessarily lead to an enhancement of therapeutic efficacy.[21]

Hence, the supreme court of India cleared India's stance against evergreening, only those inventions can be patented that results in enhanced efficacy, merely manipulating the molecules in order to increase the patent term and delaying patent cliff results in defeating the purpose of regulating patents in India and is clearly against public health and access to medicines.

Addressing the criticism:

There are several contentions and arguments against and in favour of this decision of the supreme court of India; some of the major contentions are:

- Paul Herrling, the chairman of the board of the Novartis Institute for Tropical Diseases in Singapore, argues that since Gleevec has never been patented in India, Evergreening is not possible there.[22] He also argues that the Indian courts interpret "enhanced efficacy" strictly to justify patent protection. However, he contends that this interpretation does not account for cases where modifications to a molecule provide medical benefits, such as better patient safety, fewer side effects, and improved

[17] Novartis AG v. Union of India, (2013) 6 SCC 1, ¶¶ 37.3, 77,78 (India).
[18] Patents Act, No. 39 of 1970, § 2(1)(j) (India).
[19] Patents Act, No. 39 of 1970, § 2(1)(ja) (India).
[20] Patents Act, No. 39 of 1970, § 2(1)(ac) (India).
[21] Novartis AG v. Union of India, (2013) 6 SCC 1, ¶ 166 (India).
[22] R. Collier, Drug Patents: The Evergreening Problem, 185 CMAJ E385 (2013), https://doi.org/10.1503/cmaj.109-4466.

adherence to treatment.[23]

They also argue that Patent monopolies are not hampering access to medications in the developing nations as most of the drugs on WHO's list of essential medicines are those who do not have patents.

- Jim Keon, the president of the Canadian Generic Pharmaceutical Association, standing on the other side of the boat argues that the modified drugs do not provide enough advantages over the original molecules. Standing against the 'me-too drugs' he states that release of a new version of the product just before it's expiry is helping no one but the company itself(i.e., their bottom line) rather than to the consumers. He further argues that the contention that a company invests a lot in their research and development is a reason for doing so, does not hold enough weight. [24]

(B) Case study on Insulin:

As per World Health Organization, Diabetes affects over 830 million people globally, most of whom reside in low- and middle-income nations. Over 50% of individuals with diabetes do not receive treatment[25]. Insulin is used as a primary treatment for diabetes, Despite being developed more than a century ago, insulin is still Expensive in nations like the United states[26]. Pharmaceutical giants have developed insulin analogs, which are modified versions of insulin, as a strategic tactic to extend their market monopoly, ultimately leading to patent evergreening. The Policies of the Government in any state plays a critical role in balancing innovation and affordability. In India the average cost of Insulin is almost 52.6% less than that in the USA. India's strict stance has its own loopholes but maintaining an equilibrium between Innovation and Accessibility is the need of the hour. These cases again impose questions such as 'Despite the need for innovation, should patents be granted for beyond a reasonable period?', Whether a nation needs strong patent regulation to uphold public health or a flexible market open for innovation? These questions have not straightforward answers, we have to analyze it nation wise as developed nations have different priorities as that of developing nations.

[23] Id.
[24] Id.
[25] World Health Organization, Diabetes, https://www.who.int/health-topics/diabetes#tab=tab_1 (last visited Jan. 28, 2025).
[26] A. Olsen et al., Patents and Regulatory Exclusivities on FDA-Approved Insulin Products: A Longitudinal Database Study, 1986-2019, 20 PLOS MED. e1004309 (2023), https://doi.org/10.1371/journal.pmed.1004309.

(C) Case study on Johnson v. Johnson 's bedaquiline[27]

The Indian government has recently declined the application to extend the patent of 'Bedaquiline' a drug for treatment of drug-resistant Tuberculosis, by Johnson and Johnson pharmacy, after a wholesome period of 8 years. The end of patent marks the generation of this "wonder drug " at generic level and makes it more affordable for the general population in treatment of TB which is one of the most challenging diseases in developing countries like India. The refusal to extend the patent will play a key role in strengthening the National programme to 'END TB' , This decision carries broader implications, establishing an example for improved availability of reasonably priced drugs, diagnostics , and treatments for illnesses with widespread outbreaks in nations with limited resources like India. Despite patent protection being necessary for advanced innovation, mechanisms to ensure global accessibility to essential medications remain the main concern. Further reduction of costs will make the drug more accessible to the population in low income and developing countries like India .Bedaquiline unique mechanism of action makes it less susceptible to cross resistance , it's only limitation was is high cost which can be overcome once the ample amount generic drug will be generated in markets , Furthermore compared to other drug combination the time duration for which extensive drug resistance tuberculosis to be treated by bedaquiline based combination was way less, which improve patient compliance. Hence extending the patent term of Bedaquiline can severely Impact the public health which is against the national interest. Therefore, national health has to supersede the incentives for further advancements.

The list of the cases above mentioned is inclusive, it includes thousands of such examples where the Indian courts have interpreted section 3(d) of patents act with one lens only i.e., to prevent Evergreening. However, social justice is crucial, but in order to guarantee national progress, the legislation must also promote economic advancement and creativity. India is stepping ahead to promote innovation and global competitiveness. The **Indian Pharmaceutical Sectorial System of Innovation (IPSSI) Report (2023)** demonstrates the necessity for India to prioritize global competitiveness and broader innovation and not just public health issues. It highlights that the Indian pharmaceutical industry must include **Industry 4.0 technology**, increase biopharmaceutical research, and fortify international market ties, even though affordability and accessibility are still vital.[28]

[27]S. Yadav, India Declines Patent Extension Application of Bedaquiline: A Remarkable Step Towards Tuberculosis Elimination, 15 CUREUS e48146 (2023), https://doi.org/10.7759/cureus.48146.
[28]United Nations Indus. Dev. Org. & Dep't of Sci. & Tech., Gov't of India, Indian Pharmaceutical Sectorial System of Innovation (IPSSI) Report (2023).

V. CONCLUSION

The Indian pharmaceutical industry has witnessed remarkable growth, expanding from $40.8 billion in 2020 to a projected $130 billion by 2030, at a CAGR of 12.3%. [29]This growth highlights the sector's vital role in India's economy and its global pharmaceutical influence. However, challenges persist, particularly the practice of evergreening, which directly hampers the accessibility of generic drugs and threatens public health. A strong generic drug market can mitigate the harm caused by evergreening. It is essential to foster an environment where generic drugs can enter the market freely and efficiently. At the same time, balancing innovation with access to medicines is crucial. While nations with flexible patent laws often face exploitation by pharmaceutical companies, countries with overly rigid regulations may find it challenging to incentivize innovation. A well-calibrated legal framework, therefore, is critical in striking a balance between public health priorities and pharmaceutical advancements. Governments can support this balance by providing incentives for innovation, such as tax breaks, grants for research and development, or by creating transparent and fair patent policies. The international cooperation is necessary to ensure that countries regulations do not conflict with global public health needs . The establishment of a robust regulatory framework that balances innovation and accessibility will enable India to sustain its leadership in the global pharmaceutical industry while upholding its commitment to "*universal access to equitable, affordable, and quality healthcare services*."

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[29] Id.

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