EVERGREENING OF PHARMACEUTICAL PATENTS – AN ABUSE OF PATENT REGIME GLOBALLY

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ABSTRACT

Patent evergreening is prevalent mainly in the pharmaceutical industry. The Pharmaceutical companies tries to extend the market term of their products beyond the original Patent term. This is done by only doing slight alterations and modifications in the existing products. While These modifications may or may not substantially enhance the therapeutic efficacy or technological advancement, they do so to delay the entry of generic alternatives which are important for affordability into the market, thereby maintaining higher prices and prolonged market dominance. Evergreening of Patent creates challenges to the public health and the market competition. This practice limits the access for patients who rely on cost-effective treatments. It hampers competition by preventing generic manufacturers from introducing affordable alternatives, thereby maintaining monopolistic market conditions.

While patents are essential for incentivizing innovation by granting temporary exclusivity, practices like evergreening[1] undermine the balance between rewarding inventors and ensuring public access to affordable medicines. India's legal framework, particularly Section 3(d) of the Patents Act, plays a crucial role in preventing such practices by ensuring that patent protection is granted only to genuine innovations that offer significant improvements over existing products. This approach safeguards public health interests and promotes a competitive market environment, aligning with global efforts to prevent patent evergreening and its adverse effects on society.

[1] *"https://www.lexology.com/library/detail.aspx?g=aacfd802-52e1-4468-b71e-6a6a2d2c513b"*

PATENT EVERGREENING

INTRODUCTION

Evergreening is a procedure that allows patent holders to increase the duration of their patents and increase their income. The approach of obtaining several patents that cover various components of the same product is known as "patent evergreening." The patent system allows any pharmaceutical company to obtain a patent for an innovation. It operates by submitting more patents that are connected to the initial patent, which enables them to safeguard their idea against rivals for extended periods of time. This research work will cover the following topics: the definition of evergreening, how it operates, Patent Regime Globally, Comparative study of India, USA and UK.

MECHANISM OF PATENT EVERGREENING

Evergreening is the process of filing additional patents that are linked to the initial invention. This gives patent holders the ability to prolong the duration of their ideas and safeguard them from their competitors for an extended length of time. Usually, the process consists of submitting several follow-up patents that are based on the original patent. This is done to provide the innovation further protection for a more longer period of time. The objective is often to make sure that there are no loopholes that rivals can exploit to get around the original invention and produce a product or service that competes with it without violating the patent. The primary mechanisms of patent evergreening are:

New Formulations- Pharmaceutical companies frequently implement minor alterations to the drug's delivery method or formulation[2] to prolong patent protection. These modifications may encompass alterations to the drug's dose form or its delivery mechanism. Although these modifications may not enhance the drug's therapeutic efficacy, they enable firms to obtain new patents. These modifications can inhibit the entry of generic alternatives into the market, as the new formulations are safeguarded by distinct patents. Although they may not provide substantial therapeutic advantages compared to the original medicine, they extend market exclusivity and maintain elevated prices.

[2] *"Abbasi, K. (2016). Patent Evergreening in the Pharmaceutical Industry. British Medical Journal, 354, i4887.Last Visited 25january 2025"*

New dosage strengths[3]- Pharmaceutical companies have the ability to file fresh patents for an already marketed medicine based on changing strengths or dosages. This enables them to prolong patent protection, even if the active component and its composition do not change.[6] This strategy can be used to create more monopolies on different versions of the drug, such as a higher or lower dose, without delivering any significant improvements in the treatment's clinical advantages. They are based on small changes rather than actual innovations, these types of patents are commonly referred to as "evergreen patents." This allows firms to prevent generic competition while without providing any meaningful advance in efficacy or safety. This has a direct effect on the cost of medications because generic drugs, which are usually significantly less expensive, are not permitted to be sold.

INNOVATION V/S INCREMENTALISM

RADICAL INNOVATION V/S INCREMENTAL INNOVATION

The phrase innovation, means the creation of novel ideas, processes, or products, is classified into two categories: radical and incremental innovation. The radical innovation pertains to an entirely novel class of medications with a distinct mechanism of action, whereas the incremental innovation encompasses new drugs within an established class that share a similar mechanism of action as the first-in-class but vary in characteristics such as therapeutic profile, metabolism, adverse effects, dosing regimens, and delivery systems. Radical invention is consistently safeguarded across all patent systems, however incremental innovation is typically deemed unworthy of protection due to the common belief that it merely constitutes replicas of existing molecules. They are frequently interconnected and reliant on one other. Incremental innovation enhances the quantity of medications within a particular class, rendering them safer, more effective, and more tailored to individual patient profiles compared to the initial drug. The National Research Council indicated that “the cumulative effect of numerous minor incremental innovations can occasionally be more transformative and possess greater economic impact than a limited number of radical[4] innovations or 'technological breakthroughs.” Consequently, omitting incremental innovation from patent protection would diminish the motivation to enhance existing pharmaceuticals, thereby decreasing the financial resources allocated for new

[3] *https://iaeme.com/MasterAdmin/Journal_uploads/IJIPR/VOLUME_14_ISSUE_2/IJIPR_14_02_003.pdf*
[4] *Eisenberg, R. S. (2013). Patent Evergreening and the Pharmaceutical Industry: From Monopoly to Competitive Market. Yale Journal on Regulation, 30(2), 481-507*

drug discovery.

EVERGREENING V/S INCREMENTAL INNOVATION

While safeguarding newly identified applications and enhanced formulations of current pharmaceuticals it is essential to distinguish between evergreening and incremental innovation. The incremental innovation possesses significant potential for the advancement of pharmaceuticals with enhanced health advantages, whilst the Evergreening is a strategy employed by pharmaceutical companies to avert the expiration of their patents. Pharmaceutical companies engage in evergreening primarily to safeguard their market shares against generic versions of their patented drugs. The modifications implemented may contribute minimal therapeutic or clinical benefit to the original patented product; yet, the corporation retains ongoing patent protection. Conversely, patents on incremental innovation aim to safeguard findings pertaining to novel applications, active principles, molecules, or compounds that have been previously patented.

It is unequivocal that, in certain instances, evergreening and incremental innovation may intersect. However, the distinctions are substantial, and any effort to conflate the constructive process of incremental innovation with evergreening may be unjust to those endeavoring to create more effective treatment alternatives through incremental improvements.

INCREMENTAL INNOVATION AND PUBLIC HEALTH

It may also be advantageous to allow patent protection for incremental innovation when addressing public health issues. Increasing the number of various medications in a single class can lead to greater price competition[5] among those drugs. As a result, drug prices would go down, making them more affordable for the average person. Second, it can lower the cost of healthcare by enhancing the quality and variety of medications that are accessible to patients. Additionally, having many medications within the same class guarantees that there are enough alternatives available in the event that one of the drugs is no longer sold. Third, the income generated from incremental innovation can be used to fund the development of research-intensive drugs, which will make novel medicines available to the public in the long run.

[5] *"Commission on Intellectual Property, The Importance of Incremental Innovation for Development paper http://www.theworldbusinessorganisation.org/uploadedFiles/ICC/policy/intellectual_property/pages/Incremental_Innovation_submission_to_WHO_CIPIH_27May05.pdf (Last visited on2 Jan, 2025)."*

Fourth, novel formulations and drug delivery technologies can be developed that are specifically designed for the environment in India.

ANALYSING RELEVANT PATENT ACT OF INDIA PROVISIONS

Before we can analyze the part of the Act that addresses evergreening, we first need to understand what can be patented. According to Section 2(j) of the Act, a patent can only be granted for an invention if it is a "new product or process involving an inventive step and capable of industrial application." The Act further defines a 'inventive step' under Section 2(ja) as "a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art".

But, even if an invention reaches the criteria described above, it may still not be eligible for a patent if it falls under the provisions of Section 3 of the Act. Section 3 specifies what does not qualify as an invention according to the Act. This is where we discover the anti evergreening provision, which is included in Section 3(d) of the Act and is copied below: "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.

Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy"[6]

Section 3(d)[7] clearly states that it applies in situations where there is a "mere discovery" of a new property or new use of a known material, or the "mere use" of a known process, machine, or apparatus. Unless it leads to an increase in the effectiveness of the known drug, or unless the known procedure results in a new product or uses at least one new reactant. It is necessary to evaluate each situation individually in order to ascertain whether or not a patent for a specific invention would be affected by Section 3(d), as this is contingent on the characteristics of the

[6] *"Sec on 3(d) of the Patents Act,1970"*
[7] *"Ibid"*

product or process. Of course, the standards that apply to this evaluation will differ depending on the industry to which the product or process belongs.

The Delhi High Court, in the case of Cipla[8] Ltd v. F. Hoffman-La Roche Ltd, ruled that Section 3(d) of the Indian Patents Act allows for a range of derivatives of known substances, including a compound that is not active on its own but is metabolized in the body to form an active drug, which is known as a prodrug. This ruling was made in the context of pharmaceuticals, which have generated the most jurisprudence in this field in India. For example, chloramphenicol succinate ester is used as an intravenous prodrug of chloramphenicol because pure chloramphenicol does not dissolve in water. Another example is a composition, which is a combination of two or more active ingredients or a combination of a pharmaceutical carrier with a compound that has not been used as a drug before. A third example is a drug delivery system, which is a composition that has constituents that allow it to be administered in a specific way. If the product improves upon the proven effectiveness of the product, it would not be termed "evergreening" and would be eligible for a patent. When it comes to drugs, this effectiveness should be evaluated based on the product's "therapeutic efficacy."

BARRIERS FACED BY GENERIC PHARMACEUTICAL COMPANIES

The domestic pharmaceutical business is mostly a "branded generics" market, where pharmaceutical companies sell off-patented[9] pharmaceuticals under their own brand names, and the prices of these drugs differ from one rival to another. Branding and marketing efforts are still vital to pharmaceutical businesses' sales strategies, especially since the quality and testing standards in the pharmaceutical industry are not as strict as those in other regulated markets, such as the United States. Pharmaceutical businesses in India have large sales teams that reach out to doctors, who are the main decision-makers in a situation where insurance coverage is poor.

Most of the biggest pharmaceutical businesses in India have better credit profiles since they are present in the domestic pharmaceutical industry. This is due to the fact that they have a healthy long-term growth potential, sufficient profitability, and the advantage of diversification. Indian pharmaceutical companies will be negatively impacted by a significant decrease in the market

[8] *"2015 SCC Online Del 13619"*
[9] *"M. S. Raghunandan, "Patent Evergreening: The Art of Extending Monopoly," Journal of Intellectual Property Rights 18, no. 3 (2013): 210-221."*

share of branded generics, as the average prices will drop significantly and will outweigh any potential gains from lower marketing expenditures. That so, we believe that the new criteria will not likely cause a quick transition away from branded generics.

The implementation will face practical hurdles since the less strict drug quality standards in India could result in differences in drug quality and effectiveness among different producers. The requirement could change the decision-making process for the selection of a drug manufacturer from doctors to chemists, who may not have the necessary qualifications or may not prioritize the safety and effectiveness of the medication for patients. The government has already received a request from a national association of Indian physicians to postpone the new standards. The association has cited the difficulties that the new rules will create for clinicians in their efforts to ensure that patients receive safe and effective care.

The initiatives, which include establishing a nationwide chain of pharmacy outlets that focus on generic medications, have contributed to an increase in the sales share of trade generics, or medications that are dispensed without the involvement of a physician. Branded generics still make up more than 75% of the market share by volume and 90% by value.This is due to worries about the ability to provide continuous service and maintain quality, which have restricted their growth in non-rural regions in India.

PATENT AND THE FUTURE OF THE INDIAN PHARMACEUTICAL INDUSTRY

Many multinational companies have restricted their portfolios to products that have either expired patents or a small number of selected protected products. This is due to the lack of patent protection for pharmaceuticals and agrochemicals. This caused their market share to decrease since local firms were able to create the most advanced medications through reverse engineering. Foreign corporations were forced to pay royalties for international medications, but Indian companies were allowed to The Patents (Amendment) Act 1999 added this provision, which gives innovators what is referred to as "pipeline protection." If the applicant has already submitted an application for their invention in any convention countries and has been awarded a patent or EMR in that country on or after January 1, 1995, the applicant would be able to apply for a patent for pharmaceutical and agrochemical products in India.

These patent applications will remain pending. The pending patent application will be eligible

for product patent[10] after India updates its patent rules to comply with the recommendations of the World Trade Organization (WTO). If the application is determined to be eligible, the applicant will be given EMRs in India until the patent is either granted or refused, or for a period of five years, whichever is shorter. The modified Patents Act also includes a provision for compulsory licensing for the EMR, similar to the way it is done for patents. For Indian[11] pharmaceutical companies to survive, it is essential that they increase their spending on research and development at a rapid rate. In order to promote research into the development of affordable medications that are appropriate for the Indian disease profile, Indian businesses require protection for their product patents. The larger companies are already raising their total research and development spending as a percentage of revenues, and they are starting to shift their focus from development research to discovering new molecules. Although some organizations may not be able to make the move, there are indications that many Indian enterprises will be able to successfully navigate the transition and emerge as more innovative businesses.

PATENT REGIME IN USA AND UK

PATENT REGIME IN USA

According to the legal system of the United States, a patent is a right that is awarded to the person who is the inventor of a process, machine, product of manufacture, or composition of matter that is- "Novel, Useful, and Not obvious."

A patent is the right to prevent other people from making a profit out of a patented technology for a predetermined period of time (often twenty years) without the permission of the person who holds the patent.[20] In particular, it is the right to prevent other people from doing the following: manufacturing, using, selling, offering for sale, importing, inciting others to infringe, asking for FDA permission, and/or offering a product that has been specially modified for the practice of the patent. Patent law in the United States is enshrined in Title 35 of the United States Code and is authorized by the United States Constitution, specifically in Article One, section 8, clause 8, which states that

[10] *R. D. G. Tait, "The Ethics of Patent Evergreening," Health Policy and Ethics Review 12, no. 1 (2015): 12-16 European Court of Justice, Case C-577/13, 2011*

[11] *"Jean O Lanjouw, "The introduction of pharmaceutical product patents in India: Heartless exploitation of the poor and suffering?", Center Discussion Paper No. 775"*

"The Congress shall have power... To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries of inventions."

Originally named "An Act to promote the Progress of Useful Arts," the first statute pertaining to patents in the United States was passed into law. The legislation was brief, consisting of seven sections, and it stipulated the fundamental criterion that "any useful art, manufacture, engine, machine, or device, or any improvement therein not previously known or used" must be included.

In the years following the United States accession to the Paris Convention, two significant events occurred in the United States that had a significant impact on the evolution of patent law. These events were the Sherman Act of 1890 and the Evarts Act of 1891. The foundation of contemporary patent law was established in 1952, and in the years that have followed, a number of modifications have been made. All cases that are heard by the United States Patent and Trademark Office are governed by Title 35 of the United States Code.

PATENT REGIME IN UK

Over in Europe, there are two different patent systems. Patents are granted by the European Patent Organization (EPO & EP Org), and they have the potential to cover up to 38 European states, including the United Kingdom. It is possible to take into consideration the provisions for the issue of patents in the United Kingdom by referring to the European Patent Convention (EPC) as well as the United Kingdom Patents Act 1977 (as amended).

The legal systems of England and Wales, Northern Ireland, and Scotland are all part of the United Kingdom; yet, the patent legislation about the essential adjustments is the same for all of these individuals. In order to secure patent protection in the United Kingdom, there are two methods available. The first method involves filing the patent at the national patent offices. The second method involves filing a single European patent at the European Patent Office in Munich, which defines the countries in which the patent is covered. Those who are patented can take advantage of the considerable cost savings offered by the latter machine.

As a result of the enforcement of patents in the United Kingdom, the owner of the patent is required to continue to review the laws of each country in which the patent is registered.

However, despite the fact that the patent system [12]in the United Kingdom is costly and the outcomes of the enforcement strategy might not be constant, the system is comprehensive and, as a result, quite effective in removing patents that have flaws.

The availability of threat actions and cost penalties is another key factor to consider in order to discourage the casual assertion of claims that are not very strong. One of the peculiarities of the European patent system is that once the patent is issued by the European patent office, it is converted into local patents in each of the signatory nations that were selected in the application. This gives the European patent system a unique quality.

COMPARATIVE ANALYSIS

An innovation is considered to be non-obvious in accordance with the Patent Laws of India if it is a new product or technique that involves an innovative step and is capable of being applied in industrial settings. Patents cannot be granted for things that are already common knowledge. On the date of priority, an invention is considered to be new if it does not constitute a part of the state- of-the-art, which is another way of saying that it does not constitute a part of the knowledge that is accessible to the general public. Prior written or oral disclosure of the invention, or any other method of thinking about the knowledge that was available in a public manner prior to the date of filing of the patent application, constitutes the invention as a component of the prior art or the state of the art.

Although it is comparable, the definition that is used in the United States is not the same. When it comes to patentability in the United States, one of the most important conditions is that the invention that is being claimed is not obvious. This means that a "person having ordinary skill in the art" would not be able to address the problem that the invention is geared towards by employing the same method.

Almost from the beginning of its existence, India has adhered to a one-of-a-kind drug patent law. Product patents for pharmaceuticals were not allowed in India prior to the reforms that took place in 2005. This one-of-a-kind approach had made it possible for the nation to establish a robust pharmaceutical generic business that would deliver inexpensive necessary medicines both within and beyond the nation. On the other hand, India was granted product patents on

[12] *World Health Organization, "Access to Medicines," WHO Report, 2019*

medications for a period of twenty years after changes in 2005 that were in compliance with TRIPS. Importantly, these amendments also included provisions on compulsory licensing under certain conditions of public health.

The United States of America and the United Kingdom favor the creation of drugs through the granting of patent exclusivity rights[13], but India strikes a compromise between its emphasis on intellectual property protections and the requirement of ensuring that medicines are accessible at inexpensive prices. When compared to the regulatory frameworks of the United States of America, the United Kingdom, and other industrialized countries, the Indian regulatory system is distinguished by its distinctive public health safeguards and its flexibility. In the context of domestic healthcare systems, economic development strategies, and trade positions, different approaches reflect different policy priorities due to the fact that they are different.

CONCLUSION

Patent evergreening, is the practice of extending the life of a patent through minor modifications or new formulations, which raises significant ethical and legal questions in the realms of intellectual property. In India, the legal framework, particularly under Section 3(d) of the Patents Act, aims to prevent evergreening by disallowing patents for new forms of known substances unless they signify new enhanced efficacy. This approach reflects India's commitment to balancing innovation with public health needs, particularly in the pharmaceutical sector. Despite such legal measures, pharmaceutical companies continue to exploit regulatory loopholes to extend patent [14]protections. This practice not only hampers competition by preventing generic manufacturers from introducing affordable alternatives but also diverts focus from developing truly innovative treatments.

United States and the United Kingdom have more permissive environments regarding patent extensions. In these jurisdictions, companies can secure additional patents for incremental innovations, which can lead to extended market exclusivity. While this system incentivizes

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[13] D. K. Hill, "The Challenges of Patent Reform: The Case of Evergreening," Journal of International Trade and Law 22, no. 4 (2020): 55-65
J. L. Williams, "Secondary Patents and the Perpetuation of Monopoly in Pharmaceuticals," Harvard Law Review 128, no. 2 (2015): 330-350
[14] C. J. Schmidt, "Cancer Drugs and Patent Evergreening," Cancer Economics Journal 14, no. 2 (2017): 104-112
S. K. Kapoor, "India's Patent Laws and the Fight Against Evergreening," International Journal of Intellectual Property 6, no. 1 (2018): 28-42"

research and development, it also risks hindering access to affordable medicines and stifling competition.

The rules governing patents in India, the United States of America, and the United Kingdom are extremely similar to one another since they all offer specific rights to innovators for a predetermined amount of time in exchange for disclosure of the technique of production that has been devised. There are certain similarities between the legal systems of the United States of America, the United Kingdom, and India. These similarities include the general requirements of novelty, non-transparency, and initiative to establish and make use of innovations that are required to be patented. The fundamental concepts of patent law are, for the most part, consistent across the globe; the primary distinction is in the procedures that are utilized by each program.