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Beyond Evergreening: Section 3(d) as a Constitutional Safeguard for the Right to Health

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Abstract

India stands at a unique crossroads where public health imperatives and intellectual property rights intersect most visibly in the pharmaceutical sector. With a substantial portion of its population dependent on affordable medicines and a domestic pharmaceutical industry widely acknowledged as the 'pharmacy of the developing world,' India has crafted a patent framework that seeks to balance innovation incentives with the constitutional right to health. At the center of this framework lies Section 3(d) of the Indian Patents Act, 1970 a provision that has attracted both domestic acclaim and international controversy. Section 3(d) prohibits the grant of patents for new forms of known substances unless they demonstrate a significant enhancement in therapeutic efficacy. Introduced through the Patents (Amendment) Act, 2005, the provision was primarily designed to counter 'evergreening' the practice by which pharmaceutical corporations seek to extend their patent monopolies through minor, often clinically insignificant, modifications to existing drugs. By doing so, it directly supports the availability of affordable generic medications. This manuscript undertakes a comprehensive descriptive examination of Section 3(d), situating it within the broader constitutional, legislative, judicial, and international contexts. The analysis spans the constitutional guarantee of health under Article 21 of the Indian Constitution, the India–TRIPS interface, landmark judicial decisions including Novartis AG v. Union of India, and the comparative position of India relative to other nations. The manuscript concludes that Section 3(d) represents a principled and constitutionally grounded tool that places human welfare above commercial patent strategy, offering a replicable model for other developing nations seeking to protect public health within the TRIPS framework.

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1. INTRODUCTION

The relationship between pharmaceutical patents and public health is one of the most contentious and consequential intersections in modern law, economics, and ethics. On one side of this divide stand pharmaceutical corporations that argue that robust patent protection is necessary to recoup the enormous costs of research, clinical trials, and regulatory approval costs that can run into billions of dollars for a single successful drug. On the other side stand governments, health advocates, and billions of individuals in developing nations who argue that monopoly pricing generated by patents places life-saving medicines beyond reach. India occupies a distinctive position in this global debate. As a country with one

of the world's largest populations, a significant proportion living in poverty, and a thriving domestic generic pharmaceutical industry, India's approach to pharmaceutical patent law has profound national and international implications[1]. India supplies a substantial portion of the world's generic drugs including critical HIV antiretrovirals, tuberculosis medications, and cancer treatments at prices that are a fraction of those charged by originator companies in Western markets2. This ability rests, in large part, on the legal architecture built around Section 3(d) of the Indian Patents Act, 1970. The historical trajectory of India's patent law reflects the evolution of its public health policy. Prior to the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, India's patent system deliberately excluded product patents for pharmaceuticals and agrochemicals, allowing domestic companies to reverse-engineer and produce affordable versions of patented foreign drugs. TRIPS compliance in 2005 required India to introduce product patents, fundamentally altering this landscape. However, India incorporated specific safeguards most notably Section 3(d) to prevent the worst excesses of pharmaceutical patent abuse[3]. This manuscript traces the legislative evolution, judicial interpretation, constitutional underpinnings, and policy implications of Section 3(d). It draws upon landmark judgments, international legal frameworks, and comparative national experiences to present a holistic analysis of this unique provision and its continuing significance as a constitutional safeguard for India's right to health[4].

2. HISTORICAL EVOLUTION OF INDIAN PATENT LAW AND THE ORIGINS OF SECTION 3(D)

2.1 Pre-TRIPS Patent Regime

India's first post-independence patent legislation the Patents Act of 1970 was a deliberate instrument of developmental policy. Enacted in the shadow of the recommendations of the Justice N. Rajagopala Ayyangar Committee (1959), the Act was designed to promote domestic industrial development and ensure affordable access to essential goods including medicines[5]. Its most consequential feature was the exclusion of product patents for food, agrochemicals, and pharmaceuticals[6]. Only process patents were permitted in these sectors, meaning that any company that found a new method to synthesize a known drug could obtain a patent on that process, but not on the drug molecule itself [7]. This structure allowed Indian pharmaceutical companies to flourish by producing generic versions of drugs patented elsewhere, provided they used different manufacturing processes[8]. The result was a vibrant domestic industry capable of meeting national health needs at low cost, and eventually supplying affordable drugs to developing countries worldwide. India's capacity to produce low-cost HIV antiretrovirals became especially critical in the early 2000s when AIDS was devastating populations in sub-Saharan Africa and South Asia.

2.2 The TRIPS Agreement and Its Challenges for India

The Agreement on Trade-Related Aspects of Intellectual Property Rights, concluded as part of the World Trade Organization (WTO) framework in 1994, fundamentally changed the global intellectual property landscape. TRIPS set minimum standards for patent protection that all member states were required to implement. Most significantly, it required product patents for pharmaceuticals, a 20-year patent term, and protections for undisclosed data submitted for drug regulatory approval. For India, TRIPS compliance posed a severe public health challenge. If pharmaceutical companies could now obtain product patents in India, they could block domestic generic production of patented drugs, dramatically increasing prices and limiting access[9]. The Indian government faced intense pressure from multinational pharmaceutical corporations and Western governments to implement TRIPS in a manner favorable to patent holders, while simultaneously facing domestic pressure from health advocates and generic manufacturers to preserve affordability[10]. India used the transition period allowed under TRIPS Articles 65 and 66 to delay full product patent implementation until January 2005. In the intervening years, it engaged in a careful legislative process to craft TRIPS-compliant amendments that incorporated maximum available flexibilities to protect public health[11].

2.3 The Patents (Amendment) Act, 2005 and the Introduction of Section 3(d)

The Patents (Amendment) Act, 2005, which came into force in January 2005, was the culmination of a decade of negotiation, advocacy, and legislative debate. It introduced product patents for pharmaceuticals as required by TRIPS, but simultaneously strengthened Section 3(d) to prevent what Parliament explicitly identified as a threat: the practice of 'evergreening.' Section 3(d), as amended, states that the mere discovery of a new form of a known substance that does not result in the enhancement of the known efficacy of that substance is not patentable. The explanatory note to the provision further clarifies that salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy[12]. The amendment represented a legislative judgment that minor chemical modifications which form the stock in trade of pharmaceutical evergreening strategies should not qualify for renewed patent protection unless they result in a genuinely improved therapeutic outcome[13]. This was a bold and unprecedented move in global patent law, drawing immediate praise from public health advocates and sharp criticism from multinational pharmaceutical companies and their home governments.

Table 1: Evolution of Indian Patent Law Key Amendments Affecting Section 3(d)

Year	Amendment	Key Change	Impact on Section 3(d)
1970	Original Patents Act	Process patents only; no product patents for drugs	No direct provision; public health by default
1999	First Amendment	Mailbox applications; EMR for pharma products	Preparation for TRIPS compliance
2002	Second Amendment	20-year patent term; PCT adherence; new definitions	Redefined invention, inventive step; microorganisms patentable
2005	Third Amendment	Product patents introduced; Section 3(d) strengthened	Efficacy-based threshold for pharma variants; anti-evergreening

3. UNDERSTANDING SECTION 3(D): SCOPE, TEXT, AND INTERPRETATION

3.1 The Statutory Text

Section 3(d) of the Indian Patents Act, 1970 (as amended in 2005) reads as follows: 'The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance' is not considered a patentable invention[14]. The Explanation to the provision states that 'salts, esters, ethers, polymorphs, metabolites, pure forms, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.' The critical operative term is 'efficacy.' In the pharmaceutical context, this has been judicially interpreted to mean therapeutic efficacy the capacity of the substance to treat, prevent, or alleviate disease in patients[15]. Enhancements in other properties, such as improved stability, better bioavailability, reduced hygroscopicity, or improved flow characteristics, do not in themselves qualify under the efficacy threshold unless they translate into enhanced therapeutic outcomes for patients.

3.2 Categories of Innovations Addressed by Section 3(d)

Section 3(d) is specifically directed at a range of pharmaceutical patent strategies that are commonly employed to extend monopoly protection beyond the original patent term. These include polymorphism the patenting of different crystalline forms of the same drug molecule, which may differ in solubility or physical properties but not in therapeutic activity[16]; salt forms the use of different salt forms of an active pharmaceutical ingredient to obtain new patents; particle size reduction patenting nano formulations or modified particle sizes that may improve dissolution but not efficacy; and combination products the combination of known drugs without demonstrating synergistic therapeutic benefit. By excluding these categories from patentability unless therapeutic efficacy is enhanced, Section 3(d) directly targets the technical strategies through which evergreening is typically accomplished. This requires pharmaceutical applicants to present clinical or pharmacological evidence of improved therapeutic outcomes, rather than merely demonstrating novel physical or chemical properties[17].

3.3 The Concept of 'Enhanced Therapeutic Efficacy'

The phrase 'enhanced therapeutic efficacy' has become the centerpiece of pharmaceutical patent disputes in India[8]. While the statute does not define the term precisely, judicial interpretation culminating in the Supreme Court's landmark decision in Novartis AG v. Union of India (2013) has established that efficacy must be understood in the context of what a drug does in the human body: its ability to prevent, treat, or cure disease. Evidence of enhanced therapeutic efficacy may include data from comparative clinical trials demonstrating improved outcomes, superior pharmacokinetic profiles that translate into better patient results, significant reduction in side effects leading to improved treatment adherence, and demonstrated superiority in biological activity compared to the known substance. Critically, the Supreme Court in Novartis held that enhanced bioavailability the rate and extent to which a drug is absorbed into the bloodstream does not automatically translate into enhanced therapeutic efficacy[18]. A drug that reaches therapeutic concentrations more rapidly may have advantages in certain clinical contexts, but unless this translates into measurable improvements in patient outcomes, it does not meet the Section 3(d) threshold.

Table 2: Comparison of Patented Drug Costs vs. Generic Drug Costs Selected Therapeutic Categories (Illustrative data based on Das M. et al., 2017; TRIPS Factsheet on Pharmaceuticals)

Drug Category	Patented Drug (USD)	Generic Drug (USD)	Cost Ratio (X times)
HIV/AIDS Antiretrovirals	10,000 – 15,000	100 – 300	~50–100x
Cancer Drugs (e.g., Imatinib)	2,600 / month	200 / month	~13x
Hepatitis C (Sofosbuvir)	84,000 / course	900 / course	~93x
Cardiovascular Drugs	1,200 / year	80 / year	~15x
Antibiotics (patented)	500 / course	20 / course	~25x

4. THE EVERGREENING PROBLEM AND SECTION 3(D) AS A STRUCTURAL REMEDY

4.1 What is Evergreening?

Evergreening refers to a range of strategies used by pharmaceutical companies to extend the effective market exclusivity of a patented drug beyond the original 20-year patent term[19]. The original patent on a drug's active molecule will eventually expire, allowing generic manufacturers to enter the market with lower-priced alternatives. To delay this competition, companies file successive patents on minor variations of the original molecule including new crystal forms, salt forms, dosage forms, delivery systems, metabolites, or new uses[20]. The economic incentive for evergreening is substantial. A single blockbuster drug can generate billions of dollars in annual revenue. Delaying generic entry by even a few years can protect enormous profit streams. For pharmaceutical companies operating in markets where generic substitution is the norm, evergreening has become a standard component of intellectual property management strategy[13]. The consequence for public health is severe. Each year of extended monopoly protection can mean that millions of patients continue to pay premium prices for medicines that could otherwise be produced and sold generically at a fraction of the cost[21-14]. In developing countries with limited healthcare financing, the difference between a patented drug and its generic equivalent can be the difference between receiving treatment and going without.

4.2 Section 3(d) as an Anti-Evergreening Tool

Section 3(d) addresses the evergreening problem at its structural root. By requiring that new forms of known substances demonstrate enhanced therapeutic efficacy to qualify for patent protection, the provision disrupts the primary mechanism through which evergreening occurs. Patent applicants cannot simply register a new polymorph or salt form and claim a new 20-year term; they must demonstrate that their new form actually treats disease better than the original substance[25]. This is a demanding standard. Most evergreening

applications rely precisely on minor physical or chemical modifications that do not improve therapeutic outcomes they improve manufacturing properties, storage characteristics, or commercial viability without translating into patient benefit. Section 3(d) effectively says: if your invention does not benefit patients, patent law will not protect it at the expense of public access. The practical effect has been profound. A number of patent applications that would routinely have been granted in the United States or Europe have been rejected in India under Section 3(d). This has allowed Indian generic manufacturers to continue producing affordable versions of these medicines, maintaining India's capacity to supply low-cost drugs both domestically and to other developing countries.

Figure 1: Decision Flow Section 3(d) Patent Assessment Process

5. JUDICIAL INTERPRETATION OF SECTION 3(D): KEY CASES

5.1 Novartis AG v. Union of India (2013): The Landmark Ruling

The Supreme Court of India's judgment in Novartis AG v. Union of India, decided in April 2013, represents the most comprehensive and authoritative judicial interpretation of Section 3(d) to date. The case arose from Novartis's application to patent the beta-crystalline form of imatinib mesylate-the active ingredient of Glivec, a revolutionary cancer drug used to treat chronic myeloid leukaemia (CML) and gastrointestinal stromal tumours (GIST). Glivec was already one of the most expensive cancer drugs on the market, priced at approximately USD 2,600 per month, far beyond the reach of most Indian patients. Generic versions were available at approximately USD 200 per month. Novartis argued that the beta-crystalline form was a new and distinct invention, exhibiting 30% greater bioavailability than the free base form of imatinib. The company contended that this improved bioavailability constituted enhanced efficacy within the meaning of Section 3(d). The Indian Patent Office, the Intellectual Property Appellate Board (IPAB), and ultimately the Supreme Court all rejected this argument. The Supreme Court, in a detailed and scholarly judgment authored by Justice Aftab Alam, held that 'efficacy' in the context of pharmaceuticals must mean therapeutic efficacy the ability to treat disease. Improved bioavailability is a pharmacokinetic property, not a therapeutic outcome measure. The Court noted that bioavailability improvements do not automatically translate into therapeutic improvements, and Novartis had not submitted clinical evidence demonstrating that the beta-crystalline form produced better patient outcomes than the earlier imatinib compound. The Court also addressed the legislative history of Section 3(d), noting that Parliament had specifically intended the provision to prevent evergreening by multinational pharmaceutical companies. The ruling thus vindicated both the letter and the spirit of the provision, setting a rigorous and clinically grounded standard for pharmaceutical patent applications involving new forms of known substances.

The significance of the Novartis judgment extends beyond its immediate outcome. It established that India's patent jurisprudence would prioritise patient access and therapeutic benefit over technical novelty or commercial innovation in the pharmaceutical sector. It demonstrated that developing countries could make independent, principled patent policy decisions that deviate from the standards of advanced economies when public health interests demand it.

5.2 Union of India v. Bayer Corporation (2010) Compulsory Licensing

While not directly about Section 3(d), the Bayer Corporation case illustrates the broader framework within which Section 3(d) operates a framework oriented toward public health and access to medicines. Natco Pharma applied for a compulsory licence to manufacture a generic version of sorafenib tosylate, sold by Bayer under the brand name Nexavar, for the treatment of liver and kidney cancer. The drug was priced at approximately USD 5,600 per month, and was unavailable in adequate quantities to meet domestic demand. The Controller of Patents granted the compulsory licence, finding that Bayer had failed to meet the working requirement under Indian patent law, that the drug was not available at a reasonably affordable price, and that it had not been manufactured in India to a sufficient extent. The Bombay High Court upheld this decision, affirming that patent rights are not absolute and must yield to public welfare in appropriate circumstances. The Bayer case demonstrated that the Indian patent system's health-orientation extends beyond Section 3(d) to encompass compulsory licensing as an equally important safeguard. Together, these provisions create a multi-layered public health protection architecture within India's patent law framework.

5.3 Cipla Ltd. v. F. Hoffmann-La Roche Ltd. (2015): Balancing Infringement and Access

The Delhi High Court's decision in Cipla Ltd. v. F. Hoffmann-La Roche Ltd. addressed a patent infringement action by Roche relating to erlotinib hydrochloride, marketed under the brand name Tarceva for the treatment of non-small cell lung cancer. Cipla produced a generic version at significantly lower cost, which Roche sought to block through injunctive relief. The Court refused to grant an interlocutory injunction, undertaking a balance of convenience analysis that explicitly weighed the public interest in access to affordable cancer treatment against Roche's commercial interests. The judgment affirmed that generic access to life-saving medicines represents a significant public interest consideration that courts must weigh in

pharmaceutical patent disputes. Although the eventual outcome on the merits remained contested, the case reinforced the principle that patent rights are not unlimited monopolies but rather conditional entitlements that must be exercised in a manner consistent with public health obligations.

Table 3: Landmark Indian Judicial Decisions on Pharmaceutical Patents and Section 3(d)

Case	Year	Court	Issue	Outcome & Significance
Novartis AG v. Union of India	2013	Supreme Court of India	Patent on beta-crystalline form of Imatinib mesylate (Glivec)	Patent denied; efficacy threshold of Section 3(d) upheld; set precedent for anti-evergreening
Union of India v. Bayer Corporation	2010	High Court / Controller of Patents	Mandatory licence for sorafenib tosylate (Nexavar)	Mandatory licence granted; balance between patent rights and public access affirmed
Cipla Ltd. v. F. Hoffmann-La Roche	2015	Delhi High Court	Patent infringement on erlotinib (Tarceva)	Injunction refused; affirmed importance of generic access for cancer treatment
Enercon India v. Enercon GmbH	2014	Supreme Court	Compulsory licensing and technology transfer	Highlighted the role of technology access in public interest cases

6. THE CONSTITUTIONAL DIMENSION: SECTION 3(D) AND THE RIGHT TO HEALTH

6.1 The Right to Health under Article 21

The Indian Constitution does not expressly enumerate health as a fundamental right. However, through a long line of progressive judicial decisions, the Supreme Court has established that the right to health is an integral component of the right to life guaranteed by Article 21. In decisions ranging from Paschim Banga Khet Mazdoor Samity v. State of West Bengal to Consumer Education and Research Centre v. Union of India, the Court has held that the right to live with human dignity encompasses the right to receive medical care and the right to be protected from public health hazards. This constitutional interpretation has direct implications for pharmaceutical patent law. If the right to health is a fundamental right guaranteed by Article 21, then laws and policies that threaten access to life-saving medicines may be subject to constitutional challenge[26]. Conversely, provisions like Section 3(d) that are designed to protect access to affordable medicines acquire constitutional significance they are not merely technical patent rules but instruments of constitutional governance.

6.2 Directive Principles and the State's Health Obligations

Beyond Article 21, the Indian Constitution imposes positive obligations on the state through the Directive Principles of State Policy (Articles 36–51). Article 39 directs the state to ensure that the health and strength of workers are not abused. Article 41 requires the state to make effective provision for securing the right to public assistance in cases of sickness and disablement[27]. Article 47 specifically directs the state to regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties. While Directive Principles are not directly enforceable, the Supreme Court has consistently held that they must be read in conjunction with fundamental rights and that legislation enacted to fulfil directive principles is entitled to constitutional protection. Section 3(d), as an instrument of health protection aligned with the directive principles, thus possesses both policy legitimacy and constitutional significance[28].

6.3 International Human Rights Dimensions

India's constitutional health obligations are reinforced by international human rights commitments. The right to health is recognized in Article 25 of the Universal Declaration of Human Rights (1948), Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966), and numerous other international instruments. India is a party to the ICESCR and is legally bound by its obligations under Article 12, which recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The UN Committee on Economic, Social and Cultural Rights, in General Comment No. 14, has interpreted the right to health to include the availability, accessibility, acceptability, and quality of health goods and services. Accessibility requires that medicines and healthcare be economically accessible affordable for all. This international standard directly supports the policy rationale of Section 3(d) [29]. Article 27(2) of the Universal Declaration of Human Rights and Article 15(1) (c) of the ICESCR also address the relationship between intellectual property rights and other human rights, recognizing the right of authors and inventors to benefit from their work, but situating this right within a broader human rights framework that includes the right to health. The intersection of these provisions underscores that intellectual property rights and the right to health are not inherently in conflict both can be accommodated within a balanced legal framework, precisely what Section 3(d) seeks to achieve[30].

7. TRIPS, THE DOHA DECLARATION, AND INDIA'S INTERNATIONAL FRAMEWORK

7.1 TRIPS Obligations and Flexibilities

The Agreement on Trade-Related Aspects of Intellectual Property Rights sets minimum standards of intellectual property protection that all WTO member states must implement. For pharmaceutical patents, the key obligations include the availability of product patents for pharmaceutical inventions, a minimum patent term of 20 years, and data exclusivity provisions. However, TRIPS also incorporates important flexibilities that allow member states to calibrate patent protection in accordance with national circumstances and public health needs[31-34]. Article 27.1 of TRIPS requires that patents be available for inventions that are new, involve an inventive step, and are capable of industrial application. However, it does not define these criteria, leaving member states considerable discretion in establishing patentability

standards. India has used this discretion to establish the enhanced therapeutic efficacy standard of Section 3(d), which represents a stricter application of the newness or non-obviousness requirement in the pharmaceutical context. Article 28 confers on patent holders the right to exclude others from making, using, or selling the patented invention. Articles 31 and 31bis address compulsory licensing, providing mechanisms for overriding patent exclusivity in cases of national emergency, public health crises, or situations where the patent holder fails to meet domestic demand at reasonable prices. India has availed itself of these provisions, most notably in the Bayer compulsory licensing case.

7.2 The Doha Declaration on TRIPS and Public Health

The Doha Ministerial Conference of the WTO in November 2001 adopted the Declaration on the TRIPS Agreement and Public Health a landmark document that affirmed the right of WTO member states to use TRIPS flexibilities to protect public health. The Declaration confirmed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health, and that it should be interpreted and implemented in a manner supportive of WTO members' right to protect public health. The Doha Declaration explicitly stated that each member has the right to grant compulsory license's and the freedom to determine the grounds upon which such licenses are granted, the right to determine what constitutes a national emergency or other circumstances of extreme urgency, and the right to establish its own regime of exhaustion of intellectual property rights. Most importantly, it affirmed that the TRIPS Agreement should be read in light of the objective to promote access to medicines for all[35-37]. India's Section 3(d) is entirely consistent with the Doha Declaration's philosophy. By maintaining high patentability standards for pharmaceutical modifications, India exercises its sovereign right under TRIPS to define what constitutes a patentable invention, consistent with the Doha affirmation that TRIPS flexibilities exist to be used when public health requires it.

Table 4: TRIPS Flexibilities Used by India to Safeguard Public Health

TRIPS Flexibility	Mechanism	Indian Implementation	Public Health Benefit
Patentability Standards	Art. 27 - Member discretion	Section 3(d) – efficacy requirement	Prevents evergreening; promotes generic entry
Compulsory Licensing	Art. 31 - National emergency	Sections 84–92A, Patents Act 1970	Allows domestic generic production of unaffordable drugs
Parallel Imports	Art. 6 - International exhaustion	Section 107A(b) – Bolar provision	Reduces drug prices via market competition
Research Exception	Art. 30 - Exceptions to rights	Section 107A(a) – research exemption	Permits generic R&D prior to patent expiry
Transition Periods	Art. 65/66 - Developing nations	India used transition till 2005	Delayed product patent obligations; maintained generic supply

8. INDIA AS THE PHARMACY OF THE DEVELOPING WORLD

8.1 The Indian Generic Pharmaceutical Industry

India is one of the largest producers and exporters of generic pharmaceutical products in the world, supplying approximately 20% of global generic drug exports by volume. Indian companies supply more than 60% of global demand for vaccines and a substantial proportion of antiretroviral drugs for HIV treatment programs in Africa and South Asia. The country is home to hundreds of WHO pre-qualified manufacturing facilities, and Indian-made generics are supplied to global health procurement programmes including those of the Global Fund, PEPFAR (the US President's Emergency Plan for AIDS Relief), and UNICEF. This capacity rests on a legal foundation built, in part, on Section 3(d). By preventing the multiplication of pharmaceutical patents through evergreening, the provision ensures that the original patent on a drug molecule expires at the end of its legitimate 20-year term, at which point generic manufacturers are free to produce and sell affordable versions. Without this safeguard, the proliferation of secondary patents on minor modifications could indefinitely extend effective market exclusivity, as occurs in countries with weaker patentability standards[38].

8.2 Economic and Public Health Impact of Generic Access

The economic significance of generic drug access is enormous. Generic drugs typically cost 80–95% less than their branded equivalents. In a country where a substantial majority of the population pays for healthcare out of pocket, access to affordable generics is not merely a matter of consumer preference it is a determinant of whether treatment is received at all. High drug prices are among the leading causes of catastrophic health expenditure and medical impoverishment in India and other developing countries. Beyond individual patients, the availability of affordable generics enables national health programs to extend their coverage more broadly and to treat more patients with the same budgetary resources. India's Revised National Tuberculosis Control Programme (RNTCP) and National AIDS Control Organisation (NACO), for example, rely heavily on generic drugs to achieve their treatment targets. The HIV treatment programs of multiple sub-Saharan African countries depend on Indian-produced generic antiretrovirals to maintain treatment for millions of patients. The role of Section 3(d) in maintaining this supply cannot be overstated. Had India allowed multinational pharmaceutical companies to evergreen their patents on antiretroviral drugs, TB medications, and cancer treatments, the resulting price increases would have placed these treatments beyond the reach of national health programs and individual patients throughout the developing world[39].

9. CRITICAL ANALYSIS: ARGUMENTS FOR AND AGAINST SECTION 3(D)

9.1 Arguments in Support of Section 3(d)

The case for Section 3(d) rests on several powerful and complementary arguments. First, from a constitutional perspective, the provision operationalizes the right to health under Article 21 by ensuring that patent protection is not used to restrict access to life-saving medicines. A patent system that

enables evergreening effectively allows private commercial interests to override the constitutional guarantee of health a constitutionally impermissible outcome. Second, from an innovation policy perspective, Section 3(d) channels innovation toward genuinely valuable therapeutics. The pharmaceutical industry's argument that evergreening supports innovation is questionable. The R&D investment required to create a new polymorph or salt form is minimal compared to the investment needed to discover and develop a genuinely new drug. Patents on trivial modifications do not incentivise the kind of innovation that delivers medical breakthroughs; they incentivise patent strategy divorced from therapeutic value. Section 3(d) realigns patent incentives with the actual purpose of the patent system: the promotion of genuine innovation. Third, Section 3(d) is consistent with and supported by international law, specifically the TRIPS Agreement, the Doha Declaration, and human rights instruments that affirm the right to health. India's exercise of TRIPS flexibilities through Section 3(d) is legitimate, principled, and consistent with its WTO obligations. The provision demonstrates that TRIPS compliance and public health protection are not mutually exclusive goals[40].

9.2 Criticisms and Counterarguments

Opponents of Section 3(d) principally the multinational pharmaceutical industry and certain developed country governments have advanced several criticisms. The most common is that the provision is excessively restrictive and creates legal uncertainty, discouraging pharmaceutical R&D investment in India. Some critics argue that by setting a higher patentability standard than is common in other major economies, India places itself at a competitive disadvantage in attracting pharmaceutical innovation partnerships. A related criticism is that 'enhanced therapeutic efficacy' is an ambiguous standard that creates unpredictability for patent applicants. The argument is that without clear and objective criteria for what constitutes enhanced efficacy, patent decisions may be inconsistent, arbitrary, or politically influenced. This critique has some merit: The Novartis judgment, while authoritative, does not provide a comprehensive operational framework for assessing efficacy in all cases. A third criticism, advanced by some innovation economists, is that incremental pharmaceutical innovation the kind targeted by Section 3(d) does in fact create patient value even if it does not represent fundamental scientific advances. Improved drug formulations, better stability, reduced dosing frequency, and improved tolerability represent real benefits that patients and clinicians value. Denying patent protection for such improvements, critics argue, may reduce the incentive to invest in beneficial refinements. These criticisms must be assessed in light of the specific context of pharmaceutical patents in developing countries. The empirical evidence on whether pharmaceutical R&D investment is significantly influenced by patent standards in individual developing countries is limited. The incentive arguments for incremental innovation, while not without merit, must be weighed against the demonstrated public health costs of evergreening costs that fall disproportionately on the poorest and most vulnerable populations.

10. COMPARATIVE PERSPECTIVE: SECTION 3(D) IN GLOBAL CONTEXT

India's Section 3(d) is unique among major economies in its explicit statutory restriction on pharmaceutical evergreening. A comparative survey reveals significant variation in how different countries approach this issue, highlighting both the distinctiveness of India's approach and its potential as a model for other developing nations. In the United States, the patent system does not have a specific provision comparable to Section 3(d). Minor pharmaceutical modifications new polymorphs, salt forms, and delivery systems-are routinely granted patent protection provided they meet the standard requirements of novelty, non-obviousness, and utility. The US patent system has been widely criticised for facilitating evergreening, with studies documenting that the majority of pharmaceutical patents granted in recent decades relate to modifications of existing drugs rather than genuinely new molecular entities. The European Patent Convention requires that inventions be novel, non-obvious (inventive step), and industrially applicable, but does not impose a therapeutic efficacy threshold for pharmaceutical modifications. European patent practice has evolved a doctrine of 'therapeutic selection inventions' that can provide patent protection for known compounds used in new dosing regimens or patient populations, but this falls short of the anti-evergreening standard of Section 3(d). Brazil, one of the other large developing economies with significant pharmaceutical interests, has a system of prior examination by its National Health Surveillance Agency (ANVISA) for pharmaceutical patent applications, which provides some public health scrutiny beyond purely technical patentability assessment. However, Brazil lacks a statutory provision equivalent to Section 3(d). Thailand has used compulsory licensing actively to override pharmaceutical patents and secure access to affordable generic treatments, but without the upstream statutory filter that Section 3(d) provides. South Africa, which has faced some of the most severe public health challenges from pharmaceutical patent restrictions, including the landmark case in which multinational pharmaceutical companies initially sought to block the country's access to generic AIDS medications, has subsequently undertaken patent law reform informed in part by India's Section 3(d) experience. The African Regional Intellectual Property Organization (ARIPO) has also begun to examine higher patentability standards for pharmaceuticals in light of India's model.

Table 5: Comparative Analysis of Evergreening Restrictions across Major Economies

Country / Region	Patentability Standard	Evergreening Restriction	Generic Market Strength	TRIPS+ Pressure
India	High – efficacy enhancement required (Sec. 3d)	Strong – statutory provision against trivial changes	Very High – global generic hub	Moderate
USA	Utility, novelty, non-obviousness	Low – minor variants routinely patentable	Moderate	Low (sets standards)
European Union	Novelty + inventive step	Moderate – via patent opposition proceedings	Moderate	Low
Brazil	Prior examination by health authority (ANVISA)	Moderate – administrative rejection possible	High – domestic generics	Moderate

South Africa	Weak – lacks specific efficacy provision	Low – no statutory equivalent of Sec. 3(d)	Moderate – improving	High
Thailand	Moderate – compulsory licensing used actively	Low – limited statutory provision	Moderate	High

11. SECTION 3(D) AND INDIA'S NATIONAL HEALTH PROGRAMMES

The practical significance of Section 3(d) can be illustrated through its impact on India's major national health programmes and the populations they serve. India's National AIDS Control Programme has been one of the most dramatic beneficiaries. The programme's ability to provide antiretroviral therapy to millions of HIV-positive patients at affordable cost rests critically on the availability of generic fixed-dose combination antiretroviral drugs. Multiple antiretrovirals, including tenofovir, efavirenz, lamivudine, and combination products, have been the subject of patent applications in India that have been denied or challenged under Section 3(d). Without these rejections, the cost of HIV treatment in India would be multiples of its current level, placing treatment beyond the reach of the majority of patients. The Revised National Tuberculosis Control Programme (RNTCP), later renamed the National Tuberculosis Elimination Programme (NTEP), similarly depends on access to affordable generic anti-tuberculosis drugs. India carries one of the largest burdens of tuberculosis infection in the world, including a rising tide of drug-resistant TB strains requiring second-line and third-line treatments. The affordability of these treatments, including newer drugs like bedaquiline and delamanid, is directly influenced by the patent regime governing their production and supply. India's National Cancer Control Programme has also benefited from Section 3(d), most visibly in the aftermath of the Novartis judgment. The availability of generic imatinib at approximately one-thirteenth of the Glivec price has transformed the treatment landscape for chronic myeloid leukaemia patients in India, dramatically expanding access to what was previously an effective but unaffordable treatment. Similar access benefits have accrued for other cancer drugs, including generic versions of sorafenib, erlotinib, and other targeted therapies. Reproductive and maternal health programmes, including the National Health Mission's Reproductive and Child Health Programme, have benefited from the availability of affordable generic contraceptives, antibiotics, and maternal health medications. India's Jan Aushadhi scheme, which operates a network of generic drug retail outlets to provide affordable medicines to the general population, is similarly dependent on the availability of competitively priced generic drugs an availability that Section 3(d) helps maintain.

12. THE WAY FORWARD: REFORM PROPOSALS AND POLICY RECOMMENDATIONS

12.1 Clarifying the Therapeutic Efficacy Standard

The primary challenge in implementing Section 3(d) is the ambiguity of the 'enhanced therapeutic efficacy' standard. While the Novartis judgment provides valuable guidance, the application of this standard to novel pharmaceutical technologies including biologics, nano formulations, gene therapies, and personalized medicines may require further clarification. The Indian Patent Office should develop detailed examination guidelines, in consultation with the Central Drugs Standard Control Organization (CDSCO) and leading pharmacologists, to provide clearer criteria for assessing therapeutic efficacy claims in pharmaceutical patent applications. These guidelines should specify the types of evidence clinical trial data, comparative pharmacodynamic studies, real-world effectiveness data that will be considered in assessing efficacy claims, and the standards of proof that applicants must meet. Greater clarity would serve the interests of applicants and the public alike, reducing litigation uncertainty and improving the consistency and quality of patent decisions.

12.2 Strengthening Institutional Capacity

Effective implementation of Section 3(d) requires patent examiners with sufficient expertise in pharmaceutical science, pharmacology, and clinical medicine to critically assess efficacy claims. The Indian Patent Office has made significant progress in building technical capacity, but continued investment in training, access to scientific literature, and interdisciplinary collaboration with health regulatory authorities is essential. A specialised pharmaceutical patent examination unit, drawing on scientific expertise from both patent and health regulatory domains, would strengthen the quality of patent decisions under Section 3(d).

12.3 Enhancing Transparency and Access to Patent Information

India currently lacks a unified, publicly accessible database that comprehensively tracks pharmaceutical patent applications, grants, oppositions, and linkage with drug regulatory approvals. Such a database potentially modelled on the US FDA's Orange Book or the patent transparency initiatives of several European countries would enable health authorities, generic manufacturers, civil society organisations, and patients to monitor the pharmaceutical patent landscape and identify potential threats to generic access. Greater transparency would also enhance accountability in patent decision-making and facilitate research into the operation and impact of Section 3(d).

12.4 Promoting Research and Development for Neglected Diseases

Section 3(d)'s critics argue that it discourages pharmaceutical research investment in India. The appropriate response is not to weaken the provision but to develop alternative innovation incentive structures that do not rely on monopoly pricing. These may include government-funded research prizes for the development of treatments for neglected tropical diseases, public-private partnerships for priority drug development, open-source drug discovery initiatives, and differential pricing agreements for developing country markets. India, with its large and sophisticated pharmaceutical industry, is well positioned to develop and pilot innovative R&D financing models that decouple research incentives from access-restricting monopoly rights.

12.5 International Cooperation and South-South Learning

India's experience with Section 3(d) represents a valuable body of legal knowledge that other developing countries can adapt to their own circumstances. Active international cooperation through sharing of patent examination practices, judicial reasoning, and policy experiences can strengthen the capacity of developing countries to use TRIPS flexibilities effectively. India should engage proactively in multilateral forums, including the WTO TRIPS Council, the WHO, and regional intellectual property organizations, to advocate for policy space for health-oriented patent law reform.

13. SECTION 3(D) AS AN ETHICAL INSTRUMENT

The analysis of Section 3(d) cannot be complete without acknowledging its ethical dimension. Patent law, at its core, is a social contract: society grants inventors a temporary monopoly in exchange for the disclosure and eventual contribution of the invention to the public domain. In the pharmaceutical context, this social contract involves an implicit commitment that the benefits of patent protection in the form of incentives for innovation will ultimately serve human health and welfare. When pharmaceutical patents are used primarily as instruments of market strategy rather than innovation reward when the predominant purpose of a patent filing is to extend commercial exclusivity rather than to protect genuine therapeutic advances the social contract of patent law is violated. The public confers monopoly rights on the understanding that these rights will reward and encourage medical progress. When they are used instead to delay affordable access without corresponding benefit to patients, the ethical foundation of patent protection is undermined. Section 3(d) can be understood, in this ethical framework, as Parliament's reassertion of the social contract of patent law in the pharmaceutical domain. By insisting that patent protection be granted only for genuine therapeutic advances, the provision restores the authentic purpose of pharmaceutical patents to reward and encourage innovations that improve human health while refusing to extend those rights to strategic modifications whose primary purpose is commercial rather than therapeutic. This ethical dimension is particularly salient given the asymmetry between the beneficiaries and the victims of pharmaceutical evergreening. The beneficiaries are typically large, well-resourced multinational corporations whose profits already reflect the enormous rewards that the global patent system provides to genuine innovators. The victims are typically poor patients in developing countries who lack the political or economic power to defend their interests in international trade negotiations. Section 3(d) represents, among other things, an affirmation that the Indian legal system will not allow this asymmetry of power to translate into an asymmetry of justice.

14. RESULTS

This study undertakes a descriptive and doctrinal analysis of Section 3(d) of the Indian Patents Act, 1970, drawing upon statutory text, judicial decisions, constitutional interpretation, and international legal frameworks. The results of this analysis reveal several consistent and empirically observable outcomes. First, Section 3(d) has significantly curtailed pharmaceutical evergreening in India. Patent applications relating to new forms of known substances such as polymorphs, salts, esters, and dosage modifications have faced a substantially higher rejection rate unless accompanied by credible evidence of enhanced therapeutic efficacy. This has prevented the routine grant of secondary patents that are commonly approved in jurisdictions with lower patentability thresholds. Second, judicial interpretation most notably by the Supreme Court of India in Novartis AG v. Union of India (2013) has clarified and operationalised the meaning of "efficacy" as therapeutic efficacy rather than mere improvements in physicochemical properties or bioavailability. This interpretation has introduced a patient-centric evaluative standard into pharmaceutical patent law. Third, the implementation of Section 3(d) has facilitated sustained generic market entry following the expiry of primary patents. The absence of extended patent thickets has enabled Indian generic manufacturers to introduce affordable alternatives in critical therapeutic areas such as oncology, HIV/AIDS, tuberculosis, and hepatitis C. Fourth, the analysis indicates that Section 3(d) operates within the permissible flexibilities of the TRIPS Agreement, as affirmed by the Doha Declaration on TRIPS and Public Health. No adverse findings have been issued against India within the WTO dispute settlement framework concerning the legality of Section 3(d). Finally, the cumulative effect of Section 3(d), read alongside compulsory licensing provisions and research exceptions, has contributed to India's continued role as a major global supplier of affordable medicines, particularly to low- and middle-income countries. The following table-5 provides a concise reference summary of the key legal provisions, cases, and concepts discussed in this manuscript, intended as a quick reference guide for readers and researchers.

Table 6: Summary Reference - Key Legal Provisions, International Instruments, and Landmark Cases

Provision / Case	Description	Significance
Section 3(d), Patents Act 1970	Prohibits patents on new forms of known substances without enhanced therapeutic efficacy	Core anti-evergreening provision; protects generic access
Article 21, Indian Constitution	Right to life and personal liberty	Basis for constitutional right to health in India
Article 47, Indian Constitution	Duty of the state to improve public health and raise nutritional standards	Directive principle supporting health-oriented patent policy
TRIPS Agreement, 1994	Minimum IP standards for WTO members; includes pharma product patents	Framework India must comply with; Section 3(d) operates within its flexibilities
Doha Declaration, 2001	Affirms WTO members' right to use TRIPS flexibilities for public health	International legitimation of India's Section 3(d) approach
Novartis v. Union of India (2013)	Supreme Court denied patent on beta-crystalline imatinib mesylate; interpreted 'efficacy' as therapeutic	Landmark: set standard for therapeutic efficacy under Section 3(d)
Bayer v. Union of India (2010)	Compulsory licence granted for sorafenib tosylate at affordable price	Affirmed compulsory licensing as public health safeguard

Cipla v. Roche (2015)	Injunction refused for erlotinib patent infringement; patient access weighed	Balanced IP enforcement with public interest in generic cancer treatment
Article 12, ICESCR (1966)	Right of everyone to highest attainable standard of health	International human rights foundation for right to medicine access

15. CONCLUSION

Section 3(d) of the Indian Patents Act, 1970 is more than a technical provision of patent law. It is the expression of a constitutional, ethical, and policy commitment to ensuring that the rights and welfare of India's citizens are protected against the potentially adverse effects of global intellectual property rules. By requiring that new forms of known pharmaceutical substances demonstrate enhanced therapeutic efficacy to qualify for patent protection, the provision prevents the most common strategy used to extend pharmaceutical monopolies evergreening and preserves the availability of affordable generic medicines. The landmark judgment in Novartis AG v. Union of India has given Section 3(d) authoritative judicial construction, establishing that therapeutic efficacy not physical or chemical novelty is the relevant standard for pharmaceutical patent protection in India. This construction is consistent with the text, purpose, and legislative history of the provision, and aligns Indian patent law with the constitutional guarantee of health as a dimension of the right to life under Article 21. India's approach under Section 3(d) demonstrates that TRIPS compliance and robust public health protection are not mutually exclusive goals. By thoughtfully employing the flexibilities available under TRIPS, and by having the institutional and judicial capacity to implement these flexibilities effectively, India has created a patent regime that rewards genuine pharmaceutical innovation while refusing to allow the patent system to become an instrument of healthcare exclusion. The challenges ahead are real. The expanding frontier of pharmaceutical biotechnology, including biological drugs, biosimilars, gene therapies, and precision medicine, will create new patentability questions that Section 3(d)'s therapeutic efficacy standard must be applied to address. International pressure on India to weaken its pharmaceutical patent standards through bilateral trade agreements, diplomatic channels, and commercial litigation will continue. And the institutional capacity of India's patent examination and adjudicatory systems will need to keep pace with the increasing complexity of pharmaceutical patent disputes. However, none of these challenges require the abandonment of the principles that Section 3(d) embodies. They require, rather, the ongoing refinement and strengthening of those principles through clearer legislative guidance, stronger institutional capacity, greater transparency, and deeper international cooperation. In the final analysis, Section 3(d) stands as a model for how law can function as an instrument of both innovation and compassion rewarding genuine scientific creativity while ensuring that the fruits of human ingenuity in medicine remain accessible to all who need them, regardless of their economic circumstances. It demonstrates that a country can engage with the global intellectual property order on its own constitutional terms, asserting the primacy of human health over commercial privilege without rejecting the legitimate incentive functions of patent protection. This balance principled, pragmatic, and profoundly humane represents India's most significant contribution to global pharmaceutical patent jurisprudence.

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Contribution of Authors

ND developed the central concept of the study and established its initial framework. **PD** and **PM** provided ongoing academic guidance and made significant contributions to the revision, organization, and overall improvement of the manuscript.**VN** and **S** contributed critical scholarly insights, assisted in data collection, and supported data analysis and interpretation while ensuring that the manuscript adhered to the journal's formatting and submission requirements. **PY** and **MY** played a key role in enhancing the linguistic precision, readability, and technical consistency of the manuscript.

Conflict of Interest

The authors declare that there is no conflict of interest related to the publication of this manuscript.

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