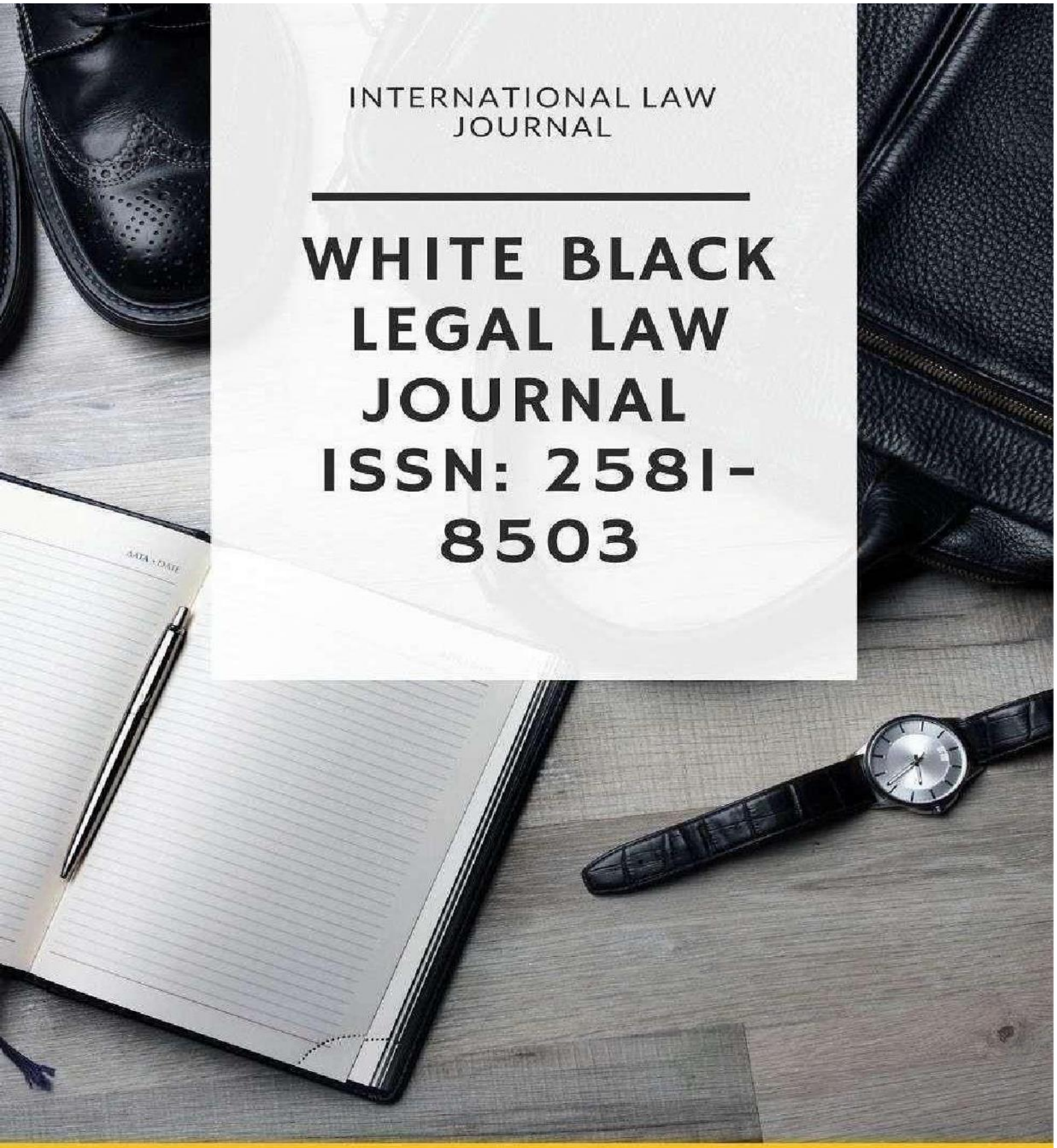

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PATENT EVERGREENING IN THE PHARMACEUTICAL INDUSTRY: BALANCING INNOVATION, MONOPOLY, AND PUBLIC WELFARE

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Abstract

The paper will present an in-depth analysis of the dimensions of evergreen patents. It will cover the development of patent law in the international context and the emergence of the issue of the evergreen patent. This research will identify the reasons behind the growth of evergreen patenting and its impact in connection with society and various theories. It will determine whether evergreen patenting is a real issue or just a market strategy for saving innovations and getting proper creators' reward. The paper will delve into the impact of the evergreen patent, primarily considering the views on societal welfare and the capitalist approach. The paper will reveal the practices and strategies employed by industrialists to extend the patent's lifespan, examining their impact on the general public and market competition. The research will provide a comparative analysis with special emphasis on India and its legal evolution. The research will delve into the depth of evergreening reasons and ways, while providing multiple suggestions that can be implemented by the patent offices to negate or reduce the impact of patent evergreening on public welfare.

Keywords: Evergreen Patent, Strategies, Novartis, Comparative Analysis

Table of Contents

List of Abbreviations

S. No.	Abbrevation	Full Form
1.	AIDS	Acquired Immunodeficiency Syndrome
2.	FDA	Food and Drug Administration
3.	Hon'ble	Honourable
4.	HC	High Court
5.	HIV	Human Immunodeficiency Virus
6.	OECD	Organisation for Economic Co-operation and Development
7.	SA	South Africa
8.	TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
9.	US	United States
10.	WIPO	World Intellectual Property Organisation
11.	ZIN	Dutch National Healthcare Institute

1. Introduction

A patent is an intellectual property right that grants the inventor exclusive rights to use and gain monetary benefits from an innovation or the development of an existing technology with a different output. The patent rights are awarded to the innovator for a specific period of duration, depending on the country and various international forums like WIPO, TRIPS, etc. The Patent Act of 1970 regulates the durations, granting conditions, etc, in India.

1.1. History and Development -

The special laws granting a market monopoly as an incentive to innovation can be traced back to the 15th century. According to the historian Romanin, the state of Venice had introduced a law in the year 1474, granting a ten-year privilege to inventors of new engines and machines.[1] This law is widely considered as the first patent law, and nearly a hundred privileges were granted or applied for various industrial inventions such as machines for raising water, grinding corn, draining land, etc.[2] The infringement of the patent would have caused a fine of 100 Ducats and the destruction of the infringing machine.[3] Another record for the system of patents dates back to the 16th century, when the Crown granted monopoly rights to reward favourites and secure loyalty under the reigns of Elizabeth and James I.

The system was largely criticised by the public for covering daily necessities like salt, oil, and vinegar.[4] In 1602, the famous case known as Darcy V. Allin shaped the common law, stating that exclusive rights over trade for private gain are violations of the liberty and benefit of the subjects and against the fundamentals of common law.[5] However, the Parliament of the United Kingdom passed the Statute of Monopolies while declaring the royal monopoly void in the year 1624.[6] The next major step in the development of patent law is the Paris Convention for the Protection of Industrial Property of 1883, which comprises

[1] 3 Romanin & Samuele, Storia documentata di Venezia, (1855).
[2] A.A. Gomme, Patents of invention: origin and growth of the patent system in Britain (1946).
[3] See *Id.*
[4] Penrose, The Economics of the International Patent System (1951).
[5] Edward Darcy Esquire v Thomas Allin of London (1602) 74 ER 1131 (UK).
[6] Karnika Seth, History and Evolution of Patent Law: International and National Perspective, PAT. & TRADE MARK REP., pt. 1 & 2, (Jan.–June 2004).

various key principles, including National Treatment and the Right of Priority.[7] Currently, the domain of Intellectual Property is governed by the WIPO and TRIPS, influencing the national laws and enforcement mechanisms. The term of 20 years, fixed by the TRIPS agreement, is often considered as a severe point of contention due to the duration of a drug in getting a regulatory approval and reaching the relevant market.[8]

The concept of patent evergreen has seen a considerable rise in the pharmaceutical industry during the last decade of the 20th century, where the global market has become extremely competitive, and business strategies have grown in response to the dynamic landscape.[9] The line between a genuine innovation and a second patent has been blurred by the modifications, providing some benefits.[10] Various strategies, such as filing multiple overlapping patents over different components of the same product, introducing variations in the composition, and modifying the impact and usage of the product, have become common practice in the pharmaceutical industry.

1.2. Methodology -

The paper will investigate and examine the relevant legislation in the context of evergreening of patents while using the legal dogmatic method with the use of empirical research method in the critical examination of a comparative study, and providing pragmatic recommendations. This paper will examine the development of patents from the medieval period to the modern era with the help of various books and research papers. The paper will develop into the legislation and the steps of international organisations to determine the scope of evergreening of patents and the impact on society.

The paper will largely put emphasis on the development of evergreen patents in the Indian context with the help of case laws, doctrines, and legislation.

[7] Margrit Seckelmann, From the Paris Convention (1883) to the TRIPS Agreement (1994): The History of the International Patent Agreements as a History of Propertisation?, 14 JAHRBUCH DER JURISTISCHEN ZEITGESCHICHTE 38, 60 (2013).

[8] Amy Kapczynski, Addressing Global Health Inequities: An Open Licensing Approach for University Innovations, 20 BERKELEY TECH. L.J. (2005).

[9] Gina Campanelli, Feeling Evergreen: A Case Study of Humira's Patent Extension Strategies and Retroactive Assessment of Second-Line Patent Validity (Master's Thesis, Harvard Univ. Div. of Continuing Educ. 2022).

[10] Patent Evergreening In The Pharmaceutical Industry: Legal Loophole Or Strategic Innovation? - Romil Aryan IJLSSS 3(2) 40, v. 3, issue 2, 2025.

The research will use a descriptive research method to shed light on the causes and different strategies of evergreening the patent. The socialist and capitalist approaches regarding the validity of evergreen patenting will be analysed with a social-welfare perspective in view. Furthermore, the Intellectual property rights and the competition law perspective will be used in the following to some extent for the purpose of explaining the arguments in favour of the extension of patent life and emphasising the importance of society's welfare from the innovations.

1.3. Research Objective -

1.3.1. Identify the cause of evergreening -

The paper will exclusively determine the root cause of patent evergreening, especially covering the financial and moral aspects of the inventor. Legal loopholes and market strategies used to expand the duration of exclusivity, while focusing on the institutional weakness, will be determined in this research.

1.3.2. Evaluating the positive justification and negative externalities -

The paper will investigate the positive justifications from the capitalist point of view and compare the justifications with the negative externalities from the grassroots level, and engage in a realist approach for determining whether evergreening is a necessary incentive for the promotion of innovation and securing the intellectual labour of the inventor or just a misuse of a mere irregularity in the patent law, directly impacting the masses at large.

1.3.3. Examine the legislative and judicial response in India -

The research's main objective is to examine the legislative status of India in tackling such a modern issue. The paper will also determine the judicial responses to the evergreening of patents with the help of various cases, such as Novartis AG V. Union of India. The judicial steps will be taken into consideration for finding a pragmatic solution at an international stage.

1.3.4. Identifying diverse strategies and their impact -

The paper will identify the modern strategies employed by industries, especially the pharmaceutical industry, for extending the lifespan of their products while determining the impact of such strategies on individuals, competition, the market, and societal welfare. The research will also explore the positive impacts of evergreening of patents on the industry and the social outcome, such as promotion to innovation.

1.3.5. Offering pragmatic recommendations with a comparative analysis of regulatory and judicial responses -

The paper will combine the comparative analysis results and provide a systematic recommendation for anticipating and procuring the evergreening, especially in the developing and underdeveloped nations. The recommendation will be based on a comprehensive study of existing solutions and recommendations by renowned scholars and organisations.

2. Why is Evergreening done?

The evergreening of patents is becoming a common practice in the pharmaceutical industry, as the protection of 20 years fell short due to the time spent on clinical trials and regulatory approvals required after the grant of a patent. The protection period often fails to protect the investments and recovery of high research and development costs. These challenges faced by the pharmaceutical industries often play a main cause of evergreening of patents. Some of the main causes of evergreening of patents are as follows –

2.1. One of the primary reasons behind the evergreening of patents is the phenomenon of the Patent Cliff. This phenomenon refers to the sharp drop in revenues faced by pharmaceutical companies after the expiration of patent protection. The financial drop in revenue is primarily caused by the gradual decline in sales as the generic versions of the medicines take the market share by making products available at a much lower price than the original company. According to the study of Martin Sipkoff, in 2008, annually, big pharmaceutical companies lose around $80 billion worldwide due to the loss of patent protection, the branded sales drop precipitously as much as 80% due to the arrival of a generic version.[11] This trend has continued, making the market more competitive, both in terms of innovation and creative ways for protecting and increasing the duration of a patent.

[11] Martic Sipkoff, Big Pharma Uses Effective Strategies to Battle Generic Competitors, DRUG TOPICS (2004), https://www.drugtopics.com/view/big-pharma-uses-effective-strategies-battle-generic-competitors.

2.2. Another reason or motivation for the use of evergreening is to recover the high research and development costs spent on medicine. The companies attempt to prolong the exclusive right to sell drugs in the market to secure a monopoly. The average cost for developing a new drug and gaining approval for the same is around $2.6 billion, including capitalised costs.[12] With generic medicines accounting for more than 50% of all the prescriptions in the United States and showing double-digit growth globally, challenging the sweet spot of big pharma companies.

2.3. The expiration of patents not only causes short-term challenges but also has long-term implications on the company's finances. The market share erosion has been one of the biggest challenges caused by generic alternatives, causing erosion of market dominance. Another measure that a company has to take is revenue diversification by expanding its portfolio by diversifying their portfolio. The companies also prefer evergreening to build the confidence of investors by creating a streamlined profit source, impacting their stock prices.[13]

2.4. One of the other strategies widely used by big corporations is to establish subsidiary units to compete with the generic domains. These subsidiaries enter the market before any other generic brand, with a substantial benefit because of the available raw material and sorted distribution network. These subsidiaries usually offer goods at a lower price than the competition because of low research and development costs, while supporting the main brand with financial contributions and market dominance even after the expiry of the patent.

3. Arguments of Pharmaceutical Giants

The primary argument used by pharmaceutical companies for the evergreening of patents is the incremental innovation created by the companies for secondary patents. The secondary patent can be secured by various methods, such as new formulations, delivery systems, combinations, new indications, etc. The common image of evergreening of patents has been perceived negatively, but can also result in genuine improvements in the

[12] Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, J. HEALTH ECON. (2016).
[13] Qualifyze, Understanding the Financial Implications of Patent Expirations, QUALIFYZE (2024), https://www.qualifyze.com/.

case of safety, efficacy, stability or patient adherence. Therefore, the secondary patent encourages continuous improvement rather than just one-time delivery. The follow-on innovations have been recognised as an innovation strategy under the OECD report.[14]

Another argument raised by the supporter for patent evergreening revolves around the high research and development costs invested by the companies, and the extended revenue window can reduce the financial risks attached to the patent cliff phenomenon, ensuring firms focus on new developments instead of focusing on viable options to recover the cost and keep the research and development going on without any financial constraints.

4. Impact of Evergreening

The evergreening of patents has far-reaching consequences that extend beyond the legal and corporate world. These impacts are multi-dimensional in nature and affect society in various fields such as access to medicines, innovation, the legal system and public health. This approach of evergreening is widely considered a selfish approach to create a monopoly in the market and withhold the invention from the public. There are various negative impacts that revolve around patent evergreening, some of which are as follows.

4.1. The evergreening increases the healthcare costs as patients, insurers, and the government have to pay for the brand price, while the company enjoys no competition from any generic manufacturers. It harms the developing or the underdeveloped countries with low healthcare budgets and can also make life-saving drugs unaffordable.[15]

4.2. The extension of the monopoly beyond the original protected area delays the possibility of generic manufacturers from entering the market, while creating an unhealthy monopoly of the inventor company over the commodity. This protection also provides financial leverage to the inventor while reducing access to essential medicines to the general public.[16]

[14] OECD, Pharmaceutical Innovation and Access to Medicines, OECD HEALTH POLICY STUDIES (2018), https://www.oecd.org/en/publications/pharmaceutical-innovation-and-access-to-medicines_9789264307391-en.html.
[15] Siri Silverkeke, The Winner Takes It All? (Faculty of Law, Lund Univ. 2013).
[16] Bhuvaneshwari R., Lionel Stephen & Keerthika R., Evergreening Patent on Life Saving Medicines: A Critical Study with Reference to Developing Countries, WHITE BLACK LEGAL L. J. (2014).

4.3. The evergreening of a patent also extends the monopoly of the company in the industry, enabling it to exploit its invention for a longer duration. This longer invention not only helps the inventor till the invention is protected but also helps him with the goodwill and public knowledge because of the long duration of the monopoly. This led to the diversification of the main purpose of innovation from public welfare to the increase of profit and benefits to its inventors.[17]

4.4. Another major impact of the evergreening is its challenge to true and new innovation. The slight modifications by inventors to secure new patents for maximising their profits. This leads to the shifting focus from breakthrough discoveries to creative strategies to modify the product and secure extended protection rights. This also increases the cost and complexity of research and development efforts made by other smaller firms.[18]

4.5. The impact of evergreening is not limited to the limited access or hindrance to competition, but it also poses high financial issues for the healthcare system, according to the research from the Health Savers Initiative on the impact of evergreening on healthcare systems, and the research showed the new FDA rules could reduce the federal deficits by at least $10 billion over a decade, showing the extent of losses bear by the healthcare systems due to extension of patent protection.[19]

4.6. The Evergreening of patents also poses a high risk of limiting the efficiency in the field, as the patent protects the core principles of an innovation and running around those principles creates a risk of litigation, causing financial troubles to the smaller inventors. The evergreen also reduces the availability and accessibility of the protected item, as the inventor owns a monopoly and has the right to sell items to geographical locations according to his will.

5. Evergreening Strategies

5.1. Polymorph and Salt Form Patents –

The existence of the same pharmaceutical ingredient is possible in multiple crystalline

[17] Ibid.
[18] Romil Aryan, Patent Evergreening in the Pharmaceutical Industry: Legal Loophole or Strategic Innovation?, 3 INT'L J. L., SOC. & SOC. SCI. 40, (2025).
[19] Drug Patent Watch, Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products?, DRUG PATENT WATCH (July 20, 2025), https://www.drugpatentwatch.com/blog/is-patent-evergreening-restricting-access-to-medicine-device-combination-products/.

arrangements, called polymorphs. A company can hold a patent on the base component of the drug, and it can file separate patents on the monohydrate or any specific polymorph with improved properties, thereby extending the period of protection with a monopolistic right over the product.

5.2. Combination Product Patents -

The process of combining an off-patent or near-patent active ingredient with a secondary agent in a fixed dose combination to create a new patentable product. The extended benefits of the new product create a layer of protection for the base ingredient, stopping the generic manufacturers from using the expired patented product because of the possible litigation due to the layered secondary patent.[20]

5.3. Exclusive partnerships -

The big corporations often enter into exclusive partnerships with the generic players before the expiry of the patent to enhance the brand-name drug value. The companies also prefer to use such experiments to earn royalties on the product during and after the patented protection period, to reduce the extreme fall in revenue after the expiry of the patent period. It hampers the possibility of fair competition by providing undue advantage to some firms and reducing the benefits to be given to the general public.[21]

5.4. Dosage Regimen and Method-of-Use Patents -

The patent law often allows a new dose to be protected if it is not obvious and clinically meaningful. A combination of a new dosing schedule and a new method of use that offers a better, more effective response can also lead to an extension of the product's protection. These secondary innovations are just enough to prevent generic producers from entering the market as competitors and to ensure the regular financial exploitation of the component in the market for a longer period.

[20] Drug Patent Watch, Pharma Profitability After Drug Patents Expire: The Complete Strategy Guide for IP Teams, R&D Leads, and Institutional Investors, DRUG PATENT WATCH (Mar. 12, 2026), https://www.drugpatentwatch.com/blog/top-strategies-for-pharma-profitability-after-drug-patents-expire/.

[21] Generics and Biosimilars Initiative, Drug Evergreening Strategies in India, GENERICS & BIOSIMILARS INITIATIVE (June 5, 2015), https://www.gabionline.net/generics/research/Drug-evergreening-strategies-in-India.

5.5. Franchise Extension to Successor Drugs -

The Brand manufacturers often focus on extending the market dominance by introducing a slightly modified or improved version of the existing drug before the expiry of the original patent. The manufacturers extensively promote the new medicines, shifting the market reliance before the expiry of the original patent and securing an alternative source of revenue. Various factors enable the manufacturer to extend the franchise to successor drugs, such as the success of the original formulation with a strong brand reputation, threat from generic competition, creation of a new drug with slight modifications and aggressive marketing leading to transition of market demand.[22]

5.6. Line Extension by Stockpiling -

The pharmaceutical companies had started preparing for various ways to sustain and stabilise the revenue source after 2005, when the generic market crossed the volume of branded manufacturers in volume for the first time in the United States.[23] Therefore, the companies started resorting to the "Stockpiling" method of patent by filing multiple patents over similar or relative attribute of the same product. The expiry of such a patent can extend the duration of the original product by multiple years. Even though the most important component of a valid patent is originality, the companies often engage in such practices to delay plausible competition from generic manufacturers.

6. Comparative Analysis

6.1. Brazil -

Brazil is one of the countries where the number of granted pharmaceutical patents are fewer, such as from the year 2003 to 2008, only 278 patents were granted, whereas Argentina granted 951 from 2000 to 2007, and India granted 2347 from 2005 to 2008. The numbers suggest that fewer pharma patents must lead to less monopolisation and lower prices, but the market suggests otherwise.[24]

[22] Gaurav Dwivedi, Sharanabasava Hallihosur & Latha Rangan, Evergreening: A Deceptive Device in Patent Rights, 32 TECH. SOC'Y (2010).
[23] Ibid.
[24] Marcela Fogaca Vieira & Gabriela Costa Chaves, The Patent Paradox in Brazil and Its Implication for Access to Medicines, SOUTH CENTRE (2018), https://healthpolicy-watch.news/patent-paradox-brazil-implications-access-medicines/.

Brazil has the highest pendency for patent examination, i.e., 8 to 10 years just to examine the patent application. The government has created Article 40[25], establishing a rule protecting patent applicants against the incapability of the patent office by guaranteeing a minimum validity term of 10 years for a utility patent, which was later declared unconstitutional due to its contradiction with the TRIPS Agreement.[26]

This inability of the patent office enables the pharmaceutical companies to file multiple patents for the same product, enhancing the patent life of the product. The prolonged period of the examination also enables the companies to file subsequent patents with minor modifications and exploit the period of examination as a free pass, as the generic manufacturers hesitate to produce goods that might later be declared invalid, infringing the patent. This administrative inefficiency of the Brazilian Patent Office enables the pharmaceutical companies to exploit the patent laws and evergreen their patent products. The de facto monopoly over the market has been recently criticised widely due to the high prices of essential commodities, which makes the process of evergreening legally possible and exploitative.[27]

6.2. South Africa -

Various studies demonstrate that the rate of secondary patenting is rising following TRIPS adoption. The secondary patents have skyrocketed in the 1990's as a part of a toolbox strategy followed by pharmaceutical companies to extend their legal commercial monopolies beyond the original period of protection.[28] South Africa has performed no better than other countries in granting secondary patents for minor modifications, leading to extended monopolies and high medicine prices across the country. The country has recently adopted the patentability criteria that will be developed to promote genuine innovation

[25] Industrial Property Law, Law No. 9.279 of May 14, 1996.
[26] Rob Rodrigues & Karlo Tinoco, Brazil's Patent Term Decision: Impact and Practical Tips, RNA LAW (2021), https://www.rna.law/insights/brazils-patent-term-decision-impact-and-practical-tips.
[27] Gabriela Costa Chaves & Renata Reis, Access to Medicines and Intellectual Property in Brazil, 8 SUR INT'L J. ON HUM. RTS.
[28] European Commission, Pharmaceutical Sector Inquiry: Final Report, (2009), https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

through the patent system in South Africa.[29] Still, it fails to provide explicit criteria for granting patent rights, creating legal ambiguity and enabling pharmaceutical companies to protect their weak secondary claims.

The patents are granted in SA under a 'depositary system' that grants a patent to all applications for which forms are correctly filed, and fees are paid without substantive examination of the application.[30] This registration process enables the pharmaceutical companies to get various patents that are rejected or withdrawn in other jurisdictions where proper examination is done for granting patent rights. One of the most important provisions of the TRIPS agreement, compulsory licensing, allows a country to grant a licence without the consent of the patent holder, which has not been utilised by SA due to unworkable domestic legal procedures.[31] The lack of initiatives and proper steps by the government has created a situation where pharmaceutical companies are extensively exploiting the market by extending the protection period for their products, and the alternatives, possible relief from compulsory licensing, are also not practised, causing a heavy medical burden on the SA citizens.

6.3. Netherlands -

The Netherlands has consistently ranked as one of the top 10 happiest countries in the world while having a high life satisfaction score of 7.3 out of 10.[32] The Dutch National Healthcare Institute (ZIN), while working with the Ministry of Health, Welfare, and Sports, has been committed to effectively addressing the phenomenon of evergreening with regard to pharmaceuticals. Being a part of the European Union, the Dutch government has limited influence on the patent legislation that enables the evergreening of patents; it works in its capacity to shape the impact of evergreening on the availability and innovation on the part of manufacturers. Therefore, the Dutch government has primarily relied on the

[29] Department of Trade and Industry, Republic of South Africa, Intellectual Property Policy of the Republic of South Africa: Phase 1 (2018), https://www.gov.za/sites/default/files/gcis_document/201808/ippolicy2018-phasei.pdf.
[30] Tomlinson C., Ashmore J., Yawa & Hill J., Reforming South Africa's Procedure for Granting Patents to Improve Medical Access, S. AFR. MED. J. (2015).
[31] Beall R. & Kuhn R., Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis, PLOS MED. (2012).
[32] World Population Review, Happiest Countries in the World 2006, WORLD POPULATION REVIEW, https://worldpopulationreview.com/country-rankings/happiest-countries-in-the-world.

reimbursement policy by the government themself and health insurers to reduce the influence of evergreening on social expenditure.[33]

The ZIN not only reduces the impact of evergreening by ensuring the liability bearer is a health insurer or government, but it also announces the emergence of new evergreened drugs promptly and systematically by detecting the early signs and ensuring the coverage of the drug by the government policies. The judiciary of the Netherlands had also taken the same approach as the government to protect the citizens from any unnecessary burden of hyped prices. The same can be derived from the Dutch court's order in the AstraZeneca case. The court determined that AstraZeneca has unjustly enriched itself at the expense of health insurance company Menzis and its client and ordered the same to compensate for damages. The court adjudicated that the insurance company and its client had faced high prices of the medicine, due to the enforcement of a weak patent on a slow-release version of a known patent.[34]

6.4. USA -

The United States patent system has always been favourable to the pharmaceutical patent holder, governed by the US Patent Act and interpreted in accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the World Trade Organisation. Recently, a study was conducted with the aim of studying the number of patents on already existing drugs compared to new drugs, and the study revealed that 78% of the drugs patented between 2005 and 2015 were protecting the already existing drug with minute modifications.[35] With the aim of regulating the generic medicines across the US, the legislation enacted the Hatch-Waxman Act of 1978. The act encourages generic medicine producers while allowing branded companies to extend their exclusivity through various means, such as filing for a new or modified patent, listing secondary patents in the FDA's Orange Book, and triggering 30-month stays during generic

[33] Dutch National Healthcare Institute, Analysis of Evergreening and Policy Options, STRATEGIES IN REGULATED MARKETS (2023), https://www.sirm.nl/en/publications/evergreening.

[34] Ellen 't Hoen, Dutch Court Orders AstraZeneca to Pay Damages in Patent Evergreening Case, MEDICINES LAW & POLICY(2020),https://medicineslawandpolicy.org/2020/10/dutch-court-orders-astrazeneca-to-pay-damages-in-patent-evergre ening-case/.

[35] Robin Feldman, May Your Drug Be Evergreen, 5 J.L. & BIOSCIENCES (2018).

challenges. The judicial approach, as US courts have shown limited resistance to the evergreening of a compound, unless and until it clearly lacks novelty. [36]

7. India's perspective

India is one of the largest manufacturers of generic medicines with a hold of 20% of the world's generic production, and is also known as the pharmacy of the world due to its large-scale supply of affordable medicines. A country with such a large market of generic medicines cannot grow without strict enforcement of anti-evergreening policies, as evergreening prevents the generic manufacturers from entering into the market for a prolonged duration of time, ensuring monopoly over the price and market. India's patent policy, following the essence of the Indian Constitution, has extensively focused on social welfare over corporate interest via the Patent Act of 1970. The Indian legal framework contains various provisions dealing with the evergreening and reducing its impact, as follows –

7.1. The Patent Act, 1970 -

The Patent Act of 1970 provides an exhaustive list of inventions that can not be patented for the public welfare. The section 3(d) "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant", [37] covers the processes that can be equipped to evergreen the patents and remove the possibility of extending the protection to exploit the consumers.

One of the common ways of attempting to secure a patent on an existing drug is by presenting "an improved drug"; section 3(d) combats any such practices by defining what will not be considered as an invention. The section considers salts, esters, polymorphs, metabolites, isomers, and other derivatives of known substances as the same substance unless they differ significantly in the

[36] Aryan, supra note 18, at 449.
[37] The Patents Act, 1970, § 3(d) (1970) (India).

context of efficiency.[38] This clause had been criticised by various pharmaceutical companies because of the exhaustive power of interpretation resting with the patent office; however, the public health advocates consider this as a safeguard from pharma companies with the sole purpose of making a profit.[39]

Another safeguard provided under the act is "**Compulsory Licensing"** under **section 84** of the act.[40] This provision directly affects the primary purpose behind the evergreening of the patent, i.e., to maximise profits by maintaining a monopoly over the market via legal means. This arrangement was introduced by the amendment of 2005 to the Patent Act with the aim of overcoming the issues of patent overgreening. Compulsory licensing is a process by which the Controller General of Patents grant interested parties, including the government, the right to manufacture and produce the patented medication after a minimum period of 3 years from the date of grant of patent. The provision also requires the medicine not to be available to the public at a reasonable price, or the patented invention has not worked in India. This provision has balanced the public interest and the interest of the patent holder by granting a monopoly of a minimum of 3 years to recover the cost incurred by them in research and development of their drug.[41]

7.2. Constitution of India -

The Constitution of India has influenced the intellectual rights policy of India by upholding the public interest while balancing the reward of the owner of intellectual property. The Right to Life, as described under Article 21 of the constitution interpret its scope by including the right to health and access to medicine, enabling the state to remove the protection granted to life-saving medicine while granting compensation to the founder for the loss of earnings.[42] The directive principles of the state policy, particularly Article 39 (b) and (c), also state that the ownership and control of the material resources of the community

[38] See *Id.*
[39] Shilpi Bose & Ishan Dhyani, Evergreening of Patents: Bridging the Gap Between IPR and Healthcare Laws, 7 INDIAN J. L. & LEGAL RSCH. (2025).
[40] The Patents Act, 1970, § 84 (1970) (India).
[41] Intepat Interns, Evergreening of Patents in the Pharmaceutical Industry, INTEPAT IP SERVICES (2025), https://www.intepat.com/blog/evergreening-of-patents-in-the-pharmaceutical-industry
[42] The Constitution of India, art. 21.

must be distributed to best serve the common good,[43] and the operation of the economic system shall not result in the concentration of wealth, respectively.[44]

8. Case Studies

8.1. Novartis A.G. V. Union of India[45] -

The Novartis case, being a landmark judgement, has influenced and shaped India's commitment to the prevention of evergreening. The case revolves around the application for a drug with minor modifications to the existing drug by Novartis. Novartis, a Swiss-based pharmaceutical company, filed an application for a patent for its cancer drug, Glivec, claiming the new drug to be more beneficial than its predecessor.[46] The application was primarily dismissed, but the Controller General dismissed it on the grounds of Section 3(d) of the Patent Act. The company filed an appeal before the Madras High Court, but received no relief, and the decision of the Controller General was upheld.

After the rejection from the HC, Novartis filed an appeal before the Hon'ble Supreme Court. The court, while refusing the claims of Novartis, adjudicated that the mere modification of an existing drug does not qualify as a significant improvement in therapeutic efficiency; the improvement, such as better bioavailability, improved stability, or a change in solubility, falls under the ambit of section 3(d). The court also noted that the patent law shall only protect genuine innovations rather than minor modifications aimed at prolonging the protection duration. The Court also set key principles, such as a clear distinction between minor modifications and true innovation, the requirement of comparative clinical data and the exclusion of non-therapeutic advantages such as stability, solubility or ease of production.[47]

8.2. Bayer Corporation V. Union of India[48] -

This case revolves around the concept of compulsory licence on life-saving drugs with limited accessibility due to high prices and import restrictions. The Controller General of Patents granted a compulsory licence to Natco Pharma Limited, allowing it to manufacture and sell Bayer's anti-cancer drug for kidney and liver cancer patients.

[43] The Constitution of India, art. 39, cl. b.
[44] The Constitution of India, art. 39, cl. c.
[45] Novartis A.G. v. Union of India, (2013) 13 S.C.R. 148.
[46] "Evergreening Patent on Life Saving Medicines", by Bhuvaneshwari R, Lionel Stephen A and Keerthika R, White Black Legal, Vol. 2, Issue 16, 2024.
[47] Interpat, supra note 40.
[48] Bayer Corporation v. Union of India, (2014) 60 PTC 277 (Bom).

The Bayer Corporation filed an appeal before the Hon'ble Supreme Court against the granting of a licence. The Controller General's primary argument was that the particular drug was not produced in India, and the price of the same has been very high due to the imports. This heavy pricing of a life-saving drug leads to a limited availability of the medication to cancer patients. The Supreme Court upheld the granting of the compulsory licence while emphasising that the comprehensive process laid down by the Patent Act, 1970, must be followed in any such instance.

8.3. Other Cases -

Since the ruling of the Novartis case uploaded the judicial stance on patent evergreening, the number of refusals to grant patents with minor modifications or therapeutic efficiency has also increased. One of the significant decisions where the Indian Patent Office rejected the application of Johnson & Johnson. The application was filed for a fumarate salt form of Bedaquiline, a drug used to treat multidrug-resistant tuberculosis. The application was rejected on the grounds of Section 3(d), which prevents the registration of patents consisting of new forms of known substances unless they show a significant increase in therapeutic efficiency. The inability of the Bedaquiline to meet the threshold of a valid patent and fall under the ambit of section 3(d) led to the rejection of the application. This decision reflects a consistent approach by the Indian judiciary and the Patent Office in upholding the provisions of the Patent Act while ensuring adequate safeguards for public health by preventing the extension of monopolies. The Controller General of Kolkata also refused a patent application on the grounds of Section 3(d) of the Patent Act. In November 2024, the Controller General refused the application for Dolutegravir, a drug used for the treatment of HIV/AIDS. The applicant was seeking patent protection on a new form of an existing drug, but the Controller General refused to grant a patent as the new drug does not show any enhancement in therapeutic efficiency. The decision prevented the unjustified extended protection over important drugs, prioritising the public welfare over the profits of the pharmaceutical companies.[49]

9. Suggestion

The patent offices shall adopt a stricter scrutiny examination, especially in the case of an application for a secondary patent relating to salts, polymorphs, dosage forms, combinations or new uses of existing medicines. Mere modifications shall not qualify for protection as a patent unless the modifications bring significant therapeutic efficiency. The same principle as

mentioned under section 3(d) of the Patent Act has been upheld by the Indian Supreme Court in the Novartis A.G. V. Union of India case and shall be practised by the patent offices all around the world to discourage the practice of evergreening of patents. The offices shall also focus on maintaining transparency by publishing examination reports, objections, and scientific evidence relied upon by the patent office, especially in the pharmaceutical patents, as they directly influence the public interest.

The members of the TRIPS agreement can also utilise compulsory licensing as a means to reduce the impact of the evergreening on the public while balancing the rights of the founder by providing them with financial compensation for the same. The concept of compulsory licensing is defined under Section 84 of the Indian Patent Act, which works as the best way to overcome the issues of affordability and availability at the same time. The patent offices all around the world shall take adequate steps to simplify the procedural requirements for the granting of compulsory licences if the medicine is essential for public health. The governments should also actively support the generic manufacturers and the generic industry by smoothing the regulatory barriers with efficient approval processes before the expiry of patents. The generic medicines increase the competition in the market while reducing the price of medicines and increasing accessibility by making the medicines affordable.[50]

The World Intellectual Property Organisation shall also assist the patent offices with limited resources, leading to administrative inefficiency, technical backlog and lack of scientific expertise, enabling the pharmaceutical companies to exploit the framework and maximise their profit. The creation of specialised patent review bodies can improve the quality of examination and reduce the chances of evergreening of patents. The governments can also introduce provisions of penalties for the filing of frivolous or abusive patent applications. The penalty provisions will stop the pharmaceutical companies from filing weak patent applications with the aim to delay generic medicines entry in the market. With the implementation of these suggestions, the governments can balance the innovations with public welfare, ensuring that intellectual property rights do not become an instrument of indefinite market control.

[49] Bose, supra note 38.
[50] Bhuvaneshwari, supra note 45.

10. Conclusion

The evergreening of patents is an effective way for companies to extend their legal monopoly on the product over the market for a prolonged period of time. This phenomenon has grown over a period of time and has shown a subsequent increase from the 1990's with the development of the generic medicine industry. The patent evergreening has been one of the most controversial consequences of the development of patent law, as the pharmaceutical companies started extensive utilisation of secondary patents by minor modifications, dosage changes, combinations or by successor drugs to extend the period of protection of the primary patent. Although the patent evergreening or secondary protection has some benefits, such as improved efficiency, patient safety, better delivery system and continuous scientific progress.

The research discovers the primary reasons behind the evergreening of the patent as the "patent cliff" phenomenon. The phenomenon studies various factors such as high research and development costs, market competition, long-term profitability and the desire of the company to maintain investors' confidence. However, the justifications of the pharmaceutical industry fall short due to the extensive social and economic consequences. The extension of protection, providing a monopoly, leads to an increase in healthcare costs, delaying the entry of generic producers, restricting access to life-saving treatments, and imposing a burden on the healthcare system. This practice also shifts the pharmaceutical sector's focus from innovation and technical breakthroughs to defensive commercial strategies to protect profits.

The paper also provides a comparative analysis of different jurisdictions while discovering the effectiveness of anti-evergreening measures. The results show that countries like South Africa and Brazil still struggle with weak patent examination systems, administrative backlogs, and excessive granting of secondary patents. On the contrary, the Netherlands government attempted to reduce the impact of evergreening on the public by providing a reimbursement mechanism, proactive healthcare policies and judicial intervention with the aim to protect public welfare. However, India has emerged as one of the world's largest producers of generic medicines. The patent framework of India contains section 3(d) of the Patent Act, 1970, which created a unique protection for the public by preventing companies from evergreening patents.

In conclusion, while the protection of intellectual property remains essential for encouraging the scientific process and rewarding inventors, the research paper provides various suggestions with the aim of preventing the evergreening of patents, such as the implementation of compulsory licensing, the creation of specialised patent review bodies, and the strengthening of the standard of patentability.

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