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Patentability of Pharmaceutical Inventions Under Indian Law: Between Innovation Incentives and Access Imperatives

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Abstract

Today, Leukemia patients in India can be kept alive with a generic drug which costs a few hundred dollars a year, and in high-income countries costs thousands of dollars a month. This marks a long shift in approaches. In this paper, patentability of pharmaceutical inventions in India is looked at, in terms of intellectual property ('IP') law and local health needs of the population. It follows development of Indian patent system since the process-patent (pro-generic) system of Patents Act 1970[2], and subsequent amendments.[3] The 2005 amendment[4] reintroduced product patent for pharmaceuticals. It is against this background that the paper examines substantive and procedural contours of patentability in Indian Patents Act with specific focus on Section 3(d), compulsory licensing, opposition and interface between patent law and drug regulatory approvals. As compared to jurisdictions in other parts of the world, including United States, European Union, Brazil and South Africa, access sensitive nature of India is distinct. The paper evaluates whether the current Indian framework strikes the right balance between incentives to pharmaceutical innovation and needs to affordable access to medicines and suggests some more limited reforms to enhance quality of patents, protect TRIPS flexibilities, and reposition pharmaceutical patent policy to be more consistent with constitutional promises of public health.

Keywords: Pharmaceutical patents, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Drug regulators, intellectual property (IP).

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[2] The Patents Act 1970 (Act 39 of 1970).
[3] *See, generally*, The Patents (amendment) Act 1999 (Act 17 of 1999); The Patents (amendment) Act 2002 (Act 38 of 2002, and The Patents (amendment) Act 2005 (Act 15 of 2005).
[4] The Patents (amendment) Act 2005 (Act 15 of 2005).

Premise

Patentability of pharmaceutical inventions is an area of international trade law, national IP policy, and governance of health especially that is notably contested.[5] This opposition is particularly keen in India. The manner in which Indian law is prescribing and restricting what constitutes a patentable invention with respect to pharmaceutical products, directly affects not only the incentive to innovate within domestic pharmaceutical sector. But also access to and affordability of drug in both India and in most other low and middle-income countries that rely on the Indian generic versions of products.

The patent policy in India has traditionally been influenced as much by developmental and public health factors of the country as by traditional reasons of protection of intellectual property.[6] the Patents Act [7] specifically chose not to patent products in food and pharmaceutical sectors, restricted protection in these areas to processes, and balanced this with comparatively short terms and a strong compulsory licensing system. This legislative structure helped in development of a robust domestic generic sector and helped in massive drug cost-cuts.[8] This settlement was however fundamentally shaken with entry of India into WTO and its enactment of TRIPS Agreement.[9]

TRIPS Agreement mandates member states to grant patents without division based on any field of technology and must have a term of at least twenty years on the date of filing.[10] The incremental conformity of India, which ended in Patents (Amendment) Act 2005,[11] reinstated product patents on pharmaceuticals and chemicals, but at the same time tried to maintain regulatory independence in a series of built-in safeguards.[12] The said safeguards, especially the Section 3(d),[13] which limits the patentability of new forms of already known substances unless they are shown to have increased therapeutic efficacy, and the enhanced procedures in pre-

[5] Ramzi Hamdani, 'Framing the Debate: Pharmaceutical Patents and the Right to Health under International Law' (2025) International Journal of Scientific Research and Management (IJSRM), volume 13, issue 07 < https://doi.org/10.18535/ijsrm/v13i07.lla02> accessed 27 December 2025.
[6] Law Commission of India, *Trade Secrets and Economic Espionage* (Report No 289, 2024) para 117.
[7] *Supra* n1.
[8] n (Report 289).
[9] The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).
[10] TRIPS Agreement art 27, 33.
[11] Patents (amendment) Act 2005.
[12] Ibid; Chandni Raina, 'Trade Secret Protection in India: The Policy Debate' (Centre for WTO Studies Working Paper No CWS/WP/200/22, Indian Institute of Foreign Trade, September 2015) <https://wtocentre.iift.ac.in/workingpaper/Trade%20Secret%20Protection%20in%20India-%20The%20policy%20debate.pdf> accessed 26 November 2025.
[13] The Patents Act 1970 (Act 39 of 1970), s3(d).

grant and post-grant opposition, a formal compulsory licensing regime, and a Bolar-type exception;[14] have produced what is now commonly referred to as a unique Indian treatment of patentability of pharmaceutical inventions. This style is also marked by a mostly conservative attitude towards so-called TRIPS-plus provisions, including regulatory data exclusivity and extensions of the term of patents, often requested in bilateral and regional trade talks.[15] Collectively, these factors make India a jurisdiction that is predominantly consonant with TRIPS Agreement, but which is strategically sensitive to maintain access to medicines and industrial policy space.

The overall normative question that drives this paper could be put this way: *to what degree, and in what doctrinal setup, must pharmaceutical inventions be patentable in India, to ensure the realization of actual therapeutic innovation without unnecessarily jeopardizing the access to affordable medicines and commitment to constitutional adherence to the health of the people?* To answer this question, it is not possible to simply describe statutory provisions. It seeks an integrated approach to analysis that is both doctrinal, historical, comparative, and policy-oriented, which places Indian patent law in a wider context of TRIPS architecture and its flexibilities, as well as it approaches the contemporary issue of evergreening, biologics, and pandemic-related technologies.

The paper has four inter-related goals. *Originally*, it follows how legal provisions of patentability of pharmaceutical inventions in India have developed since the process-patent paradigm of the 1970 Act,[16] to TRIPS-consistent yet protectionist regime that has been developed over 1999,[17] 2002,[18] and 2005[19] reforms. *Second*, it clarifies modern-day boundaries to patentability of pharmaceutical inventions in the Patents Act (as amended), with particular focus on interaction between general requirements of novelty, inventive step, and industrial applicability, on the one hand, and exclusion and qualification in section 3,[20] particularly Section 3(d),[21] on the other, and on antidotes to such mechanisms, including opposition proceedings and compulsory licensing. *Third*, it places Indian framework in the TRIPS regime and Doha Declaration on TRIPS and Public Health, how India has invoked and exercised

[14] The Patents Act 1970 (Act 39 of 1970), s107A.
[15] *Supra* n6, 9.
[16] *Supra* n4.
[17] The Patents (amendment) Act 1999 (Act 17 of 1999).
[18] The Patents (amendment) Act 2002 (Act 38 of 2002).
[19] *Supra* n3.
[20] The Patents Act 1970 (Act 39 of 1970), s3.
[21] *Supra* n10.

flexibilities of TRIPS Agreement to tune the scope of pharmaceutical patentability to the requirements of the call of public health.[22] It then *concludes* by performing a comparative and policy evaluation of Indian standards against those of the few foreign jurisdictions it has chosen to compare them with and the determination of whether the current Indian framework is effective in creating an optimal balance between the incentivized innovation of pharmaceuticals and the affordable access to medicines. Thus, paper aims to offer a more thorough description of pharmaceutical invention patentability in India as well as to contribute to more general debates on how the patent law may be structured as a tool of public good in a heavily unequal global health environment.

Conceptual Framework: Patentability and Pharmaceutical Innovation

Patentability of pharmaceutical inventions is a scientific field that needs to be analysed with fundamental ideas that define the patent law.[23] Standards of patents are not merely statements of technical qualifications. They are decisions regarding the type of knowledge and technical improvement that should be granted exclusive rights and how such rights are to be weighed with other social health and access issues.[24] In majority of modern systems, such as in India, an invention is patented; it is new, is an inventive act, and it can be applied industrially.[25] Novelty, which is a requirement of subject matter, means that subject matter is not of prior art;[26] inventive step, which is also a requirement, means that the subject matter is not obvious to a person of skill in art,[27] and industrial application which is a requirement, means that the subject matter can be made or used in industry.[28] Much of the concrete content of these criteria

[22] Tanya Aplin and Johnathon Liddicoat, 'Discussion Paper on the Interplay between patents and trade secrets in medical technologies' (WIPO Policy Document WIPO/IP/COVID/GE/2/22/PAPER, October 2023) 15.
[23] Ramesh Jois et al., 'Similar Biologics in India: A story of access or potential for compromise?' (2020) IJMR 43 <https://pmc.ncbi.nlm.nih.gov/articles/PMC8157901/> accessed 23rd November 2025.
[24] Sushmi Dey, 'Dept of pharma ignores health ministry concerns, removes price cap on patented, rare disease drugs.', The Times of India (5 January 2019) <https://timesofindia.indiatimes.com/india/controversial-move-by-pharma-department-to-push-up-drug-prices/articleshow/67390706.cms> accessed 24th November 2025.
[25] See generally, Korah Abraham, '26.4% of Indians still below poverty line: Study challenges govt's 5% claim'(5 Feb 2025) <https://www.thenewsminute.com/news/264-of-indians-still-below-poverty-line-study-challenges-govts-5-claim> accessed 24th November 2025; also see, Prashant T Reddy, 'The Data Exclusivity Debate In India: Time For A Rethink?' (2014) Indian Journal of Law and Technology 10.
[26] Anuritha & Jayshree Ds, 'The impact of TRIPS-Driven Data Exclusivity on Pharmaceutical Innovation in India: Balancing Patent and Public Health' (2024) 6 IJFMR 2.
[27] Ibid.
[28] Ibid.

is simply built up by statute, patent offices and courts and can be tuned either to be more stringent or less restrictive, particularly in such sensitive areas as pharmaceuticals.

There are two traditional differences, which are significant. *First* is the one between discovery and invention. Patent laws are not typically applicable to discovery of something that exists in nature, but they allow protection to human-created technical contributions relying on and transforming these discoveries. In pharmaceuticals dozens of border cases fall on this axis: the isolation of a natural substance, finding a novel therapeutic application, or creating a novel dosage form could be described as either innovative or simply as derivative depending on how the line between discovery-invention is drawn.[29] *Second* is process-product patent. The product patents provide exclusivity to the substance or composition as it is but process patents are granted to protect only a given mode of production.[30] This difference is a result in pharmaceutical industry: *a product-patent regime generally allows more extensive and intense control over active ingredient and formulations, whereas a process-only regime gives more space to generic manufacturers to develop other ways to run the processes and enter the market at an earlier stage.*

History of India being process patent reliant on drugs and its subsequent transition to product reliance on patents needs to be interpreted in this context.[31] The very process of pharmaceutical innovation has its peculiarities. Long, uncertain and costly R&D pipelines, massive regulatory examination and high attrition rates characterize drug development.[32] These aspects support the argument of high patent protection in this industry.

However, pharmaceuticals are not regular consumer products: they are typically medically essential, asymmetrically informational and are consumed under situations where patients possess very little bargaining power. Patents are thus abnormally direct in terms of morbidity, mortality and government spending. Besides, the tendency in investing in the pharmaceutical industry globally, demonstrates that there is systemic under-investment in the disease that

[29] Alexander C Egilman, Amy Kapczynski, Margaret E McCarthy, Anita T Luxkaranayagam, Christopher J Morten, Matthew Herder, Joshua D Wallach and Joseph S Ross, 'Transparency of Regulatory Data across the European Medicines Agency, Health Canada, and US Food and Drug Administration' (2021) 49(3) Journal of Law, Medicine & Ethics <https://www.cambridge.org/core/journals/journal-of-law-medicine-and-ethics/article/transparency-of-regulatory-data-across-the-european-medicines-agency-health-canada-and-us-food-and-drug-administration/FFD09EC615E261AEFE3E8AE88A268CBA> accessed 23 November 2025.
[30] See generally, David Green, James Pooley, Elizabeth Rowe and Ryan Calo, 'Understanding the Defend Trade Secrets Act (DTSA): The Federalization of Trade Secrecy' (2017) 50 Loyola of Los Angeles Law Review <file:///mnt/data/2999.pdf> accessed 23 November 2025.
[31] See generally, Law Commission of India, *Trade Secrets & Economic Espionage* (Law Com No 22, 2024).
[32] Ibid.

impacts poorer people, questioning the ability of patents to guide innovation towards the health and welfare priorities of the population.

In this context, evergreening has now become a key issue.[33] The term is used to refer to the methods through which subsequent patents are granted to make specific minor or incremental modifications to the existing drugs in order to extend the effective market exclusivity.[34] Some of opportunities of change are genuinely therapeutic, though others might be technically modest, and whose main goal is to delay generic entry.

Standards of patentability and in particular the application of novelty and inventive step to the claims of pharmaceutical products therefore act as filters of significance as to whether socially valuable incremental innovation is being promoted or strategic extension of monopoly. These inquiries are superimposed on the considerations of the public health and human rights.

In India, right to life has been interpreted in Articles 21[35] and 47 of the Constitution of India[36] as connoting duties of health and right and access to basic medical treatment, including medicines. Human rights law also on the international level considers access to necessary medicines a subset of right to highest attainable standard of health.[37] Access to medicines is not determined by patent law alone, or even predominantly, but it is a major point at which such constitutional and human right commitments are to be balanced against trade and innovation policy.

The following theoretical aspects allow structuring the explanations of legislative decisions made in India. It is against this context that the following section reviews the manner in which the TRIPS Agreement formulates global standards regarding the protection of pharmaceutical patents, and how its flexibility allows space to be created concerning approaches, such as that

[33] Pamela H Bucy, 'Private Justice' (1990) 76 Southern California Law Review 1; see, eg, *United States ex rel Bilotta v Novartis Pharmaceuticals Corp* 50 F Supp 3d 497 (SDNY 2014); *Vermont Agency of Natural Resources v United States ex rel Stevens* 529 US 765 (2000); *Novartis AG v Union of India* AIR 2013 SC 1311.
[34] Supriya Malviya, "Data Exclusivity And Right To Health: An Analytical Study" (2024), <https://www.cnlu.ac.in/wp-content/uploads/2025/07/Data-Exclusivity-And-Right-To-Health-An-Analytical-Study-by-Supriya-Malviya.pdf> accessed 23 November 2025; see generally, Prashant T Reddy, 'The Data Exclusivity Debate In India: Time For A Rethink?' (2014) Indian Journal of Law and Technology 10.
[35] The Constitution of India 1950, Art 21.
[36] The Constitution of India 1950, Art 47.
[37] JE Stiglitz, 'Economic Foundations of Intellectual Property Rights' available <https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1362&context=dlj> accessed 27th December 2025.

proposed by India, which aims at balancing the notion of patentability against public health needs.

TRIPS And Evolution Of Global Pharmaceutical Patent Standards

The TRIPS Agreement revolutionized legal environment of patents in pharmaceutical industry across the globe. Before TRIPS, most developing countries (India included) were not patenting pharmaceutical products, or they limited protection to processes only. Global IP tools such as Paris Convention[38] were based on concepts such as *national treatment, priority*, but were also allowed much freedom in substantive scope of patentability, especially in sensitive industries, such as medicines.[39]

The TRIPS Agreement reduced this policy space upon imposition of binding minimum standards. Article 27(1) stipulates that any invention, regardless of the area of technology, is entitled to patent in case new, contains an inventive step, and can be applied to industry. Further, it must not be discriminated in terms of the area of technology, or whether the products are imported or domestically made.[40]

Article 33 sets a minimum period of twenty years of patent protection from the filing date. In case of pharmaceuticals, it meant that WTO members finally had to offer product patenting of the drugs, as opposed to process patenting, and had to do so on generally similar terms under different jurisdictions.[41] Meanwhile, TRIPS Agreement includes a range of flexibilities that have a special significance to pharmaceuticals. Articles 7 and 8 state purposes and principles. They are focused on social and economic well-being, rights and obligations balance, and entitlement of members to take measures to safeguard health of the population.[42]

Substantively, members retain their freedom to establish boundaries of major patentability requirements. For instance, they may omit some subject matter (e.g., diagnostic, therapeutic, and surgical procedures) or devise restrictions and exceptions under Article 30.[43] Article 31

[38] *Paris Convention for the Protection of Industrial Property*, opened for signature (Mar. 20, 1883), 21 UST 1583, 828 UNTS 305.
[39] Ibid.
[40] The Trade-Related Aspects of Intellectual Property Rights Agreement Art 27(1).
[41] The Trade-Related Aspects of Intellectual Property Rights Agreement Art 33.
[42] The Trade-Related Aspects of Intellectual Property Rights Agreement Art 7, 8.
[43] The Trade-Related Aspects of Intellectual Property Rights Agreement Art 30.

gives way to compulsory licenses and government use, which is conditional. Further, TRIPS Agreement does not oblige data exclusivity in regulation or upgrading of patents. However, these are TRIPS-plus issues which are common subjects in bilateral negotiations. These flexibilities were made clear and politically reinforced in Doha Declaration on TRIPS and Public Health.[44] It confirmed that TRIPS Agreement does not and must not bar members to act to safeguard the well-being of the populace and that it could. Moreover, it must be understood and applied in a manner that is conducive to the right of WTO members to safeguard the well-being of the populace. Specifically in that regard, to promote access to medications among the populace.[45] The declaration on the TRIPS Agreement and public health (Doha Declaration)[46] expressly acknowledged that right of members to compulsory licenses, grounds of grant of compulsory licenses, and regimes of exhaustion (and hence parallel importation).[47]

In case of developing countries and least developed countries,[48] it established longer periods of patent protection of pharmaceutical products and the export-related restrictions. The TRIPS Agreement was not implemented at once. The developed countries had to do so by 1996. The developing countries by 2000. While the transitioning of pharmaceutical products patents and least developed countries had specific and additional time.[49] These transitions were used to their fullest. India was the first to introduce a mailbox system and exclusive marketing rights and only by 2005 did it reintroduce product patents on pharmaceuticals and chemicals.[50] Through this, TRIPS Agreement limited and liberated. It forced India to shift to a process-only paradigm to a product-patent pharmaceutical model. It also provided interpretive and structural space to an access-sensitive, public health focused calibration of the patentability norms.

The following section follows the development of the domestic law of India as it addresses these worldwide developments which precondition the development of the approach peculiar to India in terms of patentability of pharmaceutical inventions.

[44] A Beattie and F Williams, 'Doha Trade Talks Collapse' (*Financial Times*, 29 July 2008).
[45] David B Lewis, *Whistleblowing and the Law: A Guide to the Public Interest Disclosure Act 1998* (2nd edn, 2013); see generally *Chesterton Global Ltd v Nurmohamed* [2017] EWCA Civ 979.
[46] Declaration on the TRIPS Agreement and public health, 2001, available at <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 20 January 2026.
[47] The Trade-Related Aspects of Intellectual Property Rights Agreement Art 6.
[48] The Trade-Related Aspects of Intellectual Property Rights Agreement Art 66.1
[49] *Supra* n41.
[50] Ibid.

Historical Evolution Of Pharmaceutical Patent Protection In India

The policy of pharmaceutical invention patentability in India can be best-viewed within historical context of the transition. From its former colonial, import-oriented regime into a TRIPS-compliant but access-sensitive one, the transition expands. Until 1970, the pharmaceutical patents in India were regulated mainly by Patents and Designs Act, 1911,[51] which permitted the provision of product patents to medicines on conditions largely similar to those set by the metropolis. This eased the control of foreign multinational companies, the dearth in domestic manufacturing and was greatly condemned to have led to the elevated drug prices and the inadequate supply of basic drugs. A clear split was achieved with the adoption of the Patents Act,[52] which came as a result of suggestions of Ayyangar Committee.[53]

In case of food, medicines and chemicals, the Patents Act[54] replaced product protection with process protection, having comparatively short periods of protection and a comparatively high compulsory licensing regime. Industrial and regulatory policy along with this framework allowed a thriving competitive domestic generic pharmaceutical industry to develop, learning to bypass processes, enhance technological capacity and lead to substantial drops in drug prices. the Patents Act [55] therefore became synonymous with a developmental, public health, use of patent law. This settlement was shaken by the advent of TRIPS.

As a founding member of the WTO, India had to transition towards product protection of pharmaceuticals and other areas of technology over given periods of transition.[56] The process of reform was conducted in three main phases. The amendment of 1999[57] provided a system of a mailbox to submit the application of a patent on the pharmaceutical products in the process of transition and provided a system of exclusive marketing rights under rare conditions.[58] The amendment of 2002[59] was made to provide a more wide consideration of the regulations with TRIPS, that was, extending the period of the patent registration to twenty years since the date

[51] The Patents and Designs Act 1911 (Act 2 of 1911).
[52] *Supra* n4.
[53] Shri Justice N Rajagopala Ayyangar, *Report on the Revision of the Patents Law*, <https://www.ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-_Justice_N_R_Ayyangar_committee_report.pdf> accessed 25 December 2025.
[54] *Supra* n48.
[55] Ibid.
[56] See generally, Rajesh Sagar, 'Patent Policy in India under British Raj', *Patent cultures* (Cambridge University Press, 2020), <https://www.cambridge.org/core/books/abs/patent-cultures/patent-policy-in-india-under-the-british-raj/958C5634979C27B1230AFE6B69FA68D1> accessed 25 December 2025.
[57] *Supra* n14.
[58] *Ibid.*
[59] *Supra* n15.

of the filing of the application.[60] Consequential changes were most significant with Patents (Amendment) Act 2005[61] that finally reintroduced product patents on pharmaceuticals and chemicals.

Meanwhile, amendments of 2005[62] were well planned so as to ensure policy space was maintained. Section 3 was rewritten and amended, with Section 3(d) being the focal point of containing patents on new forms of known substances that do not prove to be more effective, specifically evergreening.[63] The pre-grant and post-grant opposition procedures were maintained and enhanced as quality-control measures. Mandatory licensing system was preserved and subsequently operationalized in pharmaceutical industry. Later, a Bolar-type exception was added to allow quicker generic access to the market once the patent had expired. It is this historical development that provides the background context on which the present Indian standards concerning patentability of pharmaceutical inventions should be interpreted. The following section looks deeper into those standards of the day having the structure of patentability of drugs in the law and in practice in more detail.

Current Indian Legal Jurisprudence

The modern Indian patentability system of pharmaceutical inventions is designed as a system that combines general standards consistent with the TRIPS and the limitations of the industry in the Patents Act.[64] At the definitional level, Section 2(1)(j)[65] and 2(1)(ja)[66] demand that an invention must be a new product or process which entails an inventive step and industrial application, and definition of that inventive step must be in form of a technical advance or economic benefit not to be found in a person having knowledge of the art.

In pharmaceuticals, but these generic norms have been put into practice in a dense mesh of exceptions in Section 3 and a jurisprudence that has actively attempted to police evergreening and maintain access to medicines.[67] Section 3(d) has taken over as key doctrinal tool to

[60] *Supra* n15.
[61] *Supra* n16.
[62] Ibid.
[63] *Supra* n18.
[64] *Supra* n4.
[65] The Patents Act 1970 (Act 39 of 1970), s2(1)(j).
[66] The Patents Act 1970 (Act 39 of 1970), s2(1)(ja).
[67] *Supra* n53.

determine patentability of drugs.[68] It also does not patent any simple discovery of a new form of a known substance, which does not lead to an increase in efficacy of known efficacy, and considers various derivatives; in salts, esters, polymorphs and combinations, to be same substance, unless they significantly differ in properties with respect to efficacy.

The ruling of Supreme Court in *Novartis AG v. Union of India*,[69] regarding beta-crystalline form of imatinib mesylate, is a source of authority. Court ruled that it should reject a patent application filed by Novartis since efficacy in the context of medicines should be construed as therapeutic efficacy rather than any advantageous physio-chemical property, and that improved bioavailability should be considered only to degree that it can be demonstrated to result in real therapeutic benefit.[70] Novartis thereby narrowed down a two-step filter to new forms of known substances: this must not only meet general novelty and inventive steps requirements, but it must also show superior therapeutic efficacy to evade bar of Section 3(d).

Section 3(d) works in collaboration with other clauses of Section 3 to make pharmaceutical patentability narrower.[71] Section 3(e) authorises examination of fixed-dose mixes and preparations as a simple admixture when no synergistic or surprise technical effect is demonstrated;[72] Section 3(i) is the exception to the methods of treatment, which keeps treatment regimens and dosage regimens out of the patent system;[73] and Section 3(j)[74] and 3(p)[75] have been applied where pharmaceutical claims are mixed with biological material or traditional medicinal knowledge. Indian Patent Office has been allowed by these provisions to reject claims based on known traditional remedies as well as plain combinations which are little beyond an aggregation of known properties.[76]

New novelty and innovative step still have a role in this exclusionary framework, and the case law is characterized by a rather restrictive attitude towards the pharmaceutical sector. In *F. Hoffmann-La Roche Ltd v. Cipla Ltd*,[77] a case of erlotinib, a lung cancer drug, Delhi High Court

[68] The Patents Act 1970 (Act 39 of 1970), s3(d).
[69] *Novartis AG v Union of India* AIR 2013 SC 1311
[70] Ibid; also, see generally, Sana Yadav, Souvagyo Banerjee, "The Novartis Legacy – From Therapeutic Efficacy to Procedural Evasion" (16 Decemebr 2025, *RSRR*), <https://www.rsrr.in/post/the-novartis-legacy-from-therapeutic-efficacy-to-procedural-evasion> accessed 20 January 2026.
[71] *Supra* n57.
[72] The Patents Act 1970 (Act 39 of 1970), s3(e).
[73] The Patents Act 1970 (Act 39 of 1970), s3(i).
[74] The Patents Act 1970 (Act 39 of 1970), s3(j).
[75] The Patents Act 1970 (Act 39 of 1970), s3(p).
[76] Patent highlights, WIPO, <https://www.wipo.int/web-publications/world-intellectual-property-indicators-2024-highlights/en/patents-highlights.html> accessed 24 December 2025.
[77] *F Hoffmann-La Roche Ltd v Cipla* (2008) 37 PTC 71 (Del).

looked at both the validity and infringement. Although factual basis of the patent was upheld, Court stressed that obviousness had to be determined in the perspective of a person of skill bearing in mind state of prior art, reasonable expectations of success and nature of technical progress.[78] In a broader sense, practice of Patent Office and decisions in India are likely to accept routine optimization in medicinal chemistry and formulation (including predictable changes or parameter variations) as self-evident unless the patentee can prove an unexpected technical effect or a solution to a known technical bias. This, together with Section 3(d), increases hurdles in case of so-called "me-too" claims on small changes or alterations to dosage that are not associated with a substantial therapeutic breakthrough.[79]

India, procedurally, has placed much reliance on pre-grant and post-grant opposition by use in Section 25[80] as a quality control tool in pharmaceutical patenting. Pre-grant opposition is open to any person, and this has made it possible to have civil society organizations, patient groups and generic manufacturers challenging applications they view as evergreening or weak. Various high-profile pharmaceutical applications have been rejected or reduced after such objections, commonly with Section 3(d) and lack of inventive step in the limelight.[81]

These cases have transformed the patent examination practice into an adversarial and participative process and have compelled Patent Office to provide the more detailed argumentation of efficacy, obviousness and application of Theorem 3 in cases of pharma.[82] Though compulsory licensing does not establish such thing as patentability, it is a part of larger pharmaceutical exclusivity architecture and it has an impact on the perception of system.

Order in *Nexavar* case, *Bayer Corporation v. Controller*.[83] *Natco Pharma Ltd*., granted compulsory licence of sorafenib tosylate on grounds that reasonable requirements of publix were not fulfilled, drug not reasonably affordable and invention was not due to be worked in India.[84] This ruling marked a milestone in that even legal pharmaceutical patenting can be put under effective public-interest limitations of its effective use. It enhances normative case

[78] Ibid.
[79] *Supra* n60.
[80] The Patents Act 1970 (Act 39 of 1970), s25.
[81] *Supra* n68.
[82] Ibid.
[83] *Bayer Corporation v Union of India* [2014] AIR Bom 178 (Bom HC).
[84] Ibid.

indirectly in favour of strict patentability sorting at the grant stage, in that the legal system is now evidently ready to step in where exclusivity is seriously damaging access.

Patent system also relates with drug regulation and TRIPS flexibilities in manners that further define effective patentability. Safety and efficacy regulatory approvals, issued by Drugs Controller General of India, do not depend on the presence of the patent and Section 107A[85] (Bolar-type exception) allows the use of patented inventions to generate data needed in regulatory submissions.

Such a structure enables generic manufacturers to be ready to enter the market when patents remain valid so as to restrict the ability to extend de facto exclusivity by regulatory initiatives. India has also opposed the adoption of regulatory data exclusivity and term extension of patents into domestic law, even when urged by other nations, which supports the position of the criterion of patentability and domestic protection as key legal factors in determining the extent and duration of protection of pharmaceutical inventions.

Put collectively, these statutory provisions and case law represent a consistent, although challenged, model: India provides TRIPS-compliant product patenting on pharmaceuticals but moderates it with a combination of substantive exclusion (in particular, Section 3(d)) and relatively stringent inventive step requirements, participatory opposition and public-interest mechanisms (in the form of compulsory licensing and Bolar exception). It is to this doctrinal and institutional set up that the Indian approach will have to be placed in comparative context and its failure or success in balancing innovation with getting medicines has to be evaluated critically.

Placing India Amidst TRIPS Flexibilities

The strategy that India takes on patentability of pharmaceutical inventions can be fully comprehended when it is found in the flexibilities that TRIPS has left to its member states. On one hand, TRIPS required recreation of product patents in pharmaceuticals, but on other hand, it did not put one model of high protection on ice. Rather, it formulated minimum standards and allowed latitude or states in the process of tuning patentability and associated devices to

[85] The Patents Act 1970 (Act 39 of 1970), s107A.

public health and development issues. India has made a strategic placement of itself at the end of this spectrum that is access-sensitive and maximizes flexibility. The doctrines of TRIPS require its members to patent all areas of technology, disclosures that are new, including an inventive step, and can be utilized in industry, however, it does not dictate how well-defined and applied are the requirements. India has taken advantage of this area to build comparatively challenging gates within pharmaceutical industry. This can be illustrated by Section 3(d), which, in combination with Sections 2(1)(j)[86] and 2(1)(ja),[87] entails a greater standard of incremental pharmaceutical inventions: in that way, Indian law makes use of a standard absent in TRIPS, which does not prohibit the calibration of Section 3(d).

Direct application of Article 30-type flexibility to secure timely generic entry is the use of patented invention under Section 107A in order to get regulatory approvals.[88] The strong interpretation of Article 31: India has read Schedule 84 and Schedule 92 in the case of *Nexavar* (sorafenib): the interpretations of reasonable requirements of public and reasonably affordable price are read as substantive limitations on pharmaceutical exclusivity and the working requirement has been taken seriously by India, indicating that it requires more than just importation at high prices in case of life-saving medicines.[89] India has also continued to oppose TRIPS-plus requirements that are usually incorporated in bilateral and regional trade agreements. India has avoided the right to enact data exclusivity, and preserved centrality of core patentability standards and internal protections over add-on exclusivities by refusing to enact a law to grant data exclusivity, and by refusing to permit twenty-year baseline plus routine extensions of central patentability standards.

This position is consistent with the spirit of Doha Declaration[90] stating that the members have a right to interpret and apply TRIPS Agreement in such a fashion that is accommodating to the public health and access to medicines. India has used procurement flexibilities institutionally to strengthen the process of patent-grant into a democracy and a discipline. TRIPS Agreement does not entail pre-grant opposition though India permits any person to oppose an application prior to grant and offers a second opportunity of post-grant opposition. These commonly employed mechanisms in the pharmaceutical industry by patient groups and generic producers,

[86] *Supra* n54.
[87] *Supra* n55.
[88] *Supra* n74.
[89] The Trade-Related Aspects of Intellectual Property Rights Agreement Art 31; also see, The Trade-Related Aspects of Intellectual Property Rights Agreement Art 31bis.
[90] *Supra* n46.

have grown to be an enforceable tool of applying TRIPS-compatible but stricter domestic requirements, especially to Section 3(d) and inventive step.

In a sense, they allow the social actors in the process of the interpretation of TRIPS flexibilities on the ground, as opposed to entrusting the task to the patent office or the courts. Installed between the flexibilities of the TRIPS Agreement, the pharmaceutical patent regime of India can be best regarded as a highly focused, defensible experiment: the regime admits major commitments of product patents and twenty-year terms, but constrains listing and patentable pharmaceutical inventions, and dilutes exclusivity by exceptions, compulsory licensing, and participatory opposition procedures. This has placed India at a strategic point to become a major provider of cheap medicines to the developing world but at the same time participate in the global networks of R&D. At the same time, it puts India at the receiving end of repetitive diplomatic and commercial pressure by the trading partners and the originator industries that want more and deeper protection.

The next section leaves this international-law perspective and goes to a more broad-based comparative evaluation; it seeks how the flexibility-maximising model of India compares to those of other jurisdictions on pharmaceutical patentability and what it suggests should be reformed in future.

Comparative Perspectives

A comparative study of the pharmaceutical patentability regimes also indicates that the differences among jurisdictions are more to do with the manner in which countries apply the novelty, inventive step, and subject-matter exclusions, and how coherent the patent law is to the pharmaceutical regulation and to the public health policy. India (with its model based on statutory exclusions and increased attention to incremental innovation) takes a unique place when compared to the large countries of the developed and developing worlds.

A) In **United States**, pharmaceutical patentability is defined by the loose interpretation of the subject matter that can be patented and a liberal attitude towards follow-on inventions. New forms, new formulations, new dose regimens and new treatment modalities are regularly patentable, so long as they meet novelty and non-obviousness

standards under 35 USC S. 102 and 103.[91] In the USA, there is no statutory equivalent to Section 3(d) of India; evergreening is dealt with by doctrines of litigative intensity, including those of obviousness, written description, and enablement. The Hatch-Waxman system is structurally supportive of pitching the lifecycle patenting extensively by linking patent performance with regulatory exclusivities and term restoration. This has seen pharmaceutical exclusivity in the US frequently becoming cumulative and layer cake-like, with access issues mediated not by *ex ante* patentability filters, but by the competition law and post-grant challenges.

B) The **European Union** via the European Patent Office is more organized yet innovation driven. The idea of patentability depends on the novelty and inventive step measured through the problem-solution means that brings analytical discipline but lacks industry-specific exclusion in cases of a pharmaceutical. Claims of second medical use, dosage regimen, and some formulations are eligible to patent protection of incremental therapeutic inventions.[92] Supplementary Protection Certificates also extend effective market exclusivity further to counter regulatory delay. Whereas in Europe the jurisprudence has added rigidity to certain aspects, the regime is generally open to incremental pharmaceutical invention and employs the inventive step analysis over statutory efficacy criteria to put a limit on the extent of patents.

C) **China** is an evolving and hybrid model. Once being accused of formalism in patent examination, China has over the last few years consolidated pharmaceutical patent protection as well as enforcement as one of its development strategies, which is innovation oriented. There are product patents such as formulation and use patents and there are new reforms such as extension of product patents term and patent linkage

[91] Defend Trade Secrets Act of 2016; US House of Representatives, Committee on the Judiciary, *Report on the Defend Trade Secrets Act of 2016* HR Rep No 114-529 (2016); see generally Sharon K Sandeen and Elizabeth A Rowe, *Trade Secret Law in a Nutshell* (2nd edn, West Academic 2018) chs 7-9, and David S Almeling, *'Seven Reasons Why Trade Secrets are Increasingly Important'* (2012) 27 Berkeley Technology Law Journal 1091; False Claims Act, 31 USC S3730(b)-(d); Pamela H Bucy, 'Private Justice' (1990) 76 Southern California Law Review 1; see, eg, *United States ex rel Bilotta v Novartis Pharmaceuticals Corp* 50 F Supp 3d 497 (SDNY 2014); *Vermont Agency of Natural Resources v United States ex rel Stevens* 529 US 765 (2000).

[92] Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law, arts 7-10, 19-21; Council of Europe, Recommendation CM/Rec (2014) 7 on the Protection of Whistleblowers (30 April 2014); European Union Agency for Fundamental Rights, *Protection of Whistleblowers: Existing Standards and Practices in EU Countries* (FRA 2016); see generally, Giulia Bianchi, 'The New EU Whistleblowing Directive and Its Three-Tier Reporting Channels' (2021) 42 Statute Law Review 80; David Lewis and Wim Vandekerckhove, 'Whistleblowing and the EU Directive: A Practical and Legal Analysis' (2020) 47 European Law Review 675; also see, European Commission; see, *Guja v Moldova* (No 1) App no 14277/04 (ECtHR, 12 February 2008), *Heinisch v Germany* App no 28274/08 (ECtHR, 21 July 2011), *Matúz v Hungary* App no 73571/10 (ECtHR, 21 October 2014), and *Bucur and Toma v Romania App* no 40238/02 (ECtHR, 8 January 2013).

system.[93] Meanwhile, the Chinese guidelines lay greater stress on substantive analysis of inventive step, and more and more on the considerations of public health in the compulsory licensing law, albeit, rarely invoked. In that way, China is closer to US- and EU-type protection of pharmaceuticals, but theoretically, policy space can be used to launch access-oriented intervention.

D) In the developing and middle-income countries, the approaches are very different, as they are based on the different capacities of industries and health priorities. The patents on pharmaceutical products are granted in **Brazil**, though historically there has been a translation of state health regulation in Brazil by such mechanisms as the involvement of health-regulators in patent examination and a system of compulsory licensing.[94] There has been increasing Brazilian scepticism about evergreening, but no statutory counterpart to Section 3(d) therefore, control is by administrative and judicial interpretation. **Thailand** has been more dependent on mandatory licensing and government use of essential medicines with the approach to patentability standards being formally TRIPS-compliant with the exclusivity offset with formidable post grant interventions.[95] Having been subject to long-standing reputation as having a poor substantive examination and many low-quality pharmaceutical patents, **South Africa** is currently undergoing policy reform to close the patentability standards, enhance examination, and more effectively exploit TRIPS flexibilities, but legislative implementation is not completely uniform.[96]

E) The **UAE** is another opposite model of the developing economies. Being a trade- and investment-oriented jurisdiction, UAE has made a comparatively protection-friendly move towards patent regime, which is well voiced by international standards, and welcoming to pharmaceutical patent, even including incremental innovations. The issues of access are met less by restrictive thresholds of patentability and more by the

[93] SAMR Order No 20, 2020; SAMR Order No 26, 2021; National People's Congress Standing Committee, *Drug Administration Law of the People's Republic of China* (adopted 26 August 2019, effective 1 December 2019); see generally Angela Huyue Zhang, Chinese Antitrust Exceptionalism: How the Rise of China Challenges Global Regulation (OUP 2021).

[94] Decreto No 8.420, de 18 de Março de 2015 (regulating Law 12.846/2013); Jorge Munhós de Souza and Liziane Paixão Silva Oliveira, 'The Brazilian Clean Company Act: An Analysis of Its Enforcement and the Role of Compliance Programs' (2017) 12 Brazilian Journal of Public Policy 213; also, see, OECD, Phase 2 Report on Implementing the OECD Anti-Bribery Convention in Brazil (OECD 2017).

[95] nTRIPS.

[96] World Intellectual Property Organization, 'Case study: IP Management and the Commercialization of Publicly Funded Research Outcomes in South Africa' <file:///mnt/data/WHOPIR_GPO_12-16August2024.pdf> accessed 23 December 2025; Lorraine Danks et al, 'The Economic Impact of Reliance on an African Medicines Regulatory Authority' (2 March 2025) <https://www.sahpra.org.za/wp-content/uploads/2025/03/The-Economic-Impact-of-Reliance-on-an-African-Medicines-Regulatory-Feb-2025.pdf> accessed 23 December 2025.

pricing regulation and procurement policy, which reflects the need to establish a distinction between the patent law and the goals of preserving the human health. In these jurisdictions, the most fundamental point of analysis in the system is the source of access protection that the system found.

Protection is concentrated by the US, EU, and China and jurisdictions like the UAE at the patentability phase and right excesses are corrected mostly by litigation, regulatory exclusivities, competition law or prices. In Brazil, Thailand and South Africa, compulsory licensing and government use is more beneficial in rebalancing access following receipt of patent. India is quaint in locating a large portion of this balancing act ex ante, on the plane of patentability itself, by statutory exclusions, by the heightened inventive-step inquiry in the pharmaceutical industry, and by systems of participation opposition.

This comparison image highlights the fact that TRIPS compliance is flexible to adopt various pharmaceutical patentability models. The formal structure of India is not an outlier, but rather the structure of the country is unique in its legislative mistrust of gradual pharmaceutical monopolies and its readiness to directly convert the social health interests into the doctrine of patentability. This ex-ante, access-based design is, however, a key question to future reforms, one directing them right to the ultimate policy critique and strategy, one that directly determines the ultimate approach to the eventual policy critique and way forward.

Critiques, Debates, And Carving a Way Out

The pharmaceutical patent regime in India has received decades-long scholarly, judicial and policy debate not due to its nominal non-conformity with TRIPS Agreement, but due to its normative decisions regarding the design of innovation incentives in a sector that is extremely closely linked to public health. The criticisms that have surfaced can only be viewed as challenges on where patent system must draw its boundaries, the manner in which innovation should be compensated and what interests are best served by the patent law. One of the core criticisms is the focus of Section 3(d) and the fact that it is being accused of deterring gradual pharmaceutical invention.

According to critics, current development of drugs has been hardly marked by groundbreaking inventions;[97] thus, it tends to follow the pattern of gradual improvements in formulation, routes of delivery, stability, safety, and adherence to treatment.[98] Section 3(d) is alleged to underestimate such refinements, and may discourage investment in adaptive or follow-on research, especially by original firms, because it requires patentability to be contingent on improved therapeutic efficacy, and discounts improvements that do not obviously lead to clinical improvements.[99] Such criticism is supported by the issue of apparent evidence heavy loads: to prove increased therapeutic effectiveness at the patent application phase would involve costly, time-consuming, or inaccessible clinical evidence.

Counter-arguments, however, question the assumption according to which all incremental innovation deserves protection of the patent. In that sense, Section 3(d) is an indication of a reset button in the reward threshold as it seeks to draw a distinction between innovations that significantly enhance therapeutic results and those that mainly prolong market exclusivity.[100] The existence of dense patent thickets surrounding blockbuster drugs in jurisdictions that lack such filters is empirically testified to support the claim that weak follow-on patents have the capability to delay generic products entry without any social benefit. According to this perspective, it is not innovation that is suppressed by the higher bar in India, but it is channelled towards a clinically significant development instead of strategic changes. The other point of debate axis is the legal uncertainty and administrative discretion. The language in Section 3(d) which is open-textured especially the definition of efficacy and the standard needed to prove enhancement have created inconsistent results at the Patent Office and in the appellate courts.

Although Novartis specified that therapeutic efficacy is the appropriate standard of medicines, it did not answer questions regarding the amount and nature of evidence that should be produced and how efficacy should be determined when using non-traditional medicines like biologics, vaccines, and gene-based medicines. According to critics, this uncertainty increases the cost of transactions, discourages investment and may lead to unequal enforcement of the

[97] Satwant Reddy, 'Report on Steps to be taken by GOI in the context of Data Protection Provisions of Art.39.3 of TRIPS Agreement' (2007) <https://chemicals.nic.in.org/sites/default/98files/DDBooklet.pdf> accessed 23 November 2025.
[98] Ibid.
[99] Prashant T Reddy, 'The Data Exclusivity Debate In India: Time For A Rethink?' (2014) Indian Journal of Law and Technology 10.
[100] Ramesh Jois et al., 'Similar Biologics in India: A story of access or potential for compromise?' (2020) IJMR 43 <https://pmc.ncbi.nlm.nih.gov/articles/PMC8157901/> accessed 23rd November 2025.

standards of patentability.[101] On systemic level, dependence of India on pre-grant opposition has received mixed responses as well. Its proponents see it as a democratising process that enhances the quality of patents and incorporates the issue of public health into examination.

The tension here is not so much procedural as it is more about whether patent examination is more technocratic process with no social contestation or this is a place where other interests of the larger population can be fairly raised.[102] These criticisms are also overlapping with more general theorisations about innovation ecosystems and industrial policy.[103] The success of India as a worldwide provider of generics has been established on a legal framework that restricts the secondary monopolies and supports the early generic entry.[104] Nevertheless, plans to shift up the pharmaceutical value chain, specifically into biologic and biosimilars and new drug discovery, raise concerns on whether the current patentability regime is robust enough to encourage high-risk, capital-intensive R&D. The issue is not that India does not have patents, but that its existing structure may be more appropriate to small-molecule generics than to new modalities based on a long development cycle and complicated regulatory routes. Drilling a path thus needs honing not backtracking.

The possible way forward, which does not undermine the essence of Section 3(d), includes creation of more specific, technology-sensitive provisions regarding the use of Section 3(d), especially in context of biologics and advanced therapeutics. Strict standards could be maintained by increasing the rigor of examiner training and making more rational and open decisions. The other opportunity is to increase incentives to complementary innovation outside the patent system, including government subsidies, prize systems, advance market commitments, and joint R&D platforms so as to encourage socially beneficial drug innovation that is not appropriately compensated through patent protection.

Normatively, sustained opposition of India to TRIPS-plus oblations is defensible at international level but must be accompanied by active participation in formulating worldwide discussions on the issues of access, innovation and transfers of technologies. At national level, reevaluating the balance between innovation and patentability does not require the discarding of Section 3(d); the more context-sensitive and evidence-based use of the provision is required, one that draws the line between the true advancement of therapeutic research and the cynical

[101] Ibid.
[102] Ibid.
[103] *Supra* n85.
[104] Ibid.

rent-seeking games. Finally, Indian example demonstrates that the pharmaceutical patent law is not just a technical area but a constitutional and developmental choice. The dilemma in future is to maintain a system that is loyal to cause of public health but one that adapts to needs of next generation of pharmaceutical innovation- and not to compromise the regulatory independence that has characterized how India has gone about patentability.

Concluding Contemplations

Indian regime of patentability of pharmaceutical inventions constitutes one of the most normatively proclaimed and deliberate experiments of post-TRIPS patent regimes. Instead of making pharmaceutical patenting a technocratic and apparently neutral activity, Indian legislation presents it as part of a wider constitutional and developmental pledge to public health, access to drugs and technological autonomy. The resulting governance is neither anti-patent nor exceptionalist, but rather a response to the structural facts of drug markets, in which exclusivity makes a direct impact on life-and-death outcomes.

This paper has revealed that the uniqueness of India is not in denying the international patent standards, but in its implementation and interpretation. India has attempted to bring about substantive scrutiny, more so by Section 3(d) strict treatment of inventive step, participatory opposition, and principled use of TRIPS flexibilities, in order to secure the fact that pharmaceutical patents are conferred on true therapeutic innovation, rather than creative extensions of monopoly. This orientation has been strengthened through judicial interventions, most prominently in Novartis, which in turn puts the very notion of patentability as a valid arena of adjudicative intervention to balance between the incentives of innovation and the interest of the people.

Simultaneously, tension is not absent in the Indian model. The demand of doctrinal refinement and institutional fortification can be justified by legal uncertainty, administrative inconsistency and worries about the incentivisation of next-generation pharmaceutical research. The experience of other countries shows that pharmaceutical patentability may not have a single international prototype; instead, the types of different jurisdictions distribute innovation protection and access protection under patent law, regulation and competition policy. The decision of India to place much of this exercise of balancing ex ante, at the threshold of

patentability, is a deliberate and justifiable one--but it requires transparency, consistency and constant readjustment.

In the future, the sustainability of the course taken by India will not be based on the rejection of its own principles and rather on extending its sophistication. With the transition process towards pharmaceutical innovation in biologics, personalised medicine, and more complex treatment methods, standards of patentability must alter their traditional ways of doing so without being disloyal to the societal health needs but take seriously the new technological realities. What is needed is effective guidelines, increased examination power and non-patent incentives at innovation, as opposed to weakening hard-earned protection.

To sum up, the pharmaceutical patent system in India demonstrates that patent legislation can be used as an instrument of ethical regulation, but not as a facilitator of the market. The case of its experience refutes the belief that more powerful patents always lead to greater innovation results and proves that accessibility, equity, and innovation can go hand in hand. It is not opposition to innovation or access, but to devise a system of patents which acknowledges the interaction between the two in ways which are enduring, and which is answerable to the social purpose to which it is ultimately dedicated.