INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 6 AND ISSUE 8 OF 2026

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

SECTION 3(D) AND THE LIMITS OF PATENTABILITY: INDIA'S LEGISLATIVE RESPONSE TO PHARMACEUTICAL EVERGREENING

AUTHOR – BHUMIKA PANDEY, STUDENT AT CHRIST (DEEMED TO BE UNIVERSITY), PUNE, MAHARASHTRA

BEST CITATION – BHUMIKA PANDEY, SECTION 3(D) AND THE LIMITS OF PATENTABILITY: INDIA'S LEGISLATIVE RESPONSE TO PHARMACEUTICAL EVERGREENING, *INDIAN JOURNAL OF LEGAL REVIEW (IJLR)*, 6 (8) OF 2026, PG. 716-727, APIS – 3920 – 0001 & ISSN - 2583-2344

ABSTRACT

One of the most significant and internationally reviewed provisions in the pharmaceutical patenting arena in the world was brought by the Patents (Amendment) Act, 2005 in India, in the form of Section 3(d) of the Patents Act, 1970. The provision was enacted as a direct legislative reaction to the perceived menace of pharmaceutical evergreening and it is categorical in its denying of coverage of patent protection to novel forms of known substances except where a significant enhancement of therapeutic efficacy is proven. The present paper will develop a doctrinal and analytical discussion of Section 3(d) starting with its legislative background of the pre-TRIPS period of the Patents Act, 1970 to the compulsions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and finally its sound jurisprudential interpretation by the Supreme Court of India in Novartis AG v. Union of India. It contends in the paper that Section 3(d) is a reflective, constitutionally acceptable adjustment of the patent law towards promoting the best possible health outcomes rather than gradual pharmaceutical innovation. It also discusses how the provision has helped retain India as the pharmacy of the world, criticisms of the provision by multinational pharmaceutical firms and the United States Trade Representative, and how well the provision balances the flexibilities framework of the TRIPS Agreement. The paper concludes that Section 3(d) is a valid, justified and internationally important tool that other developing countries can contemplate making amendments in their own home based intellectual property systems.

Keywords: Section 3(d), evergreening, TRIPS flexibilities, Novartis v. Union of India, pharmaceutical patent, access to medicines, therapeutic efficacy, compulsory licensing.

1. Introduction

The pharmaceutical industry is in an ambivalent position with regards to patents. On the one hand, the temporary monopoly they guarantee compensates the significant expenditure involved in finding, developing and commercializing a new drug. Conversely, the price premium which accrues to patented medicines may leave the populations in the low- and middle-income countries unable to afford the essential treatment. This tension is not just a hypothetical abstraction; it has influenced trade talks, foreign policy wrangles, domestic laws and historic lawsuits throughout the globe. This tension is more illustrative in India where the experience with pharmaceutical patent law is the most acute since the country became a member of the World Trade Organisation in 1995 and started following the TRIPS Agreement.

Before TRIPS, the Patents Act, 1970 in India was an intended developmental decision. The law, which was passed as per the suggestions of the Justice Ayyangar Committee Report of 1959,[867] only recognised process patents of food,

[867] N.R. Ayyangar, *Report on the Revision of the Patents Law* (1959) (India)

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 6 AND ISSUE 8 OF 2026

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

medicine, and agrochemicals, and thus allowed Indian manufacturers to manufacture generic versions of patented drugs through reverse engineering.[868] This policy decision was not a coincidence. It was a deliberate attempt to develop a local pharmaceutical industry that could provide cheap medicines to a population that is typified by abject poverty and a poor healthcare system. That policy was a tremendous success, by the beginning of the 2000s, India was the largest exporter of generic medicines in volume supplying not only local patients, but also treatment programmes in Africa, South Asia and Southeast Asia.

TRIPS essentially upset this balance. Article 27 of the Agreement required all WTO members to afford patent protection on inventions in any area of technology, such as pharmaceuticals, a term not less than twenty years of protection since the filing date.[869] A transition period till January 1, 2005 was given to India in order to align its domestic law. With the enactment of the Patents (Amendment) Act, 2005 to allow the introduction of product patents in pharmaceuticals, the Indian Parliament also added as a protective measure the new Section 3(d) against the evergreening of patents which multinational pharmaceutical companies commonly use. Since that time, the provision has been the most controversial in the whole intellectual property law around the world, with both supporters and opponents of it being vocal about it, both in praise and criticism.

The following is the flow of this paper. Section 2 develops the conceptual framework, which determines the very notion of pharmaceutical evergreening and locates it in the context of the overall discussion of the quality of patents. Section 3 follows the history of the legislation of Section 3(d) and its association with TRIPS flexibilities. Section 4 is a doctrinal analysis of the provision which discusses its parts and questions of interpretation they present. Section 5 examines a historic case of the Supreme Court in Novartis AG v. Union of India. Section 6 discusses the public health impacts of the provision, specifically in access to medicines in India and the developing world. Section 7 discusses the objections that have been raised against the provision and their soundness. Section 8 is about comparative views, and Section 9 ends by looking back on the relevance of the provision in the future.

2. Pharmaceutical Evergreening: Conceptual Framework

The expression of evergreening does not occur in any statute or treaty on the international level. It is a phrase of art, created by opponents of pharmaceutical patent practice, to describe a family of tactics whereby originator companies are attempting to create an effective market exclusivity of a drug independent of the existence of an original patent by filing further, successive, and minor patents. The literature outlines a number of unique techniques which are all part of the evergreening toolkit.

Most frequently, this is through the patenting of new salt forms, enantiomers or other chemical derivations of an active pharmaceutical ingredient already existing. As the original molecule approaches patent expiration, the originator firm then can reformulate the drug with either of these variants, take out a new patent, replace the market with the new formulation, and thus deprive the generic companies of a clear runway to launch on the original compound. An adjoining plan is the patenting of new delivery systems, modified-release, combinations with other drugs, new dosage schedules or its new therapeutic applications. They are sometimes referred to as secondary or derivative patents, and are not used to protect anything truly new in the chemical realm; instead, they take the advantage of the lead compound of a given inventor and make minor alterations to it.

The question of whether evergreening is a valid use of the patent system or an abuse is debated.

[868] Patents Act, No. 39 of 1970, § 5 (India) (repealed 2005)

[869] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Annex 1C, 1869 U.N.T.S. 299

Advocates suggest that even small-scale advances might have a clinical impact (a new polymorph with an improved bioavailability, a modified release formulation that minimizes dosing schedule and enhances adherence, or a new formulation that streamlines treatment regimens). In this light, the patent system is rightfully compensating such endeavors and the derogatory term evergreening blurs the true worth such innovations can bring to patients.

Opponents counter that when the clinical advantages do exist, they are usually small, and the burdens of the protracted monopoly pricing are high. Empirical analysis of the database of United States Food and Drug Administration drug approvals has repeatedly demonstrated that most new drug approvals are not of entirely novel chemical entities but reformulations or line extensions of a pre-existing product and that the alleged clinical benefits of new drugs are frequently small.[870] More to the point, the intention behind such filings is not the intent to reward clinical innovation on the forefront but to thwart generic competition and sustain revenues. These implications, when it comes to developing country situations, are that the medicines which would otherwise be produced generically at a fraction of the branded cost are still held in patent, and are beyond the reach of millions of patients.

Under this landscape is where the Indian Patents Act 3(d) gains meaning. Instead of turning the determination of the patentability of secondary pharmaceutical patents over to an adversarial system of post-grant challenge, as the United States and European systems effectively do, India instituted the anti-evergreening filter as part of the substantive test of patentability.

3. History of legislation: Ayyangar Report to TRIPS Compliance

The Patents Act, 1970 came as a result of a long legislative struggle to bring the Indian intellectual property system to a level of dynamism in terms of its developmental concerns. Intellectual basis of Ayyangar Committee This report commissioned by the Government of India to investigate the patent system and its relation to Indian industrial development published in 1959. Justice Rajagopala Ayyangar decided that the patent regime subsisting under the Patents and Designs Act, 1911, was not in favour of the Indian industry and welfare, but rather in the favour of foreign multinational interests. He suggested that food, medicine, and chemical product patents should be abolished and that patents on processes only allowable in these areas, which was approved by the 1970 act. This led to a legal framework that was specifically tailored to allow Indian manufacturers to manufacture any drug by any new method irrespective of whether the finished product was patented in another country.

The resultant effect in the next three decades was a surge in the pharmaceutical manufacture in India into a pharmaceutical powerhouse in the world. Cipla, Ranbaxy, Dr. Reddy Labs, and Sun Pharma companies became able to manufacture quality generic analogs of patented drugs at a small fraction of the original drugs costs.[871] This capability was hurled into the international relief by the HIV/AIDS crisis of the late 1990s and early 2000s: at between ten thousand and fifteen thousand US dollars per patient per year, entirely unaffordable by the patients in sub-Saharan Africa, the antiretroviral combination of drugs offered by multinational companies was priced, when comparatively cheap generic antiretroviral medicines were

The move to make India TRIPS compliant was thus one that was politically charged. International law required the government to implement product patents of pharmaceuticals by January 1, 2005, but it was subjected to strong domestic pressures on access by generic drug manufacturers, civil society groups, patients groups, and health professionals that unrestricted product patents would cause the same occurrence of access crises elsewhere.

[870] Food & Drug Admin., Novel Drug Approvals for 2023 (2024)

[871] Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* 45–67 (Oxford Univ. Press 2005)

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 6 AND ISSUE 8 OF 2026

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

The legislative response was in the form of Patents (Amendment) Act, 2005, which aimed to meet the requirements of TRIPS but minimized their effect on public health with a combination of strategies: a rigorous standard of patentability in Section 3(d), pre-grant improvement in Section 25(1), a substantial set of compulsory licensing obligations under Sections 84-92, and restrictions on Section 3(d) was not an addition. The clause was developed as the result of a lengthy debate in parliament and was a considered policy decision. The 2005 amendment made it expressly clear in its Official Statement of Objects and Reasons that it was meant to allay worries about ever-greening and also to make sure that the patent system did not hinder the manufacture and export of cheap pharmaceuticals.[872] The Parliament knew the controversy the provision was to cause in the international community - the United States and many European countries had already given notice of their disapproval in the consultations - but they decided to do it. By so doing, India had enjoyed a policy space that on one hand could not be described as an unlimited one but on the other side, it could enjoy the flexibility that the framework of the TRIPS Agreement allowed.

4. Doctrinal Analysis of Section 3(d)

4.1 The Statutory Text

In the Patents Act, 1970, as amended in 2005 (Section 3(d)) states as follows:

"The sheer discovery of a new form of a known substance which does not lead to an increase in the known efficacy of the known substance or even the sole discovery of any new property or any new use of a known substance or even the mere use of a known process, machine or apparatus unless the known process results in a new product or uses at least one new reactant."

The rationale to the same appears to be as follows: that salts, esters, ethers, polymorphs, metabolites, the pure form, particle size, isomers, mixtures of isomers, complexes and combinations and other derivatives of known substance will be considered to be the same, unless they chance to differ in the property with reference to efficacy.

Together the provision and its explanation prove a number of propositions of the form of many of the same. To be considered patentable a new form of a known substance- such as any one of the chemical variations listed- is considered to be the same substance as the known compound. Second, this premise of identity can be invalidated by demonstrating the existence of a considerable variation in properties as far as efficacy is concerned. Third, the difference in efficacy should be an increase of the known efficacy, as well as any difference. Fourth, the section also discusses new properties and the new use of- existing already-known substances; however these are different terms used above this section.

4.2 The Meaning of 'Efficacy'

The most controversial interpretative question of the subsection 3(d), concerns the meaning of such terms as efficacy. The Patents Act does not provide a definition of the term. There have been two opposing positions in the patent battle about Gleevec. The longstanding interpretation imposed by Novartis was to give the term efficacy a broader meaning other than therapeutic efficacy within the literal sense of pharmacological efficacy but instead as the physico-chemical properties of e.g. solubility, bioavailability, stability and processability. In this interpretation, the improved bioavailability of a new polymorph that met the increased efficacy criterion would fulfill the requirement of improved clinical outcomes although no real improvement of the new polymorph was established compared to the known compound.

The latter, more signal sense of efficacy, proclaimed by the Intellectual Property Appellate Board and later overruled by the Supreme Court, was that the term efficacy in the drug context has to require therapeutic efficacy,

[872] Patents (Amendment) Act, No. 15 of 2005, Statement of Objects and Reasons (India)

i.e., the capacity of the drug compound to bring out the desired curative or prophylactic effect in the patient. The effect of the provision of Section 3(d) does not apply to physico-chemical gains which are not translated into patient gains. This is because in both granting a pharmaceutical patent what is being given has to serve the purpose of encouraging the creation of medicines that are valuable to the patient; anything that enhances the manufacturing process or increases the time that the monopoly can last does not deserve the social cost of the existing monopoly.

There are practical implications of the adoption of the standard of therapeutic efficacy on the Supreme Court in Novartis. This suggests that an applicant could run afoul of the Section 3(d) standard by simply demonstrating a higher level of solubility but will also have to demonstrate that the higher level of solubility translates into a higher level of therapeutic effect in a patient population. It is a very rigorous criterion and the deployment of this criterion necessitates the Patent Office and the courts to mingle with clinical and pharmacological data that goes beyond the typical gauge of novelty and inventive move.

4.3 Relationship with Conventional Patentability Requirements

Section 3(d) is an additional and distinct filter to pharmaceutical patents on top of the customary patentability criteria of novelty, inventive step and industrial applicability of Sections 2 and 25 of the Patents Act. A novel pharmaceutical compound, which includes an act of invention, and is capable of being industrially utilised may yet fail the test under Section 3(d) in case it is a new form of the familiar substance that does not have a greater therapeutic effect. Conversely, a compound passing Section 3(d) however ought to in itself qualify the other patentability requirements.

This quality of form has been criticized because it sets a unique, superior level of pharmaceutical inventions, which is not applicable to the other areas of technology. Article 27(1) of TRIPS states that such patents shall be available on equivalent conditions in all areas of technology and Articles 27(2) and 27(3) offer very few reasons why inventions can be denied protection as patents by its member countries. The Section 3(d) is a competitive form of a discrimination essentially on the basis of pharma inventions as interpreted by the critics.

The answer to this is that it is not provided in a way that constitutes discrimination which is not legal. The idea of improved efficacy becomes just the application of the existing standards of patentability, i.e. the fact that an invention must offer some inventive contribution, to the specific case of pharmaceutical chemistry, where the inventive contribution of a new form of an old substance needs to be evaluated by its therapeutic efficacy. Most commentators have construed the non-discrimination aspect of TRIPS Article 27(1) to mean that it does not preclude discrimination on the basis of the field of technology itself, but rather that exactly the same set of rules of patentability should be applied in dissimilar technologically relevant sectors. Such an interpretation is substantiated by the preamble to TRIPS that acknowledges the right of the members to take a necessary action to save the public health and nutrition.

5. Novartis AG v. Union of India: A Landmark in Global Pharmaceutical Patent Law[873]

5.1 Background

The case which resulted in the landmark 2013 Supreme Court ruling began with the application filed by Novartis AG to patent imatinib mesylate, the beta-crystalline form of the free base imatinib, the active ingredient in the brand name drug Gleevec or Glivec, the treatment of chronic myeloid leukaemia and some other types of cancer. In a 1993 patent application (but not an application because of anticoagulation), its predecessor, Novartis, had revealed Imatinib free base. Mesylate salt of beta-crystalline was

[873] Novartis AG v. Union of India, (2013) 6 SCC 1 (India)

later found, and Novartis argued that this salt, with thirty percent higher bioavailability, was much better than the free base.

In January 2006, the application was refused by the Chennai Patent Office as it did not meet the criteria of Section 3(d): imatinib mesylate was a derivative of the pre-existing drug imatinib, and the purported increase in bioavailability did not amount to an increase in therapeutic effect since no clinical data was available to support this. In 2009, the rejection was upheld by the Intellectual Property Appellate Board. Novartis appealed against the rejection as well as the constitutionality of the Section 3(d) itself in the Madras High Court which upheld the rejection in 2007, observing that TRIPS did not deprive the member states of ample policy space to sound out extra conditions of patentability and the Section 3(d) did not contravene Article 14 of the Constitution of India.

5.2 The Supreme Court's Reasoning

The opinion of the Supreme Court, rendered by a bench of Justice Aftab Alam and Justice Ranjana Prakash Desai, is a complex and finely crafted bit of judicial reasoning, which carefully considers the textual meaning, the history of the statute, the nature of imatinib and the relevant standards of judicial review. The fundamental issue raised by the Court was as follows: was the beta-crystalline form of imatinib mesylate an increased efficacy of imatinib?

The Court did not accept the idea of the Court that, independently of other measures, bioavailability improvements may also meet the efficacy requirement. By interpreting the canon that statutes should be read purposely and with reference to the Parliamentary intent as manifested in the statement of objects and reasons, the Court believed that the intent of Section 3(d) was not only to make certain that evergreening was avoided, but also to make sure that patent protection remained available to true advances in therapeutics. A boost in a physicochemical characteristic like bioavailability would find application under Section 3(d) only to the extent it led to increased therapeutic efficacy - a test of clinical effectiveness which Novartis had failed.

More importantly, the Court depicted the wider scope of Section 3(d) to the public health system of India as well. The judgment includes a number of passages which frankly recognize the social intent of the provision and place it within the constitutional obligation of the right to health as part of the basic right to life of Article 21 in India.[874] The Court took note of the observation that the patent system is not merely to benefit the inventors but to benefit the society as well and that in a country where most people in the population cannot afford the price of patented drugs, the government should have a legitimate interest in not granting patents to make minor changes to a drug that will not help advance the therapeutic frontier.

Not all of the interpretive problems that were presented by Section 3(d) were settled by the judgment. It left unsolved, e.g., what exactly and how much clinical evidence in regard to favorable therapeutic action are needed, the position of bioavailability improvements which are arguably pertinent to therapeutic outcome in particular patient sub-populations, and the role which comparative clinical trials evidence should play. As these open questions are still the source of litigation and commentary, it means that the interpretation development of this provision is not yet exhaustive.

5.3 The Significance of the Constitutional Challenge

Novartis filed a constitutional objection against Section 3(d) in two folds: that it infringed Article 14 of the Constitution guaranteeing an equal protection by treating pharmaceutical inventions contrary to rationality, and that it was contrary to the commitments that India had under TRIPS and was thus ultra vires. The Madras

[874] India Const. art. 21; *see also* Paschim Banga Khet Mazdoor Samity v. State of West Bengal, (1996) 4 SCC 37 (India) (recognising right to health under Article 21)

High Court dismissed each challenge and the Supreme Court saw no reason to provide constitutional validity an issue but decided to adjudicate upon the validity of the dispute on the basis of statutory interpretation. The constitutional issues were thus left unanswered authoritatively and it remained open to the hypothetical possibility that a differently composed bench might reconsider these issues.

Nevertheless, all the weight combined, of the reasoning of the High Court, and the implicit approval of the Supreme Court, is that it is unlikely that a successful constitutional challenge to Section 3(d) will be made. The purpose meets a legitimate legitimate goal, namely preventing evergreening of pharmaceuticals and encouraging the use of affordable medicines, by means that is rationally related. The biased treatment of a pharmaceutical invention can be explained by the fact that there are special public health considerations that put the pharmaceutical industry apart compared to other technological industries. A justification under minimum rationality test used by Indian courts to test economical and social legislation is possibly adequate.

6. Section 3(d) and the Public Health Dimensions of Pharmaceutical Patenting

6.1 India as the Pharmacy of the World

The structure of the pharmaceutical industry in India has a special place in world health. By early 2020, India had become the largest supplier of generic medicine in the world in terms of volumes, a leading source of an over sixty per cent of the world's demand on vaccines, and more than eighty per cent of the supply of antiretroviral medicines purchased by international health programmes such as PEPFAR and the Global Fund. Indian manufacturers have also played a key role in providing medicines against neglected tropical diseases, paediatric formulations, and drug-resistant tuberculosis treatments - relatively low commercial interest areas traditionally by proprietary manufacturers.

This industrial capacity is directly subject to such a legal framework that is provided by the Patents Act, 1970, and such provisions of the Act as Section 3(d). Indian generic companies can manufacture and export the respective medicines without paying any royalty in cases where the secondary pharmaceutical inventions via patent applications have been rejected on Section 3(d) grounds, thus sustaining the price differentials that such makes global health procurement affordable. On the other hand, should India lower the Section 3(d) standard, be it by enacting new legislation, by Patent Office practice, or by reinterpreting the Section as judged, the expandative effect of pharmaceutical patents coverage could impose a hefty burden on the affordability of the medicines that could be purchased by international health programmes and domestic patients alike.

6.2 Pre-Grant Opposition and Section 3(d)

Section 3(d) then does not see its light of day when it comes to litigation but instead in pre-grant opposition proceedings that is created in Section 25(1) of the Patents Act. One can oppose a pharmaceutical patent application by pre-grant opposition due to reasons that the invention described by the applicant falls under Section 3(d) among other reasons. This is done as a widespread procedure since 2005 by non-governmental organisations representing the patients and the general interests involving the healthcare industry in defying patent applications of secondary pharmaceutical inventions.

There have been successful pre-grant opponents to patent applications in new versions of tenofovir (used to treat HIV), new polymorphs of imatinib (used in the application of Gleevec) and new forms of dasatinib and nilotinib (both applied in treating cancer) and new versions of several antibiotics. In both cases, the winning challenge witnessed the permittance of Indian manufacturers to produce and sell generic varieties of these medications, with a seventy to ninety percent reduction in

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 6 AND ISSUE 8 OF 2026

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

prices of the original drug produced by the originator. When these outcomes are combined over the affected groups of patients, the overall public health value is great.

6.3 Compulsory Licensing as a Complementary Mechanism

Section 3(d) is one part of an extended mechanism of public health in the Indian Patents Act. One such way of achieving access where the patented medicines are not available in the market at market rates that are fairly affordable is the compulsory licensing provisions in Chapter XVI of the Act even to where a patent passes the 3(d) test. Its presence and limits are demonstrated by the access to the mechanism and its limited applicability, which is the only mandatory licence in India to date to Bayer sorafenib (Nexavar) a cancer drug, made in favour of Natco Pharma. Intellectual Property Appellate Board and subsequently Bombay High Court upheld compulsory licence finding the de-stratification of the bombs (approximately five thousand dollars per month) made the medicine unavailable to a large part of the patients by Bayer.[875]

Connection between Section 3(d) and compulsory licensing is the sign of stratified character of an Indian access-to-medicines system. Section 3(d) is actant, at the grant of the patents, to avoid granting patents over medicines which are not considered as real therapeutic advances. Compulsory licensing is ex post, such that access is still hindered by a validly licensed patent. All these mechanisms aim to be sure that the patent system is able to serve both an incentive purpose that is to compensate for real innovation and a public interest purpose that is to put the fruits of innovation into the hands of people who need them.

7. Criticisms and Responses

7.1 The TRIPS Compatibility Argument

The most conspicuous denunciation of the Section 3(d) in a legal discourse is that it goes against the mandate of India in the TRIPS Agreement through inserting a discriminatory condition of patentability which does not fall on TRIPS Article 27. Novartis has actively presented this argument in the Indian courts and in other forms of the argument has repeated the argument in the section of the United States Trade Representative Special 301 Reports which has continually placed India on the Priority WatchList, claiming that section 3(d) was a market entry obstacle.[876]

The compatibility of TRIPS which is argued is not convincing based on a number of reasons. Firstly, the inventions that will be taken under the patent shall be new, they should have an inventive step and must be industrializable - all these again are not articulated in detail in the Agreement and the member state is at great liberty on what was invented and what was inventive step as long as their domestic legislation is concerned. Second, WTO members passed, on November 2001, the Doha Declaration on the TRIPS Agreement and Public Health which expressly stated that the TRIPS Agreement did not and should not prevent efforts made by the members to safeguard their own health, and claimed that every member was free in deciding what was an emergency to the health of its population and the full taking of the flexibilities of the TRIPS. Third, none have been convened in the Section 3(d) against India under the WTO dispute settlement procedure suggesting even the most cynical countries in respect of the provision have rationalized that they would not likely pass through the formal dispute resolution process of the Agreement.

7.2 The Innovation Disincentive Argument

The second wave of criticism is that the interpretation of Section 3(d) is to discourage

[875] Natco Pharma Ltd. v. Bayer Corp., C.L.A. No. 1 of 2011 (Controller of Patents, India 2012), *aff'd* Bayer Corp. v. Union of India, (2014) 212 DLT 35 (Del.) (India)

[876] Office of the U.S. Trade Representative, *2023 Special 301 Report* 48–51 (2023)

innovation in the pharmaceutical industry because in the case of an incremental upgrade, which potentially could also be of clinical value, no patent is provided. Without firms being able to secure their new formulations with either patenting or new ways of existing drugs, the argument goes, then the firms will be less inclined to invest in improving existing drugs. The result of this in the long run could be inefficient production of drugs, a reduction in the number of improved preparations, an insignificant number of paediatric preparations, an insignificant number of fixed-dose combinations that do harm patients.

This is a feasible argument theoretically depending on factual assumptions difficult to uphold in the Indian setting. The predominance of small-scale pharmaceutical developments under Section 3(d) scrutiny is overwhelmingly dominated by the huge multi-national corporations all of which are primarily operating in the high-income markets of the world where patents are not being subjected to a filter of a 3(d)-provided one. The Indian patent protection on an invention made later is not lost in favor of the person who made the invention in the worldwide rent of the innovation; it merely gives up the right to take the rent of the Indian patients. Moreover, it is also difficult to functionalise on theory but perhaps a little bit easier at least when, as is mandated by Section 3(d) that the criterion be the therapeutic efficacy which is capable of being established by clinical evidence. ELF: The positive changes in patient outcomes are considered innovations, but even ones that in reality are positive changes can be patented; the ones that are not should be properly excluded.

7.3 The Uncertainty Argument

The third criticism is linked with the legal vagueness caused by the open textured standard of Section 3(d). The condition does not say how closely it is required that the improvement must be prescribed, or that an average of a specified number of words needs to be shown to have occurred in order to be considered an enhanced efficacy, or what sort of evidence shall be admissible. An applicant in patent matters may not predict the success of their application, foreign companies new to Indian patent business may not be able to predict success of their application and the uncertainty about success may cause a lack of filing or investment.

This indictment has more actionable strength, especially in the post-Novartis world where the criteria of therapeutic efficacy has been validated yet whose outlines are yet to be developed. These answers do not mean abandoning the standard but rather evolve it with time as things get more frequently advised by the Patent Office, examined and case law. Guidelines laid out by the Patent Office in India on pharmaceutical patents lend some clarification but more explanation (especially on the place of comparative clinical trial data, what is known of therapeutic equivalence and the provision of improvements at the sub-population level) would help to increase predictability without undermining the content of the provision.

8. Comparative Perspectives

8.1 The TRIPS Flexibilities Framework in Other Jurisdictions

This is not the sole case of India making use of TRIPS flexibilities to limit evergreening in pharmaceuticals although the most codified and judicial developed example of this is still the application of Section 3(d). Other developing countries have caught up with India and made similar arrangements in their own national patent laws or have made parallel plans in this field. The Industrial Property Law of Brazil has provisions situated, which allows the National Health Surveillance Agency to have a prior consent system to patent pharmaceuticals and the effect is one that vetoes patents that are likely to impede availability of life saving medicines. Argentina has (but has not yet) established a set of pharmaceutical patent examination guidelines similar to the concept of

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]
VOLUME 6 AND ISSUE 8 OF 2026
APIS – 3920 - 0001 *(and)* ISSN - 2583-2344
Published by
Institute of Legal Education
https://iledu.in

Section 3(d): it sets standards of patentability on the concept of incremental innovations.

Compulsory licensing (Thailand): This experience can be used as an example of how a supplementary or alternative access mechanism (compulsory licensing) could help in terms of access. In 2006 and 2007 compulsory licences were introduced in Thailand in relation to antiretroviral drugs and a heart medication which prompted a heavy international outrage on the originator companies and their government clients.[877] The episode pointed out the validity of compulsory licensing which is within the bounds of TRIPS and the great political price third world countries pay to exercise such a right in reality. By targeting the grant phase of patent, instead of the post-grant phase, India has managed to save some of these political expenses but with similar outcomes on their public health.

8.2 The European and United States Approaches

It is instructive when compared to the approaches used by the European and the United States in regard to secondary pharmaceutical patents. The European Patent Office and the United States Patent and Trademark Office have patentability standards which are paper-based, formally rigorous but in practice have achieved the ease with which someone can satisfy the criterion to obtain a high volume of secondary-grade pharmaceutical patents. Surveys of the patent archive of the United States indicate that a significant percentage of pharmaceutical patents being awarded during the last few decades are related to modifications of formulation, new dosing formulations, and alternative dosing regimens etc., as opposed to new chemical compounds.[878] The availability of post-grant administrative review, including inter parties review in the United States, opposition proceedings in the European Patent office is a kind of corrective measure, but adversarial and expensive and is not suitable as a large-scale testing procedure of the secondary-depth of patents.

The United States method also corroborates the sucking up power of the pharmaceutical industry in the local political system, which cannot be directly compared to India. To counter the secondary patent abuse, the Congress has on a few occasions paid attention to legislative action to do so, many forms of patent reform bills have been introduced to address the issue, however no wholesale reform similar to that in Section 3(d) has had success. The implication is that the US healthcare system, as well as American patients incurs massive costs due to evergreening which are not incurred necessarily in India.

9. Future Directions and Policy Implications

Section 3(d) has been in operation now 20 years and its fundamental legal form has been validated by the Supreme Court. There are a number of trends which will influence its growth and performance in the next few years. To begin with, the pharmaceutical innovation landscape is evolving. Biologic medicines - big-molecule drugs made by living organisms are inherently gaining importance in the management of cancer, autoimmune, and other severe conditions. These products pose a varied patent issue compared to small-molecule drugs and the applicability of Section 3(d) to claims involving biologic variants, biosimilars, and new therapeutic uses of biologics remains a field that is yet to be developed.

Second, the Indian pharmaceutical industry has grown significantly. Investigations and registration of patents are carried out in India and overseas by Indian firms, which are making original research. With Indian innovators both patent holders and generic makers, the domestic political economy of pharmaceutical patent law might change, putting pressure on standards that support both incremental Indian company innovation and foreign innovation. The

[877] James Love, *Recent Examples of the Use of Compulsory Licenses on Patents*, Knowledge Ecology Int'l Research Note (2007)

[878] Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & Biosci. 590, 593–600 (2018)

difficulty will lie in preserving the integrity of the standard of therapeutic efficacy in such a way that the truly useful Indian innovations are not hurt.

Third, global access to medicines is a challenge that constantly develops. The COVID-19 pandemic revealed the weakness of medicine supply chains around the world and the constraints of the intellectual property system in favoring proprietary over collaboration. The controversy surrounding the TRIPS Waiver proposal that was sponsored by India and South Africa has given rise to critical thinking on the issue of the relationship between intellectual property and fair access to medical technologies. Section 3(d) only deals with one aspect of this difficulty, though it is a vital and practically demonstrated instrument in the wider perspective of the access-to-medicines.

Policymaking-wise, the Indian case of Section 3(d) can be used to impart a few lessons on other developing nations and their deliberations of reforming their pharmaceutical patent laws. The effectiveness of this provision highly relies on the ability of an independent and competent examination of patent image, which necessitates an investment in technical skills and lack of political and commercial influence. It also rests upon an available and resource-rich pre-grant opposition system, based on the consistency of a compulsory licensing system to deal with those that get through the initial sieve, and on the capability of the judicial system to address complex technical and policy issues. Those countries that apply the Section 3(d)-style provisions without the no-analogueous institutional requirements might experience that all the promise the provision offered is not reflected in the actual effect of the provision.

10. Conclusion

In India, section 3(d) of the Patents Act, 1970 was one of the most notable efforts of a developing nation to tune its pharmaceutical patent system in line with the welfare of society, and not with the goal of providing maximum protection to patents. Passed in the context of compliance with the TRIPS agreement, years of experience with the social health impacts of pharmaceutical patent monopolies, and reaffirmed by judicial interpretation over the decades, including the landmark of the recent landslide decision by the Supreme Court against Novartis, the provision has proven both its legal soundness and its practical utility as a tool to combat evergreening.

The main contribution of the provision to the discussion of intellectual property in the world is that it defines a standard of therapeutic efficacy as a method of a distinction between a real drug innovation and a simple improvement. Section 3(d), by obligating new forms of known substances to show improved therapeutic activity, as opposed to just improved physicochemical properties, is quite a simple and significant question: does this patent claim that patients are better? It is a question that the pharmaceutical patent system, in developed and developing nations, would be well advised to pose: in the information that is at the core of the argument supporting the existence of patents on pharmaceutical products.

Those who are critical are correct in the fact that section 3(d) creates an interpretative uncertainty and that the standards in this section should be elaborated. They are wrong, however, in describing the provision to be inconsistent with TRIPS, or an unjustifiable obstacle to pharmaceutical innovation. The clause is a lawful exercise of the policy room which TRIPS purposely leaves to member states, and serves a goal in the public interest, namely; to ensure that true advances in therapeutic progress are actually rewarded and incremental changes are not allowed to cripple access to generic products, which are both legally justified and ethically imperative.

With the impacts of technological and commercial competition, as well as the oxygen of the health of the people, the global pharmaceutical patent system will keep on changing. The Section 3(d) of India is an advanced, empirically valid and constitution-

based way of handling such tensions. The fact that it has lasted over twenty years and has shaped the intellectual property law debate in other developing nations indicates that it should not remain just a domestic curiosity but also an important input in the global effort to create intellectual property systems that can be used to the benefit of humanity.

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 6 AND ISSUE 8 OF 2026

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

CLIMATE CHANGE AS A THREAT MULTIPLIER IN ARMED CONFLICTS: A CRITICAL ANALYSIS OF INTERNATIONAL LEGAL FRAMEWORKS AND GOVERNANCE MECHANISMS

AUTHOR – Ms. E.A. VIDHYABHARATHI, ASSISTANT PROFESSOR IN LAW, KMC COLLEGE OF LAW, TIRUPUR, PH.D. RESEARCH SCHOLAR, SECOND YEAR, THE TAMIL NADU DR. AMBEDKAR LAW UNIVERSITY, SOEL, CHENNAI.

BEST CITATION – Ms. E.A. VIDHYABHARATHI, CLIMATE CHANGE AS A THREAT MULTIPLIER IN ARMED CONFLICTS: A CRITICAL ANALYSIS OF INTERNATIONAL LEGAL FRAMEWORKS AND GOVERNANCE MECHANISMS, *INDIAN JOURNAL OF LEGAL REVIEW (IJLR)*, 6 (8) OF 2026, PG. 728-733, APIS – 3920 – 0001 & ISSN - 2583-2344

Abstract

Climate change has emerged as a defining challenge to contemporary international law, fundamentally reshaping the relationship between environmental degradation and armed conflict. Increasingly conceptualized as a "threat multiplier," it does not directly cause conflict but intensifies existing structural vulnerabilities such as resource scarcity, socio-economic inequality, weak governance, and political instability. This paper critically examines the climate–conflict nexus through a legal and interdisciplinary lens, exploring the pathways through which climate change contributes to violence, including displacement, food insecurity, ecological degradation, and state fragility.

The study evaluates the adequacy of existing international legal frameworks—particularly International Humanitarian Law, international environmental law, human rights law, and the global climate regime—in addressing these emerging challenges. It highlights significant normative and institutional gaps, including the limited protection for climate-displaced persons under the 1951 Refugee Convention, the high threshold for environmental war crimes under the Rome Statute of the International Criminal Court, and the absence of binding mechanisms within the Paris Agreement to address security implications. The paper concludes by advocating for legal reforms that incorporate climate security into international law, strengthen preventive and accountability mechanisms, recognize climate-induced displacement, and promote climate justice. Such an approach is essential for addressing the complex realities of climate-induced conflicts and ensuring sustainable peace in an increasingly fragile global environment.

Keywords: Climate Change; Armed Conflict; Threat Multiplier; International Humanitarian Law; Environmental Governance; Resource Scarcity; Climate Justice.

I. Introduction

The traditional architecture of international law has long been structured around clearly defined categories of war and peace, environment and security, state responsibility and humanitarian protection. However, the accelerating impacts of climate change challenge these conceptual boundaries by introducing complex, interdependent risks that cut across legal regimes.[879] Climate change is no longer confined to environmental discourse; it has become a central determinant of socio-political stability and international security.

[879] Intergovernmental Panel on Climate Change, Climate Change 2021: The Physical Science Basis (2021).

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]
VOLUME 6 AND ISSUE 8 OF 2026
APIS – 3920 - 0001 *(and)* ISSN - 2583-2344
Published by
Institute of Legal Education
https://iledu.in

The notion of climate change as a "threat multiplier" reflects a sophisticated understanding of its role in amplifying existing vulnerabilities.[880] Rather than directly causing conflict, climate change interacts with underlying conditions such as poverty, inequality, demographic pressure, and weak governance, thereby increasing the probability of violence. This perspective has gained increasing recognition within international institutions, particularly the United Nations Security Council, where climate-security linkages are now part of regular deliberations.[881] Scientific findings from the Intergovernmental Panel on Climate Change further substantiate the connection between climate variability and heightened conflict risks. [882]

This paper examines the climate–conflict nexus through a legal lens, focusing on the capacity of international law to address emerging challenges. It adopts a doctrinal and analytical approach, drawing upon treaties, case law, and scholarly literature to assess the adequacy of existing frameworks and propose reforms.

II. Conceptual and Theoretical Framework

A. Environmental Security and Legal Paradigms

Environmental security theory expands the traditional understanding of security by incorporating ecological stability as a prerequisite for peace.[883] Within this framework, environmental degradation is not merely a background condition but an active contributor to instability.

The work of Thomas F. Homer-Dixon provides a foundational understanding of how environmental scarcity contributes to conflict. He identifies two key mechanisms: resource capture, where powerful actors monopolize scarce resources, and ecological marginalization, where vulnerable populations are displaced into fragile environments. These dynamics create conditions ripe for conflict.[884]

B. Multi-Dimensional Pathways

Climate change influences conflict through interconnected pathways:

1. Ecological degradation, reducing resource availability
2. Economic disruption, undermining livelihoods
3. Social dislocation, causing migration and demographic stress
4. Political fragility, weakening state capacity

These pathways interact synergistically, making climate change a systemic risk factor rather than an isolated cause.

III. Climate-Induced Drivers of Conflict

A. Resource Scarcity and Geopolitical Competition

Climate change significantly alters the distribution and availability of natural resources. Water scarcity, in particular, has emerged as a critical driver of conflict, especially in transboundary river basins.[885] As river flows become increasingly unpredictable, states and communities compete for diminishing resources, leading to disputes that may escalate into armed conflict. Similarly, desertification and soil degradation reduce agricultural productivity, intensifying competition over arable land. In agrarian economies, such pressures can destabilize entire regions.

B. Climate-Induced Displacement

One of the most visible consequences of climate change is large-scale displacement. However, individuals displaced by environmental factors fall outside the scope of the 1951 Refugee Convention, which is limited to persecution-based claims.[886]

[880] Thomas F. Homer-Dixon, Environment, Scarcity, and Violence (Princeton Univ. Press 1999),
[881] United Nations Security Council, U.N. Doc. S/PV.7730 (2016) (debate on climate and security).
[882] Intergovernmental Panel on Climate Change, Climate Change 2022: Impacts, Adaptation and Vulnerability (2022).
[883] Barry Buzan, People, States and Fear (Harvester Wheatsheaf 1991).
[884] Thomas F. Homer-Dixon, supra note 2.
[885] Aaron T. Wolf, Shared Waters: Conflict and Cooperation, 32 Ann. Rev. Env't & Resources 241 (2007).
[886] 1951 Refugee Convention, art. 1A (2), July 28, 1951, 189 U.N.T.S. 137.