RETHINKING SECTION 3(D): BALANCING INNOVATION AND EVERGREENING IN PHARMACEUTICAL PATENTS

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Abstract

Patents are a form of intellectual property that grants the inventor an exclusive right over their invention for a specific period of time. Patents ensure that there is no problem of free riders, and the inventor can recover the costs spent in developing the invention. To extend the benefits of the monopoly patent holders tend to file for subsequent patents for minor improvements in the product. To prevent evergreening of patents Section 3d was introduced in the Patents Act 1970, which was later amended in 2005 to make it compatible with TRIPs agreement. The provision grants patent to known pharmaceutical substances only of there is a substantial improvement in the therapeutic efficacy. The provision and the judiciary failed to define what efficacy means, creating an uncertain domain where patent offices granted patents to substances which showed no such improvement. The provision indirectly supports the monopoly as it has a higher threshold for granting patents, which discourages other players in the market from investing in making any improvements in the drug. This paper shall analyze if the existing interpretation and application of Section 3d is sufficient to achieve the balance between innovation and public health. The paper also suggests other ways to interpret the provision to achieve the equilibrium as envisioned by the legislature. In conclusion, the paper seeks to fill the gaps in the existing framework by advocating for a different approach in interpreting Section 3d.

Keywords: Patents, Evergreening, Monopoly, Pharmaceutical, Innovation

1. Introduction

Intellectual Property rights evolved in order to protect a person's innovation which are not always tangible. The World Trade Organization defines Intellectual

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Property as "the rights given to persons over the creation of their minds. They usually give the creator an exclusive right over his/her creation for a certain period of time".[1] Patents are a form of intellectual property provided to persons who make new innovations. This ensures that the patentee has exclusive rights over his innovation for a specific period of time, during which he can enjoy the monetary and other benefits arising out of such innovation. Patents encourage further research and development as it provides incentives for innovation. The World Intellectual Property Organization defines patent as an "exclusive right granted for an invention".[2]

The goal of Intellectual Property (IP) policies is to carefully balance the public's strong desire to obtain the invention at affordable costs with a private monopoly right that promotes innovation. The problem of this equilibrium is never more glaring than in the field of public health.[3] Although it used to be very uncommon for public health issues to be brought up in IP discussions, it is now generally acknowledged that public health plays a crucial role in the social contract that underpins the granting of IP rights. Evergreening of Patents is a major issue in the pharmaceutical industry, were companies file for secondary patent for a known substance in order to maintain monopoly over the product. In order to weed out such less substantial secondary patents and prevent evergreening Section 3d of Patent Act, 2005 was introduced.[4] The section was enacted with the aim to achieve the equilibrium between affordable public health and innovation. S. 3d was immediately challenged in the courts for being violative of the TRIPS agreement[5] and the constitution. The validity of the provision was upheld. However, the interpretation of S. 3d is still very narrow and does not effectively achieve the equilibrium.

Part I of the paper provides a brief history of the statutory development of S.3d and the judicial interpretation of the provision. Part II of the paper analyses if the existing interpretation is sufficient to achieve the equilibrium between public health and innovation. Part III of the paper focuses on providing solution to achieve the equilibrium.

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1 "WTO | Intellectual Property (TRIPS) - what are Intellectual Property Rights?", *available at*: https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm (last visited on October 09, 2024).

2 "Patents," *available at*: https://www.wipo.int/web/patents (last visited on October 09, 2024).

3 Shamnad Basheer, "Trumping TRIPS: Indian Patent Proficiency and the Evolution of an Evergreening Enigma," 18 *Oxford University Commonwealth Law Journal* 16–45 (2018).

4 Bhaven N. Sampat, Kenneth C. Shadlen, *et.al*., "Challenges to India's Pharmaceutical Patent Laws," 337 *Science* 414–415 (2012).

5 Agreement on Trade-Related Aspects of Intellectual Property Law, *available at:* https://www.wto.org/english/docs_e/legal_e/27-trips.pdf (last visited on January 13, 2025)

2. Evolution of Section 3d

2.1. Statutory Development of Section 3(d)

India's patent regime started as early as 1856 during the colonial period. The first patent act was the India's Act VI of 1856 enacted by the colonial administration based on the 1852 British Patent Law.[6] The legislation provided 14 years exclusive privilege to inventors. The act was repealed in 1857 as it was enacted without the Crown's approval. The Inventions and Design Act in 1888 was enacted following many amendments.[7] It was subsequently replaced by the Indian Patents and Designs Act of 1911[8] which created a system for patent application and mandatory examination. The act was also the first to establish a Controller of Patents in India to oversee patent administration in the colony.[9]

Post-independence in 1947, India wanted to have its own patent system that was in line with the nations goals and interests, independent from colonial influence. To achieve the same, the government appointed a committee under the Chairmanship of Justice Bakshi Tek Chand in 1948. The committee was tasked to review the 1911 Act. The committee submitted its full report in 1950 making recommendations for ensuring availability of medical devices at cheap rates to the public and adequate compensation to the patentee[10]. The report resulted in a new bill[11] in the Lok Sabha in 1953 which unfortunately lapsed as the house was dissolved. Inn 1957 a second committee was commissioned under the chairmanship of Justice N. Rajagopala Ayyangar to offer a new perspective on the Indian patent system. The committee recommended the use of process patents for pharmaceutical industry to advance research in that field as done in the German system. The report was submitted in 1959, based on which the Patents Act 1970[12]

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6 Janice M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation" (Social Science Research Network, Rochester, NY, 2006).
7 *Supra* note 3.
8 The Patents and Designs Act, 1911 (Act 2 of 1911).
9 Janice M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation" (Social Science Research Network, Rochester, NY, 2006).
10 *Supra* note 3.
11 Bill 59 of 1953.
12 The Patents Act, 1970 (Act 39 of 1970).

came into force replacing the Patents and Designs Act, 1911. The 1970 act made India a leading producer of generic drugs at a low price as it followed a process patent system.[13]

India being a member of the World Trade Organisation (WTO), was required to comply with the TRIPS agreement which mandated its members to provide full patent protection to pharmaceuticals. WTO granted developing countries including India a transition period of 10 years to bring its domestic patent law in accordance with TRIPS.[14] This meant India had till January 2005 to make product patent available to the pharma industry. To discharge its obligation under the agreement the government introduced the Patents (Amendment) Ordinance, 1994[15] amending the 1970 act. The ordinance was followed by the the Patents (Amendment) Act 1999.[16] Three years later the Patents (Amendment) Act, 2002[17] brought large amendments to the 1970 act. However, India has still not granted product patent to pharmaceutical products. In order to not default on its obligation, the Government brought the Patents (Amendment) Ordinance,[18] 2004 with effect from January 1, 2005. The ordinance opened doors for the grant of product patent to pharma products by doing away with Section 5 of the 1970[19] Act that patents for medical substances. The ordinance was replaced by the Patents (Amendment) Act, 2005.[20] Introduction of product patent for medicines was greatly opposed in the parliament. The government reassured the members that there will be no exploitation of the product patent regime as clause (d) of Section 3[21] would take care of any such abuses. Section 3(d) is one of the rigorous patent filters used by India to ensure only high-quality inventions are patented. Section 3(d) prohibits evergreening, allowing patenting of drugs that show an increase in 'efficacy'.[22]

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13 Janice M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation" (Social Science Research Network, Rochester, NY, 2006).
14 The Trade-Related Aspects of Intellectual Property Rights, 1994, art. 27.
15 The Patents (Amendment) Ordinance, 1994 (Ordinance 13 of 1994).
16 The Patents (Amendment) Act, 1999 (Act 17 of 1999).
17 The Patents (Amendment) Act, 2002 (Act 38 of 2002).
18 The Patents (Amendment) Ordinance, 2004 (Ordinance 7 of 2004).
19 The Patents Act, 1970 (Act 39 of 1970), s. 5.
20 The Patents (Amendment) Act, 2005 (Act 15 of 2005).
21 *Supra* note 19, s. 3 cl. d.
22 *Ibid.*

2.2. Judicial Interpretation of Section 3(d)

The intent of the legislature when drafting section 3(d) was to ensure that product patent regime is not exploited and essential drugs are available to the public at affordable cost. The provision was a clever way used by the parliament to ensure TRIPS compliance and at the same time protecting its national interest. The provision ensured that pharma companies do not maintain monopoly by patenting minor changes to their drugs.

While the provision's spirit is commendable in that it gives patent offices a more precise rule-oriented foundation to assist them in differentiating between innovations that are patentable and those that are not, its phrasing leads to uncertainty. As anticipated, the Supreme Court of India soon became involved in a hotly debated interpretation of this clause.

To understand the decision of the Supreme Court it is important to trace how the appellant's patent application was filled. The Appellant (Novartis AG) filed[23] for patent of Imatinib Mesylate in beta crystalline form on 1998 in the Chennai Patent Office. The Indian patent system was in a transitional phase at the time the application was submitted, and it was handled through the "mailbox procedure". Following the implementation of the new patent regime in 2005, the application was removed from the mailbox. However, there had already been five pre-grant objections to the application. After hearing arguments from both sides, the Assistant Controller of Patents denied the appellant's application in January 2006. Section 3(d) was one of the reasons for rejection.

The appellant directly challenged the Assistant Controller's ruling in the Madras High Court because the Intellectual Property Appellate Board (IPAB) had not yet been established. The appellant filed two writ petitions contesting the legality of Section 3(d) and contested the five orders issued by the assistant controller. After the IPAB was constituted, the High Court forwarded the five petitions contesting the order to it. The division bench of the Madras HC heard the two writ petitions in ***Novartis AG v. Union of India***.[24] Section 3(d) was challenged under two grounds: 3(d) not compatible with TRIPS, 3(d) violative of Article 14 of the Constitution. The court held that it does not have the jurisdiction to see if Section 3(d) is compatible with TRIPS. The court also

[23] Application No. 1602/MAS/1998.
[24] (2007)4MLJ1153.

decided that a clause cannot be declared unconstitutional if it uses vague language, fails to define "enhancement of known efficacy", and leaves it up to the court to interpret. It further stated that the applicant must show that the substance discovered has better therapeutic effect. The court held the section has a built-in measure to guide the statutory authority, and 3(d) is not ambiguous, vague or arbitrary. As a result, Section 3(d) cannot be declared unconstitutional on the grounds that power abuse may occur, and its constitutionality is maintained. The appellant did not contest the HC's ruling any further.

The IPAB heard the appellants challenge against the five orders passed by the assistant controller in ***Novartis AG v. Union of India***.[25] The appellate board ruled in 2009 that the innovation was accountable to section 3(d), which states that bioavailability and therapeutic efficacy are not the same thing. Due to the therapeutic similarity between Imatinib Mesylate and its beta crystalline form, patent registration was rejected. The applicant explicitly challenged this IPAB order in the Supreme Court.

The supreme court heard the case under article 136 in Novartis AG v. Union of India.[26] The Supreme Court ruled that the efficacy test under Section 3(d) would vary based on the intended outcome of the product in question. It would be therapeutic efficacy in the case of medication, and therapeutic efficacy needs to be evaluated strictly and narrowly. Ultimately, it was decided that Imatinib Mesylate's beta crystalline form fails the test under Section 3(d), and the patent for it was rejected.

To protect the interest of the pharmaceutical companies the IPAB and High courts have come up with various guidelines. In ***Fresenius Kabi Oncology Ltd v. Glaxo Group Ltd***.,[27] the IPAB held that when an objection under non-patentability is raised under section 3(d) by the patent office they need to specifically allege and identify the following: (i) what is the 'known' substance in question? (ii) why the claimed substance is a new form or derivative of a known substance? (iii) what is the basis to assert that the alleged 'known' substance and the claimed substance have the same known efficacy?

In ***DS Biopharma Limited v. The Controller of Patents and Designs***[28] the patent controller did not find any of the three grounds mentioned in ***Fresenius Kabi Oncology***

[25] [2009] IPAB 35.
[26] AIR 2013 SC 1311.
[27] ORA/22/2011/PT/KOL.
[28] C.A.(COMM.IPD-PAT) 6/2021.

Ltd v. Glaxo Group Ltd.[29] The Delhi High Court held that in the absence of prior identification of the known substance in the hearing notice issued by the patent controller and lack of proper opportunity to respond to the objection, then the order cannot be sustained. These cases highlight that the courts are trying to provide applicants of pharmaceutical substances with a fair opportunity to contest objections under 3(d) instead of blindly denying patents when objections under the section is raised. However, the question is if such measures alone are sufficient to effectively balance innovation and public health, the paper in the following section will address the same.

3. Analysis of Section 3d

3.1. Economics behind Patents

The core principle of a patent system is when there is a new innovation people develop and commercialize the product which benefits society. If the information is publicly disclosed people can improve the innovation.[30] This premise is majorly agreed by everyone, the important question here is how patent systems ensure that social benefits are more than the social cost.

In economic terms, patents are largely non-rival and non-excludable, as they are intangible i.e. information.[31] Such knowledge becomes a public good. Patents are non-rival as a large number of people can access the information at the same time. They are non-excludable as the only way to exclude others from having access to your ideas is by not telling it to anyone. But that does not lead to any improvement in social benefit and benefit of the inventor. Once you disclose your idea, there are no means to stop people from replicating it and enjoying the benefit of your hard work. This leads to the problem of free-riding, as anyone without making any investment can make money out of the inventor's idea. In the case of pharmaceutical industry, it takes millions of dollars to come up with a safe, effective and marketable drug. It is easier to copy someone's inventions in this field rather than to invent something new. This is where a patent system comes into place. The incentive theory tells that when the state provides protection to the inventor's rights and saves them from free riders there tends to be more innovation. This

[29] ORA/22/2011/PT/KOL.
[30] Roger D. Blair and Thomas F. Cotter, *Intellectual Property: Economic and Legal Dimensions of Rights and Remedies* 8-9 (Cambridge University Press, 2005).
[31] *Ibid.*

in turn will lead to additional social benefits as the creation, commercialization and disclosure of new inventions increase. Patents are a legitimate way to influence the excludability characteristics of an otherwise pure public benefit by giving inventors property rights over their discoveries.[32]

Patents provide a substantial incentive to invent in certain industries like pharmaceuticals, where sunk costs are high. It is essential to incentivize industries that have incurred higher costs that cannot be recovered.[33] While the social benefit of patents is innovation, commercialization, etc. it also has social cost. The cost includes monopoly, evergreening, etc. for which any efficient patent regime must have a balanced patent system that ensures that the benefits are more than the costs.

A drug's development has high fixed costs (F), yet its manufacture has low unit costs (c). Without a patent, the inventor would not be able to recoup investment since rivals may replicate the medication and sell it for production cost.[34] A brief monopoly granted by a patent enables the inventor to charge a price (M_p) that is higher than the cost of production, guaranteeing a profit (Π), which encourages innovation.[35] However, because the drug is more expensive during the patent period, fewer people take it than they would if it were offered at a competitive price. The price society pays for promoting innovation is this inefficiency (lower production and consumption). The medicine can be produced efficiently (at price c) when the patent expires, optimising the social benefit.[36]

Section 3d of the Patent Act, 1970[37] was brought in to achieve the balance. It tries to prevent the cost of evergreening in pharmaceutical products by not granting patents to inventions of known substances that have not shown an increase in therapeutic efficacy. The provision only considers therapeutic efficacy as a criterion for patenting, this will lead to a decrease in investment in pharmaceutical industries as there is no incentive if the result shows any other forms of increase in efficacy. The pharmaceutical industry

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32 Corinne Langinier and GianCarlo Moschini, "The Economics of Patents: An Overview" *Intellectual Property Rights and Patenting in Animal Breeding and Genetics* (2002).
33 *Supra* note 30.
34 Nordhaus, "Inventions, Growth and Welfare: A Theoretical Treatment of Technological Change." *MIT Press* (1969).
35 Scherer, "Nordhaus' Theory of Optimal Patent Life: A Geometric Reinterpretation," 62 *American Economic Review* 422–427 (1972).
36 *Supra* note 32.
37 The Patent Act, 1970 (Act 39 of 1970), s. 3 cl. d.

already has a high sunk cost, patents provide a way for them to recover the costs of creating the invention. The narrow meaning of efficacy for pharma products discourages invention and improvement as companies do not have the opportunity to make profits if there is no increased therapeutic efficacy.

The intention of the state is to ensure affordable health care. To achieve this goal, it is essential to prevent pharma companies from monopolizing a drug by getting subsequent patents for minor improvements. The interpretation of S. 3d to only include therapeutic efficacy does not achieve this goal efficiently. While it may seem as though big pharma companies have been successfully stopped from monopolizing, in the long run there will be no incentive to innovate.

The Supreme Court in ***Novartis AG v. Union of India***[38] held that what amounts to therapeutic efficacy in the case of medicines must be judged strictly and narrowly. It also stated that all advantageous properties will not be considered to be relevant. Only those properties that directly relate to efficacy which in the case of medicines is therapeutic efficacy will be considered when checking if a substance passes the test of section 3(d). This interpretation is problematic as it restricts the scope of what can be efficacy to be too narrow, this in turn will result in decreased innovation as there is no incentive to do Research and Development.

Patents are also essential to incentivize research and development. In the absence of patents, inventors have no incentive to invest in costly R&D as competitors could replicate the invention at a lower cost.[39] Although patents encourage innovation, they also result in inefficiencies such as increased costs and limitations on access to protected goods over the duration of the patent. Patents by granting a temporary monopoly ensures that the inventor has exclusive rights over the product for a specific period of time. Businesses fight to be the first to come up with an innovation in the "winner-takes-all" competition. In industries like pharma there is a pre-innovation competition, where the firm that gets the patent wins all. In the post-innovation market that firm enjoys the monopoly.[40] There is a temporary restriction on competition. The monopoly can be replaced only by another monopoly that has a better version of the product. This is why, even though a patent

[38] AIR 2013 SC 1311.
[39] *Supra* note 32.
[40] *Ibid.*

temporarily reduces competition, the monopoly it creates is essential for encouraging innovation instead.

The only way to replace a monopoly is by another monopoly. The primary monopoly does not have any incentive to further innovate as it is already dominating the market. The only way to remove it is by bringing in another monopoly that has a better version of the product, which drives the primary monopoly out of business. This way innovation can be promoted only if patent is granted for subsequent innovations. Section 3d tries to prevent monopolies from forming by deterring evergreening of patents. While it may sound like this provision encourages a competitive market, it ends up indirectly supporting the monopoly by discouraging innovation in the field. The pharma company that has the patent will enjoy the monopoly for a certain period, so it has no incentive to innovate. The provision by granting patents to known substances only if there is an increase in therapeutic efficacy takes away the incentive of other pharma firms to innovate and replace the monopoly. So, by having a narrow definition of what amounts to efficacy in pharma products section 3d ends up promoting the monopoly and deterring innovation.

3.2. Does S. 3(d) Achieve the Balance between Public Health and Innovation

As already understood an indicator of a good patent regime is a balance between innovation and commercialization. In the pharma industry, this equilibrium is achieved when there is an increase in innovation and healthcare products are easily accessible. The purpose of S. 3d is also to achieve this goal. The aim of section 3d was to prevent evergreening of patents of known substances which delays the entry of generic medicine into the market.

Since structurally similar forms of already-existing chemical entities, such as isomers, polymorphs, and novel salt forms, are likely to be functionally identical, Section 3(d) is based on this assumption. If this is not the case, the patent applicant must provide evidence to support her claim to a patent. Section 3(d) prohibits evergreening and encourages incremental innovation, which is the process of improving therapeutic products by turning existing drugs and biological substances into better ones.[41] The provision's wording is far from ideal, despite its admirable purpose, which gives patent

[41] Shamnad Basheer and Prashant Reddy, "'Ducking' TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)," 20 *National Law School of India Review* 131–155 (2008).

offices a more precise rule-oriented foundation to assist them in differentiating between innovations that are patentable and those that are not.[42]

However, s. 3d has not been effective in shutting down evergreening as patent offices continue to provide patents to known substances even after the Madras High Court verdict that narrowed the definition of efficacy.[43] Over the last decade, the patent office has failed to provide an effective mechanism to filter out repetitive patents. The legislature's intent is still not put into practice. The Supreme Court in its judgment has failed to define what 'efficacy' means. This un-uniform, unregulated and undefined meaning of efficacy has created a lot of uncertainty resulting in patent offices granting patents to known substances that do not show any increase in therapeutic efficacy. This gap in the law has prevented generic medicine from entering the market as patents continue to grant monopoly to one company.

The introduction of generic medications has been postponed by some of these granted patents. A medication called *trastuzumab* is used to treat breast cancer that is *HER2 positive*. Roche markets the patent in India. In India, Roche offers this medication under two different brand names. The first is *Herceptin*, a well-known worldwide brand that retails for a maximum retail price (MRP) of Rs. 1,34,000. The MRP of the second brand is Rs 75,000. The original molecule of the drug is not patented in India[44]. The subsequent patent was granted in 2005 (Patent No. 205534) by the Kolkata Patent Office. In the patent claim, there is no indication of an increase in therapeutic efficacy. Still, a patent was granted to this application which is preventing the generic entry of *Trastuzumab* in India. Lack of clear definition of what 'efficacy', in the case of pharma products 'therapeutic efficacy' means has led to the obstruction of generic entry. This has resulted in people still not being able to afford health care. The intent of the legislature has not been properly translated in practice by the patent office and the judiciary. So instead of preventing evergreening and making health care accessible, S. 3d has been blocking innovation and encouraging monopoly.

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42 *Supra* note 3.

43 K M Gopakumar, "The Need to Curb Patents on Known Substances," 48 *Economic and Political Weekly* 55–57 (2013).

44 "Health Ministry Recommends Compulsory Licensing of three Anti-Cancer Drugs," *Livemint*, 16 January 2013.

S. 3d was introduced to deter companies from patenting products that have slight modifications on existing drugs, this ensures patents are granted to significant modifications of known substances, in the case of pharma products only when there is an increase in therapeutic efficacy. This provision is similar to the inventive step and non-obviousness threshold used in the United States and the European Union where patent is not provided if there are structural similarities between the new drug and the existing one.[45] However, the patent can be obtained if it is proved that there is an unexpected result making the drug non-obvious.

S. 3d is different from this as it provides for a higher threshold as a mere demonstration of an unexpected result is not sufficient and the focus is only on increase in 'therapeutic efficacy'. While any improvement could qualify for patent in other jurisdictions, the criteria is narrow in India.[46] The inventive step looks if a skilled person could have arrived at the derivative. However, S. 3d is only concerned with the end result, making the process more straightforward and less resource intensive.

As it allows for interpretive uncertainty and concentrates solely on efficacy rather than the entirety of invention, Section 3(d) is insufficient in avoiding evergreening, notwithstanding its practical utility. It may not adequately strike a balance between promoting true innovation and the need for inexpensive healthcare, even while it forbids the patenting of some blatant changes. To effectively serve as a bright-line rule against evergreening while guaranteeing that genuine advances are rewarded, the section needs more judicial or legislative clarification because it is unclear in some cases. Because of its limited emphasis on therapeutic efficacy and interpretive difficulties, Section 3(d) fails to strike a balance between innovation and public health concerns, allowing pharmaceutical companies to continue their evergreening practices.

4. Way Forward

Section 3d of the Patents Act, 1970 following its amendment in 2005 is a heavily contested provision in India. S.3d has failed to promote invention and make health care affordable. The key issue of the provision is the narrow definition of efficacy to mean only therapeutic efficacy for pharma products. It is suggested to make the scope of

[45] *Supra* note 3.
[46] *Ibid.*

efficacy broader for pharma products so innovation is encouraged. This will lead to more investment in research and development resulting in increased improvements in the pharma field. Making health care affordable is essential for a country to develop, so making a broad definition of efficacy may sound deterrent to this goal. It is clear that even a narrow definition did not aid in making health care affordable. What is needed is a definite definition were the patent offices follow a uniform method to weed out unnecessary patents. This ensures generic medicines can also enter the Indian market. Removing the higher threshold of therapeutic efficacy will make any substantial improvement in pharma product worthy of a patent.

In the case of ***Novozymes v. Assistant Controller of Patents and Designs***,[47] patent claim was made for 'Phytase variants with improved thermostability'. On the basis of Section 3(d), the claim was denied. The appellants appealed the order to the High Court of Madras. The main argument of the appellants, who filed the patent for a biological substance, was that section 3(d) only applied to chemical and medicinal substances, not biochemical substances. They explained that the term "known substance" in 3(d) does not apply to biochemicals like Phytase by citing the Supreme Court and High Court's Novartis Judgement. The court held that by reading the judgements it is clear that the Explanation and certain portions of the main clause is applicable only to pharmaceutical products, however it does not mean that the whole provision is limited in its application. The supreme court held that the test of efficacy will depend on the product in question, in case of pharmaceutical substances it is therapeutic efficacy. The appellants contended that 'improved thermostability' in the Phytase should be considered as enhancement of known efficacy and is sufficient to pass the hurdle of section 3(d). The respondents contended that since Phytase is an enzyme, increasing its efficacy solely entails increasing its enzymatic activity and not its additional functions. The patent claim was turned down because improvements in proven efficacy should only be made to Phytase hydrolysis, which improves the breakdown of indigestible phosphorus into digestible form. The court however held that the primary function of the Phytase is to aid in digestion, but that does not mean it should be an essential requirement to pass the test under section 3(d). Increase

[47] (T) CMA (PT) No. 33 of 2023 (OA/6/2017/PT/CHN).

in thermostability is also critical to improve the conditions of the animal feed and fuel industries, and the same is sufficient to pass the filter of 'enhancement of known efficacy'.

A similar approach must be followed for pharmaceutical substances as well. Efficacy need not mean improvement in the primary function alone; it can be improvement in any function. Efficacy for pharma products should not be limited to therapeutic efficacy i.e. the ability to cure a disease. Other improvements that aid in the performance of the substance should also be considered.

A pharmaceutical ingredient must show an improvement in therapeutic efficacy in order to be eligible for patent protection in India, according to Section 3(d) of the Patents Act. This clause was put in place to guarantee that the general population could obtain reasonably priced medications and to stop evergreening. Limiting patent eligibility to only increases in therapeutic efficacy, however, may deter innovation in other important areas of pharmaceuticals, including improved stability, bio-availability, or delivery systems, which can have a big impact on medication development and patient outcomes.

In order to remedy this, my paper makes the case that secondary enhancements like improved solubility or thermostability have to be taken into account when determining patent eligibility. The bar for what constitutes an "enhancement" in these secondary activities should be raised above the bar for therapeutic efficacy, nevertheless, in order to avoid evergreening. This preserves the integrity of patent law and protects public health by guaranteeing that only significant improvements in secondary functions are recognised, which promotes meaningful innovation.

5. Conclusion

Section 3(d) of the Indian Patent Act was created to guarantee access to reasonably priced healthcare and stop pharmaceutical patents from evergreening. Unexpected repercussions have resulted from its exclusive focus on therapeutic efficacy as the criterion for patent issuance. By setting a high bar for patent eligibility in the pharmaceutical industry, the clause has unintentionally impeded innovation even if its goals are to prevent monopolies and advance public health. As secondary improvements in known substances are frequently overlooked, this has decreased incentives for research and development.

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Both the demand for innovation and public health issues requires a more balanced approach. Extending the definition of efficacy beyond therapeutic advancements may promote more significant innovation without jeopardising the availability of reasonably priced medications. To guarantee that the law successfully weeds out pointless patents while still encouraging real pharmaceutical breakthroughs, it is imperative that Section 3(d) be interpreted consistently and with clearer rules. India could better strike the intended balance between promoting innovation and maintaining public health by modifying the clause.

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