FROM EVERGREENING TO EVER-PREDICTING: RECASTING SECTION 3(D) FOR AI-ASSISTED PHARMACEUTICAL INNOVATION

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ABSTRACT

Section 3 (d) of the Patents Act, 1970 was enacted to prevent pharmaceutical evergreening by denying patent protection to advance claims of therapeutic nature that are not yet tested upon or demonstrated, however AI assisted drug discovery is testing the framework differently, through prediction led claims where promising results supersede concrete biological proof. Section 3(d) of the Patents Act, 1970 offers a very singular position in Indian Pharmaceutical patent law, it was enacted as a statutory response to evergreening, withholding patent protection from new forms of known substances unless being able to demonstrate a legally meaningful efficacy enhancement. In Novartis AG v Union of India, the Supreme Court gave an extremely important clarification, holding that, if the molecule modified has enhanced therapeutic benefits and not solely better physical properties or bioavailability individually, it may bypass the safeguards under section 3d. AI assisted drug discovery is changing the stage at which patents could be filed. AI platforms design novel molecules, predicting how they will bind to a target protein and behave in the body, and companies would file patents based on those predictions before any biological test has been done. An empirical study by Freilich and Rai in 2025 found that only 23% of AI generated drug patents include any in-vivo validation data. This paper proposes an in-depth analysis within AI generated patents and its validity under Section 3(d) of the Patents Act in India.

Introduction

In February 2022, a patient enrolled in a clinical trial and became the first human being to receive a drug molecule designed entirely by AI, namely, Rentosertib, developed by Insilico Medicine, for idiopathic pulmonary fibriosis, a fatal lung scarring disease. It moved from computational design to Phase I human trial in under 30 months, with fewer than 80 compounds synthesized along the way.[1] It was a remarkable demonstration of what AI drug discovery can achieve. Also a demonstration of what the Indian patent office has not yet dealt with, a molecule that reached patent filing before it was tested biologically. Legally, this creates a very serious issue, Section 3(d) of the Patents Act, 1970 requires that new forms of known pharmaceutical substances demonstrate enhanced therapeutic efficacy before a patents is granted.[2] AI drug discovery, by contrast, produces molecules whose 'efficacy' is merely a score, a machine learning estimate of how well the molecule might bind to its target, but no evidence that it reliably does so in any living beings[3]. Freilich and Rai's 2025 study makes the scale of this gap visible, only 23% included any in vivo data, the mean number of compounds tested in vivo per patent was 0.8%.[4] These are not patents on the margins of the therapeutic efficacy standard, these are patents that do not engage it at all.

This paper identifies the doctrinal and constitutional implications of this shift, it argues that computational prediction cannot satisfy the therapeutic efficacy requirement under Section 3(d), and that the acceptance of such claims by the Indian Patents Office risks undermining both statutory intent and constitutional obligations under Art. 21. This paper proceeds by first clarifying the doctrinal structure of Section 3(d), then demonstrating how AI driven drug discovery disrupts that structure, and finally proposing a narrowly tailored interpretive standard that restores coherence without requiring legislative amendment.

Therapeutic Efficacy as a Legal Threshold.

Section 3(d) establishes a distinct threshold within Indian patent law. It provides that the mere discovery of a new form of a known substance does not constitute an invention unless it results

[1] Xu Z and others, 'A Generative AI-Discovered TNIK Inhibitor for Idiopathic Pulmonary Fibrosis: A Randomized Phase 2a Trial' (2025) Nature Medicine <https://doi.org/10.1038/s41591-025-03743-2> accessed 7 March 2026; Ren F and others, 'Identification of a Highly Potent, Selective, and Novel TNIK Inhibitor' (2024) Nature Biotechnology <https://doi.org/10.1038/s41587-024-02143-0> accessed 7 March 2026.
[2] Patents Act 1970 (India) s 3(d), as amended by Patents (Amendment) Act 2005 s 3.
[3] Janet Freilich and Arti K Rai, 'What Patents on AI-Derived Drugs Reveal' (2025) 388 Science 924, 925.
[4] ibid 925–26.

in enhanced efficacy.[5] Its Explanation reinforces this by treating derivatives such as salts, esters, polymorphs, and isomers as the same substance unless they demonstrate differences in properties relating to efficacy. The purpose of this provision as inserted by the Patents (Amendments) Act, 2005 was to be unambiguous, to prevent pharmaceutical companies from extending patent monopolies through minor chemical modifications that produced no genuine therapeutic advancements. A deliberate choice to make Indian patent law harder to exploit than in Europe and the United States[6]. The Supreme Court's interpretation of 'efficacy' in Novartis amended its operational content, on basis of therapeutic efficacy. The capacity to produce a curative or ameliorative effect in a patient.[7] Improved bioavailability does not satisfy this standard because better absorption does not imply better treatment. The Court described Section 3(d) as creating 'a second tier of qualifying standards' designed to keep the door open for genuine innovation while closing it firmly against 'repetitive patenting or extension of the patent term on spurious grounds.'[8] Delhi High Court in Natco Pharma v. Novartis AG (2024) reaffirmed the same.[9] Sampat and Shadlen's empirical study documents a marked increase over time in IPO examiners raising Section 3(d) objections, including on principal claims.[10]

The standard in short, is settled, a pharmaceutical patent applicant must produce data, clinical, preclinical or at a minimum, in vitro, showing that the claimed compound actually treats the disease better than what already exists[11].

The Efficacy Fiction: How AI Drug Discovery Breaks the Standard

The phrase 'efficacy fiction' describes a specific and systematic problem. AI drug discovery introduces a fundamental mismatch between the nature of patent claims and the evidentiary requirements of Section 3(d). The evidence they generate is of predicted molecule behaviour, computational estimates of binding affinity, pharmacokinetic profiles, and structural compatibility with a biological target, generated by models trained on data from compounds that have been biologically tested in the past. The prediction may be statistically grounded but

[5] Patents Act 1970 (India) s 3(d).
[6] Shamnad Basheer and T Prashant Reddy, 'The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)' (2008) 5 SCRIPTed 232, 235
[7] Novartis AG v Union of India (2013) 6 SCC 1 [189] (India).
[8] ibid [190].
[9] Natco Pharma v Novartis AG FAO(OS)(COMM) 178/2021, 2024:DHC:3198-DB (Delhi HC, 24 April 2024) [42] (India).
[10] Bhaven N Sampat and Kenneth C Shadlen, 'Indian Pharmaceutical Patent Prosecution: The Changing Role of Section 3(d)' (2018) 13(3) *PLoS ONE* e0194714.
[11] Novartis AG v Union of India (2013) 6 SCC 1 [189] (India)

is still a prediction which has never been tested physically. This distinction is important since within the Novartis judgement, a differentiation between properties of a compound and its therapeutic performance biologically.[12] A docking score is a modelled prediction of how the compound might interact with a target protein, which still doesn't hold to be enough unless it demonstrates bioavailability, a measured property of actual in vivo behaviour.

If one were to pave way for AI discovered drug patents without any safeguards, predictions would be treated as proxies for proof, and the statutory requirement of demonstrated efficacy would be replaced. The problem extends beyond evidence into structure. Section 3(d) was designed for incremental innovation, where a known compound is modified in limited ways. In contrast, AI platforms generate large volumes of structurally novel molecules targeting the same biological pathways.[13] These molecules may evade classification as derivatives under the explanation to Section 3(d), but yet perform the same therapeutic function.

This creates a new form of evergreening. Instead of extending patents through minor modifications of a single compound, firms can crowd the therapeutic testing with multiple AI generated variants, yet collectively block market entry.[14] The framework is oriented towards one to one comparisions, and is not equipped to address 'many to one' dynamic. This efficacy fiction operates on two levels, it replaces proof with prediction and it replaces incremental modification with scalable variation. Both forms undermine the core logic of Section 3(d) which is to link patent protection to demonstrable therapeutic contribution.

Article 21 and the constitutional cost of getting it wrong

The misapplication of Section 3(d) in the AI generated pharmaceutical patents context is not merely a doctrinal issue, it has a direct constitutional implication under Article 21. The Supreme Court has consistently interpreted Article 21 to include the right to health and access to medical treatment.[15] This interpretation imposes a positive obligation on the State to ensure conditions which are necessary for the preservation of life. Patent law operates within this framework, as grant of a patent confers market exclusivity which directly affects the price and

[12] ibid [189].
[13] Freilich and Rai (n 3) 926.
[14] Ryan Abbott, 'Everything Is Obvious' (2019) 66 *UCLA Law Review* 2, 4.
[15] Consumer Education and Research Centre v Union of India (1995) 3 SCC 42 [24] (India); Paschim Banga Khet Mazdoor Samity v State of West Bengal (1996) 4 SCC 37 [9] (India); Bandhua Mukti Morcha v Union of India (1984) 3 SCC 161 [10] (India); Constitution of India art 47.

availability of medicines. Judicial decisions have repeatedly recognized this, Courts have balanced patent rights against access considerations, often prioritizing the latter when life saving drugs are involved. Compulsory licensing decisions and injunction refusals demonstrate that patent law cannot be applied in isolation from public health concerns.[16]

AI generation within patents further intensify this. Unlike traditional cases, where the validity of the patent isn't in question, the patents may lack the evidentiary basis required for granting. The issue is not how to balance monopoly and access, but whether the monopoly should exist at all or not. The proportionality standard in the Puttaswamy judgement provides a structured way to analyse this.[17] A restriction on a fundamental right must pursue a legitimate aim and maintain a rational nexus between means and ends.

Pharmaceutical patents serve the legitimate aim of incentivizing therapeutic innovation. However, where a patent is granted without demonstrated efficacy, the nexus breaks down. The monopoly persists, but the innovation it's meant to reward does not. This results in a disproportionate restriction upon access to medicines. Patents bear the cost of exclusivity without receiving the corresponding benefit of proven therapeutic advancement. In such cases the grant of the patent itself constitutes a constitutional failure. The role of the Indian Patent Office must therefore be understood in constitutional terms too. As a state authority, it is bound to exercise its statutory powers in consonance with Article 21.[18] Granting patents based on predictive claims, without biological testing or validity, risks violating this obligation.

From Prediction to Proof: An Interpretative Standard

The reforms proposed in this paper are deliberately limited and kept administratively feasible. It does not require statutory amendments or judicial innovations. It merely requires consistently applying of the already existing law. The proposed standard is; where a pharmaceutical patent application involves a molecule generated through artificial intelligence, where it targets a known biological pathway, and claims to enhance therapeutical efficacy, the applicant must

[16] F Hoffmann-La Roche v Natco Pharma FAO(OS)(COMM) 43/2025, 2025:DHC:8943-DB (Delhi HC, 9 October 2025) [22] (India); Natco Pharma Ltd v Bayer Corporation CLA No 1 of 2011 (Controller of Patents, Mumbai, 9 March 2012), upheld IPAB Order No 45/2013 (4 March 2013) (India); F Hoffmann-La Roche v Cipla (2008) 37 PTC 71 (Del) [45] (India).
[17] K S Puttaswamy v Union of India (2017) 10 SCC 1 [180] (India) (Chandrachud J).
[18] Paschim Banga Khet Mazdoor Samity v State of West Bengal (1996) 4 SCC 37 [9] (India); Emmanuel Kolawole Oke, 'The Right to Health in Pharmaceutical Patent Disputes' South Centre Research Paper No 145 (2022) 12.

provide atleast some form of biologically applied data, including human trials for verification of authenticity, prior to its claim and its examination under Section 3(d).

Computational outputs, including docking scores, predictive modelling alone cannot this requirement. They may however be used as aids to guide research further. But they cannot substitute the need for testing. This standard can be implemented as a part of guidelines issued by the Indian Patents Office. Administrative guidance has been used within other jurisdictions abroad, without causing any legislative delay to address emerging technological issues[19]. India could apply the same here. A necessary addition to this standard would involve disclosures, Applicants must be required to disclose AI use in molecule generation as well submit generated data and the modifications further made to tweak results. Without such disclosures undertaken, examiners would not apply the specific guidelines for biological data for them. Transparency should therefore be a precondition for effective enforcement.

India's standards occupy a unique position comparatively, the United States lack an equivalent to Section 3(d) and does not impose a therapeutic efficacy threshold at the patentability stage.[20] European Union Laws recognize a right to health but hasn't added it into its examination of patents[21]. India combines a statutory anti-evergreening provision, a constitutional right to health, and a vast history of jurisprudence that prioritises access. This creates both the capacity as well as the obligation to respond to challenges posed by AI driven pharmaceutical innovation.

Conclusion

AI use today is inevitable, if not performatively more effective, it can analyse data and generate probabilities and combinations faster than the human mind could ever comprehend. It holds great possibilities in terms of healthcare and life saving treatments. The central claim of this paper is very straightforward, Section 3(d) requires demonstrated therapeutic efficacy and artificial intelligence produces predicted therapeutic potential. The two are not equivalent. However, the idea is to treat AI generated data as 'potential' and not as completed data. The distinction here is not merely semantic, it determines whether patent protection is granted on the basis of proven medical benefit or merely speculative inference. Especially in a domain

[19] USPTO, Inventorship Guidance for AI-Assisted Inventions (February 2024).
[20] Thaler v Vidal 43 F 4th 1207, 1213 (Fed Cir 2022) (US), cert denied 143 S Ct 1783 (2023).
[21] European Union, Charter of Fundamental Rights of the European Union [2000] OJ C364/1 art 35; Regulation (EU) 2024/1689 of the European Parliament and of the Council (AI Act) [2024] OJ L2024/1689, Recital 62.

where patents directly affect access to life-saving treatments, that distinction carries a lot of constitutional weight. Doctors find irregularities within historically proven facts and the symptoms presented ever so often. The human body cannot be considered as a standardized dataset, especially when scientists conclude our knowledge of the human body to be limited.

Artificial Intelligence, may work as an aid or a guide to advance pharmaceutical advancements but should be limited and treated as hypotheses instead of facts. Existing legal principles already provide the necessary tools to address this issue. Section 3(d) as interpreted in Novartis already establishes the standards[22], Article 21 establishes the constitutional grounding and administrative guidance from the patents office provides the mechanism for implementation.

What has changed is not the law, but the technology. AI has made it possible to generate and patent pharmaceutical propositions at scale without its corresponding evidentiary tests or validity. This creates pressure on a framework designed for a different model of innovation. Enforcement is the required response, not expansion. The therapeutic efficacy standard must be applied, however, a separate provision or requirement could be made for AI generated patents, but with full recognition of the distinction between prediction and proof. Anything less would risk converting Indian patent law from a system that rewards genuine innovation into one that rewards computational possibilities which would be a shift with consequences measured in access, affordability, and ultimately in lives.

[22] Novartis AG v Union of India (2013) 6 SCC 1 [189] [190] (India).