Page 1328 - 1340 **DOI:** *https://doij.org/10.10000/IJLMH.114175*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 6 | Issue 1

2023

Ever Greening of Patents: A Study on Legal Position in India

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ABSTRACT

Pharmaceutical sector is a lifeline for the human population, which suffers from a variety of diseases and health problems. The pharmaceutical sector has a divine obligation to safeguard the health and best interests of patients. Patent protection for a limited length of time incentivizes the time and resources devoted to the development of pharmaceuticals so that corporations can profit from them. In certain instances, however, avarice trumps the obligation of open and fair transfer of information to the public domain, and pharma corporations resort to techniques such as the evergreening of patents to extend the duration of patent protection. Novartis Case which sent shockwaves throughout the world regarding the interpretation of evergreening provisions in India is analyzed at length. This paper examines the notion of patent evergreening and its status in India with a comparative analysis.

Keywords: *Patents, Evergreening, TRIPS.*

I. INTRODUCTION

Evergreening refers to the approach employed by patentees who wish to extend the duration of their patent protection by filing for secondary patents on related or derived technology. At first glance, the concept of evergreening seems antithetical to the core ideas of the patent system, which offer 'new' inventions with limited-term protection. Consequently, the technique of evergreening has been criticized for effectively extending patent protection beyond the initial term despite very minor modifications to the invention. Most frequently, multinational pharmaceutical companies are accused of misusing the patent system in this manner.[3]

Ever greening is defined by Alkhafaji, Trinquart, et al. (2012) as a technique for owners of pharmaceutical products to extend their monopolistic privileges with their products by utilizing a variety of strategies, such as patent laws and small pharmacological adjustments.[4]

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[3] Robert Chalmers, Evergreen or Deciduous? Australian Trends in relation to the 'Ever Greening' of Patents, 30 MULR 31 (2006).
[4] Alkhafaji et al., Impact of Ever greening on Patients and Health Insurance: A Meta Analysis and Reimbursement Cost Analysis of Citalopram/Escitalopram Antidepressants, 10 BMC Medicine 142 (2012).

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Evergreening is defined by Rathod (2010) as a technique through which technology producers, through the use of serial secondary patents and other procedures, maintain their product sales protected for longer periods of time than the law typically permits.[5]

Evergreening is a misuse and abuse of the patent system. It refers to the continuous renewal of patents. It refers to the practice of pharmaceutical corporations pursuing additional patents on small variants of the original medicine - new mechanisms of release, new dosages, new combinations or variations, or new forms, such as transforming a tablet to a capsule, etc. In this method, a little modification is made to an existing product, which is then claimed as a new invention. Typically, drug companies engage in evergreening by submitting new patent applications and modifying existing compounds to demonstrate originality. Ever-greening of patent is a term used to describe practices that have developed in certain countries in which a minor modification to an existing product is made and then claimed as a new invention. The coverage/protection offered by the purportedly fresh innovation is subsequently utilized to extend the patentee's exclusive rights over the product, so prohibiting competition. Typically, these modifications are introduced to blockbuster pharmaceuticals just before their patents expire. Numerous nations, such as Australia and the United States, permit evergreening since their legal requirements for obtaining a patent are quite lax. For decades, several strategies of medication delivery (such as prolonged release) have been understood. When one of these known delivery techniques is paired with a known medicine, however, the patent office deems the combination creative enough to warrant a new 20-year patent. New use patents contribute directly or indirectly to the sustainability of industrialized nations. The United States' low standards for inventiveness and utility enable the patenting of insignificant drugs. According to the National Institute of Health Care Management on Pharmaceutical Innovation, over 75% of patented pharmaceuticals are new forms of known compounds, so preventing competition, extending monopolies, making drugs unaffordable, and negatively impacting the right to health.[6]

Evergreening provides a monetary incentive for the study and development of new, creative medications, according to its proponents. According to critics, it is a reward for non-innovation that negatively impacts public health by hindering the market entry of low-cost generic medications. Patent stacking, according to critics, can deprive patients in low-income nations

[5] Sandeep Kanak Rathod, Ever-Greening: A Status Check in Selected Countries, 7.3 JGM 227 (2010).
[6] Dr. Lisa P. Lukose, Patent Ever Greening: Law and Ethics, 7th International Conference on Information Law and Ethics.

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access to potentially affordable, life-saving therapies.[7]

Patent layering was a non-issue in low-income countries and states with booming generic medication businesses during the majority of the 20th century; patent rules in these countries usually excluded all pharmaceuticals patents.[8] No longer is this the case. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which went into effect in 1995, necessitates all members of the World Trade Organization (WTO) to allow pharmaceutical product patents, and a myriad of intellectual property-related agreements, including over 3,000 international investment agreements (IIAs), protects foreign pharma manufacturers from the exploitation of these patents.[9] Given the current global patent protection structure, governments that desire to restrict patent layering frequently have few options.

This research investigates India's one-of-a-kind rule against patent layering and highlights it as a great system for states who desire to prohibit the practice in an extremely hard regulatory system. This research will examine the international context of evergreening, followed by an examination of the Indian stance on the topic in light of the **"**Novartis Case.**"**

II. INTERNATIONAL SCENARIO

TRIPS

The Uruguay Round of deliberations concluded on January 1, 1995, with the foundation of the WTO, whose members were required to sign the new, legally binding TRIPS agreement. Patents are covered in Section 5 of Part II of this agreement, and Articles 27 and 28 provide pharmaceutical inventors with robust patent protections. Article 27 establishes a limit for patentability requirements by mandating that patents be obtainable "for any inventions... in all fields of technology, provided they are new, inventive, and capable of industrial application."The article seconds that all TRIPS signatories are required to permit pharmaceutical product patents. Article 28, that specifies the rights accorded by a patent, prevents third parties from "manufacturing, using, offering for sale selling, or importing" a patented invention without the patent holder's permission. Thus, it prevents generic drug companies from violating patents for pharmaceutical products. Articles 27 and 28 of TRIPS establish a system of global patent protection for pharmaceuticals. At the beginning of 1995,

[7] Greg Martin, et al., Balancing Intellectual Monopoly Privileges and the Need for Essential Medicines, Globalization and Health (June 12, 2007), available at http://www.globalizationandhealth.com/content/3/1/4 (Last visited on October 22, 2022).
[8] Carlos M. Correa, Public Health and Patent Legislation in Developing Countries, 3 Tul. J. Tech. & Intell. Prop. 1, 2 (2001).
[9] UNCTAD, World Inv. Report 2010: Investing in a Low-Carbon Economy (July 22, 2010), UNCTAD/WIR/2010, 81, available at www.unctad.org/en/docs/wir2010ch3_en.pdf (Last visited October 22, 2022).

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over seventy countries, including Portugal, Brazil, Spain, Mexico, Egypt and India, endorsed the TRIPS agreement. 159 signatories to the TRIPS, Articles 27 and 28 enjoy near-universal authority. Signatories that contravene these Articles or any other portion of the TRIPS agreement may be brought before the WTO's dispute settlement body, which may permit other signatories to enforce retaliating trade sanctions. However, the patent safeguards conferred by Articles 27 and 28 are limited. First, the terms "new," "inventive step," and "industrial application" are not defined in Article 27. Thus, TRIPS signatories are allowed to define these concepts in a manner that makes obtaining pharmaceutical patents more difficult.[10] Second, Article 27 enables patentability exclusions when essential to maintain public order or morality. This exclusion, however, cannot be made "just because the exploitation is restricted by [a state's] law"; rather, it must be tied to a comprehensive restriction on the commercialization of the prohibited invention. This is a fairly limited restriction, as it only permits TRIPS members to restrict pharmaceutical product patents if all pharmaceuticals in the nation are manufactured and distributed noncommercially. In addition, the decision of a signatory to utilize this exclusion is subject to review by a WTO tribunal.[11] Thirdly, Article 31 of TRIPS restricts the applicability of Article 28 by permitting signatory states to implement compulsory licencing programmes for patents if certain circumstances are met. When a government licences or authorises a third party to licence a patent holder's exclusive right to use, produce, import, or sell its patented invention without the patent holder's approval, this is known as compulsory licencing.[12] Article 31 permits TRIPS signatories to licence the product patents of branded medication producers to generic drug companies without the former's approval, for reasons such as poverty or high illness prevalence. However, signatories who engage in compelled licencing must give patent holders "appropriate compensation."

Though TRIPS enables brand-drug producers with a level of international patent protection never before seen, this protection has limitations. The aforementioned restrictions demonstrate that TRIPS signatories have multiple measures at their disposal to limit drug makers' market exclusivity. Low-income TRIPS signatories are likely to utilize the following: Proposed by a number of low-income nations, the Doha Declaration of 2001 states that the TRIPS agreement "may and should be read and implemented in a manner supportive of WTO members' right... to encourage access to medicines for all."[13]

[10] UNCTAD-ICTSD, Resource Book on Trips and Development, 359–61 (2005).
[11] Kevin J. Nowak, Note, Staying within the Negotiated Framework: Abiding by the Non-Discrimination Clause in TRIPS Article 27, 26 MICH. J. INT'L L. 899, 917 (2005).
[12] World Trade Org., Glossary Term: Compulsory Licensing, http://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm (Last visited on October 23, 2022).
[13] Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2 (Nov. 14,

USA

The research-intensive pharmaceutical business in the United States is the most competitive and successful industry in the world and one of the country's industrial crown jewels. Its devotion to research and development is unprecedented, resulting in an astonishing array of innovative biomedical medicines, which is one of the main reasons for its success. The safeguarding of intellectual property is fundamental to the industry's survival.[14]

Under 35 U.S. Code § 101, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Three categories of patents exist: utility, design, and plant. The majority of patents of importance in the pharmaceutical industry are utility patents. Utility patents cover the invention of new compositions of matter (such as new medications), devices, and processes, as well as their enhancements. In the chemical and pharmaceutical fields, there are various types of inventions, including substances, compositions, manufacturing processes, and uses. In addition to being patentable, new synthetic techniques are usually cost-saving as they are streamlined and enhanced. Process patents may also have the benefit of extending the life of a composition patent by making the original process more difficult and expensive to utilize and by maintaining exclusivity over more cost-efficient techniques. Inventing new uses for current products is also patentable.[15]

Australia

Prior to the implementation of the AUSFTA, it was permissible to participate in so-called evergreening and to seek an extension of protection for the original patent's terms. Since 1998, the Patents Act 1990 has included the possibility to request a five-year extension for pharmaceutical material patents with a limited-term extension provision for drug patents. This specific extension is viewed as recompense for the lengthy regulatory approval procedure and safety testing to which new pharmaceuticals are subjected, and is a standard component of many patent regimes. This extension was never, however, available for a 'use' claim. In *Boehringer Ingelheim International v. Commissioner of Patents*, [16] the Federal Court of Australia

2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [hereinafter "the Doha Declaration"]. (Last visited on October 23, 2022).

[14] Gerald J. Mossinghoff and Thomas Bombelles, Intellectual Property Protection and The Pharmaceutical Industry, available at http://www.oblon.com/publications/intellectual-property-protection-and-the-pharmaceutical-industry/ (Last visited on November 3, 2022).

[15] Dennis B. Worthen, American Pharmaceutical Patents from a Historical Perspective, 7.6 IJPC 38 (2003).

[16] [2001] AIPC 91-670.

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interpreted the phrase "pharmaceutical per se" to impose this restriction. Australian Patent Office procedures now explicitly reflect this, including some specific examples of claims to which applications for term extensions will be rejected as non-compliant. The so-called 'ever greening' of pharmaceutical patents has become an issue of major public concern in the wake of the Australia–United States Free Trade Agreement and the amendments it requires to the Therapeutics Goods Act 1989. The effect of these amendments was to place additional obligations on manufacturers of generic (unpatented) pharmaceuticals. Some additional provisions were also included in an attempt to safeguard against potentially 'illegitimate' patent infringement action taken by patentees against such manufacturers.[17]

III. INDIAN POSITION ON EVERGREENING

India's existing patent rules are intrinsically linked to its aim, following independence from the United Kingdom, to construct a patent system that prioritizes its country-specific objectives over Western objectives. The Indian Patents Act of 1970 (1970 Act) expressly forbade patenting of pharmaceutical products, but permitted patenting of pharmaceutical compound-making procedures.[18] The 1970 Act was a deliberate attempt to revive the lagging Indian economy by encouraging indigenous drug production.[19] The Ayyangar Committee Report, a 1959 report commissioned by the Indian government, advocated that "underdeveloped" countries such as India establish patent law protections that would safeguard them against profiteering by developed nations.[20] Without product patents, Indian enterprises were able to produce, distribute, and use foreign-invented pharmaceuticals at extremely low prices. The generic medication sector in India flourished over the next three decades, profiting on innovations by multinational corporations (MNCs) that were unable to obtain patents under Indian legislation. India's growing generic pharmaceutical sector and export of generics earned it the moniker "pharmacy of the world." In 1995, however, India attempted to become one of the WTO's founding members, which changed the course of events. Although it opposed a pact guaranteeing broad intellectual property rights and urged that patent protection be suited to a country's degree of economic advancement, it ultimately signed TRIPS as a condition of entering the WTO because of fear of export restrictions if it did not. However, India negotiated a transitional period until January 1, 2005, during which it was mandated to bring its patent system into strict conformity with TRIPS. India enacted the Patents (Amendment) Act of 2005

[17] Supra Note 1.
[18] Linda L. Lee, Trials and TRIPS-ulations: Indian Patent Law and Novartis A.G. v. Union of India, 23 BERKELEY TECH. L.J. 290-291 (2008).
[19] Ibid.
[20] N. Rajagopola Ayyangar, Government of India, Report on the Revision of the Patent Law 19-20 (1959).

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(2005 Amendment) in 2005 in an effort to comply with the TRIPS. The 2005 Amendment authorised the patenting of pharmaceutical items, among other things. Nevertheless, Section 3(d) limited the development of pharmaceutical patents by prohibiting the patenting of the mere discovery of a new form of a known substance that does not result in 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. According to the 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 a known substance shall be considered to be the same substance unless they differ significantly in efficacy-related properties. As has been explained ad nauseam in the literature, the goal of this clause is to limit "evergreening."[21]

Numerous generic drug manufacturers, patients associations, as well as non-governmental organisations (NGOs) such as Lawyers Collective and Medicines Sans Frontières (MSF) have touted Section 3(d) as crucial to preventing the 2005 Amendment's negative effect on patients access to affordable generic medicines. Once the initial patent on the active pharmaceutical ingredient expires, section 3(d) assures that generic producers are permitted to sell subsequent versions of a medicine. Since Novartis never won a first patent in India on imatinib free base, generics producers are allowed to manufacture generic Glivec. Generic businesses are able to market the drug at far lower pricing than Novartis since they did not expend substantial costs on research and development creating and gaining approval for the drug.

A detailed analysis of the ***Novartis AG v. UOI***[22] which has drawn the world's attention to Section 3(d) is discussed below.

IV. NOVARTIS AG V. UOI & EVER GREENING

(A) Facts of the case

Jürg Zimmermann created several derivatives of N-phenyl-2- pyrimidineamine, one of which being CGP 57148 in its free base form (later granted the Global Non-proprietary Name "Imatinib" by the World Health Organization). Such derivatives, including Imatinib2, are able to inhibit certain protein kinases, particularly protein kinase C and PDGF (platelet-derived

[21] Lisa Latrimore Ouellette, How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing 17 MUCH. TELECOM. & TECH. L. REV. 299, 304-05 (2010).
[22] AIR 2013 SC 1311.

growth factor)-receptor tyrosine kinase, and consequently are precious anti-tumor characteristics and can be utilized in the preparation of pharmacological compositions for the treatment of warm-blooded animals, such as anti-tumor drugs and anti-atherosclerosis drugs. The patent for the N-phenyl-2-pyrimidine-amine derivatives, including Imatinib, was issued on May 28, 1996. (US Patent No. 5,521- the Zimmermann Patent). The Zimmermann compounds (N-phenyl-2-pyrimidine-amine derivatives) were also given a European patent (Patent No. EP-A-0 564 409).

Application No.1602/MAS/1998) for grant of patent for Imatinib Mesylate in beta crystalline form was subsequently filed in India on July 17, 1998 at the Chennai Patent Office. The application asserted that the beta crystal form of Imatinib Mesylate has (i) more favourable flow properties; (ii) better thermodynamic stability; and (iii) lower hygroscopicity than the alpha crystal form. Further, it was asserted that the aforementioned characteristics made the product "new" and dominant because it "stores better and is easier to process;" has "better processability of the methanesulfonic acid addition salt of a compound of formula I" and has "additional processing and storage advantages." Briefly, Novartis submitted an application to the Chennai patent office for a medicine called GLIVEC, which was a slightly modified version of its 1993 anti-leukemia drug patent.

Even before patent application was considered, the appellant filed an application (Application No. EMR/01/2002) for exclusive marketing rights (EMR) under the former section 24A of the Patent Act on March 27, 2002, and on November 10, 2003, EMR was awarded. The patent application was removed from the "mailbox" for examination only when the Patents Act was amended effective January 1, 2005. In accordance with section 25(1) of the Act, the application had garnered five pre-grant oppositions at that point. On 15.12.2005, the Assistant Controller of Patents and Designs denied the patent application under section 3(d) on the grounds that (i) the invention claimed by the appellant was anticipated by a prior publication, namely the Zimmermann patent, and (ii) the invention claimed by the appellant was obvious to a person skilled in the art in view of the disclosure in the Zimmermann patent specifications.

(B) Decision of High Court of Madras

Against the orders, the Madras High Court received a writ. Novartis petitioned the court to rule that section 3(d) of the Patent (Amendment) Act 2005 to be in violation of the TRIPS Agreement and Article 14 of the Constitution. The issue about Article 14 of the Indian Constitution was founded on the Patent Controller's arbitrary discretion in determining improved efficacy. The Madras High Court affirmed the constitutionality of section 3 (d) by

determining that "efficacy" means "therapeutic efficacy." While rejecting the writ petitions challenging section 3(d) of the Act, the High Court made the following observation: "When the Appellant was holding the right as EMR on GLEEVEC, it charged Rs.1,20,000/- per month for a requisite dose of the medication from a cancer patient, which, in our opinion, is too expensive for the poor cancer patients in India. In addition, it was observed that granting a patent towards this application could wreak havoc on the lives of poor cancer patients and their family members for whom this treatment is useful. This will also have terrible effects on society. In considering all of the facts of the appeals the Court concluded that the Appellant's alleged invention is not deserving of a product patent on the grounds of its challenged application, not only due to not fulfilling the precondition of section 3(d) of the Act, but also for its possible catastrophic results on such grant as stated above, which also is being drawn by the provisions of section 3(b) of the Act, which restricts the granting of patents on inventions which are not novel or inventive. The Court stated that the purpose of the Amendment was to avoid evergreening, enable individuals with convenient access to life-saving pharmaceuticals, and fulfil their constitutional commitment to provide health care to its citizens.

(C) Decision of IPAB

In the same case, the Intellectual Property Appellate Board (IPAB) determined that section 3(d) of the Act invalidated the patentability of the relevant product. As India is requiring a higher bar of inventive step by implementing the modified section 3(d) of the Act, patentable inventions in other jurisdictions are not patentable in India. The purpose of the modified section 3(d) of the Act is to mandate a higher threshold of inventive step in the statute, especially for drug/pharmaceutical products.

(D) Decision of Supreme Court

Article 136 of the Constitution was invoked to dispute the IPAB's order before the Supreme Court. The court exhaustively interpreted section 2(1)(j) defining invention as "a new product or process involving an inventive step and capable of industrial application" and section 2(1)(ja) defining inventive step as "a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and makes it not obvious to a person skilled in the art," and determined that Imatinib Mesylate did not qualify the definition of invention.

On appeal, the Supreme Court of India rejected the argument that section 3(d) is an ex majore cautela provision and an exemption to clauses (j) and (ja) of section 2(1) of the Act. As stated by the court, the amended segment of section 3(d) clearly establishes a second tier of qualifying

standards for chemical substances/pharmaceutical products so as to open up the door for true and genuine inventions while preventing any endeavour at repetitive patenting or extension of the life of the patent on sham grounds. By giving a purposeful interpretation of subsections (j) and (ja) of section 2(1) in conjunction with sub-section 3(d), the court determined that the Act sets different criteria for qualifying as "inventions" things belonging to various classes, and for medicines and drugs and other chemical substances, the Act raises the invention threshold by consequence of the 2005 amendments to subsection 3(d).

The Supreme Court determined that the Zimmemmman patent and the newly claimed chemical are substantially identical. Regarding the issue of "efficacy," the court remarked that the measure of efficacy would rely on the product's function, utility, or intended use. In the event of a drug that professes to cure a condition, the only applicable test of efficacy is therapeutic efficacy. The court was of the belief that a drug's 'therapeutic efficacy' must be evaluated strictly and narrowly. Concerning the issues of 'enhancement of the known efficacy' and the explanation that requires the derivative to 'differ significantly in properties relating to efficacy,' the court stated that not every advantageous or beneficial properties are significant, but only those properties that relate directly to efficacy, which in the case of a pharmaceutical, is its therapeutic efficacy. The mere change of shape with qualities inherent to that form just wouldn't constitute as a "enhancement of efficacy" for an existing substance. This section describes what should not be deemed therapeutic efficacy.

In ***Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design,***[23] The Delhi High Court ruled that the direct compression method for manufacturing a solid form (tablet) of a pre-existing drug is not patentable. The Court has affirmed the Respondent's argument that the Appellant's application relates to a tablet form of the compound Tofogliflozin, wherein the tofogliflzin is present in the form of monohydrate crystal, and the said compound Tofogliflozin is a pre-existing drug in the prior art; therefore, the application is neither a new product nor a new process.

Therefore, it can be observed from the above decisions that Indian Courts have a very strong approach towards preventing evergreening of patents under the Indian Patent laws.

V. ARGUMENTS FOR AND AGAINST EVER GREENING

Proponents of patent layering as well as other sorts of patent evergreening argue that it incentivizes pharmaceutical invention, so encouraging drug producers to make the substantial

[23] C.A.(COMM.IPD-PAT) 4/2021, Delhi High Court. Date of Judgment: 6th April, 2022.

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investments required to discover new, novel medicines. Advocates of patent evergreening also stress the incremental nature underlying pharmaceutical innovation. A patent structure that permits drug companies to protect incremental innovations enables them to pursue aspirational research goals, with the confidence that a series of patents would safeguard every step of the process.[24]

These reasons are dismissed by opponents of patent evergreening. First, they note that enhanced patent protection for pharmaceutical inventors doesn't really result in greater innovations. It has resulted in a reduction in the development of new chemical entities for pharma use over the past decade, despite the fact that the TRIPS agreement has guaranteed branded drug manufacturers an unfathomable level of global patent protection.[25]

Secondly, critics point out that the majority of newly patented chemical entities don't really reflect genuine therapeutic invention, but rather produce therapeutic effects equivalent to those of old drugs; it is dubious whether such "incremental innovations" inevitably result in new therapeutic breakthroughs.[26]

Thirdly, sceptics argue that even though pharmaceutical invention is resource-intensive, drug makers have ample resources to pursue such innovation irrespective of whether patent evergreening is permitted. According to a study published in the British Medical Journal, branded drugs companies devote an average of 1.3% of their earnings to the discovery of new cures, relative to 25% for marketing. The analysis demonstrates that while the expense of drug research has increased substantially over the previous decade, drug industry revenues have surged six times more rapidly.[27] For opponents of patent evergreening, though, the market exclusivity afforded to a medication by a single patent is more than sufficient compensation for pharmaceutical inventors.

Evidence that evergreening procedures may have harmful consequences for public health strengthens the case against patent evergreening. Patent evergreening methods prevent generic medication makers from manufacturing reverse-engineered replicas of branded drugs by

[24] Albert I. Wertheimer and Thomas M. Santella, Pharmacoevolution: The Benefits of Incremental Innovation, IPN Working Papers on Intellectual Property, Innovation and Health 3, available at http://www.who.int/intellectualproperty/submissions/Pharmacoevolution.pdf (Last visited on November 4, 2022).
[25] Aaron S. Kesselheim & Jerry Avorn, Using Patent Data to Assess the Value of Pharmaceutical Innovation, 37 J.L. MED. & ETHICS 176, 176 (2009).
[26] Bruce M. Psaty & Rita F. Redberg, Evidence of Pharmaceutical Innovation and Therapeutic Enthusiasm, 172 ARCHIVES OF INTERNAL MED. 683, 683 (2012).
[27] Donald W. Light & Joel R. Lexchin, Pharmaceutical research and development: what do we get for all that money?, BRITISH MED. J. ONLINE (Aug. 7, 2012), available at http://www.bmj.com/content/345/bmj.e4348?ijkey=Y1g4ZVUImIbtXOI&keytype=ref. (Last visited on November 6, 2022).

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extended pharmaceutical inventors market exclusivity.[28] Generic medications are less expensive than the branded counterparts partly as their makers do not have to engage in the research, development, and marketing of original drugs,[29] however, because the release of these medications generates competition in the market among drug producers.[30] Therefore, an action that hinders the entry of generic pharmaceuticals to a market will maintain high drug costs for consumers and impede their access to potentially life-saving therapies. This effect is especially evident in low-income countries.

Countries might resist patent evergreening for reasons outside medicine accessibility. Low- or middle-income nations with booming generic medication industries, such as India, China, and Brazil, may wish to restrict patent evergreening in order to allow local generic drug manufacturers to issue reverse-engineered replicas of these goods without fear of legal repercussions. Advocates for and opponents of patent evergreening have their concerns known on the national arena of many major economies. Worldwide, however, high-income nations with established branded drugs companies support patent evergreening, while low-income nations particularly those with indigenous generic drug industries and non-governmental organizations working on drug accessibility issues oppose such practices.[31]Through bilateral and international trade and investment agreements, countries that support patent layering, such as the United States, have helped build the current global patent protection framework, which offers branded pharma producers with unparalleled levels of patent protection. Nations that function in this environment, but desire to limit patent layering, must enact anti-layering legislation that complies with their commitments under these agreements, also as countries that support patent layering press for new international treaties that more consciously protect the practice.

VI. CONCLUSION

The patent system offers the essential incentives for research expenditure and encourages innovators to engage in new fields of R&D, hence fostering further innovation. Nonetheless, critical areas such as public health should be given priority, and governments must employ the TRIPS flexibilities to exclude/revoke patents in order to defend public health.

The Novartis case demonstrates that India will no longer accept patents to be renewed

[28] Christine S. Paine, Brand-Name Drug Manufacturers Risk Antitrust Violations By Slowing Generic Production Through Patent Layering, 33 SETON HALL L. REV. 479, 506 (2003).
[29] Ganapati Murdur, Indian Patients Go to Court Over Cancer Drug, 329 BMJ 419 (2004).
[30] Henry G. Grabowski and Margaret Kyle, Generic Competition and Market Exclusivity Periods in Pharmaceuticals, 27 MANAGERIAL DECISION ECON. 491, 491 (2007).
[31] Susan K. Sell, TRIPS-Plus Free Trade Agreements and Access to Medicines, 28 LLR. 41 (2007).

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indefinitely at the risk of public health and at the expense of poor patients. The decision sends a clear message to the international community that India will only grant pharmaceutical corporations an extended market monopoly if a medicine is truly new and entails substantial innovation. The judgement prevents pharmaceutical corporations from seeking evergreening of patents in India by prolonging patents on well-known pharmaceuticals, delaying the emergence of inexpensive generic alternatives. It would undoubtedly expedite the introduction of generic versions of other drugs to the market. The impact would not only be felt in India, but also in the developing nations that rely on Indian generic versions. Novartis is a precedence for establishing the patentability of "minor modifications in other nations. No legal system should allow the skillful drafting of claims by pharmaceutical behemoths to determine the scope of patent law. The judgement states: “We certainly do not wish the law of patent in this country to develop along lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not by the intrinsic value of the invention but by the artful drafting of its claims by skilled lawyers; and where patents are traded as a commodity not for the production and marketing of the patented products but to search for someone who will produce and market the patented products.”

Thus, the Novartis court did not oppose patent law. The Novartis decision is not in conflict with the patent laws. The court's decision was based solely on public interest and public health. In many regions of the world, the right to health is a major problem. One-third of the world’s population does not have access to essential medicines, with the majority of this population living in Africa and Asia. Due to the fact that price is one of the primary determinants of accessibility, this decision was of tremendous importance as it permitted many developing nations to purchase the patented drug at reasonable costs.

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 [ISSN 2581-5369]