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# EVERGREENING AT THE GATE: SECTION 3(D) OF THE PATENTS ACT, 1970, THIRTEEN YEARS AFTER NOVARTIS


***~ Gurnika Dhillon***


## I. INTRODUCTION

When India reintroduced product patents for pharmaceuticals in 2005 to meet its obligations under the TRIPS Agreement, Parliament also rewrote a short clause that has since drawn more foreign attention than almost any other line of Indian legislation.[1] Section 3(d) answered a specific fear. Product patents, it was thought, might be used less to reward new medicines than to stretch monopolies over old ones through minor chemical changes.[2] This practice, known as "evergreening", uses fresh filings on the salts, polymorphs or esters of a known molecule to extend exclusivity. Section 3(d) treats such variants as non-inventions unless they differ significantly in efficacy.[3]

The Supreme Court settled the meaning of the clause in *Novartis AG v. Union of India* in 2013.[4] Much has changed since. The Intellectual Property Appellate Board was abolished in 2021 and its patent work moved to the High Courts.[5] The Intellectual Property Division of the Delhi High Court is now the main forum for disputes under Section 3(d). New Patents Rules and trade agreements have also reshaped the procedure around the clause. This article argues that the substance of Section 3(d) has survived and in some respects has grown stricter. What is under strain is the procedure on which it depends.

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[1] The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India); 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].

[2] Shamnad Basheer & Prashant Reddy, *"Ducking" TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)*, 20 NAT'L L. SCH. INDIA REV. 131 (2008).

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

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

[5] The Tribunals Reforms Act, 2021, No. 33, Acts of Parliament, 2021 (India).

## II. THE STATUTORY FRAMEWORK

The Act defines an "invention" as a new product or process that involves an inventive step and is capable of industrial application. An "inventive step" is a feature involving technical advance or economic significance (or both) that makes the invention non-obvious to a person skilled in the art.[6] Section 3 then lists what is not an invention at all. Clause (d) excludes the mere discovery of a new form of a known substance that does not enhance its known efficacy. It also excludes the mere discovery of a new property or new use of a known substance. Its Explanation treats salts, esters, polymorphs, isomers, combinations and other derivatives as "the same substance, unless they differ significantly in properties with regard to efficacy".[7]

Section 3(d) does not replace the tests of novelty and inventive step. It sits above them as an extra filter and can be raised in pre-grant opposition, post-grant opposition and revocation.[8] It also works alongside compulsory licensing and the duty to disclose working. Together these give effect to the principle in Section 83 that patents should not obstruct public health.[9]

The international footing of the clause is sound. Article 27(1) of TRIPS requires patents for inventions that are new, inventive and industrially applicable, yet it never defines "invention". Article 1(1) leaves members free to choose how to implement the Agreement. Articles 7 and 8 permit measures needed to protect public health.[10] The Doha Declaration later confirmed that TRIPS should be interpreted in a manner supportive of access to medicines for all.[11] Section 3(d) therefore uses a permitted flexibility. The Madras High Court accepted as much in 2007 when it dismissed Novartis's constitutional challenge to the clause.[12]

## III. JUDICIAL INTERPRETATION

### A. NOVARTIS AND THE THERAPEUTIC-EFFICACY STANDARD

*Novartis* concerned the beta crystalline form of imatinib mesylate, sold as Glivec. The Supreme Court held that for a medicine, "efficacy" in Section 3(d) means therapeutic efficacy. Novartis relied on a thirty per cent rise in bioavailability, shown in rat studies and measured against the free base instead of the known mesylate salt. The Court held that better physical properties of

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[6] Patents Act §§ 2(1)(j), 2(1)(ja).
[7] *Id.* § 3(d) explanation.
[8] *Id.* §§ 25(1)(f), 25(2)(f), 64(1)(d).
[9] *Id.* §§ 83, 84, 146; The Patents Rules, 2003, r. 131 (India).
[10] TRIPS, *supra* note 1, arts. 1(1), 7, 8, 27(1).
[11] World Trade Organization, Declaration on the TRIPS Agreement and Public Health of 14 November 2001, ¶ 4, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).
[12] *Novartis AG v. Union of India*, (2007) 4 MLJ 1153 (India).

this kind would not qualify without proof of a real therapeutic advantage.[13] Section 3(d) thus became a second and stricter test for pharmaceutical substances. Among the pre-grant opponents was the Cancer Patients Aid Association.[14] Patient groups have long used the opposition route alongside rival manufacturers.

## B. THE DELHI HIGH COURT TAKES OVER

The Delhi High Court engaged with Section 3(d) well before 2021. In *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*, Roche's separate application for the Polymorph B form of erlotinib hydrochloride had been refused under Section 3(d). The Division Bench nonetheless held that Cipla's Polymorph B product fell within Roche's compound patent.[15] A refused new-form application thus shaped how far the underlying product patent reached.

The modern revival came in April 2024 with *Natco Pharma Ltd. v. Novartis AG*.[16] Novartis had protected eltrombopag olamine, a salt of eltrombopag, through a species patent after its genus patent expired. The Division Bench set aside the injunction granted by the single judge. It repeated that a granted patent carries no presumption of validity. It then held that the salt was caught by Section 3(d) because it showed no significant gain in therapeutic efficacy over the known free acid. Following *Novartis*, the Bench again refused to equate better bioavailability with better efficacy.

The risdiplam litigation of 2025 moved the contest onto neighbouring ground. In March 2025, a single judge refused Roche an interim injunction against Natco.[17] On 9 October 2025, a Division Bench upheld that refusal, mainly on the ground of prima facie obviousness under Section 64(1)(f) over Roche's own genus patents.[18] The Bench also said that the mere "coverage" of a compound in a genus claim is not its "disclosure". It questioned the approach taken in *AstraZeneca AB v. Intas Pharmaceuticals Ltd.*,[19] a part of the reasoning that has drawn criticism.[20] Natco soon launched its generic at ₹15,900 a bottle against about ₹6.2 lakh for

[13] *Novartis*, (2013) 6 SCC 1.
[14] *Id.* (recording the pre-grant opposition filed by the Cancer Patients Aid Association).
[15] *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*, 2015 SCC OnLine Del 13619 (India).
[16] *Natco Pharma Ltd. v. Novartis AG*, FAO(OS)(COMM) 178/2021, 2024:DHC:3198-DB (Del. HC Apr. 24, 2024) (India).
[17] *F. Hoffmann-La Roche AG v. Natco Pharma Ltd.*, CS(COMM) 567/2024 (Del. HC Mar. 24, 2025) (India).
[18] *F. Hoffmann-La Roche AG v. Natco Pharma Ltd.*, FAO(OS)(COMM) 43/2025 (Del. HC Oct. 9, 2025) (India).
[19] *AstraZeneca AB v. Intas Pharms. Ltd.*, 2021 SCC OnLine Del 3417 (India).
[20] Bharathwaj Ramakrishnan & Praharsh Gour, *Delhi High Court Risdiplam DB Judgement: A Few More Thoughts*, (Oct. 14, 2025).

Roche's Evrysdi, a cut of roughly 97 per cent.[21] On 17 October 2025, the Supreme Court declined to interfere.[22]

Two lessons follow. Evergreening disputes are now fought largely through the genus-species and coverage-disclosure framework, with Section 3(d) as one tool among several. Courts also weigh affordability openly at the interim stage. This makes the "credible challenge" threshold almost as decisive as the substantive law.

### C. DISCIPLINING THE PATENT OFFICE

A second line of cases concerns examination. In *DS Biopharma*, the Court required the Controller to identify the "known substance" before raising a Section 3(d) objection. It also required applicants to present comparative efficacy data precisely.[23] In *Tapas Chatterjee*, decided in October 2025, a Division Bench criticised decisions taken by rule of thumb on the subjective views of examiners and insisted on reasoned findings.[24]

Two decisions of 2026 pull in different directions. In *Syngenta Participations AG*, the Court set aside the refusal of an agrochemical polymorph because the Patent Office had dismissed improved thermal stability without scientific basis. Efficacy, the Court indicated, must be judged by what the product is meant to do in its own field.[25] In *Intra-Cellular Therapies*, Justice Tushar Rao Gedela upheld the refusal of deuterated antipsychotic compounds. He observed that better bioavailability does not by itself prove better therapeutic efficacy. Critics note that the judgment rests mainly on novelty.[26]

The pattern is consistent. On substance, the High Court stays close to *Novartis*. On procedure, it demands reasons, a named known substance and real engagement with the evidence. Outcomes under Section 3(d) therefore depend heavily on the quality of examination.

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[21] *Natco Disrupts Orphan Drug Market with $179 Risdiplam Generic, Undercutting Roche by 97%*, PHARMA LETTER (Oct. 14, 2025), https://www.thepharmaletter.com/generics-news/natco-disrupts-orphan-drug-market-with-179-risdiplam-generic-undercutting-roche-by-97-percent.
[22] Praharsh Gour, *Supreme Court Refuses to Interfere in the Risdiplam Case, Rejects Roche's SLP*, SPICYIP (Oct. 17, 2025).
[23] *DS Biopharma Ltd. v. Controller of Patents & Designs*, 2022 SCC OnLine Del 3211 (India).
[24] *Tapas Chatterjee v. Assistant Controller of Patents & Designs*, LPA 836/2023 (Del. HC Oct. 6, 2025) (India).
[25] *Syngenta Participations AG v. Controller of Patents & Designs*, C.A.(COMM.IPD-PAT) 49/2023 (Del. HC May 4, 2026) (India).

## IV. PROCEDURAL AND TRADE PRESSURES

The Patents (Amendment) Rules, 2024 changed the procedural ground.[27] A pre-grant opposition, once free, now costs ₹20,000 for large entities and ₹4,000 for others. The Controller must first find a prima facie case before notifying the applicant. Working statements in Form 27 are now due once every three financial years instead of every year.[28] Each change can be defended on grounds of efficiency. Taken together, they raise the cost of challenging weak patents for exactly the kind of opponent that *Novartis* shows to matter. Oppositions were already rare. The Controller General recorded 420 pre-grant oppositions against 94,744 published applications in 2022-23. The figure fell to 366 the following year.[29]

Trade agreements point the same way. The India-EFTA Trade and Economic Partnership Agreement came into force on 1 October 2025.[30] Critics point to provisions in it that allow unfounded pre-grant oppositions to be dismissed and that narrow working disclosures.[31] The India-UK Comprehensive Economic and Trade Agreement, signed on 24 July 2025, limits requests for working information to once in three years, though it leaves compulsory licensing intact.[32] The 2026 Special 301 Report again kept India on the Priority Watch List and named it among the countries whose compulsory licensing practices the United States will monitor.[33]

Administrative guidance is shifting too. On 4 September 2026, the Controller General released draft guidelines for the examination of pharmaceutical applications. The draft reaffirms the focus on therapeutic efficacy. Yet the public was given only fifteen days to comment. Commentators have also found errors in some of its illustrations.[34]

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[27] The Patents (Amendment) Rules, 2024, G.S.R. 211(E) (Mar. 15, 2024) (India).
[28] *Patent Amendment Rules 2024: Key Changes*, OBHAN & ASSOCS. (2024), https://obhanmason.com/blog/patent-amendment-rules-2024-key-changes/.
[29] OFF. OF THE CONTROLLER GEN. OF PATENTS, DESIGNS & TRADE MARKS, ANNUAL REPORT 2022-23 (India); Tanishka Goswami, *Looking Beyond the Numbers: What Does the 2023-24 IP India Annual Report Say on Patents?* (Apr. 19, 2025).
[30] Press Release, Ministry of Com. & Indus., India-European Free Trade Association Trade and Economic Partnership Agreement (TEPA) to Come into Effect on 01 October 2025 (2025), https://www.pib.gov.in/PressReleasePage.aspx?PRID=2173138.
[31] *EFTA-India Free Trade Agreement and Patents Rules Amendment: Compromising Public Accountability and Transparency in the Indian Patent System* (Apr. 2024).
[32] Comprehensive Economic and Trade Agreement, India-U.K., ch. 13, July 24, 2025.
[33] OFF. OF THE U.S. TRADE REPRESENTATIVE, 2026 SPECIAL 301 REPORT 6, 25 (2026).
[34] Ambika Aggarwal, *SpicyIP Tidbit: CGPDTM Calls for Comments and Suggestions on New Draft Pharma and Biotech Patent Application Guidelines (2026)* (Sept. 4, 2026).

## V. A COMPARATIVE PERSPECTIVE

The United States has no efficacy filter and tests secondary patents mainly for obviousness. In *Pfizer, Inc. v. Apotex, Inc.*, the Federal Circuit held the besylate salt of amlodipine obvious.[35] The European Patent Convention takes the opposite path and expressly allows claims to known substances for a new medical use,[36] which is what the "new use" limb of Section 3(d) rules out. The UK Supreme Court in *Actavis v. ICOS* relied on obviousness to strike down a patent over a dosage regime.[37]

Most systems catch evergreening late, through inventive step analysis in litigation. India tries to stop it at the door. This design gives generic manufacturers more certainty, but it works only if examination is consistent. It can also overreach. Sampat and Shadlen found a sharp rise in the use of Section 3(d) against primary patent applications, which the clause was never meant to target.[38]

## VI. CHALLENGES AND RECOMMENDATIONS

Four reforms follow from this analysis.

*First*, the final pharmaceutical guidelines should set an evidentiary standard for "therapeutic efficacy". They should state what comparative data are expected, at what stage and how pharmacokinetic benefit is to be told apart from clinical benefit. The standard should build on *Novartis*, *Natco* and *Intra-Cellular*. The guidelines should also be reissued with a longer consultation period.

*Second*, the meaning of efficacy outside pharmaceuticals, raised in *Syngenta*, needs field-specific guidance. Without it, the clause will continue to be applied mechanically to agrochemicals and materials.

*Third*, the opposition fee should be waived for patient groups and public interest opponents. The prima facie screen under the 2024 Rules should end in a short reasoned order open to challenge.

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[35] 35 U.S.C. § 103; *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007).
[36] Convention on the Grant of European Patents art. 54(4)-(5), Oct. 5, 1973, 1065 U.N.T.S. 199 (as revised Nov. 29, 2000).
[37] *Actavis Grp. PTC EHF v. ICOS Corp.* [2019] UKSC 15 (appeal taken from Eng.).
[38] Bhaven N. Sampat & Kenneth C. Shadlen, *Indian Pharmaceutical Patent Prosecution: The Changing Role of Section 3(d)*, 13 PLOS ONE e0194714 (2018).

*Fourth*, the Patent Office should publish annual figures on Section 3(d) objections, oppositions and outcomes. Better data would check examiner overreach and give negotiators evidence with which to defend the clause, much as India has kept compulsory licensing available since *Bayer*.[39]

## VII. CONCLUSION

Thirteen years after *Novartis*, Section 3(d) is secure in doctrine. The Delhi High Court has repeatedly refused to accept bioavailability as a stand-in for therapeutic efficacy. The real risk to the clause is procedural. Higher opposition costs, rarer working disclosures, hurried guidelines and trade commitments could each shrink its practical reach while its text stays untouched. If India wants Section 3(d) to remain a real check on evergreening, it must protect the procedures that enforce the clause as carefully as it has protected the words.

[39] *Bayer Corp. v. Union of India*, 2014 (60) PTC 277 (Bom.) (India).