SUPREMO AMICUS

VOLUME 40 | February, 2026 Peer Reviewed | Refereed Journal

PHARMACEUTICAL PATENTABILITY IN INDIA: A CRITICAL ANALYSIS WITH REFERENCE TO PUBLIC ACCESS TO MEDICINE

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ABSTRACT

India's pharmaceutical industry holds a place in global public health that is difficult to overstate. As the single largest supplier of generic medicines by volume in the world, the country's ability to produce affordable drugs has, quite literally, kept millions of people alive — from HIV patients in sub-Saharan Africa to tuberculosis sufferers across South and South-East Asia. That position, however, has never been legally secure. Since India amended its Patents Act in 2005 to comply with the TRIPS Agreement, a quiet but consequential legal battle has been fought over just how strong pharmaceutical patent protection ought to be. Section 3(d) of the Patents Act — a provision with no real parallel anywhere else in the world — sits at the centre of that battle. It bars patents on new forms of known drug molecules unless they show meaningfully better therapeutic results, directly targeting the industry practice of 'evergreening.' This paper examines India's pharmaceutical patentability framework from the ground up: its colonial roots, the post-independence legislative design, the landmark Novartis AG v. Union of India judgment of 2013, India's compulsory licensing experience, and the ongoing pressures from the TRIPS-plus agenda in international trade negotiations. The central argument is that India's framework, for all its imperfections, represents a defensible and important balance — one that other developing nations would do well to study.

Keywords: *Pharmaceutical patents; TRIPS Agreement; Evergreening; Compulsory licensing; Novartis; Patents Act 1970.*

I. INTRODUCTION

Let us begin with a basic but uncomfortable question: should a company be able to charge USD 2,600 per patient per month for a cancer drug when an equivalent generic version is available for USD 200? Most people, on instinct, would say no. But that is precisely the scenario that played out in India before the Supreme Court's 2013 Novartis judgment — and it illustrates, as clearly as any case can, the fault line running through pharmaceutical patent law.

India's position in this debate is unique. It supplies roughly 20% of global generic medicine exports by volume and provides approximately 62% of global vaccine demand.[1] Its pharmaceutical industry is not a minor player — it is the backbone of affordable healthcare for a large part of the world. At the same time, India itself remains a country where out-of-pocket health expenditure constitutes a dangerously high share of household income,[2] meaning that medicine prices are not an abstract policy concern but a matter of daily survival for hundreds of millions of people. The stakes, in other words, could not be higher.

The 2005 amendment to the Patents Act, which introduced product patents for pharmaceuticals as required by TRIPS,[3] threatened to transform this landscape fundamentally. For the first time since independence, pharmaceutical companies could patent not just the process of making a drug but the drug itself. The concern — and it was a well-founded one — was that this would enable originator companies to lock out generic competitors, drive up prices, and put medicines beyond the reach of ordinary patients. Section 3(d) was Parliament's primary

[1]Ministry of Chemicals & Fertilizers, Pharma Vision 2047 (Government of India, 2023) 12.

[2]World Health Organization, 'India: WHO Statistical Profile' (WHO, 2023); National Health Accounts Estimates for India 2019–20 (Ministry of Health and Family Welfare, 2022).

[3]Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), Annex 1C, Marrakesh Agreement Establishing the WTO, 15 April 1994, 1869 UNTS 299, art 27(1).

response to that concern. Whether it has worked, and whether it is adequate to the challenges India now faces, is the subject of this paper.

The analysis proceeds as follows. Part II traces how India's patent regime evolved from the colonial period through the TRIPS transition. Part III breaks down the patentability framework in detail, with particular focus on Section 3(d). Part IV examines the key judicial decisions. Part V turns to compulsory licensing. Part VI situates the framework within international TRIPS flexibilities. Part VII offers a critical assessment of the framework's strengths and gaps. Part VIII concludes with recommendations.

II. HISTORICAL EVOLUTION

A. The Colonial Starting Point

It is worth remembering that India's earliest patent law was not designed with India in mind. The Patents and Designs Act of 1911 was a colonial transplant, modelled on English legislation of 1907 and serving primarily British industrial interests. It allowed full product patents on pharmaceutical substances — which meant that the development of an indigenous drug manufacturing industry was effectively foreclosed. Medicines had to be imported, typically from British and later European and American companies, at prices set to suit foreign markets rather than Indian pockets. This was not an accident; it was the design.

B. Independence and the 1970 Act: A Deliberate Choice

The post-independence generation of Indian policymakers was acutely conscious of this colonial legacy. The Ayyangar Committee, appointed in 1957 to review the patent system, produced a report in 1959 that remains one of the most thoughtful documents in Indian IP policy history.[4] Its core recommendation was straightforward: abolish product patents for food and pharmaceutical substances, and allow only process patents. The reasoning was simple — if you could patent only the method of making a drug but not the drug itself, multiple manufacturers could develop different routes to the same compound, competition would flourish, and prices would fall.

The Patents Act of 1970 enacted this vision.[5] Section 5, as it then stood, expressly prohibited product patents for medicines. The results, over the following three decades, were remarkable. Companies like Cipla, Ranbaxy, Dr. Reddy's, and Sun Pharma built world-class manufacturing capabilities and became global exporters of affordable generic drugs.[6] By the 1990s, India had earned its reputation as the 'pharmacy of the world' — a title rooted not in luck or geography but in a deliberate legislative choice made in 1970.

C. TRIPS and the Forced Transition: 1994–2005

The WTO's TRIPS Agreement, which India signed in 1994, undid much of this in one stroke. Article 27(1) required product patent protection in all fields of technology — including pharmaceuticals.[7] To be fair, India did not accept this without resistance. The TRIPS negotiations, as Drahos and Braithwaite have documented in considerable detail, were shaped heavily by the lobbying power of multinational pharmaceutical corporations, working through the US and EU trade negotiating machinery to secure maximum IP protection globally.[8] India pushed back, and secured a transitional period under Article 65(4) that deferred implementation until 1 January 2005.[9] In the meantime, a mailbox system for pharmaceutical patent applications and a framework for exclusive marketing rights were put in place.[10]

The decade between 1995 and 2005 was consequently one of intense debate. Pharmaceutical multinationals lobbied hard for strong product patents with minimal safeguards. Public health organisations — led most visibly by Médecins Sans Frontières — campaigned

[4]N Rajagopala Ayyangar, Report on the Revision of the Patents Law (Government of India, 1959) ('Ayyangar Report').

[5]Patents Act 1970 (Act No 39 of 1970) s 5 (prior to amendment in 2005).

[6]Sudip Chaudhuri, The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries (OUP 2005) 45–68.

[8]Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries (OUP 2001) ch 3; Peter Drahos and John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? (Earthscan 2002) 200–218.

[9]TRIPS Agreement (n 2) art 65(4).

[10]TRIPS Agreement (n 2) arts 70.8 and 70.9; Patents (Amendment) Act 1999 (Act No 17 of 1999).

just as hard for robust access protections.[11] What emerged from this contestation was the Patents (Amendment) Act, 2005: a compromise, of sorts. Product patents came in, as TRIPS required. But so did Section 3(d), strengthened compulsory licensing provisions, and enhanced opposition mechanisms. Whether that compromise has held is the question this paper interrogates.

III. PATENTABILITY UNDER THE PATENTS ACT, 1970

A. The Basic Framework

At its core, Indian patent law requires the same three things as most other patent systems: novelty, inventive step, and industrial applicability. Section 2(1)(j) defines 'invention' as 'a new product or process involving an inventive step and capable of industrial application.'[12] 'Inventive step' under Section 2(1)(ja) means a technical advance over existing knowledge, or economic significance, or both, that makes the invention non-obvious to a person skilled in the relevant field.[13] And 'new invention' under Section 2(1)(l) requires that the invention has not been previously published, used, or known anywhere in the world before the filing date.[14]

These are fairly standard requirements. What makes the Indian pharmaceutical patent framework distinctive — and controversial — is not the general criteria but the specific exclusions that overlay them, most importantly Section 3(d).

B. Section 3(d): The Provision That Changed Everything

Section 3(d) is, in the words of one commentator, India's 'most creative contribution to global patent law.'[15] Inserted by the 2005 Amendment, it provides that the mere discovery of a new form of a known substance — such as a new salt, ester, polymorph, or isomer — shall not be treated as an invention unless that new form shows significantly enhanced efficacy over the known substance.[16] The Explanation goes further: it lists salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, complexes, and combinations as all being deemed the same substance as the original compound, unless efficacy differs significantly.[17]

Why does this matter? Because pharmaceutical evergreening — the practice of tweaking a known drug molecule just enough to obtain a new patent and extend market exclusivity — has become one of the defining strategies of the global pharmaceutical industry. Change the salt form. Switch to a different polymorph. Alter the particle size. None of these modifications typically produce any meaningful improvement for the patient; they are primarily exercises in patent portfolio management, designed to keep generic competitors off the market for additional years or decades.[18]

Section 3(d) is a direct legislative answer to that strategy. It says, in effect: if you want a patent on a modified version of a drug we already know about, you had better show us that it actually works better for patients. Not just that it has better bioavailability, or longer shelf life, or improved stability — but that it genuinely produces better therapeutic outcomes. That is a demanding standard. It is meant to be.

Scholars have noted that Parliament's deliberate choice of the word 'efficacy' — rather than the broader 'utility' — signals a specifically therapeutic, clinically-focused threshold.[19] The burden is on the applicant to demonstrate that the new form produces a meaningfully better curative effect. If that cannot be shown, the application fails — regardless of how novel the chemistry may be in an abstract sense.

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[11] Médecins Sans Frontières, 'Patents and Access to Medicines in India: Briefing Note' (MSF Access Campaign, 2005).

[12] Patents Act 1970, s 2(1)(j).

[13] Patents Act 1970, s 2(1)(ja).

[14] Patents Act 1970, s 2(1)(l).

[15] Shamnad Basheer and Prashant T Reddy, 'The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)' (2008) 5(2) SCRIPTed 232, 240.

[16] Patents Act 1970, s 3(d), as inserted by the Patents (Amendment) Act 2005 (Act No 15 of 2005) s 3.

[17] Patents Act 1970, s 3(d) Explanation.

[18] Anitha Ramanna, 'Policy Implications of India's Patent Reforms' (2002) 37(36) Economic and Political Weekly 3601, 3605.

C. Sections 3(b), 3(e), and 3(i): The Supporting Framework

Section 3(d) does not operate in isolation. Several other exclusions under Section 3 collectively shape the pharmaceutical patent landscape. Section 3(b) bars inventions whose exploitation would be contrary to public order, morality, or human health. Section 3(e) excludes substances obtained by mere admixture — ruling out patents on simple combinations of known active compounds where the only 'innovation' is putting two things together.[20] Section 3(i) excludes methods of treatment of human beings or animals from patentability altogether, ensuring that therapeutic techniques remain in the public domain. Together, these provisions reflect a legislative design oriented around the primacy of public welfare over private exclusivity in the pharmaceutical domain.

D. Opposition Mechanisms: The Gatekeeping Role

One of the underappreciated strengths of the 2005 Amendment is the robustness of the opposition mechanisms it introduced. Section 25(1) allows any person — not just a party with a direct commercial interest — to oppose a patent application before it is granted, on grounds including Section 3(d) violations, lack of novelty, and absence of inventive step. Section 25(2) provides for post-grant opposition, which must be filed within twelve months of publication of grant.[21]

These are not paper rights. The pre-grant opposition filed by the Cancer Patients Aid Association against Novartis's imatinib mesylate application in 2006 before the Chennai Patent Office[22] — which succeeded, and triggered the decade-long litigation culminating in the Supreme Court's judgment — is the most celebrated example. But there have been many others: post-grant oppositions have resulted in the revocation of patents on antiretrovirals including tenofovir, lopinavir, and ritonavir, and on cancer drugs including dasatinib. The opposition system, in practice, has served as a meaningful and accessible quality control mechanism for the pharmaceutical patent register.

IV. JUDICIAL INTERPRETATION

A. Novartis AG v. Union of India (2013): The Case That Defined the Debate

There are judgments that decide a case, and there are judgments that define an era. The Supreme Court's 2013 ruling in Novartis AG v. Union of India[23] falls firmly in the second category. It is, without exaggeration, one of the most important decisions on pharmaceutical patent law delivered anywhere in the world in the past two decades — and its implications extend far beyond India's borders.

The facts are worth setting out in some detail, because they illustrate the stakes precisely.[24] Novartis AG had a patent — the so-called Zimmermann patent, dating from 1993 — on imatinib, the active molecule in the groundbreaking cancer drug Gleevec/Glivec. That patent covered imatinib in free base form and as a number of salts including imatinib mesylate. After 2005, Novartis sought a fresh patent on a specific crystalline form of imatinib mesylate — the beta-crystalline polymorph — on the basis that it showed better bioavailability than the compound in the original patent. Novartis priced Gleevec at approximately USD 2,600 per patient per month in India. Indian generic manufacturers, who had been producing imatinib under the previous process-patent regime, offered equivalent products at roughly USD 200 per month.

The legal question was whether the beta-crystalline form of imatinib mesylate was a patentable 'new form' under Section 3(d) — or whether it was simply a modification of a known substance without significantly enhanced efficacy. The Supreme Court held that it was the latter. In doing so, it delivered a ruling of extraordinary doctrinal and practical consequence.

The Court's key interpretive holding was on the meaning of 'efficacy' in Section 3(d).[25] Novartis had

[20]Patents Act 1970, ss 3(b), 3(e), 3(i).

[21]Patents Act 1970, ss 25(1) and 25(2).

[22]The Cancer Patients Aid Association filed the pre-grant opposition before the Assistant Controller of Patents and Designs, Chennai, in 2006. The opposition was allowed, precipitating Novartis's writ petition before the Madras High Court and ultimately the Supreme Court litigation.

[23]Novartis AG v Union of India & Others (2013) 6 SCC 1 (SC) ('Novartis').

[24]Novartis (n 21) [2]–[10].

[25]Novartis (n 21) [181]–[190].

argued that improved bioavailability — the fact that the beta-crystalline form was absorbed more readily into the bloodstream — demonstrated enhanced efficacy. The Court rejected this, firmly and unambiguously: 'efficacy' in Section 3(d) means 'therapeutic efficacy' — the capacity of the drug to produce a curative, healing effect in the patient. Better bioavailability is a pharmacokinetic property, not a therapeutic one. It does not satisfy the Section 3(d) test unless it translates into a demonstrated improvement in clinical outcomes. For the millions of cancer patients who depend on affordable generic imatinib, this was not merely a doctrinal point — it was the difference between treatment and no treatment.

The Court also engaged carefully with the legislative history of Section 3(d),[26] tracing the Parliamentary debates of 2005 and concluding that the provision was enacted with a clear and specific purpose: to prevent pharmaceutical evergreening and protect the supply of affordable medicines. This purposive approach lent the judgment a robustness that has made it difficult to dislodge. On the TRIPS compatibility question,[27] the Court held — correctly, in this writer's view — that Article 27(1) of TRIPS does not impose a uniform global definition of novelty or inventive step; it sets minimum standards, leaving member states a genuine margin of discretion in how they define and apply patentability criteria.[28] Section 3(d) is, on this analysis, a legitimate exercise of that discretion.

Not everyone agrees with this assessment. Critics argue that the therapeutic efficacy standard, as interpreted by the Court, creates a zone of legal unpredictability that may deter investment in genuine pharmaceutical innovation — particularly in drug reformulation projects that deliver real, if modest, clinical advantages.[29] There is something to this. A new polymorph that significantly reduces adverse side effects, or a salt form that enables once-daily rather than twice-daily dosing, may carry genuine patient benefit while struggling to satisfy the Novartis therapeutic efficacy test. The Court's formulation, one might argue, is a blunt instrument applied to a nuanced problem. That said, the alternative — allowing incremental modifications to pass through the Section 3(d) filter without clinical justification — would effectively permit the evergreening the provision was designed to prevent. The imprecision of the standard is a real problem, but it is a problem that legislative clarification, rather than judicial dilution, should address.

B. F. Hoffmann-La Roche Ltd. v. Cipla Ltd. (2009)

The Roche v. Cipla case, decided by the Delhi High Court's Division Bench, added an important dimension to the pharmaceutical patent landscape: the explicit incorporation of public health considerations into the intellectual property enforcement calculus.[30] Roche sought an interlocutory injunction to stop Cipla selling generic erlotinib (Tarceva), a lung cancer drug, pending the outcome of a patent infringement suit. The Court declined. The balance of convenience, it held, did not favour shutting off the supply of an affordable cancer treatment to patients who could not afford the originator price. This was not a finding on the validity of the patent; it was a finding about remedy. But it mattered enormously in practical terms — and it signalled that Indian courts were prepared to weigh the downstream human consequences of IP enforcement decisions, not merely the abstract property rights of patent holders.

C. Bristol-Myers Squibb v. Natco Pharma (2013)

Less celebrated than Novartis but equally instructive is the IPAB's 2013 decision revoking Bristol-Myers Squibb's patent on dasatinib (Sprycel) in post-grant opposition proceedings brought by Natco Pharma.[31] Dasatinib is another targeted cancer therapy — and another example of a drug whose patent application failed the Section 3(d) test. The IPAB found that the compound, as a modification of a known substance, could not demonstrate significantly enhanced therapeutic efficacy. The revocation cleared the path for generic production and affordable supply. The

[26]Novartis (n 21) [91]–[101].

[27]Novartis (n 21) [163]–[167].

[28]Carlos M Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (OUP 2007) 271–284.

[29]Kristina M Lybecker, 'Pharmaceutical Patents and the Public Interest in India' (2014) 17(5–6) Journal of World Intellectual Property 243, 255–259.

[30]F Hoffmann-La Roche Ltd v Cipla Ltd 148 (2008) DLT 598 (Delhi HC, Division Bench 2009).

[31]Bristol-Myers Squibb Holdings Ireland Unlimited Company v Natco Pharma Ltd OA/35/2012/PT/CH (IPAB 2013).

case demonstrates, if further demonstration were needed, that Section 3(d) is not merely aspirational language — it has real teeth, and it can be applied effectively through the post-grant opposition mechanism.

V. COMPULSORY LICENSING

A. The Legal Framework

Compulsory licensing — allowing a government to authorise a third party to manufacture a patented product without the patent holder's consent — is perhaps the most politically charged TRIPS flexibility available to developing countries. India's framework, under Sections 84 through 92A of the Patents Act, is comprehensive at least on paper.

Section 84 is the primary route. Any interested person may apply to the Controller of Patents for a compulsory licence three years after a patent is granted, on three grounds: that the reasonable requirements of the public have not been satisfied; that the patented invention is not available at a reasonably affordable price; or that the invention is not being worked in India.[32] The Controller must consider factors including the nature of the invention, what steps the patent holder has taken to exploit it, and the applicant's capacity to work it.[33] Any licence granted must be non-exclusive, non-assignable, predominantly for domestic supply, and subject to adequate remuneration to the patent holder.[34] Section 92 provides for emergency licences without the prior negotiation requirement. Section 92A — inserted by the 2005 Amendment — enables export of generics to countries without manufacturing capacity.[35]

B. The Natco-Bayer Decision: Promise and Precedent

India's first compulsory licence, granted in March 2012 to Natco Pharma for sorafenib tosylate (Nexavar, used to treat kidney and liver cancer), was a landmark moment.[36] The numbers told the story starkly: Bayer priced Nexavar at INR 2,84,428 per patient per month. Natco proposed to supply it at INR 8,880 per month — a reduction of approximately 97%.[37] The Controller found all three Section 84(1) grounds satisfied: the drug was not available at an affordable price, Bayer had not manufactured it in India, and its import volumes fell far short of meeting patient need. Bayer appealed, vigorously, all the way to the Supreme Court. It lost at every stage.[38]

The significance of the decision was not just domestic. Brazil, Thailand, Malaysia, and other developing countries cited it as a model. It showed that the compulsory licensing mechanism, properly invoked, could withstand legal challenge even against a large multinational pharmaceutical company with deep resources and a strong interest in defeating the precedent.

C. Why Has Compulsory Licensing Been Used So Rarely?

And yet — here is the uncomfortable reality — the Natco-Bayer case remains, as of the time of writing, the only compulsory licence actually granted under Section 84. Subsequent applications for dasatinib and saxagliptin were rejected. An application for trastuzumab (Herceptin, a breast cancer drug) effectively collapsed.[39][40] Why? The mechanism exists. The law is clear. The need is obvious. So what is stopping it from being used?

Several factors are at work. The three-year waiting period from patent grant under Section 84(1) creates

[32]Patents Act 1970, s 84(1).

[33]Patents Act 1970, s 84(6).

[34]Patents Act 1970, s 90(1).

[35]Patents Act 1970, ss 92 and 92A; WTO General Council Decision WT/L/540 (30 August 2003).

[36]Natco Pharma Ltd v Bayer Corporation, Compulsory Licence Application No 1 of 2011 (Controller of Patents, 9 March 2012).

[37]Natco Pharma Ltd v Bayer Corporation (n 30): sorafenib tosylate priced at INR 2,84,428/month by Bayer vs INR 8,880/month proposed by Natco.

[38]Bayer Corporation v Union of India WP No 1323 of 2013 (Bombay HC, 15 July 2014), affirmed in SLP (C) No 30145 of 2014 (SC).

[39]KM Gopakumar, 'Product Patents and Access to Medicines in India: A Critical Review' (2010) 1(2) Law and Development Review 325, 347–352.

[40]MSF, 'India's Decision to Reject Compulsory Licence Application for Herceptin a Devastating Blow for Cancer Patients' (MSF Press Release, 20 September 2013).

an immediate access gap — patients cannot wait three years for a compulsory licence while their cancer progresses. The prior negotiation requirement adds procedural complexity and delay. The risk of being placed on the USTR's Special 301 Priority Watch List — India has been there since 2014[41] — and the associated diplomatic and trade consequences create a powerful political deterrent. And the experience of prolonged and expensive litigation in the Bayer case itself has arguably chilled subsequent applications by smaller generic manufacturers who cannot afford a similar legal battle.

The deeper problem is structural. Compulsory licensing is a downstream remedy — it addresses access failures after they have already materialised, rather than preventing unmeritorious patents from issuing in the first place. A cancer patient denied affordable treatment for three years while waiting for a compulsory licence to become available has already suffered the harm the system was meant to prevent. This is why upstream patentability standards — and Section 3(d) in particular — are so critical. The gate is better than the escape hatch.

VI. TRIPS FLEXIBILITIES AND INDIA'S INTERNATIONAL POSITION

A. The Doha Declaration: A Turning Point

The Doha Declaration on TRIPS and Public Health, adopted in November 2001, matters more than most WTO documents. It was adopted at a moment of acute global health crisis — millions of people dying of AIDS in Africa without access to patented antiretroviral drugs — and it carried a political and moral weight that gave it interpretive force beyond its formal legal status.

Paragraph 4 stated plainly:[42]

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

Paragraph 5(b) confirmed the right to grant compulsory licences on grounds of each member's own choosing.[43] Paragraph 5(c) clarified that public health crises — including HIV/AIDS, tuberculosis, malaria, and other epidemics — qualify as national emergencies.[44] Paragraph 6 acknowledged the particular difficulties of least-developed countries with limited manufacturing capacity.[45]

For India, the Doha Declaration was not just a political document — it was a legal resource. The Supreme Court in Novartis drew on it directly in upholding Section 3(d)'s consistency with TRIPS. The Declaration confirmed that member states retain genuine discretion in calibrating their patentability standards to public health needs, and India has used that discretion — perhaps more effectively than any other developing country.

B. The TRIPS-Plus Threat: A Battle Not Yet Won

But the battle over pharmaceutical IP standards is far from over. Bilateral and multilateral free trade agreements — particularly those negotiated between developed and developing countries — have increasingly included 'TRIPS-plus' provisions: IP obligations that go beyond what TRIPS requires, and that would, if adopted, significantly narrow India's policy space.[46]

Data exclusivity is perhaps the most dangerous of these. Under a data exclusivity regime, a generic manufacturer cannot rely on the originator's clinical trial data to obtain regulatory approval for a specified period — typically five to ten years — even if the patent on the drug has expired or never existed. This effectively creates a parallel exclusivity regime entirely independent of the patent system. Patent

[41]United States Trade Representative, 2023 Special 301 Report (USTR, 2023) 45–47.

[42]WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health WT/MIN(01)/DEC/2 (14 November 2001) ('Doha Declaration') para 4.

[43]Doha Declaration (n 39) para 5(b).

[44]Doha Declaration (n 39) para 5(c).

[45]Doha Declaration (n 39) para 6; WTO General Council Decision WT/L/540 (30 August 2003).

[46]Preeti Bhatt, 'TRIPS-Plus Provisions and Access to Medicines' (2012) 14(3) Journal of World Intellectual Property 258.

linkage is another favourite TRIPS-plus demand: it ties the grant of marketing approval for generic drugs to the patent status of the originator product, giving patent holders a regulatory lever to delay generic entry beyond what the patent itself justifies.

India has so far resisted these demands. The India-EU FTA negotiations stalled partly on these very IP issues; India refused to accept data exclusivity or patent linkage in that context. But the pressure has not gone away. The USTR's annual Special 301 reports continue to name India as a Priority Watch List country,[47] and the pharmaceutical industry continues to use trade negotiations as a vehicle for constraining the policy space that Doha and TRIPS themselves preserve. Maintaining India's current position will require ongoing political commitment and legal vigilance.

VII. A CRITICAL ASSESSMENT

A. What India Has Got Right

Let us be direct: India's pharmaceutical patent framework is, in this writer's assessment, broadly well-designed. Section 3(d) does what it was intended to do. It prevents pharmaceutical companies from evergreening known drug molecules without genuine therapeutic benefit, and it has done so repeatedly and effectively — as the Novartis case, the dasatinib revocation, and numerous patent office oppositions demonstrate. The compulsory licensing framework, while underused, provides a real access lever when political will exists to invoke it.

The global public health consequences of this design are not speculative. Competition from Indian generic manufacturers drove first-line HIV antiretroviral prices from over USD 10,000 per patient per year in 2000 to under USD 100 by 2016.[48] That is not a small thing. It is one of the most significant public health achievements of the twenty-first century, and it was made possible in substantial part by the framework established by the Patents Act of 1970 and preserved — with adaptations — in the 2005 Amendment.

There is also a broader developmental argument that tends to get lost in the technical legal debate. As Ha-Joon Chang has documented, the industrialised nations that today advocate most forcefully for high IP standards relied on weak or absent product patent protection during their own periods of industrial development.[49] TRIPS, from this perspective, is a form of 'kicking away the ladder' — denying developing countries the policy tools that rich countries used on their own ascent. India's resistance to that logic, embodied in Section 3(d), is not merely self-interested; it reflects a principled rejection of a historically selective application of IP norms.

B. Where the Framework Falls Short

None of which means the current framework is adequate. Several significant problems deserve attention.

The most pressing is the vagueness of the Section 3(d) standard itself. The Novartis judgment authoritatively established that 'efficacy' means 'therapeutic efficacy,' but it left a number of subsidiary questions unresolved.[50] What quantum of evidence of enhanced therapeutic efficacy is required? Does pre-clinical or in vitro evidence suffice, or is clinical trial data necessary? How is the efficacy of the modified compound to be compared with the 'known substance' when the prior art field contains multiple relevant compounds? These are not hypothetical questions — they arise in every pharmaceutical patent examination, and the absence of clear answers produces both inconsistency in patent office decisions and uncertainty for applicants.[51]

Then there is the patent office itself. The Indian Patent Office has faced persistent criticism for inconsistent examination standards across its different technical art units, resulting in pharmaceutical patents being granted that should have been refused under Section 3(d), and applications being rejected that deserved to succeed.[52] The average pendency of patent applications remained alarmingly high as of 2022–23, creating delays that serve neither patent applicants nor the public interest. These are solvable institutional

[48]Médecins Sans Frontières, Untangling the Web of Antiretroviral Price Reductions (18th edn, MSF 2016).

[49]Ha-Joon Chang, 'Intellectual Property Rights and Economic Development: Historical Lessons and Emerging Issues' (2001) 2(2) Journal of Human Development 287.

[50]Novartis (n 21) [186].

[51]Basheer and Reddy (n 16) 246–252.

[52]Patent Office, Annual Report 2022–23 (CGPDTM, 2023).

problems — but they require investment, training, and sustained administrative attention that has not always been forthcoming.

The underutilisation of compulsory licensing is a third serious gap. The mechanism exists, the law supports it, the need is demonstrable — and yet it is barely used. The structural reasons have been discussed above, but the consequence is a system in which the theoretical access remedies available on paper are largely unavailable in practice to the patients who need them most.

C. COVID-19: What the Pandemic Taught Us

The COVID-19 pandemic was, among many other things, a stress test for the global pharmaceutical IP system — and the system did not perform well. Vaccines developed at extraordinary speed, with massive public investment, were locked behind patent monopolies and supply agreements with wealthy nations, producing grotesque vaccine inequity. India and South Africa proposed a comprehensive TRIPS waiver in October 2020[53] that would have enabled all countries to manufacture COVID-19 vaccines and treatments without IP barriers. The proposal attracted the support of over 100 WTO members. It was blocked for eighteen months by the US, EU, Switzerland, and the UK.

The eventual compromise adopted at the WTO's Twelfth Ministerial Conference in June 2022[54] provided only a narrow, conditional waiver limited to vaccines — widely regarded as wholly inadequate. India's own experience in mid-2021, when a devastating second wave of the pandemic coincided with severe vaccine shortages, illustrated in the starkest possible terms the human cost of IP-related supply constraints.[55]

What the pandemic demonstrated — if demonstration were still needed — is that leaving the allocation of essential health technologies to patent-based market mechanisms is a policy choice with foreseeable and severe humanitarian consequences. India's engagement with alternative innovation models that de-link R&D cost recovery from product pricing — prize funds, advance market commitments, open licensing — will be an increasingly important dimension of its pharmaceutical IP policy in the years ahead.

VIII. CONCLUSION AND RECOMMENDATIONS

India's pharmaceutical patent framework is, this paper has argued, a broadly defensible and historically important legal structure. It is imperfect — sometimes frustratingly so. The vagueness of the therapeutic efficacy standard, the institutional limitations of the Patent Office, and the structural underutilisation of compulsory licensing are real problems that deserve sustained legislative and administrative attention.

But the core design — Section 3(d)'s efficacy filter, the opposition mechanisms, the compulsory licensing framework, the resistance to TRIPS-plus demands — reflects a coherent and empirically grounded set of policy choices in favour of public health and equitable access. The Novartis judgment gave those choices judicial blessing and international visibility. The Natco-Bayer case showed they can be practically enforced.[56]

The following recommendations are advanced to strengthen and develop the framework:

1. **Legislatively clarify Section 3(d):** Parliament should amend Section 3(d) or issue subordinate regulatory guidance specifying what constitutes 'significantly enhanced therapeutic efficacy,' with worked examples addressing common pharmaceutical modifications. This should include clarification of the evidentiary threshold and the comparator standard, developed in consultation with clinical pharmacologists, patent practitioners, and public health experts.[57]

[53]India and South Africa, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19' IP/C/W/669 (2 October 2020).

[54]WTO, Ministerial Decision on the TRIPS Agreement WT/MIN(22)/30 (17 June 2022).

[55]Achal Prabhala, Burcu Kilic and Brook Baker, 'Rethinking Production of COVID-19 Vaccines' (2021) 397 The Lancet 1036.

[56]See generally Chaudhuri (n 6); t'Hoen (n 57); Correa (n 26).

[57]KM Gopakumar and Sangeeta Shashikant, 'The Draft Patent Manual and Patentability Standards' (Third World Network Briefing Paper No 67, 2011).

2. **Invest in Patent Office capacity:** The Indian Patent Office needs sustained, substantial investment in pharmaceutical patent examination — including technical training in pharmacology and clinical therapeutics, robust quality control mechanisms, and an audit framework to identify and correct inconsistent examination practices. Reducing application pendency is not merely an administrative goal; it has direct consequences for both innovation incentives and access to generic medicines.
3. **Reform compulsory licensing procedures:** The three-year waiting period under Section 84(1) should be reconsidered, particularly for medicines treating life-threatening or rapidly progressive conditions. Clearer and more objective criteria for 'reasonably affordable price' and procedural streamlining for emergency situations would make the mechanism practically usable rather than merely theoretically available.[58]
4. **Resist TRIPS-plus demands:** India's trade negotiating position must continue to treat pharmaceutical IP as a non-negotiable public health priority. Data exclusivity, patent linkage, and extended patent term provisions should not be accepted in any bilateral or multilateral agreement. The legislative space that TRIPS and the Doha Declaration preserve must be actively defended, not surrendered in pursuit of other trade objectives.
5. **Champion alternative innovation models:** India should expand its support at the WTO and in multilateral forums for de-linked innovation mechanisms — prize funds, advance market commitments, open licensing for publicly-funded research — that ensure the fruits of pharmaceutical R&D are accessible regardless of a patient's ability to pay. Domestically, public investment in pharmaceutical R&D should be expanded with a focus on diseases of poverty and conditions disproportionately affecting the Indian population.
6. **Integrate patent policy with a holistic access framework:** Patent law is only one part of the access puzzle. Supply chain strengthening, rational medicines use programmes, universal health coverage financing, and procurement reform must accompany IP policy to ensure that legal victories in patent offices and courts translate into actual medicines in the hands of patients who need them.

India did not arrive at its current pharmaceutical patent framework by accident. It was built, deliberately and painstakingly, over decades of legislative design, policy contestation, and judicial interpretation — shaped by the conviction that a patent system should serve people, not the other way around. That conviction remains as important today as it was in 1970, or in 2005, or in 2013. The challenge now is to defend and develop it — with intellectual rigour, institutional commitment, and the same public health seriousness that produced Section 3(d) in the first place.[59]

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[59]Ellen FM t'Hoen, Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines (Health Action International 2016) ch 7.

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