Jus Corpus Law Journal

Open Access Law Journal – Copyright © 2026 – ISSN 2582-7820

Editor-in-Chief – Prof. (Dr.) Rhishikesh Dave; Publisher – Ayush Pandey

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Beyond Section 3(D): Comparing India's and America's Legal Answers to Pharmaceutical Evergreening

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Received 10 September 2026; *Accepted* 10 October 2026; *Published* 14 October 2026

A patent provides a creator with a temporary monopoly in exchange for ensuring that the public is informed of how the invention functions. Once this period has elapsed, generic items may enter the market, and costs decrease. However, pharmaceutical companies have figured out how to prolong this situation. They register patents for minor alterations of a current drug, such as a new coating, a new salt, or a new dosage, at a time when the original patent is about to expire. The analysis in this article focuses on how India and the United States manage the situation. India relies heavily on its patent law, section 3(d), which bars the issuance of patents on new versions of existing drugs unless they are effective. The Supreme Court applied this law in the famous Novartis case in 2013, and the patent office has again used it to deny patents on Bedaquiline (2023) and Dolutegravir (2024). But section 3(d) is not the only method in India in this situation. Unlike India, the USA does not have any law that resembles India; in Novartis v Union of India, the Supreme Court prevented the patent under section 3(d). However, it stops evergreening afterwards through antitrust principles and 'pay-for-delay' settlements, for instance, FTC v Actavis (2013). Both countries follow different approaches but share the same aim of ensuring companies receive monopolistic rights only if they have invented something novel.

Keywords: *patent evergreening, section 3(d), compulsory licensing.*

INTRODUCTION

Patent law is based on the simple idea that when an inventor creates something novel, they explain that new creation to the public and how it works. In return, the inventor gets the exclusive right to make and sell it for a limited period, usually lasting 20 years. After that, the patent expires, and anyone can make the same product, which may become much cheaper than it was when under patent protection.[1]

Making a new medicine takes a lot of time and money. Therefore, drug companies believe they deserve patent protection to recover those expenses. However, some drug companies try to extend their control over medicines by making small changes to existing drugs through mere admixture or rearrangement. They can apply for a new patent for this change, even though the main drug is not genuinely novel. This practice is called evergreening. The problem with evergreening is that it is unfair and blocks cheaper generics. Generic medicines are usually cheaper than brand medicines.[2] If generic medicines cannot enter the market due to extended patent protection, patients may have to pay higher prices, reducing access for those who need them. This shows that evergreening can restrain innovation by preventing other creators from advancing existing drugs or technologies. It focuses on making money and profit rather than on human lives.

This paper shows how India and the US use different approaches to stop this. Section 3(d)[3] prevents patents on minor changes to existing products unless they demonstrate a required improvement in efficiency. The US does not have an equivalent rule like Section 3(d) of the Patent Act 1970. Instead, they use competition law or antitrust law to examine the agreement, which may delay the entry of generic medicines.

WHAT EVERGREENING ACTUALLY LOOKS LIKE:

The concept of Evergreen can manifest in different ways as well. A pharmaceutical company may apply for a new patent for a small change in its existing medicine. Some of these changes

[1] Gaurav Dwivedi et al., 'Evergreening: A deceptive device in patent rights' (2010) 32(4) Technology in Society <https://doi.org/10.1016/j.techsoc.2010.10.009> accessed 08 September 2026
[2] Shilpi Bose and Ishan Dhyani, 'Evergreening Of Patents: Bridging The Gap Between Intellectual Property Rights And Healthcare Law' (2025) 7(3) Indian Journal of Law and Legal Research <https://www.ijllr.com/post/evergreening-of-patents-bridging-the-gap-between-intellectual-property-rights-and-healthcare-law> accessed 08 September 2026
[3] The Patents Act 1970

may benefit the patient, such as making a medicine cheaper to take or allowing it to work for a longer period.[4] However, these small changes do not automatically mean they create novelty or innovation. The concern arises when the company uses minute changes to obtain additional patents and extend its control over the existing medicine. This creates an unfair practice and delays the entry of cheaper generic medicines into the market, potentially keeping prices higher.

A 2018 study shows that 72% of pharmaceutical patents granted between 2009 and 2016 were secondary patents claiming minor improvements. The study suggests that some of these grants may have raised concerns under the Indian anti-evergreening process. Evergreening means extending patent protection for existing drugs by obtaining additional patents on changes, rather than developing a completely new substance.

SECTION 3(d): INDIA'S FIRST DEFENSE MECHANISM

Patents Act 1970 sets the rules for pharmaceutical patents. It's designed to encourage research and innovation, but not at the cost of public health. Once you get a patent, you have 20 years from your application date during which only you can make, use, sell, or import the product unless you give permission.

Before 2000, India mainly allowed process patents for medicines. As a result, Indian pharmaceutical companies could develop different methods of producing medicines and supply them affordably. This helped India develop a strong pharmaceutical industry and contributed to India's reputation as the 'pharmacy of the developing world'.

However, the World Health Organisation and its obligations under the TRIPS agreement led to India's change in the patent system. The Indian patent system contains several safeguards that are particularly important in the patent sector. The 2005 amendment made a significant change for pharmaceutical companies by introducing product patents for medicines and pharmaceutical products. At the same time, provisions such as section 3(d) and the provision on compulsory licensing were retained to address public health concerns.

[4] Dherya Maheswari, 'EXPLOITATION OF PATENTS: A STUDY OF EVERGREENING IN THE PHARMACEUTICAL DOMAIN' (2022) 1(2) NLUA Journal of Intellectual Property Rights <https://nluassam.ac.in/docs/Journals/IPR/vol1-issue-2/10.pdf> accessed 08 September 2026

Section 3 deals with what is not an invention. It also deals with substances obtained by mere admixture, in which only the compound's properties change.

- Section 3(d) is an important anti-evergreening provision as it prevents certain new forms of known substances from receiving patents unless the legal requirements are fully satisfied. In the case of new forms of known substances, the provision requires enhancement of therapeutic efficiency.[5]
- Section 3(e) states that a combination of two known drugs can obtain a patent only if the combination produces a specific effect that neither drug produces on its own.[6]
- Section 84 (1) enables the availability of patented medicines to the public at an affordable price through compulsory licensing. After three years from the date of the patent, a person can apply for a compulsory license.[7]

NOVARTIS v UNION OF INDIA

This case is one of the most important cases in Indian history. At its heart, the case concerns Novartis. This Swiss pharmaceutical company developed a new form of a drug and already held a US patent on a group of compounds that included Imatinib. Later, they created a new form of the drug called Imatinib mesylate, and then an even newer beta crystalline version. The company wanted a patent in India. The Indian Patent Office rejected the patent application. Novartis challenged the decision and took the case to the Supreme Court. The main issue here is whether a new form is a genuine invention or if a small change to an existing one can create a patent. Under Section 3 (d), a new form of an existing drug cannot be patentable merely because it has the same or a similar feature. The Supreme Court sided with the Patent Office. It rejected Novartis' appeal, making it clear that Indian patent law exists to strike a balance between rewarding genuine invention and preventing the granting of patents, which could completely monopolise the market.[8]

[5] Patents Act 1970, s 3(d)
[6] Patents Act 1970, s 3(e)
[7] Patents Act 1970, s 84(1)
[8] *Novartis AG v Union of India & Ors* (2013) 6 SCC 1

Novartis Aftermath –

Bedaquiline (2023): Despite the Novartis case establishing a strong precedent regarding Section 3(d) in India, this provision continued to be invoked to prevent evergreening practices in the country. In 2023, the patent office declined the application for a new crystalline salt of bedaquiline, a drug for treating drug-resistant tuberculosis made by Johnson & Johnson. The argument was that this could be a case of evergreening of the company's monopoly in TB medicines. It was mentioned that the method aimed at patenting would not be patentable due to the well-known, established nature of this solution.[9]

Dolutegravir (2024): After nearly a decade of legal battle, in 2024, the Indian Patent Office rejected ViiV Healthcare's patent application for HIV drugs, known as dolutegravir. These cases show us that Section 3(d)is still being used to prevent minor changes to existing ones. No improvement in therapeutic efficacy is demonstrated in this specific case.[10]

THE AMERICAN APPROACH

Unlike India, the US does not have a rule like Section 3(d) of the Indian Patent Act. In India, a company seeking a patent for an existing drug must show enhanced therapeutic efficacy under Section 3(d). In the US, a new formulation of any substance may be patentable if it satisfies patent requirements such as novelty and non-obviousness. The company does not generally have to prove that the new form of a known substance is better just because it is a modification of the existing drug. The US is concerned about evergreen generic drug competition and focuses on competition rules and antitrust rules.

The main act the US focuses on is the Hatch-Waxman Act, which was introduced to balance two interests: encouraging pharmaceutical companies to develop new medicines and helping generic companies bring affordable medicines to market and patients. Generic companies can use the original manufacturer's data, making generic medicines faster and less expensive for patients.

Reverse payment settlements, as seen in FTC v Actavis in 2013, address the problem of brand-name companies paying generic companies to delay the sale of cheaper medicines. In this

[9] kamala Thiagarajan, 'India rejects application to extend patent on TB drug bedaquiline' (2023) 380 BMJ <https://doi.org/10.1136/bmj.p724> accessed 08 September 2026

[10] *ViiV Healthcare Ltd v Controller of Patents* (2024) Indian Patent Appl No 2017/018876

case, the US held that the agreement can be examined under antitrust law.[11] Antitrust law related to patent disputes does not automatically protect such agreements from scrutiny. However, the court did not declare every reverse payment settlement illegal. The court must examine each agreement under a rule of reason, considering factors such as the size of the payment and whether there are genuine justifications. A patent dispute does not automatically protect such an agreement from competition law. The United States rely more on ordinary patent requirements and faster generic drug approval.

US CHALLENGE REGARDING THE PROVISIONS UNDER SECTION 3(D) OF THE INDIAN PATENT ACT

Section 3(d) of the Indian Patent Act has become contentious in US circles because it creates a hurdle for pharmaceutical companies seeking patents for new forms of existing medicines in India. In the 2014 Special 301 report, the United States placed India on the Priority Watch List due to concerns about intellectual property protection. The report pointed out problems linked with Section 3(d), the security of industrial property, and the enforcement of intellectual property rights. As stated in Section 3D, an existing substance in a new form cannot be patented unless it provides significant progress in its medicinal effectiveness. This policy helps avoid evergreening and the monopolisation of medicines by pharmaceutical companies and ensures the use of already available drugs.

According to the Special 301 report,[12] the US lists countries where it believes intellectual property rights are not adequately protected. The report was introduced in response to complaints from American businesses about violations of their intellectual property rights, including patents, trademarks, and copyrights, in foreign countries. A study by the US International Trade Commission (USITC) found that European-American companies lost billions of dollars because of IP piracy in foreign countries. In 1986, the US believed that weak IP protection could harm its business, reduce investment, and discourage innovation and creativity, leading to the formation of a special committee. According to India, its patent law meets the requirements of the TRIPS Agreement, and the flexibility of international law is essential for safeguarding public health and reducing drug prices.

[11] *FTC v Actavis Inc* [2013] 570 US 136
[12] *2014 Special 301 Report* (Office of the United States Trade Representative, 2014)

COMPARISONS BETWEEN INDIA AND THE US

Both India and the US force companies to take the long route in their attempts to stop monopolisation through minor changes. India relies on Section 3(d), which prevents patenting of certain new forms of some existing drugs that are not shown to have any added therapeutic efficacy. The Novartis v Union of India case illustrates how this provision, Section 3(d), operates. India also has other tools, such as compulsory licensing under Section 84, which helps improve access to medicine for everyone. The United States does not have rules such as Section 3(d); instead, it relies on the Hatch-Waxman Act to encourage generic competition and on antitrust law to address such matters. In the FTC v Actavis case in 2013, the Supreme Court held that certain pay-for-delay agreements between competitors can be examined under competition law. The main difference between the two countries is that India tries to stop certain forms of evergreening at an early stage, and patents are revoked.

In contrast, the US often addresses potential anti-competitive behaviour through competition law and disputes between brand and generic medicines. Both approaches have their limitations. Section 3(d) mainly addresses new forms of excessive conduct, while US antitrust cases can address other forms of anti-competitive conduct. The ultimate aim of both countries is to keep medicine accessible and affordable to the patients, though outcomes take time and depend heavily on the facts of the case.

CRITICISM AND THE ROAD AHEAD

There are some criticisms of the US-India deal on pharmaceutical equity. The first one is access versus innovation. Drug companies argue that Section 3d may discourage the development of useful improvements to existing medicines. However, public health groups believe that the law is necessary to prevent companies from monopolising without making meaningful improvements. This creates a real problem. The second one is evergreen patenting. Even after rules and regulations and the Novartis case, pharmaceutical companies continue to apply for secondary patents in India. This shows that having laws and regulations is not enough. Proper implementation mechanisms also play a key role. The third point is that compulsory licensing is rarely used in India. Under Section 84 of the Patent Act, India has the power to grant compulsory licenses for patent applications. This option is not

used as often due to pressure from other companies, making it difficult to exercise that power.

CONCLUSION

The provisions of Section 3(d) of the Indian Patents Act help to curb pharmaceutical evergreening. In Novartis v Union of India, the Supreme Court denied a patent on a small modification of an already existing drug. In contrast, the US legal system has no counterpart to Section 3(d) and uses competition law to evaluate the practices of pharmaceutical corporations that seek to delay the introduction of generic drugs to market. A properly functioning patent system is one that motivates pharmaceutical companies to bring new medications to the market, as opposed to using the provisions of law to get exclusivity rights or monopolise the market.