EXPLOITATION OF PATENTS: A STUDY OF EVERGREENING IN THE PHARMACEUTICAL DOMAIN

Dherya Maheswari[*]

Abstract

Inventors can protect their innovations and financial interests by obtaining patents, which require full disclosure of the invention in exchange for exclusive rights to use and profit from it for a limited period of time before it becomes a part of public domain. Particularly in the high-revenue pharmaceutical industries, monopolies over patent rights are increasingly being maintained after the expiration of the first patent. This research examines how patent rights are misused by inventors, notably in the pharmaceutical industry. As a result, this paper starts with an explanation of the idea of "evergreening", the TRIPS perspective on it, and what evergreening strategies are frequently used by branded pharmaceutical companies as a strategy to get around current patent laws and reduce competition from generic drugs. It will then explore the Indian perspective, which has managed to somewhat limit evergreening and explores its infamous Novartis case. The paper would further examine if there are any remaining areas where the legislature may attempt to strike a balance between the public interest and private rights while preventing evergreening. The paper closes with the suggestions which might be taken into account for consideration.

Keywords: Evergreening, Pharmaceutical, Monopoly, Balance of Rights, Novartis, Strategies, Exploitation.

1. Introduction

It is well acknowledged across the world that innovation is critical for competitive advantage, value creation, and sustainable growth. In the age of globalisation, the rate of expansion of innovation has also accelerated in order to generate value-added products to fulfil the world's ever-increasing needs. As a result, policymakers have recognised this crucial part of the invention by granting patent rights to these innovators.

In simple terms, a patent is an exclusive right granted by the authorities to an inventor for a certain period of time, which allows the inventor to prevent others from

[*] B.A. LLB(H), 4th year Student, Bennett University, Times of India Group.

selling, making, or using the invention without their permission. approach tries to strike a balance between rewarding innovation and promoting progress by encouraging knowledge diffusion through disclosure. These short-term monopoly rights allow the innovator to commercially utilise his or her innovation, providing an incentive for disclosure. The revelation of these innovations to the public, in turn, enables others to build upon and improve them, further driving innovation and progress. After the monopoly term expires, others are allowed to utilise or commercialise the innovation which was made simpler through disclosure.

After years of massive investment in both time and resources, branded pharmaceutical firms harness all of their efforts to enjoy the bountiful rewards and profits as their patented product transits from "on the shelf" to "off the shelf".[1] However, the innovative organisation can only utilise this chance for the next 20 years,[2] after which the formula enters the generic market where the price drops steeply. When a patent expires, generic versions of the medicine enter the market, making significant inroads into the sales of brand-name pharmaceuticals. Pfizer, for instance in 2011, stands to lose an estimated $10 billion in annual revenue when the patent term on its blockbuster drug Lipitor expires and generic firms cut into its blockbuster sales.[3]

As a result, it is critical for pharmaceutical firms to extend the life cycle or the monopoly rights of their products as much as feasible. The practice by which they attempt to extend their monopoly rights is known as evergreening which has evolved as an enabling strategy among large pharmaceutical firms for the life-cycle management of their medicines in order to keep their profits high from their products.

2. Concept of Evergreening in the Pharmaceutical Domain

Although not a legally recognized concept, the phrase "evergreening" refers to the various ways that patent holders of pharmaceutical drugs utilise the patent laws to prolong their monopoly rights beyond the regular legal specific timelines, particularly

---

1 G. Dwivedi, S. Hallihosur, *et. al*., "Evergreening: A deceptive device in patent rights", 32 *Technology in Society* 324-330 (2010).

2 World Intellectual Property Organisation (WIPO), FAQ, "Patent protection is generally granted for the term of 20 years" *available at:* https://www.wipo.int/patents/en/faq_patents.html#:~:text=Patent%20protection%20is%20granted%20for,Patents%20are%20territorial%20rights., (last visited on October 16, 2022).

3 Duff Wilson, "Drug Firms Face Billions in Losses in '11 as Patents End", *New York Times* (March 6, 2011) *available at*: https://www.nytimes.com/2011/03/07/business/07drug.html, (last visited on October 16, 2022).

over highly profitable pharmaceuticals. While most of these evergreening tactics adhere to the letter of the law, a lot of the time they appear to go against the original intent of the patent laws. By establishing private monopolies that abuse the patent system and negatively impact vulnerable groups of the population who cannot afford necessary medications, the deceptive device known as "patent evergreening" in patent rights is accused of preventing the market from receiving cheaper, generic versions of medicines.[4] Generic versions of medicines are essentially the same as the original branded drugs in terms of their efficacy, quality, and safety, but are sold at significantly lower prices, making them accessible to a wider range of people.

Evergreening can be referred to as steps taken by pharmaceutical patent owners to essentially prolong the period of their patented drugs by including changed versions of the same medication, new methods for delivering the medication, new applications for the medication, and similar things.[5] Ever-greening is a tactic adopted by pharmaceutical companies to recoup high expenditures incurred by them in Research and Development as well as a way of protecting any minimal changes that are purposefully made to the parent patent in order to obtain different patents on the same drug and thus creating a monopoly by extending the time period.[6] Thus, prolonging the patent protection term hinders or delays the arrival of generic versions of the medicine, and keeps the patients away from access to affordable medicines.

3. TRIPS Perspective on The Pharmaceutical Patents

The General Agreement on Tariffs and Trade (GATT) Uruguay Round negotiations between 1986 and 1994 resulted in the most major agreement on international trade policy, which is known as Trade-Related Aspects of Intellectual Property Rights.[7] With the aim of fostering technological transfer, technological innovation, and technology dissemination to the mutual benefit of innovators and

---

4 Marta Radelli, "Patent evergreening technological advancement and abusive commercial practices. Availability of essential medicine in the case of access to insulin", 2 *Queen Mary Law Journal* 66 (2021).

5 J.R. Thomson, "Patent "Evergreening": Issues in Innovation and Competition", *Congressional Research Service* 7 (2009).

6 Arun Kumar, Arun Nanda, "Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries", 6 *Pharmaceutical Regulatory Affairs* 2 (2017).

7 Mani Abinaya K, "What is the Impact of TRIPS on Pharmaceutical Industry in India? A Comprehensive Analysis", *Academike*, August 2, 2021, *available at*: https://www.lawctopus.com/academike/impact-of-trips-on-pharmaceutical-industry/#_ftn1, (last visited on October 17, 2022)

consumers of technological knowledge, as well as in a way that promotes socio-economic welfare and creates a balance of rights and duties,[8] TRIPS establishes the minimal degree of assurance for intellectual property rights that must be adhered to by the member countries.

The developing countries even though have to sign the agreement pursuant to international pressure, they argued that it is not a beneficial bargain as the new conditions in the TRIPS agreement will lead to an increase in the price of pharmaceutical patents which will ultimately lead to inaccessible of medicines to common masses. For instance, the Indian Patent Act of 1970, which was amended in 2005 in accordance with the TRIPS agreement, only recognised process patents, not product patents.[9] Due to the granting of process and product patents after 2005, generic pharmaceuticals were not allowed to reverse engineer and thus affecting their market.

Even though TRIPS is not considered a beneficial bargain, it cannot be completely criticised either. Different provisions of the agreement reflect liberal treatment towards developing countries and strive to strike a balance between rights and duties, paving the path for the achievement of broader public policy objectives, such as ensuring access to vital medicines. For instance, Article 7 aims to maintain a balance between innovation and socio-economic welfare, Article 8 gives States the liberty to incorporate the measures required to protect public health and to advance public importance in fields crucial to their socio-economic status and technological development, and Article 27(2) enables a State to impose restrictions on the patentability of inventions based on a variety of factors, such as a hazard to human health or life. Furthermore, Article 30 gives member states the limited exemptions to grant exclusive rights provided that they do not unreasonably exploit the rights of the patentee and Article 31 provides the list of conditions where a law of a member state to TRIPS Agreement can allow the use of particular subject-matter without the consent of the patent holder. These articles also serve as the foundation for compulsory licencing, which is the

[8] The TRIPS Agreement, art. 7.
[9] The Patents (Amendment.) Act, 2005 (Act 15 of 2005), s.5.

act of a government providing a licence to utilise a patent without the patent owner's consent.[10]

From the discourse above, it is apparent that the TRIPS Agreement seeks to preserve a balance between innovators and the socio-economic welfare of the public, however, brand-name pharmaceutical companies abuse the patent provisions utilising different tactics that are covered in the section below.

4. Evergreening Strategies Followed by Pharmaceutical Companies

To overcome the constraints of generic competition, pharmaceutical firms have been relying on the strategic use of the patent system in recent years. Some patent term extension or evergreening strategies usually followed by pharmaceutical companies globally include:

4.1 The Hatch-Waxman Act: 30 Months Stay Provision in USA

In the United States, every new drug authorised by the FDA (Food and Drug Administration) is published in a publication referred to as the "Orange Book", which is used as a reference by generic companies looking to manufacture their own generic variants.[11] The Hatch-Waxman Act mandates these generic firms to file an ANDA i.e., Abbreviated New Drug Application, if they want to market their generic equivalents. The Act provides for "Para IV Certification" if the patent is invalid or will not be infringed by the generic producer. Using the Para IV Certification, the generic manufacturer must notify the patentee of its decision, and the brand name company or patentee has 45 days to contest the generic application.[12] If the brand name firm chooses to contest, the Hatch-Waxman Act automatically places a 30-month stay on the generic approval.[13] The purpose of this stay provision was to settle the dispute between the parties, but it is seen that brand name companies frequently exploit this provision to extend the patent term.[14]

---

[10] A. Anurag, "Pharmaceutical Patents and Healthcare: A Legal Conundrum", *SCC Blog*, (September 3, 2019), *available at:* https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/#_ftn17, (last visited on October 17, 2022).

[11] *Ibid.*

[12] *Supra note* 5.

[13] *Ibid.*

[14] Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law* (Thomson Reuters, 2018).

4.2 De-listing Reference from "Orange Book"

As aforementioned the new patented drug in the USA gets listed in Orange Book on approval from FDA and the generic firm has to file ANDA for proving that their generic variant is bio-equivalent to the patented drug. Since, the patented drug acts as a reference for manufacturing new generic medicine, the de-listing of reference from the Orange Book is another tactic that big pharmaceutical companies use.[15] For instance, Ferring the brand company applied to FDA for de-listing the innovator drug to prevent Glenmark to launch its generic variant. However, later on, on a petition by Glenmark against de-listing, the generic drug variant of Glenmark was approved.[16]

4.3 Minor Modification

By this strategy, the innovator firm develops a new molecule through minor modifications in the previous patent for the treatment of a specific disease, which entitles the firm to obtain patent protection for diverse components of the parent drug; and thus, extends the overall term of the parent patent along with preventing a generic drug company from launching a generic variant.

4.4 Pay-for-Delay

One anti-competitive strategy used by pharmaceutical companies to extend the life of their patents is to pay generic companies to delay the market of their generic variations of the same drugs. The innovator company signs a settlement agreement with the generic firm in which the generic firm agrees not to introduce their generic version of the medication for a defined time period.[17] In exchange for preventing the advent of generic drugs, generic firms are compensated handsomely. In the case of *re Cardizem CD Antitrust Litigation*[18] in 2003, an appellate court in the United States ruled that such agreements between brand name and generic companies are unlawful. However, since 2005, numerous courts have misinterpreted antitrust laws and ruled that such

15 *Supra note* 6 at 6.
16 *Glenmark Generic Ltd v. Ferring B.V.*
17 Federal Trade Commission, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions", (2010), *available at:* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (last visited on October 19, 2022).
18 332 F.3d 896 (6th Cir. 2003).

arrangements are legitimate,[19] allowing these large pharmaceutical corporations to exploit not just patent rights but also customers.

However, there have been instances in other countries also where such pay-for-delay agreements have been found to be illegal. For instance, in 2014, the European Commission fined French pharmaceutical company Servier €332 million for delaying the market entry of generic high blood pressure medicine perindopril.[20] In another instance, the European Commission fined Novartis and Johnson & Johnson a total of €16 million for delaying the entry of less expensive generic medicine in the Netherlands.[21]

Other strategies which are used by pharmaceutical companies for evergreening their patent includes establishing their own generic units, brand migration, switching to the OTC (over-the-counter), the combination of two or more than two drug products, etc.[22]

However, to combat the unethical practice of patent evergreening and exploitation of patent rights, India implemented the new patentability criteria in 2005. The primary objective of these provisions was to ensure that patentees not only enjoy monopoly rights, but that the awarded patents also served some social and economic purpose for the benefit of people and maintained the equilibrium of rights. One such unique provision is section 3(d) which requires the innovator company to prove enhanced efficacy from the previously known substance.

5. Section 3(d): The Indian Perspective

India's existing patent rules are closely linked to the country's ambition, following its independence in 1947, to construct a patent system that emphasises social welfare over Western goals. Article 47 of the Indian Constitution stipulates that it is the obligation of the Indian Government to improve public health. Furthermore, Article 12 of India's adoption of the ICESR[23] provides that States have the commitment to promote

---

19 *Supra note* 17.

20 P. O'Donnell, "Commission fines Servier over pay-for-delay settlements on drugs", *Politico*, July 9, 2014, *available at:* https://www.politico.eu/article/commission-fines-servier-over-pay-for-delay-settlements-on-drugs/ (last visited on October 19, 2022).

21 Brussels, "EU fines Johnson & Johnson, Novartis $22mn", *Business Standard*, December 11, 2013, *available at:* https://www.business-standard.com/article/international/eu-fines-johnson-johnson-novartis-22-mn-113121100052_1.html, (last visited on October 19, 2022).

22 S. Midha, "Strategies for Drug Patent Ever-Greening in the Pharmaceutical Industry", 3 *International Journal of Pharmaceutical Sciences and Business Management*, 11-24, (2015).

23 The International Covenant on Economic, Social, and Cultural Rights, 1966.

the right to health. Thus, the Government of India relies on the premise that the pharmaceuticals industry is crucial for the people and hence, the important healthcare necessities must not only be available but also be available at affordable prices. Consequently, this vision serves as the cornerstone for India's view of the right to health as the right to life which is enshrined in Article 21 of the Constitution of India. Accordingly, Indian policymakers endeavour to meet these constitutional requirements while also boosting the country's innovation environment and protecting the legitimate interests of Multi-National Companies.

On the recommendation of the Ayyangar Committee Report, the Indian Patents Act of 1970 incorporated the provision under section 5 where only processes or methods were patentable and not the products.[24] The idea was to protect developing countries like India from exploitation by developed countries.[25] The exclusion of product patents fuelled the growth of the generic drug sector in India, allowing them to manufacture and sell medicines at highly competitive prices, elevating India's status to be that of the "pharmacy of the world".[26]

However, things took a turn between 1995-2005 when India participated in the GATT (General Agreement on Tariffs and Trade) framework debates which led to its entry into WTO (World Trade Organisation) and eventually submitting to sign TRIPS Agreement which was a pre-condition to join WTO and hence necessitated it to strengthen and amend its patent laws in compliance with TRIPS within 10 years i.e., 2005.[27] In 2005, through the Patents (Amendment) Act of 2005, section 5 was repealed and thus enabling products to be patented as well.[28]

While India amended its laws to comply with TRIPS requirements, the criticism and concern over the drug prices due to pharmaceutical patents compelled the Indian government to strike a balance between incentives for innovation and the cost of these

---

[24] The Indian Patents Act, 1970 (Act 39 of 1970), s. 5.

[25] N. Rajagopola Ayyangar, Government of India, "Report on The Revision of the Patent Law", 19-20 (1959).

[26] J. M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*",* 68 *University of Pittsburgh Law Review* 491-537 (2007).

[27] L. L. Lee, "Trials and TRIPS-ulalions: Indian Patent Law and Novartis AG v. Union of India", 23 *Berkeley Technology Law Journal*, 281 (2008).

[28] *Supra* note 9.

patented drugs.[29] The significant means by which the Indian government had tried to mitigate the effect of the 2005 amendment to limit product patents in the pharmaceutical sector was the institution of s.3(d) in the 1970 Act.[30] Section 3(d) of the Indian Patents Act of 1970 precludes the patent if it is-

> "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."

Consequently, the innovators now have to demonstrate that the new intended patent is therapeutically more beneficial than their previous version.[31] The explanation to this provision states that "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".[32] Thus, the provision is to limit the practice of 'evergreening' while making it tougher to get patents unless there is 'enhanced efficacy'. The case of *Novartis AG v. Union of India & Ors.*[33] , demonstrates how a precedent is set through s.3(d).

6. The Novartis Case[34]: A Check On Evergreening

The legality of S.3(d) was challenged just after one year of its incorporation in the 1970 Act when in 2006 Novartis AG petitioned against their patent claim rejection on the beta crystalline version of their anti-cancer medication named Imatinib Mesylate. The Indian Patent Office rejected the application on the following counts: (i) the claimed invention was anticipated by earlier publication, (ii) was apparent to a person skilled in

---

29 A. Dutta, "From Free Entry to Patent Protection: Welfare Implications for the Indian Pharmaceutical Industry", 93(1) *The Review of Economics and Statistics*, 162 (2011).

30 The Indian Patents (Amendment) Act, 2005 (Act 15 of 2005), s. 3.

31 R. Ahmed & A. Sharma, "Novartis Fights India for Cancer Pill Patent", *Wall Street Journal*, (August 19, 2012), *available at:* https://www.wsj.com/articles/SB10000872396390444233104577594973786074692#articleTabs%3Darticle, (last visited on October 20, 2022).

32 The Indian Patents Act, 1970, explanation to s.3(d),

33 AIR 2013 SC 1311.

34 *Id.*

the art, and (iii) did not fulfil the Section 3(d) criteria.[35] Novartis filed an appeal before Madras High Court against the Patent Office's decision and again filed an appeal to Intellectual Property Appellate Board (IPAB) when it was operational in 2007. Subsequently, Novartis against the decision of IPAB filed an appeal in the Supreme Court of India.[36]

There were mainly two grounds on which Novartis appealed in Madras High Court- first, it was contrary to Article 1(1) and Article 27 of the TRIPS Agreement and second, it is violative of Article 14 of the Indian Constitution.[37] On the first issue, the court held that it didn't have jurisdiction over it and left the issue to the dispute settlement body of the World Trade Organisation and on the second issue, the court held s.3(d) to be constitutionally valid- and observed that legislature has clearly laid down the parameters to get patent on an invention which is the duty of the innovator to show that the new invention has led to the enhancement of efficacy under s.3(d). The legislature's objective was to prevent the practice of evergreening, provide easy access to medications and fulfil its constitutional duty.[38] Although the court refused to give its judgement on the first issue, it made an interesting observation that Article 7 of the TRIPS agreement provides enough room to any member country in the interest of social and economic welfare to make a balance between rights and obligations. Moreover, Article 1 of the TRIPS agreement allows the member country the flexibility to creatively safeguard the public interest.[39]

In the appeal filed before IPAB when it became functional in 2007, the finding of the Patent Office that the beta crystalline version of the anti-cancer medication Imatinib Mesylate didn't pass the test of novelty and non-obviousness was reversed. However, the appeal against patent rejection was rejected on the ground that it didn't fulfil the criteria laid down in section 3(d). The board observed that the objective of s.3(d) is to make the requirements under the inventive step of a high standard and particularly in the pharmaceutical domain.

---

[35] B. Dhar and R. K. Joseph, "The Challenges, Opportunities and Performance of the Indian Pharmaceutical Industry Post-TRIPS", in Liu, KC., Racherla, U. (eds), *Innovation, Economic Development, and Intellectual Property in India and China* 299-323, (Springer, 2019).

[36] *Id.*

[37] *Novartis AG v. Union of India*, (2007) 4 MLJ 1153, para 2.

[38] *Id.*

[39] *Supra* note 37.

The Indian Supreme Court concurred with the IPAB finding that Novartis had not demonstrated "enhanced therapeutic efficacy" over the previously patented invention, and hence had failed to fulfil the criteria envisaged under s.3(d). The following principles can be drawn from the Novartis case to overcome the challenges presented under s.3(d):[40]

i. Determining the new form of the already known invention and efficacy in case of pharmacological properties;
ii. Comparing the pharmacological characteristics of the previous and new form of the known substance;
iii. Including comparative data on improved effectiveness via affidavits or in the application of patent;
iv. Excluding physicochemical criteria such as "better flow characteristics," "better thermodynamic stability," and "reduced hygroscopicity" for considering therapeutic efficacy;
v. The therapeutic efficacy in the case of medicines should be strictly and narrowly judged;
vi. The application must expressly assert and substantiate by research findings a link between bioavailability and improved therapeutic efficacy;
vii. For patents considering the pharmaceuticals and chemicals, the innovator not only has to prove the enhanced efficacy but also that the new substance is an "invention" and an "inventive step".

However, the Court did not articulate the meaning of "enhanced efficacy" as per section 3(d) and is thus left open for open interpretation.

Patent changes in India had a significant extraterritorial influence. On one hand, the European Union and the United States both strongly opposed India's measure to reform and restructure patent rules to restrict evergreening. Countries like China, Brazil, Malaysia, Argentina, Indonesia, South Africa and the Philippines, on other hand, have either mirrored or firmly supported India's approach.[41] Furthermore, other nations are

[40] F. Ali, S. Rajgopal, *et. al*., "Pharmaceutical Patent Grants in India: How our safeguards against evergreening have failed, and why the system must be reformed", A*ccessibsa*, 28 (2018).

[41] Arun Kumar and Arun Nanda, "Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries", 6 *Pharmaceutical Regulatory Affairs*, 5 (2017).

keeping a close eye on India's stance on employing the flexibilities provided under the TRIPS framework.[42]

7. Post-Novartis: Did Patent Exploitation Stop?

Although the US and EU criticise India based on Novartis Judgement, the reality is that even after the ruling, the patent rights are still exploited to some extent. Despite the fact that the claims of innovator companies go through a strict legal framework, the paradox is that the majority of these companies misuse the process of regulations governing patent authorisation. According to a research[43], on pharmaceuticals patents which were granted between 2009-16, the majority i.e., 72 % were secondary patents and were given for marginal improvements. The same report suggests that applicants are able to overcome these stringent requirements and only 15% of patents granted are going through detailed scrutiny.

After 2013, pharmaceutical innovators have to clear certain criteria or principles which have been laid down as 'Novartis Standard'. Further, in 2014 new guidelines for pharmaceutical patent applications were laid down which also need to be followed.[44] However, the strategy which innovators generally follow is that they argue that the relevant provision for their patent application is s.3(e) and not s.3(d). Wherein s.3(d) they need to show the "enhanced therapeutic efficacy" from the previous known substance, in s.3(e) the applicants only need to demonstrate that the new combination has a synergistic effect. Thus, their strategy is to draft the patent application in the form of combination/formulation/composition to prevent scrutiny under s.3(d).[45] Even in some cases the observation made by IPAB in the case of *Ajantha Pharma Limited v. Allergan Inc. and Ors.*[46], is cited to bypass the authority of s.3(d) which states that:

> "The combination mentioned in the Explanation can only mean a combination of two or more of the derivatives mentioned in the Explanation or

---

42 *Id.*
43 *Supra* note 40 at 6.
44 Intellectual Property India, Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, (2014), *available at:* https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf (last visited on October 22, 2022).
45 *Supra* note 40 at 26.
46 ORA/21/2011/PT/KOL of Order no. 173 of 2013, para 84.

combination of one or more of the derivatives with the known substance which may result in a significant difference with regard to the efficacy".[47]

This narrow interpretation, which IPAB provided as a passing remark while rejecting a patent on the basis of patentability, is untenable because there is no instance of different forms of the same substance being mixed in pharmaceutical products, and thus this narrow interpretation defeats the very purpose for which s.3(d) was instituted.[48]

Another strategy used to overcome the objections contemplated under sections (d) and (e) is by invoking the rationale of section 2(1)(j) of the 1970 Act, which defines 'invention' and states that the product must be novel, involving an innovative step, and be capable of industrial application. Though it was made clear in the Novartis case that the conditions for patentability of a product in s. 2(1)(j) should be distinguished from the exceptions to patentability provided in s.3 and both criteria should be fulfilled for the product to be patentable. Conversely, the report claims that 19 of the total analysed patents were awarded using the basis of s.2(1)(j), which is not only perplexing but also unlawful.[49]

8. Public Interests v. Private Rights: In Quest of Equilibrium

It is difficult to modify the administrative and procedural features of the patent law system to strike a balance between private and public rights. The patent system is supported by the idea that pharmaceutical firms ought to have the ability to prevent competitors from using a protected technology for a set period of time in order to recover their R&D expenses. That couldn't, nevertheless, come at the expense of everyone's health. In this regard, Henry Sigerist, a Medical Historian was precise to note that one of the necessities of life is that every person has a right to health; wherever this idea is accepted, the logical outcome is to make all efforts to protect and restore health available to everyone at no cost; medicine, like education, ceases to be a trade and becomes a government/State function.[50] Since the UDHR's Article 27(2)[51] and the ICESCR's Article

[47] *Supra* note 40.
[48] *Supra* note 40 at 26.
[49] *Id.*
[50] *All India Lawyers Union v. Govt. Of NCT of Delhi & Ors*., WP(C) No.5410/1997, (2009), Para 31.
[51] Right of everyone to "benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

15(1)(c)[52] both attempt to correlate intellectual property rights with other categories of human rights, some scholars have come to the conclusion that these provisions serve as a legal foundation for patent rights and other types of IPRs.[53]

The concerns of developing countries regarding pharmaceutical patents were highlighted and clarified in the 2001 Doha Declaration on TRIPS and Public Health. According to the Doha Declaration, the TRIPS Agreement's clauses should be interpreted to support "access to affordable medicines for all". This statement emphasised how a country may potentially make use of the TRIPS Agreement's flexibilities, particularly the compulsory licencing.[54] The Declaration expressly acknowledges concerns about how intellectual property protection may affect costs while also recognising the need for intellectual property protection "for the development of new medicines."[55] The 'Doha Declaration' which reiterated the rights of states to apply built-in WTO public health provisions and other readily available methods to achieve access to affordable medicines, stated that public health takes precedence over private patent rights.[56]

It should be highlighted that the Doha Declaration and the TRIPS agreement constitute an international effort to balance the delicate task of providing rewards for R&D as well as the need to safeguard public interests related to health.[57] Even with such a robust framework, developing nations' problems still persist. In this regard, the paper will offer suggestions in the following section, taking the Indian perspective into particular consideration.

9. Conclusion

Evergreening techniques as they currently exist are obviously contrary to the original intent of patents, which was not only to incentivise the innovator but also to foster innovation. Evidently, by taking advantage of regulatory loopholes, evergreening practices subvert this admirable goal of the patent rules. Companies try to extend their

---

52 Everyone has the right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

53 J. Millum, "Are Pharmaceutical Patents Protected By Human Rights?" 25 *Journal of Medical Ethics* 34 (2008).

54 *Supra* note 7.

55 S. C. Roy, "Health Security and National Strategy Under the Patents Regime: Issues and Concern" 6 *Chanakya National Law Journal*, 80 (2016-17).

56 *Supra* note 10.

57 *Ibid.*

monopoly by applying for patents on variants that barely qualify as inventions. Patent extensions may involve minor alterations, fresh applications for currently available medications, and even new dosing procedures. Even if they are legal, these actions go against the intent of the patent system. To ensure there is always a motivation to innovate, it is crucial that patent rights are granted for a specific amount of time. By the time the patents on their blockbuster products expire, companies should focus their resources on constructive research and development to create new, potent medications. Additionally, it is incredibly anti-competitive to use gaps in patent laws to prevent generic products from entering the market. This goes against consumer interests.

Given the prevalence of evergreening strategies, it is necessary to constantly analyse the law to identify any potential loopholes. While the patent laws in developed nations like the United States and the European Union are too lax to prevent ever-greening practices, India made it abundantly clear through the Novartis case that it would not endanger the lives of underprivileged patients or the general public by allowing these practices. However, Pharmaceutical companies have devised means and legal loopholes to evergreen their products, even after the Novartis case. A robust patent protection framework is thus required to put a halt to ever-greening by clearly differentiating between increment inventions and frivolous patent applications. In order for the courts to provide swift judgments, the legal system needs to be updated keeping the balance between the rights of innovators and the general public.

10. Suggestions

The most apparent suggestion to promote access to essential medications, after careful reading of the facts presented in this study, would be to change the patentability standards for secondary patents. The ‘inventiveness’ requirement is the most important factor in protecting the market share from arbitrarily prolonged exclusivity. Patients would see a fall in medicine prices as a result of increased competition from generic medications if this patentability threshold is raised.

It is suggested that India improve the effectiveness and appropriateness of patent awards. Creating an updated manual for patent examiners is the first step. The current anti-evergreening provisions do not expound on how these provisions should be applied. To ensure that patent controllers follow the spirit of the Supreme Court ruling on

the matter of evergreening patents, the principles outlined by the Supreme Court in the Novartis Case should be the guiding document. The guidelines for evaluating pharmaceutical applications must take into account the principles borne out of the Novartis case.[58] Efforts should be taken to avoid "evergreening" and the granting of frivolous patents. To ensure that there is no chance of issuing spurious patents, the Indian Patent Office should develop and strictly follow detailed guidelines while reviewing patent applications in the pharmaceutical sector domain. Every application that may be used for secondary patenting must go through careful review at several levels. If a state decides to combat abusive secondary patenting, it must first acknowledge the existence of patent evergreening and then seek to strengthen administrative and regulatory facets of patent law. Furthermore, it is recommended that every nation take proactive steps to guarantee that everyone has access to healthcare, including insurance plans that cover even the lowest of the poor. Additionally, the government should finance R&D in the pharmaceutical domain so that affordable medicines become reality for every section of the society. This could be done by providing grants or tax incentives for pharmaceutical companies that invest in research for developing affordable drugs. The government could also establish public-private partnerships to collaborate on research and development of affordable medicines. Rules and regulations on patent rights must be continually evaluated to address any gaps that threaten the fine balance between the innovator's patent rights and the people's rights to get affordably priced generic medications.

[58] *Supra* note 40.