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EVERGREENING OF PHARMACEUTICAL PATENTS IN INDIA: A LEGAL ANALYSIS UNDER THE INDIAN PATENT ACT IN THE LIGHT OF TRIPS AGREEMENT

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ABSTRACT

The concept of evergreening in pharmaceutical patents has emerged as a critical issue at the intersection of intellectual property law and public health in India. Evergreening refers to the strategic practice by pharmaceutical companies of obtaining multiple patents on minor modifications of existing drugs, thereby extending their market exclusivity beyond the original patent term. This study undertakes a comprehensive legal analysis of evergreening within the framework of the Indian Patents Act, 1970, particularly focusing on Section 3(d), and examines its compatibility with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

India has adopted a cautious and public health-oriented approach to patent protection, aiming to balance innovation incentives with access to affordable medicines. Section 3(d) serves as a key safeguard by denying patents to new forms of known substances unless they demonstrate enhanced therapeutic efficacy. This provision has been instrumental in preventing the misuse of patent rights through incremental innovations that lack substantial clinical benefit. The landmark judgment in *Novartis AG v. Union of India* is analyzed to understand the judicial interpretation of Section 3(d) and its role in curbing evergreening practices.

The research further evaluates whether India's patent regime aligns with its international obligations under TRIPS, which mandates minimum standards of patent protection while allowing member states certain flexibilities. It argues that India has effectively utilized these flexibilities to design a patent system that prioritizes public health without violating TRIPS norms. The study also highlights ongoing debates surrounding the tension between pharmaceutical innovation and accessibility, especially in developing countries.

By critically examining statutory provisions, judicial precedents, and international frameworks, this paper concludes that India's legal stance on evergreening represents a balanced and pragmatic model. It not only discourages trivial patent extensions but also ensures that genuine innovations are rewarded. The analysis underscores the importance of maintaining this equilibrium to promote both technological advancement and equitable healthcare access in the evolving global patent landscape.

INTRODUCTION

The pharmaceutical sector plays a vital role in advancing public health by encouraging the development of new and effective medicines. Patent protection is a key mechanism used to promote such innovation, as it grants inventors exclusive rights over their inventions for a limited period. This exclusivity allows

pharmaceutical companies to recover research and development costs and incentivizes further investment in drug discovery. However, the patent system has also been subject to misuse, particularly through practices aimed at extending monopoly rights without significant therapeutic advancement. One such practice is known as evergreening.

Evergreening refers to the strategy adopted by pharmaceutical companies to obtain additional patents on existing drugs by making minor modifications, such as changes in dosage forms, formulations, or methods of use. While these modifications may be legally presented as new inventions, they often do not result in meaningful improvements in efficacy. As a result, evergreening can delay the entry of generic medicines into the market, leading to higher drug prices and reduced accessibility for patients, especially in developing countries like India.

India's approach to pharmaceutical patent protection is distinct and carefully structured to address these concerns. The Indian Patents Act, 1970, as amended to comply with international obligations, incorporates specific provisions to prevent the abuse of patent rights. Notably, Section 3(d) plays a crucial role in restricting the patentability of new forms of known substances unless they demonstrate a significant enhancement in therapeutic efficacy. This provision reflects India's commitment to safeguarding public health while still encouraging genuine innovation.

At the international level, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets out minimum standards for patent protection that member countries must follow. However, TRIPS also provides flexibilities that allow countries to design their patent laws in a manner that addresses domestic priorities. India has effectively utilized these flexibilities to create a balanced patent regime that seeks to prevent evergreening without violating its international commitments.

This study aims to critically examine the legal framework governing evergreening of pharmaceutical patents in India. It explores the effectiveness of statutory provisions, judicial interpretations, and policy considerations in addressing the challenges posed by evergreening. By analyzing the interplay between national law and international obligations, the research highlights how India has attempted to maintain a delicate balance between fostering innovation and ensuring access to affordable medicines.

Concept and Practice of Evergreening in Pharmaceutical Patents

Evergreening in the pharmaceutical industry refers to a set of legal and strategic practices through which patent holders attempt to extend the duration of their exclusive rights beyond the standard term of protection. This is typically achieved by seeking additional patents on modified versions of an existing drug rather than introducing a completely new invention. Such modifications may include changes in formulation, dosage, method of administration, or even minor chemical alterations that do not significantly enhance the drug's therapeutic value. While these practices may appear to fall within the scope of patent law, they often raise serious concerns regarding their impact on competition and public access to medicines.

The rationale behind evergreening lies in the commercial interests of pharmaceutical companies. Developing a new drug involves substantial investment, extensive clinical trials, and regulatory approvals, all of which require considerable time and financial resources. Once a patent is granted, the company enjoys a period of market exclusivity, usually lasting twenty years. However, as the expiration date approaches, companies may face competition from generic manufacturers, which can significantly reduce profits. To counter this, they engage in evergreening strategies to prolong

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their monopoly, thereby delaying the entry of cheaper generic alternatives into the market.[50]

Common techniques of evergreening include obtaining patents for new salts, esters, polymorphs, metabolites, or combinations of known drugs. In some cases, pharmaceutical companies also patent new methods of using an already known substance or claim novel delivery mechanisms such as extended-release formulations. Although these changes may involve some degree of innovation, they often do not contribute to a substantial improvement in therapeutic efficacy. Consequently, critics argue that evergreening undermines the fundamental objective of patent law, which is to reward genuine innovation rather than incremental or trivial modifications.[51]

In the Indian context, evergreening has been a particularly sensitive issue due to the country's role as a major supplier of affordable generic medicines. Prior to 2005, India did not grant product patents for pharmaceuticals, which allowed domestic companies to manufacture generic versions of patented drugs using alternative processes. However, with the introduction of product patent protection in compliance with international obligations, concerns regarding evergreening became more pronounced. To address this issue, the Indian legislature introduced specific safeguards within the Patents Act, most notably Section 3(d), which restricts the patentability of new forms of known substances unless they demonstrate enhanced therapeutic efficacy.[52]

The interpretation and application of these safeguards have been shaped significantly by judicial decisions. Courts in India have consistently emphasized the need to prevent the misuse of patent law for extending monopolies without genuine innovation. The judiciary has adopted a strict approach in assessing claims related to incremental inventions, thereby reinforcing the legislative intent behind provisions like Section 3(d). This approach ensures that patents are granted only when there is a meaningful contribution to the existing body of knowledge and a tangible benefit to patients.[53]

From a broader perspective, evergreening also raises important ethical and policy considerations. On one hand, pharmaceutical companies argue that incremental innovations can lead to improved patient compliance, reduced side effects, and better drug delivery systems. On the other hand, public health advocates contend that such practices primarily serve commercial interests and hinder access to affordable medicines. This tension highlights the need for a balanced patent regime that encourages innovation while preventing exploitation of legal loopholes.[54]

In conclusion, evergreening represents a complex and often controversial aspect of pharmaceutical patent law. While it is rooted in the legitimate objective of protecting intellectual property, its misuse can have far-reaching consequences for public health and market competition. The Indian legal framework, through its stringent provisions and judicial scrutiny, seeks to address these challenges by distinguishing between genuine innovation and mere extensions of existing knowledge. This distinction is crucial for maintaining the integrity of the patent system and ensuring that it serves its intended purpose of promoting both innovation and accessibility.

Legal Framework Governing Pharmaceutical Patents in India

The legal structure regulating pharmaceutical patents in India is primarily governed by the Patents Act, 1970, which has undergone significant amendments to align with global intellectual property standards. The most notable transformation occurred in 2005, when

[50] F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, World Health Organization, Geneva, 2002.
[51] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford University Press, 2007.
[52] P. Narayanan, *Patent Law*, 4th Edition, Eastern Law House, 2006.
[53] N.S. Gopalakrishnan & T.G. Agitha, *Principles of Intellectual Property*, 2nd Edition, Eastern Book Company, 2014.
[54] Christopher Arup, *The New World Trade Organization Agreements: Globalizing Law Through Services and Intellectual Property*, Cambridge University Press, 2000.

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India introduced product patent protection for pharmaceuticals in compliance with its obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This shift marked a transition from a process-patent regime to a product-patent system, fundamentally altering the landscape of pharmaceutical innovation and access in the country.[55]

Despite adopting international standards, India has carefully crafted its patent laws to safeguard public health interests. The Patents Act incorporates specific provisions that aim to prevent the misuse of patent rights, particularly in the pharmaceutical sector. Among these, Section 3(d) stands out as a crucial safeguard against evergreening. It restricts the patentability of new forms of known substances unless there is a demonstrable enhancement in therapeutic efficacy. This provision ensures that only genuine innovations receive patent protection, thereby maintaining a balance between rewarding inventors and promoting access to affordable medicines.[56]

In addition to Section 3(d), the Act includes other important provisions such as compulsory licensing under Section 84, which allows the government to authorize third parties to produce a patented product without the consent of the patent holder under certain conditions. This mechanism is particularly significant in situations where patented drugs are not available at reasonable prices or in adequate quantities. Such provisions reflect India's commitment to ensuring that patent rights do not override public health needs.[57]

Furthermore, the Indian patent system is supported by judicial oversight, which plays a critical role in interpreting and enforcing statutory provisions. Courts in India have consistently emphasized the importance of strict scrutiny in granting pharmaceutical patents, especially in cases involving incremental innovations. This judicial approach reinforces the legislative intent of preventing trivial modifications from being granted patent protection.

Overall, the Indian legal framework represents a balanced approach that integrates international obligations with domestic priorities. By incorporating safeguards against evergreening and ensuring access to essential medicines, India has developed a patent regime that seeks to protect both innovation and public welfare.

Section 3(d) of the Indian Patents Act: A Safeguard Against Evergreening

Section 3(d) of the Patents Act, 1970 occupies a central position in India's approach to regulating pharmaceutical patents, particularly in preventing the practice of evergreening. This provision explicitly excludes from patentability the mere discovery of a new form of a known substance unless it results in a significant enhancement of therapeutic efficacy. By doing so, it introduces a higher threshold for patent protection in the pharmaceutical sector, ensuring that only inventions demonstrating real clinical advancement are rewarded with monopoly rights.

The legislative intent behind Section 3(d) is rooted in the need to strike a balance between encouraging innovation and safeguarding public access to medicines. Pharmaceutical companies often attempt to extend patent protection by making minor modifications to existing drugs, such as changes in crystalline structure, formulation, or dosage. While these changes may involve technical ingenuity, they do not always translate into improved therapeutic outcomes. Section 3(d) addresses this issue by requiring applicants to prove that such modifications offer a tangible enhancement in efficacy, thereby preventing the grant of patents for insignificant variations.[58]

[55] P. Narayanan, *Patent Law*, 4th Edition, Eastern Law House, 2006.
[56] N.S. Gopalakrishnan & T.G. Agitha, *Principles of Intellectual Property*, 2nd Edition, Eastern Book Company, 2014.
[57] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries*, Zed Books, 2000.
[58] Shamnad Basheer, "India's Tryst with TRIPS: The Patents (Amendment) Act, 2005," *Indian Journal of Law and Technology*, 2005.

The interpretation of "therapeutic efficacy" has been a subject of considerable legal debate. Indian courts have clarified that efficacy must be understood in terms of the drug's ability to produce a desired therapeutic effect, rather than merely improved physical or chemical properties. This interpretation ensures that patent protection is not granted for superficial changes that do not benefit patients in a meaningful way. As a result, Section 3(d) has become a powerful tool in maintaining the integrity of the patent system and curbing attempts to unjustifiably extend patent monopolies.[59]

Moreover, Section 3(d) reflects India's use of the flexibilities provided under international intellectual property law. While the TRIPS Agreement mandates minimum standards of patent protection, it allows member states to define the criteria for patentability within their domestic legal frameworks. India has utilized this flexibility to incorporate public health considerations into its patent regime, thereby ensuring that access to affordable medicines is not compromised.[60]

In conclusion, Section 3(d) serves as a critical safeguard against evergreening by setting stringent standards for patentability. It reinforces the principle that patent protection should be granted only for genuine innovations that offer real therapeutic benefits, thereby aligning the objectives of intellectual property law with broader public health goals.

Judicial Approach to Evergreening in India

The role of the judiciary in India has been instrumental in shaping the legal response to evergreening in pharmaceutical patents. Courts have consistently interpreted patent law provisions with a focus on preventing the misuse of intellectual property rights while ensuring that genuine innovations receive appropriate protection. Through landmark decisions, the judiciary has reinforced the legislative intent behind restrictive provisions such as Section 3(d), thereby strengthening the legal framework against unwarranted patent extensions.

One of the most significant contributions of the Indian judiciary lies in its strict interpretation of patentability criteria, especially in cases involving incremental innovations. Courts have emphasized that minor modifications to existing drugs should not qualify for patent protection unless they demonstrate a clear and substantial improvement in therapeutic efficacy. This approach discourages pharmaceutical companies from seeking patents for trivial changes that do not offer meaningful benefits to patients. By doing so, the judiciary ensures that the patent system remains aligned with its core objective of promoting genuine scientific advancement.[61]

A landmark case that exemplifies this approach is *Novartis AG v. Union of India*, where the Supreme Court denied a patent for a modified version of a known cancer drug on the ground that it did not meet the enhanced efficacy requirement under Section 3(d). The judgment clarified the scope and application of the provision, setting a strong precedent against evergreening practices. It highlighted that improvements in properties such as stability or bioavailability alone are insufficient unless they translate into enhanced therapeutic outcomes. This decision has had a far-reaching impact on pharmaceutical patent jurisprudence in India.[62]

Furthermore, Indian courts have adopted a balanced perspective by recognizing the importance of both innovation and public health. While they do not deny patent protection to genuine inventions, they remain cautious about granting monopolies that could restrict access to essential medicines. Judicial scrutiny thus acts as a safeguard against the exploitation of legal loopholes, ensuring that

[59] P. Narayanan, *Patent Law*, 4th Edition, Eastern Law House, 2006.
[60] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford University Press, 2007.
[61] N.S. Gopalakrishnan & T.G. Agitha, *Principles of Intellectual Property*, 2nd Edition, Eastern Book Company, 2014.
[62] Aparna Viswanathan, *Intellectual Property Law in India: Law and Practice*, Oxford University Press, 2016.

patent rights are not used to undermine public interest.[63]

In conclusion, the Indian judiciary plays a crucial role in curbing evergreening by applying strict standards of patentability and upholding the principles of fairness and public welfare. Its decisions have significantly contributed to maintaining a balanced patent regime that supports innovation while safeguarding access to affordable healthcare.

TRIPS Agreement and Its Impact on Pharmaceutical Patent Regulation in India

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has played a transformative role in shaping the global intellectual property regime, particularly in the field of pharmaceutical patents. As a member of the World Trade Organization (WTO), India is bound by the obligations set out in TRIPS, which establish minimum standards for the protection and enforcement of intellectual property rights. The incorporation of these standards into domestic law significantly influenced India's patent framework, especially with regard to pharmaceutical inventions.

Prior to the implementation of TRIPS, India followed a process-patent regime under the Patents Act, 1970, which allowed only the patenting of manufacturing processes and not the pharmaceutical products themselves. This system enabled domestic manufacturers to produce generic versions of patented drugs using alternative methods, thereby ensuring affordability and accessibility. However, with the coming into force of TRIPS, India was required to introduce product patent protection for pharmaceuticals. This transition was completed through the Patents (Amendment) Act, 2005, marking a significant shift in the country's intellectual property landscape.[64]

Despite mandating product patents, TRIPS provides certain flexibilities that allow member states to tailor their patent laws according to national priorities. These flexibilities include provisions related to compulsory licensing, parallel importation, and the definition of patentability criteria. India has effectively utilized these flexibilities to design a patent regime that balances innovation with public health concerns. For instance, the inclusion of Section 3(d) reflects India's effort to prevent the grant of patents for trivial modifications, thereby curbing evergreening practices while remaining compliant with TRIPS obligations.[65]

Another important aspect of TRIPS is its emphasis on the protection of public health. The Doha Declaration on the TRIPS Agreement and Public Health, adopted in 2001, reaffirmed the rights of member countries to take measures necessary to protect public health and promote access to medicines for all. This declaration clarified that TRIPS should not prevent countries from addressing public health crises and encouraged the use of flexibilities such as compulsory licensing. India has relied on this framework to justify its patent policies, particularly in ensuring the availability of affordable medicines to its population.[66]

However, the implementation of TRIPS in India has not been without challenges. Critics argue that stronger patent protection can lead to increased drug prices and reduced access to essential medicines, especially in developing countries. At the same time, proponents contend that robust intellectual property protection is necessary to attract foreign investment and encourage innovation in the pharmaceutical sector. This ongoing debate highlights the complexity of balancing competing interests within the framework of international law.[67]

Furthermore, India's approach to TRIPS compliance has often been scrutinized by developed countries and multinational pharmaceutical companies. Concerns have

[63] P. Narayanan, *Patent Law*, 4th Edition, Eastern Law House, 2006.
[64] P. Narayanan, *Patent Law*, 4th Edition, Eastern Law House, 2006.
[65] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford University Press, 2007.
[66] World Trade Organization, *Doha Declaration on the TRIPS Agreement and Public Health*, 2001.
[67] N.S. Gopalakrishnan & T.G. Agitha, *Principles of Intellectual Property*, 2nd Edition, Eastern Book Company, 2014.

been raised regarding the strict patentability standards imposed by Indian law, particularly under Section 3(d). Nevertheless, India has consistently defended its position by emphasizing that TRIPS allows member states the flexibility to define their own standards, provided they meet the minimum requirements. This stance underscores India's commitment to protecting public health while fulfilling its international obligations.[68]

In conclusion, the TRIPS Agreement has had a profound impact on the regulation of pharmaceutical patents in India. While it necessitated the introduction of product patents, it also provided the legal space for India to incorporate safeguards against evergreening and ensure access to medicines. By effectively utilizing TRIPS flexibilities, India has developed a patent regime that seeks to strike a balance between encouraging innovation and addressing public health needs. This balanced approach continues to serve as a model for other developing countries navigating similar challenges in the global intellectual property system.

Impact of Evergreening on Access to Medicines in India

The practice of evergreening has significant implications for access to medicines, particularly in a developing country like India where affordability remains a critical concern. By extending patent protection through minor modifications of existing drugs, pharmaceutical companies can delay the entry of generic alternatives into the market. This delay often results in sustained high prices, making essential medicines inaccessible to a large segment of the population. Consequently, evergreening not only affects market competition but also raises serious public health concerns.

Generic medicines play a crucial role in India's healthcare system by providing cost-effective alternatives to patented drugs. The availability of generics ensures that life-saving treatments are accessible to economically weaker sections of society. However, when evergreening practices are employed, the introduction of these affordable alternatives is postponed, thereby limiting consumer choice and increasing the financial burden on patients. This situation is particularly problematic in cases involving chronic diseases, where long-term treatment is required and high drug prices can lead to treatment discontinuation.[69]

Moreover, evergreening can undermine the effectiveness of government policies aimed at improving public health. India has implemented various initiatives to promote access to affordable medicines, including price control mechanisms and public distribution schemes. However, extended patent monopolies can weaken these efforts by restricting the supply of low-cost alternatives. This creates a tension between intellectual property protection and the state's obligation to equitable healthcare access for its citizens.[70]

From a broader perspective, the impact of evergreening extends beyond individual patients to the healthcare system as a whole. Increased drug prices can place additional strain on public healthcare budgets, limiting the resources available for other essential services. In a country with a large population and diverse healthcare needs, such financial pressures can have far-reaching consequences. Therefore, controlling evergreening is not only a legal necessity but also a policy imperative.

In conclusion, evergreening poses a significant challenge to the accessibility and affordability of medicines in India. By delaying the entry of generic drugs and maintaining high prices, it adversely affects both patients and the healthcare system. The Indian legal framework, through provisions like Section 3(d), seeks to address these challenges by preventing the grant of patents for insignificant modifications.

[68] Christopher Arup, *The New World Trade Organization Agreements*, Cambridge University Press, 2000.

[69] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries*, Zed Books, 2000.

[70] N.S. Gopalakrishnan & T.G. Agitha, *Principles of Intellectual Property*, 2nd Edition, Eastern Book Company, 2014.

Ensuring strict enforcement of these safeguards is essential to protect public health and promote equitable access to medicines.

CONCLUSION:

The issue of evergreening in pharmaceutical patents remains a critical concern within the Indian intellectual property regime. The Indian Patent Act, particularly through Section 3(d), reflects a deliberate legislative effort to strike a balance between encouraging genuine innovation and safeguarding public health. By setting a higher threshold for patentability in the case of incremental pharmaceutical inventions, the law aims to prevent the extension of monopoly rights through minor modifications that do not result in significant therapeutic efficacy.

India's approach stands as a unique model among developing countries, demonstrating how domestic patent law can be aligned with international obligations under the TRIPS Agreement while still prioritizing access to affordable medicines. TRIPS provides flexibility to member states in defining standards of patentability, and India has effectively utilized this space to curb abusive practices such as evergreening. Judicial interpretations, particularly in landmark cases, have reinforced the intent of the legislature by emphasizing that only genuine innovations deserving of protection should be granted patents.

However, the debate is far from settled. Pharmaceutical companies argue that incremental innovations often require substantial investment and contribute to improved drug safety, efficacy, and patient compliance. From this perspective, a restrictive approach may discourage research and development. On the other hand, public health advocates stress that allowing evergreening would delay the entry of generic medicines, thereby affecting affordability and accessibility, especially in a country like India where a large population depends on low-cost drugs.

Ultimately, the Indian framework represents a careful balancing act. It neither rejects patent protection nor allows its misuse. Instead, it promotes a system where innovation must be meaningful and beneficial from a therapeutic standpoint. This approach aligns with the broader constitutional vision of ensuring the right to health and access to essential medicines.

In conclusion, India's legal stance against evergreening, supported by statutory provisions and judicial scrutiny, serves as a robust mechanism to prevent the misuse of patent rights while remaining compliant with international standards. It offers a pragmatic model that other developing nations may consider in addressing similar challenges at the intersection of intellectual property and public health.

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