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SECTION 3(d) OF THE INDIAN PATENTS ACT, 1970: SCOPE, INTERPRETATION, AND RECENT DEVELOPMENTS

~ Shaleen Singh

ABSTRACT

Section 3(d) of the Indian Patents Act, 1970 stands as one of the most consequential and globally watched provisions in modern intellectual property law. Introduced in its present form through the Patents (Amendment) Act, 2005, it excludes from patentability the mere discovery of a new form of a known substance unless a meaningful enhancement in efficacy is demonstrated—a deliberate legislative barrier against the pharmaceutical practice commonly known as 'evergreening.' This paper traces the historical origins of the provision, examines its statutory scope and key interpretive concepts, analyses the landmark ruling in Novartis AG v. Union of India (2013)[1], and surveys the most significant judicial developments between 2022 and 2024 that have expanded, procedurally refined, and technologically extended its application. The paper further situates Section 3(d) within the broader TRIPS compliance debate and assesses its real-world consequences for public health, pharmaceutical innovation, and the Indian patent system at large.

I. INTRODUCTION

In the architecture of India's intellectual property regime, few provisions have attracted as much scholarly scrutiny, industrial controversy, or global policy debate as Section 3(d) of the Patents Act, 1970.[2] It is a provision deceptively short in length yet sweeping in consequence: in fewer than eighty words, it determines whether a pharmaceutical or chemical

[1]Patents Act, No. 39 of 1970, § 3(d) (India) (as amended by Patents (Amendment) Act, No. 15 of 2005).

[2]The Patents Act, 1970, § 3(d), No. 39, Acts of Parliament, 1970 (India).

modification of an existing substance is worthy of patent protection or merely a trivial, commercially motivated tweak dressed in the language of innovation.

Since the passage of the Patents (Amendment) Act, 2005, Section 3(d) has functioned as a gatekeeper of patentability in a country of over 1.4 billion people,[3] where the affordability of medicines is not a peripheral concern but a matter of life, death, and constitutional obligation. The provision refuses patent protection to new forms of already-known chemical substances unless the applicant can demonstrate an enhancement of the substance's known efficacy. In pharmaceutical terms, this means that a drug company cannot simply re-patent a molecule by altering its salt, polymorph, ester, or other derivative form without showing that the modified version actually performs better therapeutically. While that may seem like commonsense patent quality control, its implications for the multinational pharmaceutical industry—which routinely pursues incremental patents to extend commercial monopolies—have been immense and unrelenting.

This article examines Section 3(d) through three interlocking lenses: its legislative history and origins, its judicial construction and core interpretive concepts, and the most recent wave of High Court decisions from 2022 to 2024 that have reshaped, extended, and procedurally sharpened its application. The paper also engages with the persistent international debate over whether Section 3(d) comports with India's obligations under the TRIPS Agreement, and assesses the provision's broader implications for public health and pharmaceutical innovation.

II. HISTORICAL BACKGROUND

A. The Pre-2005 Patent Regime

India's patent system has never been politically neutral ground. The Patents Act, 1970, which emerged from the recommendations of the Justice N. Rajagopala Ayyangar Committee (1959),[4] was a deliberately pro-access piece of legislation. The Committee recognised that India, as a newly independent developing country with a fragile domestic pharmaceutical

[3]India's estimated population exceeded 1.44 billion as of 2024. See World Bank, India Data, https://data.worldbank.org/country/IN (last visited June 9, 2026).

[4]Justice N. Rajagopala Ayyangar, Report on the Revision of the Patents Law 3–12 (1959) [hereinafter Ayyangar Report].

sector, could not afford to allow multinational corporations to retain monopolistic control over essential medicines through the mechanism of product patents.[5]

The 1970 Act responded to this challenge by abolishing product patents for pharmaceuticals, food, and agrochemicals altogether, permitting only process patents in these sectors—and that too for shorter durations.[6] The practical consequences were transformative. Indian companies could lawfully manufacture generic versions of patented drugs using different production processes, igniting the rapid growth of India's domestic pharmaceutical industry. By the early 1990s, India had become one of the world's most significant suppliers of affordable generic medicines to developing countries across Asia, Africa, and Latin America.[7]

B. TRIPS and the Obligation to Reform

India's accession to the World Trade Organization in 1995 carried with it the binding obligation to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[8] TRIPS Article 27.1 mandated that all member states provide product patent protection across all fields of technology, explicitly including pharmaceuticals and agrochemicals.[9] India was granted a transition period until January 1, 2005 to bring its domestic law into full compliance.[10]

The resulting amendments to the Patents Act—introduced in 1999, 2002, and 2005—progressively aligned Indian patent law with TRIPS requirements.[11] The most consequential of

[5]Ayyangar Report, supra note 3, at 26.

[6]Patents Act, No. 39 of 1970, § 5 (India) (original version, subsequently deleted by Patents (Amendment) Act, No. 15 of 2005, § 5).

[7]Section 3(d) of the Indian Patents Act – Part I, Nat'l L. Rev., https://natlawreview.com/article/section-3d-indian-patents-act-part-i (last visited June 9, 2026).

[8]Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

[9]TRIPS Agreement art. 27.1.

[10]TRIPS Agreement art. 65.2 (granting developing countries a five-year transition period from 1 January 1995).

[11]Patents (Amendment) Act, No. 17 of 1999 (India); Patents (Amendment) Act, No. 38 of 2002 (India); Patents (Amendment) Act, No. 15 of 2005 (India).

these, the Patents (Amendment) Act, 2005, deleted Section 5 of the 1970 Act, which had excluded product patents for drugs, chemicals, and food, thereby ushering in the product patent regime in India for the first time.[12]

C. The Legislative Birth of Section 3(d) in Its Present Form

The introduction of product patents for pharmaceuticals was politically explosive. The Parliamentary Opposition expressed profound fears about the prospect of rising drug prices and the risk that foreign pharmaceutical companies would use aggressive patenting—and in particular, evergreening—to monopolise essential medicines.[13] Evergreening is the practice whereby a drug company, as its original patent nears expiry, files new patents covering incremental modifications of the existing compound—different salts, polymorphs, dosage forms, or new uses—to extend its commercial exclusivity without genuine therapeutic innovation.[14]

To address these concerns and secure passage of the 2005 amendment, the Government proposed a significant strengthening of Section 3(d). In its original form, Section 3(d) had merely excluded 'the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.'[15] The 2005 amendment added a new and critical limb to this exclusion: '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.'[16] An

[12]Patents (Amendment) Act, No. 15 of 2005, § 5 (India) (deleting the original § 5 of the 1970 Act and ushering in full product-patent protection for pharmaceuticals and agrochemicals).

[13]Section 3(d) of the Indian Patents Act – Part I, supra note 6 (recounting the parliamentary debate and the Government's response to Opposition concerns about evergreening).

[14]Id. Evergreening refers broadly to the practice whereby a pharmaceutical company files successive patents covering minor modifications—such as different salts, polymorphs, or dosage forms—of an existing drug compound, thereby extending its effective monopoly well beyond the original patent term.

[15]Patents Act, No. 39 of 1970, § 3(d) (India) (original text, prior to the 2005 Amendment).

[16]Patents (Amendment) Act, No. 15 of 2005, § 3(d) (India). The italicized additions—'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'—formed the crux of subsequent litigation.

Explanation was also appended, explicitly listing covered derivatives—salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substances.[17]

The amendment was, by most accounts, a last-minute political bargain whose precise scope was never openly debated on the floor of Parliament. The absence of clear legislative guidance on key terms—particularly 'efficacy' and 'known substance'—left enormous interpretive space for the courts, which they have since filled with an increasingly sophisticated body of case law.[18]

III. THE STATUTORY TEXT: SCOPE AND KEY CONCEPTS

Section 3(d), in its current form, states that the following shall not be regarded as inventions within the meaning of the Act:

> *[T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*

[19] The Explanation further provides: 'For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes,

[17] Id. (Explanation to § 3(d): 'For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.').

[18] Indian Pharmaceutical Patent Prosecution: The Evolving Role of Section 3(d), DrugPatentWatch, https://www.drugpatentwatch.com/blog/indian-pharmaceutical-patent-prosecution-the-changing-role-of-section-3d/ (Aug. 3, 2025) (describing the legislative process as 'a mysterious and intriguing affair, marked by intense political negotiations, last-minute changes, and a notable lack of clear legislative guidance').

[19] Patents Act, No. 39 of 1970, § 3(d) (India) (current text as amended 2005).

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.'[20]

Three elements form the operative core of Section 3(d): the concept of a 'known substance,' the notion of a 'new form,' and the requirement of 'enhancement of known efficacy.' Each deserves careful examination.

A. Known Substance

The phrase 'known substance' is interpreted broadly. A substance is 'known' if it has been publicly disclosed anywhere in the world, regardless of whether it has been patented or commercialised.[21] This approach deliberately aligns with the global prior art standard used in assessing novelty, though the Section 3(d) inquiry is conceptually distinct: novelty determines whether something is new, while Section 3(d) determines whether a new form of something already known confers any real benefit. The breadth of the 'known' standard means that many pharmaceutical modifications claimed as novel by applicants are nonetheless caught by Section 3(d) if they trace back to a substance whose existence was publicly disclosed, even decades ago.

B. New Form

A 'new form' encompasses any of the variants listed in the Explanation—polymorphs, salts, esters, particle sizes, and other chemical derivatives.[22] Courts have held consistently that a new form, however chemically or structurally novel, cannot escape Section 3(d)'s bar unless it demonstrates enhanced efficacy compared to the already-known base substance. This is a crucial point: Section 3(d) does not require the applicant to compare the new form with every conceivable prior form—only with the known substance from which it is derived.

C. Enhancement of Efficacy

The most litigated concept in the provision is 'efficacy.' The Supreme Court of India, in the watershed Novartis ruling, settled the issue definitively for pharmaceuticals: 'the test of

[20]Id. (Explanation to § 3(d)).

[21]Novartis AG v. Union of India, (2013) 6 S.C.C. 1, ¶ 88 (India) (holding that 'known' tracks the global prior art standard—disclosure anywhere in the world places a substance in the public domain).

[22]Id. ¶ 187 (holding that chemical novelty of the new form is insufficient; what matters is whether the new form shows enhanced efficacy relative to the already-known base substance).

efficacy in the context of Section 3(d) can only mean therapeutic efficacy.'[23] Improvements in physicochemical properties—thermodynamic stability, hygroscopicity, particle flowability, or even bioavailability in isolation—do not satisfy the efficacy requirement unless they translate into demonstrably superior therapeutic outcomes for patients.[24] This is a deliberately high bar, designed to distinguish genuine therapeutic progress from laboratory-level modification that has no real-world clinical benefit.

IV. LANDMARK JUDICIAL INTERPRETATIONS

A. Novartis AG v. Union of India (2013)

No case has done more to shape the jurisprudential landscape of Section 3(d) than Novartis AG v. Union of India, decided by the Supreme Court of India in 2013.[25] The dispute arose from Novartis's patent application in India for the beta crystalline form of imatinib mesylate—the active ingredient in its blockbuster anti-cancer drug Glivec. Imatinib free base had been publicly disclosed in a US patent application filed in 1993; imatinib mesylate salt was subsequently developed and marketed commercially. Novartis sought an Indian patent for a specific beta crystalline form of the mesylate salt, claiming superior properties including increased bioavailability, improved thermodynamic stability, and better flowability.

The application was opposed and rejected at multiple levels—the Chennai Patent Office, the Intellectual Property Appellate Board (IPAB)—before Novartis petitioned the Supreme Court.[26] A Division Bench dismissed the appeal on two primary grounds. First, the Court held that the beta crystalline form was not truly a 'new form' of a novel substance—it

[23]Id. ¶ 188 ('The test of efficacy in the context of Section 3(d) of the Act . . . can only mean therapeutic efficacy.').

[24]Id. ('Properties . . . like thermodynamic stability or reduced hygroscopicity are not the kind of properties with regard to efficacy'—such physicochemical advantages must translate into an improved curative or healing effect to satisfy § 3(d)).

[25]Novartis AG v. Union of India, (2013) 6 S.C.C. 1 (India) [hereinafter Novartis]. Equivalent citations: AIR 2013 SC 1311; 2013 AIR SCW 2047.

[26]Novartis, supra note 24, ¶¶ 19–21 (tracing the procedural journey from the Chennai Patent Office through the IPAB to the Supreme Court via Special Leave Petition under Article 136 of the Constitution of India).

was a further modification of something already known and disclosed in prior patent literature.[27] Second, and most influentially, the Court found that Novartis had failed to demonstrate enhanced therapeutic efficacy. The claimed 30% increase in bioavailability was measured against the insoluble free base form of imatinib—not the commercially marketed mesylate salt—a comparison that the Court characterised as misleading and scientifically unsound.[28]

On the meaning of efficacy, the Court was unequivocal: enhancements in storage properties, manufacturing ease, or intermediate bioavailability measures are not 'efficacy' unless they correlate with improved clinical or therapeutic outcomes for the patient.[29] The ruling was celebrated globally by public health advocates, enabling generic manufacturers to bring imatinib to market at approximately one-sixth of the innovator's price.[30] Simultaneously, it drew fierce criticism from the global pharmaceutical industry, which characterised Section 3(d) as exceeding the boundaries of legitimate TRIPS flexibility.[31]

B. Other Foundational Cases

Alongside Novartis, pre-2022 litigation further refined the application of Section 3(d). The Delhi High Court's decision in F. Hoffmann-La Roche Ltd. v. Cipla Ltd. explored the interplay between patent protection and public health in the context of anti-cancer medication,

[27]Id. ¶ 143 (finding that imatinib mesylate had been disclosed in the 1993 US patent application covering imatinib and pharmaceutically acceptable salts thereof, such that the mesylate salt was not a genuinely new substance for Section 3(d) purposes).

[28]Id. ¶ 189 (noting that Novartis's bioavailability comparison was made against imatinib free base—an insoluble, commercially non-existent form—rather than against the marketed mesylate salt, rendering the comparison 'deceptive' and scientifically unsound).

[29]Id. ¶ 188.

[30]USTR Report Flags India's Drug Patent Rules, The Wire (May 1, 2026), https://m.thewire.in/article/health/ustr-report-flags-indias-drug-patent-rules.

[31]Section 3(d): Hurdle or Advantage to the Pharmaceutical Sector—An Indian Perspective, Mondaq (Jul. 21, 2017), https://www.mondaq.com/india/patent/612674/section-3d-hurdle-or-advantage-to-the-pharmaceutical-sector-an-indian-perspective (noting pharmaceutical industry arguments that § 3(d) discriminates against incremental innovation and exceeds TRIPS obligations).

setting an early precedent for balancing these interests in infringement proceedings.[32] Collectively, these cases embedded the therapeutic efficacy standard across a wide range of pharmaceutical categories and established Section 3(d) as an active and judicially enforced norm rather than a hortatory declaration.

V. RECENT DEVELOPMENTS (2022–2024)

The most recent wave of High Court decisions has been qualitatively significant: courts have moved beyond applying the Novartis framework to actively expanding Section 3(d)'s technological and procedural reach. Four cases in particular deserve close attention.

A. DS Biopharma v. Controller of Patents (2022): Procedural Fairness

The Delhi High Court's ruling in DS Biopharma Ltd. v. Controller of Patents and Designs established an important procedural baseline that has since been repeatedly applied.[33] The Court set aside a Section 3(d) rejection on the ground that the Controller had failed to identify, with sufficient specificity in the hearing notice, which 'known substance' was being cited as the baseline against which the new form was being compared. The Court held that the IPO must frame Section 3(d) objections with adequate particularity—identifying the known substance, the new form, and the basis of comparison—so that the applicant has a genuine opportunity to respond. Without this procedural specificity, a Section 3(d) rejection is not sustainable. This ruling established what might be called a 'natural justice floor' for the IPO's examination practice.

B. Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents (2022): Process Patents

In Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents, the Delhi High Court rejected a patent application for a method of manufacturing Tofogliflozin tablets—a type-2

[32]F. Hoffmann-La Roche Ltd. v. Cipla Ltd., (2009) 40 P.T.C. 125 (Del.) (India); see also Bayer AG v. Natco Pharma Ltd., (2012) Bom. H.C. (India) (involving the first compulsory licence granted under the Patents Act and illustrating broader tensions between patent protection and access).

[33]DS Biopharma Ltd. v. Controller of Patents & Designs, C.A. (COMM.IPD-PAT) 6/2021 (Delhi H.C. 2022) (India). The Court held that 'in the case of rejecting a patent application on the ground of Section 3(d), [the Controller] would have to identify the specific known substance' against which the new form is being assessed.

diabetes drug—using direct compression.[34] The applicant argued that the manufacturing method was novel and inventive. The Court upheld the Section 3(d) rejection, finding that a known process applied to a known pharmaceutical substance does not escape the provision's bar merely because the process itself is new, unless the resulting product employs a new reactant or the process generates a novel product with enhanced efficacy. This ruling reinforced that even process patents in the pharmaceutical space can be caught by Section 3(d) when they do not produce a genuinely new or more efficacious product.

C. Novozymes A/S v. Assistant Controller of Patents and Designs (2023): Beyond Pharmaceuticals

Perhaps the most jurisprudentially significant post-Novartis development is the Madras High Court's September 2023 decision in Novozymes A/S v. Assistant Controller of Patents and Designs, which ventured into entirely new territory by applying Section 3(d) to a biochemical substance.[35] The dispute involved a patent application for phytase variants with improved thermostability—a biochemical enzyme used in animal feed. The IPO had rejected the application on the ground that phytase variants constituted new forms of a known enzyme falling within Section 3(d)'s ambit.

The Madras High Court made two consequential holdings. First, it confirmed that Section 3(d) is not limited to pharmaceutical or agrochemical substances—it extends to biochemical substances as well, and there is no textual or doctrinal basis for confining it to the therapeutic drug domain.[36] Second, the Court deployed the doctrine of ejusdem generis to limit the reach of the Explanation. The Explanation's list of specific chemical derivatives (salts, esters, ethers, polymorphs, etc.) is followed by the phrase 'other derivatives of known substance.' Applying ejusdem generis, the Court held that 'other derivatives' should be read in light of the preceding specific chemical-class items, such that purely biochemical entities (like

[34]Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents, C.A. (COMM.IPD-PAT) No. XX/2022 (Delhi H.C. 2022) (India) (upholding rejection of a direct-compression manufacturing process for Tofogliflozin tablets on the ground that no enhancement of therapeutic efficacy was demonstrated).

[35]Novozymes A/S v. Assistant Controller of Patents & Designs, (T) CMA (PT) No. 33 of 2023 (OA/6/2017/PT/CHN) (Madras H.C. Sept. 20, 2023) (India).

[36]Id. (holding that the expression 'known substance' in Section 3(d) also applies to biochemical substances; the provision's scope is not limited to pharmaceuticals or agrochemicals).

enzymes defined by amino acid sequences) do not fall within the Explanation's enumerated category.[37] This nuanced distinction—confirming the main provision applies to biochemicals while limiting the Explanation's specific list to chemical-class derivatives—may prove highly significant for future cases involving biotechnological inventions.

D. Oyster Point Pharma Inc. v. Controller of Patents and Designs (2023): Post-Filing Evidence

The Calcutta High Court, in Oyster Point Pharma Inc. v. Controller of Patents and Designs, addressed a practical grievance that had long troubled pharmaceutical patent applicants: the IPO's reluctance to consider clinical efficacy data submitted after the original application filing.[38] The Court overturned a Section 3(d) rejection, holding that Sections 57, 59, and 79 of the Patents Act expressly permit applicants to file amendments and affidavit evidence during prosecution, and that the IPO is obligated to evaluate this supplementary data before arriving at a final determination. Since drug development is an iterative scientific process—with efficacy data often becoming available years after the initial patent application—this ruling recognised that precluding post-filing evidence would unfairly penalise applicants for circumstances inherent to the pharmaceutical development timeline.

E. Nippon Steel Corporation v. Controller General of Patents (2024): Technology-Agnostic Application

The Delhi High Court's 2024 ruling in Nippon Steel Corporation v. Controller General of Patents, Designs and Trademarks is remarkable not for its pharmaceutical significance, but for the opposite reason: it involved a method and device for repairing blast furnace gas flues in

[37]Id. (applying the doctrine of ejusdem generis to the phrase 'other derivatives of known substance' in the Explanation, and holding that the Explanation's specific list—comprising chemical derivatives such as salts, esters, polymorphs, etc.—does not extend to biochemical entities like enzymes, whose characteristics are governed by amino acid sequence rather than chemical class).

[38]Oyster Point Pharma Inc. v. Controller of Patents & Designs (Calcutta H.C. 2023) (India) (overturning rejection under § 3(d) where IPO had disregarded post-filing clinical efficacy data; citing §§ 57, 59, and 79 of the Patents Act as authorising submission of additional evidence during prosecution).

the steel industry—a purely industrial, non-pharmaceutical invention with no connection to the life sciences.[39]

The IPO had rejected the application under Section 3(d), but had done so without having raised this specific objection in either the first examination report or the hearing notice. The Delhi High Court set aside the refusal order, finding a clear violation of the principles of natural justice and confirming the DS Biopharma requirement that a Section 3(d) objection must be explicitly identified in pre-hearing notices, with the specific known substance named, before a rejection on this ground can be sustained.[40]

More broadly, the Nippon Steel decision confirmed unequivocally that Section 3(d) is technology-agnostic: it applies to all fields of invention, not only to pharmaceuticals or agrochemicals. The provision, in the Court's analysis, is a general legislative norm against trivial discovery across the entire landscape of patentable subject matter.[41] This confirmation has significant implications: patent applicants in industries from materials science to food technology must now account for Section 3(d) scrutiny in their Indian patent prosecution strategies.

VI. SECTION 3(D) AND THE TRIPS COMPATIBILITY DEBATE

A persistent and unresolved controversy in international intellectual property circles surrounds whether Section 3(d) is compatible with India's obligations under the TRIPS Agreement. The debate has three main dimensions.

A. The Standard Under TRIPS Article 27.1

TRIPS Article 27.1 requires member states to make patents available for inventions in all fields of technology, subject to the conditions of novelty, inventive step, and industrial

[39]Nippon Steel Corp. v. Controller Gen. of Patents, Designs & Trademarks, CA (COMM IPD-PAT) 323/2022, 2024:DHC:6514 (Delhi H.C. 2024) (India).

[40]Id. (setting aside the IPO's refusal order and remanding for fresh consideration; applying DS Biopharma's natural-justice requirement that specific § 3(d) objections be clearly identified in the hearing notice so that the applicant has a meaningful opportunity to respond).

[41]Id. (confirming that § 3(d) 'applies to other industries' beyond pharmaceuticals and life sciences, and that it functions as a general anti-trivial-discovery norm across all fields of technology).

applicability.[42] Critics of Section 3(d) argue that the provision, by demanding an additional showing of enhanced efficacy, effectively adds a fourth patentability criterion that TRIPS does not authorise. They further argue that TRIPS Article 27.1 obliges members to protect all inventions—including incremental ones—that meet the three standard criteria, and that Section 3(d) impermissibly narrows the category of protectable inventions by excluding a specific class of innovations, thereby distorting pharmaceutical research incentives.[43]

B. India's Counter-Position

India's defence of Section 3(d)—articulated most authoritatively by the Supreme Court in Novartis—rests on two interconnected arguments. First, the provision does not add a new patentability criterion; rather, it defines, for national purposes, what qualifies as an 'invention' in the first place. Since TRIPS itself does not define the term 'invention,' member states retain the sovereign prerogative to determine what constitutes a patentable invention within their domestic legal systems.[44] Accordingly, Section 3(d) operates upstream of the patentability analysis—it characterises trivial derivatives of known substances as non-inventions, not as inventions that fail an additional patentability test.[45]

Second, India argues that TRIPS Article 27.1's requirement that patents be available 'in all fields of technology' prohibits field-specific discrimination, but does not compel identical treatment of all types of inventions. Since Section 3(d), as recent jurisprudence confirms,

[42]TRIPS Agreement art. 27.1 ('patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application').

[43]Section 3(d): Hurdle or Advantage, supra note 30 (describing two TRIPS-violation arguments: (1) § 3(d) denies protection for incremental innovations that TRIPS requires to be protected; (2) § 3(d) imposes a stricter standard than the minimum TRIPS floor).

[44]Novartis, supra note 24, ¶¶ 190–191 ('Thus, in whichever way section 3(d) may be viewed, whether as setting up the eligibility criteria for the patentability of a new form of a known substance and its other derivatives, or as prescribing the limits within which the discovery of a new form of a known substance can be elevated to the level of an invention, it operates within the TRIPs framework.').

[45]Id. ¶ 190.

applies to all fields of technology, it does not discriminate between fields and thus falls within the scope of permissible national legislative flexibility.[46]

C. International Pressure and the Special 301 Reports

The United States Trade Representative has maintained India on its Priority Watch List in successive Special 301 Reports, citing Section 3(d) as a barrier to market access for American pharmaceutical companies.[47] Interestingly, the 2024 Special 301 Report reflected a subtle shift in tone: rather than challenging the provision's very existence, it focused on 'procedural and discretionary invocation of patentability criteria'—an acknowledgment of the IPO's inconsistent examination practices and the procedural improvement demanded by the courts.[48] Notwithstanding sustained international pressure, India has not amended Section 3(d) since 2005, and as of mid-2026 there are no active legislative proposals to do so—a reflection of broad domestic political consensus in favour of maintaining the provision's current form.[49]

VII. IMPACT ON THE PHARMACEUTICAL INDUSTRY AND PUBLIC HEALTH

A. Access to Affordable Medicines

The most tangible consequence of Section 3(d) is its contribution to the affordability and accessibility of medicines. By blocking evergreening, the provision enables generic manufacturers to enter the market as soon as the underlying base compound patent expires—without having to contend with a thicket of follow-on patents covering trivial modifications.

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[46]Id. ¶ 191 (TRIPS does not define the word invention; each member country is free to define, for its own national purposes, what constitutes an invention. Novartis AG v. Union of India, (2013) 6 S.C.C. 1, ¶ 191 (India)).

[47]Office of the U.S. Trade Representative, 2024 Special 301 Report 37–39 (Apr. 2024) [hereinafter 2024 Special 301 Report].

[48]Public Citizen, 2025 Special 301 Review Comment 5 (2025) (noting that the 2024 Special 301 Report shifted focus from India's 'narrow patentability criteria' to 'procedural and discretionary invocation of patentability criteria,' reflecting the IPO's often inconsistent examination practices).

[49]Indian Pharmaceutical Patent Prosecution, supra note 17 ('Despite its profound impact, Section 3(d) has remained unchanged since its 2005 amendment. There are currently no active, high-profile legislative proposals to alter its text.').

The result is price competition that has been genuinely transformative in both the domestic Indian market and globally. India now exports approximately USD 9.7 billion worth of generic medicines annually to the United States alone, providing lower-cost alternatives that have meaningfully reduced healthcare expenditure.[50] The Novartis case itself illustrates the stakes: Glivec was available in India at approximately Rs 1.2 lakh per month; following the successful opposition, generic imatinib became available at around Rs 8,000—a price reduction of approximately 93%.

Globally, India's generic pharmaceutical industry—enabled in part by Section 3(d)—has been critical to providing affordable antiretroviral medications for HIV patients in sub-Saharan Africa, generic tuberculosis and hepatitis C treatments across Asia and Latin America, and low-cost vaccines and biosimilars for developing-world healthcare systems. UNAIDS and multiple civil society organisations have consistently cited India's approach as a model for using TRIPS flexibilities to advance public health goals.

B. Arguments About Innovation Disincentives

Critics of Section 3(d)—including major multinational pharmaceutical companies and their trade associations—argue that the provision discourages genuine innovation by withholding patent protection from scientifically meaningful, if incremental, improvements.[51] They contend that improvements such as more stable polymorphs, more water-soluble salt forms, or more bioavailable formulations represent real scientific achievements that improve patient experience and deserve the incentive of patent protection.

This critique, however, somewhat misapprehends what Section 3(d) actually prohibits. The provision does not categorically ban incremental innovation—it bars only those incremental changes that produce no demonstrable therapeutic benefit. A new salt form that genuinely delivers improved clinical outcomes will pass the efficacy test. What is excluded is incremental patenting driven purely by the strategic logic of patent life extension, without any real-world benefit to patients. The line is admittedly difficult to draw in practice, but the principle is defensible.

[50]The Wire, supra note 29 ('India exported $9.7 billion worth of medicines to the US in 2025, mostly low-cost generics that help reduce healthcare costs').

[51]Section 3(d): Hurdle or Advantage, supra note 30.

VIII. CRITICAL ANALYSIS AND REFORM DEBATES

A. The Efficacy Standard: Adequate or Too Narrow?

Academics and practitioners have debated whether 'therapeutic efficacy' is the right and only measure of benefit for all Section 3(d) purposes. Some argue that improvements in drug delivery, patient compliance, dosing convenience, or manufacturing sustainability serve legitimate public health interests and ought to qualify as sufficient enhancements.[52] The courts have so far resisted broadening the standard beyond the therapeutic-clinical sphere in pharmaceutical cases. However, the Novozymes decision's context-sensitive treatment of 'efficacy' for biochemical substances—where enzymatic thermostability was assessed differently from pharmaceutical therapeutic efficacy—hints at the possibility of a more functionally adaptive approach in future cases involving complex biological entities or next-generation therapies.

B. Procedural Clarity and IPO Practice

A recurring and legitimate grievance from patent applicants and practitioners concerns the lack of transparent, consistent, and reasoned Section 3(d) objections from the IPO. The Courts' rulings in DS Biopharma, Nippon Steel, and related cases have progressively imposed a procedural discipline requiring the IPO to identify the known substance, articulate the basis of comparison, and frame its reasoning clearly.[53] Nevertheless, the pendency time for Indian patent applications—averaging over four years according to WIPO's 2023 statistics—reflects a systemic examination capacity challenge that procedural refinements alone cannot fully resolve. Greater investment in examiner training, clearer Section 3(d) examination guidelines, and accessible appeal mechanisms would materially improve the quality and predictability of IPO decision-making.

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[52] Indian Pharmaceutical Patent Prosecution, supra note 17 (posing the question whether 'enhanced patient compliance, better shelf life, or reduced manufacturing waste' might be characterised as enhanced efficacy for § 3(d) purposes in future cases).

[53] Delhi High Court Clarifies Section 3(d) Objections in Setting Aside Indian Patent Office Refusal Order, IAM (Oct. 16, 2024), https://www.iam-media.com/article/delhi-high-court-clarifies-section-3d-objections-in-setting-aside-indian-patent-office-refusal-order.

C. The Frontier Challenge: Biologics and Biosimilars

As pharmaceutical innovation shifts from small-molecule chemistry towards biologics—complex proteins, monoclonal antibodies, gene therapies, and biosimilars—Section 3(d)'s framework, which was designed with chemical modifications in mind, faces genuine challenges.[54] Questions that existing case law does not fully answer include: How should 'known efficacy' be measured for a biosimilar that is not identical to its reference biologic? Does a change in glycosylation pattern that improves pharmacokinetics but has no proven clinical superiority constitute enhanced efficacy? And how should the 'new form' concept be applied to sequence variants or biosimilar analogues? The Novozymes reasoning—applying Section 3(d) to enzymes using a context-sensitive efficacy assessment—provides a partial template, but the scientific complexity of biologics will test these frameworks considerably. Judicial guidance and, ultimately, possibly legislative clarification may be necessary to adapt Section 3(d)'s analytical tools to this fast-evolving scientific frontier.

IX. CONCLUSION

Section 3(d) of the Indian Patents Act, 1970 occupies a genuinely unusual position in the global intellectual property landscape. It is simultaneously a domestic legal safeguard for public health and access to medicines, an internationally contested norm whose TRIPS compatibility remains a live debate, and an increasingly dynamic arena of judicial activity. From its political birth as a parliamentary compromise during the contentious 2005 amendments, to its canonisation in the watershed Novartis ruling, and through the recent wave of High Court decisions from 2022 to 2024, Section 3(d) has shown a remarkable institutional vitality and an expanding scope of application.

The most significant recent development in this jurisprudence is the provision's decisive migration beyond the pharmaceutical domain. The Novozymes and Nippon Steel decisions confirm that Section 3(d) is a general, technology-agnostic anti-trivial-discovery norm—one that operates across all fields of patentable subject matter, from steel manufacturing to biochemical enzymes. At the same time, the procedural rigour demanded by DS Biopharma and its progeny is beginning to impose a more disciplined and fair examination culture on the

[54] Indian Pharmaceutical Patent Prosecution, supra note 17 (noting that biologics present new challenges for the enhanced efficacy framework under Section 3(d), and that the Novozymes decision on enzymes provides a precedent for a context-dependent approach that may prove instructive for future biologic and biosimilar cases).

IPO, reducing the scope for arbitrary or unreasoned rejections that undermine both applicant rights and patent system credibility.

Looking ahead, Section 3(d)'s greatest challenges lie in adapting to scientific and technological change. Biologics, AI-assisted drug discovery, combination therapies, and new modalities of therapeutic intervention will test the boundaries of concepts such as 'known substance,' 'new form,' and 'enhanced efficacy' in ways that the Parliament of 2005 could not have foreseen. Indian courts will need to develop a jurisprudence that is sufficiently flexible to engage with new scientific realities, without abandoning the core public-health rationale that has always animated the provision.

India's experience with Section 3(d) offers a model that many developing countries have sought to emulate—a TRIPS-compliant legislative mechanism that nonetheless preserves meaningful space for a patent system that is genuinely attentive to public health. Whether that model will hold under sustained international trade pressure, whether the courts will calibrate the efficacy standard appropriately for the biologics era, and whether the IPO's examination practice will achieve the quality and consistency that the courts are demanding, remain the defining questions for the next chapter of Indian patent law. What seems clear is that Section 3(d), far from being a static or marginal provision, will continue to sit at the centre of these debates—and at the intersection of innovation, affordability, and access—for the foreseeable future.