Journal of
Intellectual Property Rights Law

ISSN: 2582-9742
Volume 6, Issue 1, 2023
DOI (Journal): 10.37591/JIPRL
(January–June)

http://lawjournals.celnet.in/index.php/jiprl/index

Research JIPRL

The Patent Paradox: Unmasking the Abusive Art of Evergreening

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Abstract

Evergreening refers to a controversial practice in the pharmaceutical industry where companies extend the life span of their patents by making minor modifications to existing drugs in order to obtain new patents. This abuse of the patent system has been a subject of intense debate and criticism, as it can hinder innovation, limit competition, and increase health care costs. This research article examines the concept of evergreening and its implications for the pharmaceutical industry, particularly in the context of intellectual property rights and public health. The article explores the different strategies used by pharmaceutical companies to evergreen their patents, such as making slight changes to the chemical structure, formulation, or dosage of an existing drug, or seeking additional patents for new uses or methods of administration. Furthermore, the article discusses the consequences of evergreening on health care systems, patients, and society at large. It highlights how evergreening can delay the entry of generic medicines into the market, leading to higher prices and reduced affordability of essential medications. The article also discusses the ethical implications of evergreening in the context of global health, particularly in low-income countries where access to affordable medicines is critical for public health outcomes. This research article sheds light on the practice of evergreening as an abuse of the patent system in the pharmaceutical industry. It highlights the various strategies employed by pharmaceutical companies to extend their patent monopolies and the legal, ethical, and societal implications of such practices. The article calls for greater scrutiny and regulation of evergreening to promote innovation, competition, and access to affordable medicines for the benefit of public health.

Keywords: Evergreening, pharmaceutical companies, intellectual property rights, public health, abuse of patent system

INTRODUCTION

The purpose of the patent system is to encourage innovation by granting inventors temporary exclusive rights to their inventions. This exclusivity enables inventors to recover their expenses for research and development, while also motivating them to create new and innovative ideas. However, the patent system has been criticized for being vulnerable to abuse, and evergreening is one such practice that has come under scrutiny [1].

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Received Date: April 20, 2023
Accepted Date: April 27, 2023
Published Date: May 10, 2023

Citation: Kriti Sharma. The Patent Paradox: Unmasking the Abusive Art of Evergreening. Journal of Intellectual Property Rights Law. 2023; 6(1): 26–31p.

Evergreening involves extending the exclusivity of a patent by making minor modifications to an existing patented invention. These modifications may include changes in dosage forms, formulations, or administration routes, or the addition of new uses or indications. The purpose of evergreening is to obtain additional patent protection and prolong the period of exclusivity, even though the modifications may not represent significant innovation [2].

Evergreening refers to the practice of extending the patent protection for existing drugs by making

minor modifications to the original drug, such as changing its formulation, dosage, or administration route. These modifications are often referred to as "secondary patents" or "evergreen patents." The primary motive behind evergreening is to maintain market exclusivity and delay or prevent competition from generic drug manufacturers, even after the expiration of the original patent. While evergreening may seem like a legitimate strategy for pharmaceutical companies to protect their investments and recoup research and development costs, it has been widely criticized for being an abuse of the patent system [3].

MEANING OF EVERGREENING PATENTING

"Evergreening patenting" refers to a strategy employed by companies or inventors to extend the life span or exclusivity of a patent for an existing invention, typically in the field of pharmaceuticals or other industries with a significant emphasis on research and development.

The term "evergreening" implies that the patent owner is attempting to keep the patent "green" or active for an extended period of time, similar to how evergreen trees retain their foliage throughout the year. This is achieved through various means, such as obtaining additional patents related to the same invention or making minor modifications to the existing invention and seeking new patents for those modifications [4].

The purpose of evergreening patenting is to maintain a competitive advantage by preventing or delaying generic or competing products from entering the market, thereby extending the period during which the patent owner has exclusive rights to manufacture, use, or sell the invention. However, evergreening patenting has been a subject of controversy, with critics arguing that it can stifle competition, limit access to affordable generic versions of patented products, and hinder innovation by prolonging monopolies.

It's worth noting that the extent to which evergreening patenting is allowed or regulated varies by jurisdiction, as patent laws and regulations differ across countries and regions. In some cases, evergreening practices may be subject to legal challenges or regulatory scrutiny to ensure that they do not unduly hinder competition or access to affordable products.

ETHICAL IMPLICATIONS OF EVERGREENING

Evergreening raises several ethical concerns. One of the main concerns is that it can impede competition and limit access to affordable medicines. When a company obtains additional patents through evergreening, it can prevent generic or biosimilar competitors from entering the market and offering cheaper alternatives. This can result in higher prices for medicines and reduce access, especially in low-income countries where affordability of medicines is a critical issue [5].

Another ethical concern is that evergreening may result in a waste of resources. Patent offices may spend valuable time and resources examining and granting patents for minor modifications that do not represent substantial innovation. This can lead to a backlog of patent applications and delay the entry of truly innovative inventions into the market.

Furthermore, evergreening can raise ethical concerns related to transparency and public health. Some argue that evergreening can be used by pharmaceutical companies to unfairly extend their monopoly and delay the entry of generic or biosimilar medicines, even when the original invention has lost its patent protection. This can limit the availability of affordable medicines, particularly in developing countries, and affect public health outcomes.

IMPACT ON ACCESS TO AFFORDABLE MEDICINES

The practice of evergreening can have a significant impact on access to affordable medicines, especially in developing countries where access to health care and medicines may already be limited.

Extended patent exclusivity through evergreening can delay or prevent the entry of generic or biosimilar medicines, which are usually more affordable, into the market. This can result in higher prices for medicines and limit access, especially for vulnerable populations who may not be able to afford expensive patented medicines [6].

The impact of evergreening on access to affordable medicines has been a contentious issue in global health debates, particularly in the context of access to essential medicines for diseases such as HIV/AIDS, tuberculosis, and malaria [7]. Advocates for affordable access to medicines argue that evergreening can impede the availability of generic or biosimilar versions of essential medicines, which are often more affordable and critical for addressing public health challenges in developing countries [8].

WORKING OF PHARMACEUTICAL PATENT SYSTEM

The pharmaceutical patent system is a legal framework that grants exclusive rights to inventors or entities to protect their new and innovative pharmaceutical inventions for a certain period of time. It is designed to incentivize research and development in the pharmaceutical industry by allowing inventors to recoup their investment in creating new drugs and incentivizing innovation [9].

The following are the main components of the pharmaceutical patent system:

Patentability Criteria

To be granted a pharmaceutical patent, an invention must meet certain criteria, which may vary depending on the jurisdiction. Typically, the invention must be new, non-obvious, and have industrial applicability. This means that the innovation must be new, not readily apparent to a person of ordinary competence in the art, and useful to the pharmaceutical sector [10].

Patent Application Process

To obtain a patent, the inventor or organization responsible for the invention submits a patent application to the appropriate patent office, such as the U.S. Patent and Trademark Office (USPTO) in the United States or the European Patent Office (EPO) in Europe [11]. The patent application typically includes a written description of the invention, including its technical details and how it works, and may also include drawings or other supporting materials. The patent application is scrutinized by the patent office to ascertain whether it satisfies the standards of patentability.

Patent Grant

The patent office examines the patent application to determine whether it complies with the requirements for patentability. A granted patent provides the inventor or entity with the exclusive right to prevent others from making, using, selling, or importing the patented invention without their permission for a specified period, which is usually 20 years from the date of filing the patent application, although the duration may vary by jurisdiction [12].

Patent Enforcement

The patent holder is responsible for enforcing their patent rights. If they believe that someone is infringing on their patent by making, using, selling, or importing the patented invention without their permission, they can take legal action, such as filing a patent infringement lawsuit, to protect their rights. If the patent is found to be valid and infringed upon, the court may issue an injunction to stop the infringing activity and may award damages to the patent holder.

Patent Disclosure

One of the key principles of the pharmaceutical patent system is disclosure. The inventor or company is obligated to reveal their innovation in sufficient detail so that others can copy it after the patent expires in exchange for the exclusive rights granted by a patent. This promotes knowledge sharing and innovation by allowing others to build upon the disclosed invention.

Patent Limitations and Exceptions

There are certain limitations and exceptions to pharmaceutical patents, such as the research and experimental use exception, which allows researchers to use patented inventions for certain purposes, such as conducting scientific research. Additionally, some jurisdictions may provide for compulsory licenses, which allow others to use a patented invention without the patent holder's permission in certain circumstances, such as to address public health needs.

It's important to note that the pharmaceutical patent system can be complex and may vary by jurisdiction, with different rules and regulations in different countries or regions. It is advisable to seek legal advice from a qualified intellectual property professional to navigate the intricacies of the pharmaceutical patent system [13].

LANDMARK CASE ON EVERGREEN PATENTING

The Novartis Case

In 2005 when a condition was inserted in Section 3 (d) of the Patent Act [14] regarding the efficacy of the drug, it was interpreted as to the therapeutic efficacy of the drug and not just the improvements in the physical characteristics or stability of the product. Novartis filed an application before the Chennai patent office related to a drug name GLIVEC which was slightly a different version of its 1993 patent for Anti Leukemia drug [15]. The Assistant Controller of Patent and design, Chennai Patent Office rejected the application under section 3(d). Novartis prayed the Court to declare section 3(d) of Patent (Amendment) Act 2005 [16] non-compliant with the TRIPS Agreement and violative of Article 14 of the Constitution. The entire argument regarding violation of Article 14 Constitution of India was based on arbitrary discretionary power vested in the Patent Controller in determination of enhanced efficacy [17].

The court said that the aim of the patent system is to discourage the extension of the patent after the expiration of the patent term of twenty years so that other firms can produce and market the drug. The Court said that the Amendment was intended to:

- Preventing ever-greening.
- To provide easy access to the denizens of this country for life saving drugs; and
- To discharge their constitutional obligation of providing health care to its citizens.

It is important to note that the judgment was not in contradiction to the patent laws. The court remarkably factored public interest while deciding the case. The right to health is a cause of concern in many parts of the world, one-third population of world does not have access to basic medicines and among this one-third, majority of population lives in African and Asian continent. Since price is one of the major factors in accessibility, this decision was of great significance as it allowed many poor countries to access the patented drug at affordable prices.

CONCLUSION

Evergreening, which refers to the practice of extending the exclusivity of a patent beyond its original term, has been a controversial issue in the realm of intellectual property and patent law. After thorough analysis, it is possible to establish that evergreening is a patent system abuse for various reasons.

First, evergreening often involves obtaining additional patents for minor modifications or improvements to an existing invention, which may not necessarily represent true innovation. This can result in a proliferation of patents that do not contribute significantly to technological advancement or societal benefit, but rather serve to maintain a monopoly and block competition.

Second, evergreening can lead to inflated prices for patented products, as the patent holder retains exclusivity for a longer period. This can limit access to affordable medicines, for example, which can have serious implications for public health and well-being.

Evergreening can also limit competition and impede the creation of new items or technology. By extending the exclusivity of a patent, evergreening can delay or prevent market entry of generic or alternative versions of a patented product, thereby reducing consumer choice and hindering innovation.

Additionally, evergreening can strain the resources of patent offices and the legal system, as they may need to process and evaluate numerous patent applications for minor changes to existing inventions. This can contribute to backlog and delays in the patent system, which may not be in the best interest of inventors, innovators, or the public.

In conclusion, evergreening can be seen as an abuse of the patent system, as it can impede competition, limit access to affordable products, hinder innovation, and strain the resources of the patent system. Balancing the need for innovation and exclusivity with the broader interests of society is crucial to ensure that the patent system is used for its intended purpose of promoting progress and benefiting humanity, rather than being exploited for anti-competitive practices.

REFERENCES

1. Kumar R, Srivastava S, Kumar S. Intellectual property rights: principles and procedures. Meerut, India: Rama Publishing House; 2017.
2. Khandelwal P. (2020) Evergreening patents: a welcome move or hidden enemy. [Online] iPleaders. Available at https://blog.ipleaders.in/evergreening-patents-welcome-move-hidden-enemy/ [Accessed on July 2023).
3. Atkinson JDM, Moodie RS. Legitimate patent extension or patent system abuse? Pharm Pat Anal. 2013; 2 (3): 317–324. doi: 10.4155/ppa.13.24, PMID 24237059.
4. Diganth Raj Sehgal. Ever greening patents—A welcome move or hidden enemy - iPleaders (2020). iPleaders. Online Available from: https://blog.ipleaders.in/evergreening-patents-welcome-move-hidden-enemy/.
5. Bylander J. (2013). The Indian Supreme Court weighs in on "patent evergreening." Health Affairs. Available at https://www.healthaffairs.org/content/forefront/indian-supreme-court-weighs-patent-evergreening [Accessed on July 2023]
6. Gamharter K. Access to affordable medicines and the TRIPS Agreement. Access Affordable Med. 2004: 3–108.
7. Hassoun, N. Global health impact: extending access to essential medicines. Delhi, India: Oxford University Press; 2020.
8. Baxi SM, Beall RF, Yang JS, Mackey TK. A multidisciplinary review of the policy, intellectual property rights, and international trade environment for access and affordability to essential cancer medications. 2019; Global Health. 18; 15 (1): 57. doi: 10.1186/s12992-019-0497-3, PMID 31533850.
9. Moir H, Gleeson D. (2023). Explainer: evergreening and how big pharma keeps drug prices high. [Online] The Conversation. Available at https://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623 [Accessed on July 2023].
10. Rockman HB. Novelty: the invention must be new. In *Intellectual property law for engineers and scientists*. Hoboken, NJ, USA: Wiley Online Library; 2022. pp. 75–86.
11. Abadi HHN, Pecht M. Artificial intelligence trends based on the patents granted by the United States patent and trademark office. IEEE Access. 2020; 8, 81633–81643.
12. Van Norman GA, Eisenkot R. Technology transfer: from the research bench to commercialization: part 1: intellectual property rights—basics of patents and copyrights. JACC: Basic Transl Sci. 2017; 2 (1): 85–97.
13. Mueller JM. No dilettante affair: Rethinking the experimental use exception to patent infringement for biomedical research tools. Wash L Rev. 2001; 76 (1). Available at https://digitalcommons.law.uw.edu/wlr/vol76/iss1/2/ [Accessed on July 2023]
14. Intellectual Property India. (1970). The Patents Act, 1970, § 3, Acts of Parliament, 1970 Available at https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf [Accessed on July 2023]

15. Ecks S. Global pharmaceutical markets and corporate citizenship: the case of Novartis' anti-cancer drug Glivec. Bio Societies. 2008; 3 (2): 165–181.
16. Embassy of India. (2005). The Patent (Amendment) Act, 2005, § 3, Acts of Parliament, 2005. Available at https://www.indianembassyusa.gov.in/ArchivesDetails?id=598 [Accessed on July 2023]
17. Raju P. (2007). The debacle of Novartis patent case in India: strict interpretation of patentability criteria under Article 27 of the TRIPS Agreement. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1030963 [Accessed on July 2023]

