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DOCTRINAL LEGAL MONOGRAPH • INTELLECTUAL PROPERTY & PUBLIC HEALTH LAW

# Patent Protection versus Access to Medicines: A Critical Study of Indian Patent Law

*Evaluating Statutory Safeguards, Judicial Interpretation, and TRIPSFlexibilities Underthe Patents Act, 1970*

AUTHORED BY - SHWETA KUMARI

| AUTHOR / INVESTIGATOR | METHODOLOGY | PRIMARY JURISDICTION | CLASSIFICATION |
|---|---|---|---|
| [Author Name], [Institutional Affiliation] | Doctrinal & Critical Legal Analysis | Republic of India (Patents Act, 1970) | IP Jurisprudence / Health Policy |

## EXECUTIVE MONOGRAPH OVERVIEW

This research paper looks at the clash between drug patent rights and fair access to essential medicines in India. India is a supplier of cheap generic drugs but must also follow the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights or TRIPS. The country has built a legal system that rewards real biomedical innovation while limiting extra patent monopolies and high prices. The book has ten chapters. It studies how the Patents Act of 1970 changed over time explains the anti-evergreening rule in Section 3(d) describes how compulsory licenses work under Sections 84 92 and 92A reviews the opposition rules before and after a patent is granted in Section 25 and covers the exemptions in Section 107A. It also examines court cases, especially Novartis AG v. Union of India and Bayer Corporation v. Union of India and offers a plan, for better pharmaceutical governance.


| Part / Sections | Thematic Scope & Doctrinal Focus | Pages |
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# Abstract and Analytical Framework

**ABSTRACT**

The connection between patent protection and getting medicines is one of the problems in today's intellectual property law. Drug patents are supposed to push companies to create medicines by giving the people who make them the only right to sell them for a certain time. This kind of control can also stop other companies from joining the market make medicine cost a lot and make it hard for people to get needed treatments, especially in poor and medium income countries. India is special in this discussion because it can make medicines in amounts it helps provide cheap copies of medicines and it has laws that stop companies from having too much power. This article looks closely at the Indian Patents Act, 1970 focusing on Section 3(d) the rules for making medicines without permission in Sections 84 and 92 and the chances to argue against a patent before and after it is given. It also talks about the exceptions for experiments and rules in Section 107A. It studies the Supreme Court's decision in Novartis AG v. Union of India from 2013 and the Bombay High Court's decision in Bayer Corporation v. Union of India from 2014. Looks at what these decisions mean for making new medicines and keeping people healthy. The article also looks at Indias duties under the TRIPS agreement the Doha Declaration on TRIPS and Public Health and the changes in the Patents Rules, 2003. It says that Indian patent law has a way to balance new medicines and public health but the success of this way depends on checking patents carefully making it easy to argue against them sharing information about medicines and using the option to make medicines without permission in the right way. The article ends by suggesting changes, to the law and the system to help people get medicines better without stopping companies from making medicines.

**INDEX KEYWORDS**

**Keywords:** Pharmaceutical patents; access to medicines; Indian patent law; Section 3(d); compulsory licensing; TRIPS Agreement; generic medicines; public health; pre-grant and post-grant opposition; Section 107A; regulatory exception; therapeutic efficacy.

**Section 3(d)**
Substantive Efficacy Threshold

**Sections 84 & 92**
Compulsory Licensing Regime

**Sections 25 & 107A**
Opposition & Bolar Safeguards

# 1 Introduction

Access to medicines is a key part of any strong public health system.. Getting medicines isn't just about medical science or how well they are made. It also depends on the laws that control how new drugs are developed and protected. Patent law plays a role here because it decides when an inventor can stop others from using or selling a new medicine.

The usual reason for giving patents to pharmaceutical companies is that developing a drug takes a lot of money a lot of time and a lot of expert knowledge. Patents are meant to help companies get their money back and make a profit from their work. This in theory encourages research and innovation. When a drug is patented and there is no similar medicine available the patent holder can be the only one selling it. That means prices and fewer choices which can make treatment too expensive for people without good insurance or government health support.

This problem is especially serious in India. The country has built a generic drug industry. It. Sells low-cost medicines both at home and around the world. India also has to follow international rules on intellectual property. These rules require it to protect pharmaceutical inventions under patent law. So, the question isn't whether India should have patents all. The real challenge is how to design patent laws so they still promote innovation but protect public health. That means deciding how patents should be granted how they should be reviewed, when they should be used and when they should be limited. All with the interest, in mind.




Figure 1.1: The Statutory Equilibrium Between Exclusive Patent Rights and Public Health Imperatives under the Patents Act, 1970

The **Patents Act, 1970**, as subsequently amended, reflects an attempt to reconcile these competing objectives. Section 3(d) restricts the patentability of certain new forms of known substances unless the statutory efficacy requirement is satisfied. Section 84 permits compulsory licensing where specified public-interest conditions are established. Opposition procedures enable interested parties to challenge applications and granted patents, while Section 107A provides limited exceptions to infringement liability, including certain acts undertaken for regulatory approval.

The Supreme Court's decision in **Novartis AG v. Union of India (2013)** and the compulsory licence proceedings involving Bayer's anticancer medicine Nexavar in **Bayer Corporation v. Union of India (2014)** demonstrate how these provisions operate in practice. This article argues that India's principal achievement lies in recognising that pharmaceutical patent protection is conditional rather than absolute. However, statutory safeguards cannot independently guarantee affordable treatment. Their effectiveness also depends on administrative capacity, competition, public procurement, healthcare financing, and the availability ofalternative suppliers.

## 1.1 Research Objectives

This study is structured around five distinct doctrinal and analytical objectives:

1. **Statutory Framework Evaluation:** To examine the legal framework governing pharmaceutical patents in India under the Patents Act, 1970, and associated procedural rules.
2. **Exclusivity-Affordability Analysis:** To critically analyse the relationship between patent exclusivity, market competition, and access to affordable medicines.
3. **Jurisprudential Appraisal:** To evaluate the judicial interpretation of Section 3(d) efficacy requirements and compulsory licensing conditions by Indian appellate courts.
4. **International Treaty Harmonisation:** To assess India's implementation of international intellectual property obligations under TRIPS and the Doha Declaration in light of public health concerns.
5. **Policy and Institutional Reform:** To propose targeted reforms that strengthen access to medicines while preserving credible incentives for genuine pharmaceutical innovation.

## 1.2 Research Questions

**CENTRAL DOCTRINAL INQUIRIES**

1. To what extent does Indian patent law balance pharmaceutical innovation against the public interest in affordable medicines?
2. Do Section 3(d) and compulsory licensing adequately prevent unjustified pharmaceutical monopolies?
3. What doctrinal and policy lessons emerge from the judicial decisions in *Novartis* and *Bayer*?
4. How should India strengthen the administrative and institutional implementation of its existing statutory safeguards?

## 2 Research Methodology and Scope

This paper uses an critical legal research approach. It looks at legal documents such as the Patents Act, 1970 important patent rules under the Patents Rules, 2003 court decisions from the Supreme Court of India and the Bombay High Court, the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health.

The study is supported by resources and information from organizations related to pharmaceutical innovation, generic competition and access to medicines. The research is mainly qualitative and interpretive. It looks at the laws and court decisions of trying to find out if there is a cause and effect relationship between patent protection and medicine costs through new economic research.

The focus is mainly on patents and what they mean for access to medicines in India. It does not claim to check how affordable every medicine that is patented is or to say that patents are the thing that affects access to health care. Other things, like how medicinesre delivered how much money the government spends, insurance coverage, how medicines are bought and how much can be made also affect whether treatment is available.

| Analytical Tier | Primary Legal & Institutional Instruments | Interpretive Focus |
|---|---|---|
| **Domestic Legislation** | The Patents Act, 1970 (Ss. 3(d), 25, 48, 84, 90, 92, 92A, 107A); Patents Rules, 2003 (as amended through 2024). | Substantive patentability, opposition procedures, working disclosure, and licensing remedies. |
| **Constitutional Norms** | Constitution of India, Article 21 (Protection of Life and Personal Liberty) and Article 47 (Public Health Duty). | Normative framework guiding statutory construction and public health obligations. |
| **Judicial Authorities** | *Novartis AGv. Union ofIndia*, (2013) 6 SCC 1; *Bayer Corp. v. Union ofIndia*, W.P. No. 1323 of 2013 (Bom. HC). | Therapeutic efficacy standard, public demand, reasonable affordability, and working requirements. |
| **International Treaties** | WTO TRIPS Agreement (Arts. 7, 8, 27, 28, 31, 31bis, 33); Doha Declaration (WT/MIN(01)/DEC/2, 2001). | Treaty compliance, sovereign flexibilities, and domestic legislative discretion. |

**METHODOLOGICAL BOUNDARY NOTE**

While patents directly govern legal market exclusivity, empirical access to medicines depends concurrently on non-patent variables—including procurement efficiency, supply-chain logistics, regulatory approval timelines, and public healthcare financing.

# 3 Historical Development of Pharmaceutical Patent Protection in India

## 3.1 The Patents Act, 1970

The Patents Act, 1970 came about when people were worried about how cheap medicines were and whether they could be made in the country. Before the Patents Act, 1970 the old patent rules gave strong protection for medicine products. That made imported medicines stay costly and the country did not grow its factories.

The Patents Act, 1970 did not allow patents on medicine products. It did allow patents on the ways medicines were made long as the rules at that time were followed. This helped the country make ways of producing medicine and to make generic drugs. Indian manufacturers could make the medicines that people needed by using methods that did not break the law.

This model was important because it helped the country grow its medicine skills learn how to make chemicals and keep prices low.. We should not think that the old process-patent rules alone made medicine more available. Things, like how factories there were the government policies, buying medicines for the public setting price limits and the overall economy also played a big part in making the Indian medicine industry strong.

**PRE-1970 COLONIAL FRAMEWORK**

Permitted strong product-patent protection that favoured foreign patentees importing finished medicines at high prices without establishing local manufacturing facilities in India.

**1970 STATUTORY REORIENTATION**

Excluded product patents for pharmaceuticals while allowing process patents for manufacturing methods, encouraging domestic reverse-engineering and chemical process innovation.

**GENERIC INDUSTRIAL EXPANSION**

Enabled Indian pharmaceutical enterprises to develop alternative synthesis pathways, lowering domestic medicine prices and building large-scale export capacity for developing nations.

**COMPLEMENTARY POLICY FACTORS**

Recognises that patent design operated alongside industrial licensing policy, public-sector chemical laboratories, procurement mechanisms, and domestic manufacturing investments.

## 3.2 The TRIPS Transition

India became a member of the World Trade Organization in 1995 and was required to bring its intellectual property framework into conformity with the **TRIPS Agreement**. This transition led to sequential legislative amendments to Indian patent law in 1999, 2002, and 2005, culminating in the reintroduction of pharmaceutical product-patent protection consistent with the applicable international obligations.

The 2005 amendments marked a significant structural transition because qualifying pharmaceutical products could thereafter receive full product-patent protection. However, the introduction of such protection did not eliminate India's sovereign capacity to regulate patentability thresholds or deploy statutory public-health safeguards.

The amended legislation retained and refined **Section 3(d)**, established a comprehensive framework for compulsory licensing under **Section 84** and related provisions, and preserved both pre-grant and post-grant opposition mechanisms. These provisions demonstrate that compliance with international patent standards does not necessarily require the indiscriminate grant of pharmaceutical monopolies. The contemporary debate consequently concerns the interpretation and effective implementation of these safeguards, rather than a simple binary choice between patent protection and no patent protection.

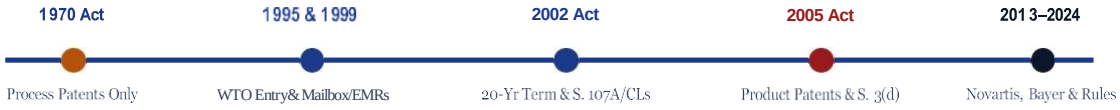



**Figure 3.1: Legislative Trajectory from the Patents Act, 1970 through the TRIPS Transition and Modern Procedural Amendments**

**CORE TRANSITION TAKEAWAY**

The 2005 amendment shifted policy focus from categorical exclusion of pharmaceutical product patents to calibrated statutory scrutiny of patent validity and post-grant exercise.

# 4 The Legal Framework Governing Pharmaceutical Patents

## 4.1 Patentability and the Limits of Exclusivity

Section 48 of the Patents Act, 1970 gives patent holders rights but only if the invention meets all the conditions set out in the Act and other relevant laws. A patent usually allows the owner to stop others from making, using, selling offering to sell or importing the product or process in India for twenty years. This is the patent term.

These rights are not absolute. Before any rights under Section 48 can be granted the invention must meet legal requirements. It must be new involve a step and be capable of industrial application as defined in Section 2(1)(j) of the Act. It also must not fall into any of the categories that're not eligible for a patent under Sections 3 and 4. So getting a patent is not automatic. It only happens when the invention clearly satisfies all these criteria.

This rule is especially important in the field. Just because a medicine is valuable or useful in treating a disease does not mean every small change—like a dosage a different chemical form or a new crystal structure—should get its own patent. A strong patent system must tell the difference, between innovation and attempts to extend market control without real invention. At the time examiners must not reject a genuine invention just because it builds on an existing drug or treatment. The challenge is to apply the rules consistently using solid scientific proof and clear reasoning.

| Statutory Provision | Core Legal Requirement | Pharmaceutical Examination Implication |
|---|---|---|
| **Section 2(1)(j)** | Defines "invention" as a new product or process involving an inventive step and capable of industrial application. | Baseline gateway requiring proof of absolute novelty and non-obvious technical advancement. |
| **Section 2(1)(ja)** | Defines "inventive step" as a feature involving technical advance or economic significance not obvious to a person skilled in the art. | Prevents routine formulation adjustments known to pharmaceutical chemists from acquiring protection. |
| **Section 3(d) & 3(e)** | Excludes new forms ofknown substances lacking enhanced efficacy (3(d)) and mere admixtures resulting only in aggregation of properties (3(e)). | Operates as a specialized filter against secondary patents on salts, polymorphs, and simple combinations. |
| **Section 48** | Confers exclusive rights to prevent unauthorised commercial exploitation of product or process patents. | Expressly made "subject to the other provisions contained in this Act," embedding public health limits. |

**SUBSTANTIVE PRINCIPLE**

Exclusivity under Section 48 is legally legitimate only to the extent that the underlying claim clears both the positive definition of invention under Section 2(1)(j) and the negative exclusions of Section 3.

## 4.2 Section 3(d): Preventing Unjustified Extensions of Pharmaceutical Exclusivity

**Section 3(d)** provides that the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, is not an invention within the meaning of the Act. Its statutory Explanation identifies several common forms of pharmaceutical modification—including salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substances—mandating that they shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

The provision is specifically intended to prevent patent protection from being extended to routine chemical modifications of known pharmacological substances unless the heightened efficacy threshold is met. This policy concern is commonly associated with "evergreening," a term used to describe commercial filing strategies that seek additional or extended patent exclusivity through successive secondary patent claims relating to an existing therapeutic product.

However, Section 3(d) should not be misinterpreted as a blanket prohibition on all incremental pharmaceutical innovation. Its application requires careful, case-by-case consideration of the claimed invention, identification of the relevant known substance, application of the statutory test, and scrutiny of empirical evidence of efficacy. Incremental innovation may genuinely improve stability, safety, delivery, dosage, or therapeutic outcomes; whether a particular improvement satisfies Section 3(d) depends on the applicable law and clinical evidence, rather than on an a priori assumption that incremental inventions are undeserving of protection. Section 3(d) is therefore best understood as a substantive patentability safeguard, not as a general price-control provision: it prevents unjustified secondary patents from being granted, but does not directly regulate the prices of validly patented medicines.

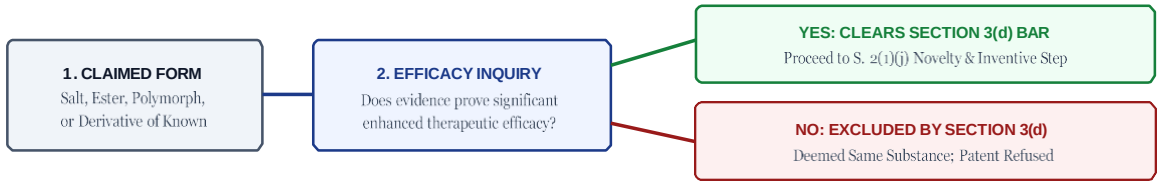



**Figure 4.1: Evidentiary Operation of the Section 3(d) Efficacy Threshold in Secondary Pharmaceutical Claims**

## 4.3 Compulsory Licensing under Section 84

Section 84 of the Patents Act, 1970 allows any person who is interested to file an application with the Controller of Patents for a licence after three years have passed from the date the patent was granted. The application can be based on any one or more of three statutory grounds:

1. **Unsatisfied Public Requirements (Section 84(1)(a))**: The reasonable needs of the public for the patented invention have not been met.
2. **Lack of Reasonable Affordability (Section 84(1)(b)):** The patented invention is not available to the public at a price that's reasonably affordable.
3. **Non-Working in India (Section 84(1)(c)):** The patented invention is not worked in the territory of India.

In adjudicating an application the Controller must look at the conditions and the required factors. Section 84(6) says the Controller should consider the type of invention how long it has been since the patent was sealed, what the patentee or any licence holder has already done to use the invention whether the applicant can use the invention for the benefit of the public and whether the applicant can take on the risk of putting capital into working the invention. The Controller must also consider the applicants efforts to get a licence from the patentee on fair terms within a fair time unless there is a statutory exception such as a national emergency.

It is important to know that a compulsory licence does not cancel the patent. It simply allows the patented invention to be used commercially by people on terms that the law sets without the patentees permission. Section 90 tells the Controller to try to keep the royalty and other payments for the patentee fair taking into account the type of invention how much the patentee spent to create or develop it and other relevant factors. The Controller must also ensure that the patented product can be sold to the public at a price that's reasonably affordable. A compulsory licence is not automatically granted because of prices. The person who wants the licence must prove the grounds with real evidence, about supply, affordability, public need and manufacturing capacity.

| Statutory Sub-Clause | Core Legal Focus | Evidentiary & Procedural Requirement |
|---|---|---|
| **Section 84(1)(a)–(c)** | Substantive grounds: public demand, affordable price, local working. | Applicant must establish a *prima facie* case supported by patient population, pricing, and Form 27 working data. |
| **Section 84(6)(iv)** | Prior voluntary licensing negotiations. | Applicant must showefforts to obtain a voluntary licence on reasonable terms over a reasonable period (typically 6 months). |
| **Section 90(1)** | Settlement of licence terms & royalty. | Balances reasonable remuneration to the patentee with making the medicine available at reasonably affordable prices. |

## 4.4 Other Statutory Safeguards

Beyond Section 3(d) and Section 84, Indian patent law incorporates several additional statutory mechanisms that directly influence the competitive landscape and access to medicines.

I notice that Section 25 introduces a two-part system for filing opposition each part governed by its rules. Section 25(1) allows anyone who sees a published patent application. For which a patent has not yet been granted, to file a written opposition against the Controller on clear statutory reasons. Section 25(2) lets anyone interested raise an opposition after a patent has been granted. Within one year from the date the grant was published. These tools help the patent office improve its review by letting it look at work, medical studies and legal complaints from community groups, patient advocates and generic makers.

I see that Sections 92 and 92A create rules for compulsory licensing. Section 92 allows the Central Government to grant licenses when there is a national emergency, an urgent need or when a product is used for public non-commercial purposes and it bypasses the earlier negotiation step set out in Section 84(6)(iv). Section 92A deals with compulsory licences for making and exporting patented drugs to countries that lack enough or any drug-making capacity to meet health needs and it follows the WTO Paragraph 6 / Article 31bis rule.

I realize that Section 107A says that if a person makes builds, uses, sells or brings in an invention only for purposes that are reasonably connected with gathering or providing information needed by any law, in India or elsewhere that controls how a product is made, built, used, sold or brought in then that action does not count as infringement. Together these rules do jobs: some decide if a patent should be given, some control how exclusive rights are used and others help generic drugs enter the market quickly after a patent ends.

**SECTION 25(1) & 25(2): DUAL OPPOSITION**

Permits "any person" pre-grant and any "person interested" post-grant (within 1 year) to submit prior art and Section 3(d) objections, strengthening examination quality.

**SECTION 92: GOVERNMENT NOTIFICATION**

Enables expedited compulsory licensing during national emergencies, extreme urgency, or public non-commercial use upon notification by the Central Government.

**SECTION 92A: EXPORT LICENSING**

Authorises compulsory licences for manufacturing and exporting patented medicines to countries lacking domestic pharmaceutical manufacturing capacity.

**SECTION 107A: REGULATORY SAFE HARBOUR**

Exempts bioequivalence testing and regulatory dossier preparation from patent infringement, preventing post-expiry delays in generic market entry.

# 5 Judicial Interpretation: A Critical Analysis

## 5.1 Novartis AG v. Union of India (2013)

The Supreme Court's landmark decision in **Novartis AG v. Union of India, (2013) 6 SCC 1** (also accessible via **Indian Kanoon, 2013**), stands as the leading authority on pharmaceutical patentability under Section 3(d) of the Patents Act, 1970. The dispute concerned a mailbox patent application filed by Novartis relating to the beta-crystalline form of imatinib mesylate, a pharmacological substance associated with the life-saving Chronic Myeloid Leukaemia (CML) medicine marketed globally as Glivec or Gleevec. The central legal issue before the Court was whether the claimed polymorph satisfied the applicable requirements of patentability under the amended Act, including both the definition of invention under Section 2(1)(j) and the enhanced-efficacy requirement under Section 3(d).

The Supreme Court rejected Novartis's appeal and upheld the refusal of the product patent. In an exhaustive doctrinal analysis of the legislative history of the 1970 Act and the 2005 TRIPS transition amendments, the Court examined the structural relationship between the general statutory definition of invention and the specific exclusion under Section 3(d), focusing particularly on the precise legal meaning of "efficacy" in the context of pharmaceutical substances.

The judgment is doctrinally significant for three foundational reasons. First, it affirmed that formal compliance with the general requirements of novelty and inventive step under Section 2(1)(j) does not automatically overcome a specific statutory exclusion under Section 3; pharmaceutical patentability must be assessed holistically under the Act as a whole. Second, the decision emphasised that in the case of a medicine that claims to cure a disease, the relevant test of "efficacy" under Section 3(d) can only be "therapeutic efficacy," which must be judged strictly and narrowly rather than established merely by showing advantageous physical or physico-chemical properties (such as improved thermodynamic stability, lower hygroscopicity, or improved flow properties) unrelated to clinical therapeutic effect. Third, the judgment demonstrated that India's international patent obligations under the TRIPS Agreement do not prevent Parliament from adopting a rigorous, public-health-sensitive domestic patentability standard within the sovereign interpretive space of the international framework.

**CASE BRIEF: NOVARTIS AG V. UNION OF INDIA, (2013) 6 SCC 1**

**Court & Date:** Supreme Court of India, decided 1 April 2013.
**Subject Matter:** Patent application for the beta-crystalline form of Imatinib Mesylate (Glivec/Gleevec).
**Core Holding:** For pharmaceutical substances, "efficacy" in Section 3(d) means *therapeutic efficacy*. Physico-chemical improvements (such as flow properties, thermodynamic stability, or 30% increased bioavailability without demonstrated clinical therapeutic enhancement over the known substance) do not automatically satisfy Section 3(d).

The *Novartis* decision has also attracted sustained scholarly and industry criticism. A highly restrictive interpretation of patentability may, critics argue, reduce the commercial incentive to pursue valuable forms of incremental pharmaceutical research—such as paediatric formulations, heat-stable versions suited to tropical climates, or sustained-release mechanisms that improve patient compliance. That concern deserves serious consideration, particularly where incremental improvements yield meaningful clinical benefits for patients.

However, this critique must be assessed against the actual statutory standard articulated by the Supreme Court. Section 3(d) does not require every new pharmaceutical invention to demonstrate clinical superiority over all existing treatments, nor did the Court permanently foreclose the possibility that increased bioavailability might, in an appropriate case supported by empirical clinical evidence, result in enhanced therapeutic efficacy. Rather, Section 3(d) addresses the particular category of claims covered by its statutory language where an applicant claims a new form of an already known substance. The more defensible policy approach is therefore to insist on rigorous, evidence-based examination rather than either automatically granting or automatically rejecting secondary pharmaceutical patents. The judgment's broader contribution is its insistence that patent protection must be justified by statutory requirements; it does not establish that every secondary patent is invalid, nor does it directly guarantee affordable medicines.

## 5.2 Bayer Corporation v. Union of India (2014)

A second landmark judicial development arose from India's first post-TRIPS compulsory licence, granted to domestic generic manufacturer Natco Pharma for sorafenib tosylate, a patented drug marketed by Bayer under the brand name Nexavar and used in the treatment of advanced kidney (renal cell carcinoma) and liver (hepatocellular carcinoma) cancer. In March 2012, the Controller of Patents granted Natco a compulsory licence under **Section 84**. The decision was upheld by the Intellectual Property Appellate Board (IPAB), and the Bombay High Court subsequently dismissed Bayer's writ petition in **Bayer Corporation v. Union of India, W.P. No. 1323 of 2013**, decided on 15 July 2014 (see also **Indian Kanoon, 2014**).

| Section 84 Ground | Bayer's Position (Patentee) | Controller / High Court Assessment |
|---|---|---|
| **Section 84(1)(a): Public Requirements** | Contended that supplies alongside patient assistance and infringing generic sales met demand. | Held that patentee supply reached only a negligible fraction of eligible patients; an infringer's sales cannot be credited to the patentee. |
| **Section 84(1)(b): Reasonable Affordability** | Argued price (~₹2,80,000/month) reflected global R&D costs and innovation risk. | Held affordability must be judged from the purchasing power ofthe public; Natco's price (~₹8,800/month) demonstrated vast disparity. |
| **Section 84(1)(c): Working in India** | Maintained that commercial importation from overseas constituted working in India. | Examined the extent of importation alongside the failure to manufacture locally or supply adequate quantities on a commercial scale. |

The *Bayer* proceedings carefully considered the statutory requirements relating to public demand, reasonable affordability, and the working of the patented invention in India. The reported record described a substantial disparity between Bayer's monthly treatment price and Natco's proposed price, alongside evidence examining the extent to which domestic patient demand was being met. The decision illustrates that a compulsory licence is not simply a punitive sanction imposed on a patentee for charging a high price; rather, it is a structured statutory remedy requiring holistic assessment of specified conditions and concrete evidence. Its importance lies in demonstrating that patent rights must operate within the public-interest conditions established by Parliament: where the statutory grounds are satisfied, the patentee's exclusive rights may be limited through a non-exclusive licence that preserves reasonable royalty remuneration while permitting additional supply. Nevertheless, the decision should not be read as establishing that importation can never amount to working a patent in India, or that any price differential automatically justifies a compulsory licence in every case. The legal assessment remains strictly fact-sensitive.

## 5.3 Lessons from the Two Decisions

The decisions from Novartis and Bayer deal with two different parts of the patent process. In the Novartis case the main legal question was about whether a certain type of change to a drug was eligible for a patent in the place. In the Bayer case there was already a patent and the issue was whether the conditions for forcing the patent holder to allow others to use the drug were met.

This difference is very important for how policiesre created. A strong review process before a patent is given helps make sure that exclusive rights are not given when they should not be, which keeps competition from versions from the start. Compulsory licensing is for a problem: when a patent is already given and valid but the company is not meeting certain public needs and the law says that someone else should be allowed to use the drug. These two things are not the same. A good system for making sure medicines are available needs both rules, for giving out patents and strong ways to deal with problems after the patent is given.

| Analytical Dimension | Novartis AG v. Union of India (2013) | Bayer Corp. v. Union of India (2014) |
|---|---|---|
| **Lifecycle Stage** | Pre-Grant Patentability Examination. | Post-Grant Exercise of Exclusive Rights (after 3 years). |
| **Core Statutory Provision** | Section 3(d) read with Section 2(1)(j) & (ja). | Section 84 read with Section 90. |
| **Legal Effect on Patent** | Refusal of patent application; compound remains in public domain. | Patent remains valid; non-exclusive licence granted with royalty to patentee. |
| **Policy Function** | Prevents unjustified secondary monopolies (anti-evergreening). | Remedies inadequate supply, unaffordable pricing, or non-working ofvalid patents. |

# 6 International Obligations and the Right to Public Health

## 6.1 The TRIPS Agreement

The TRIPS Agreement sets out minimum standards for intellectual property protection that all World Trade Organization members must apply in their legal systems. Article 27 deals with what can be patented. It says that patents must be available for any invention whether it is a product or a process in any area of technology long as the invention is new involves an inventive step and can be used in industry. Article 28 outlines the rights that patent owners get. Article 33 sets a patent term of twenty years starting from the date of filing.

Trips does not create a rigid or completely closed system when it comes to pharmaceutical exclusivity. (See WTO, TRIPS and Public Health). A key point is that the Agreement does not define what counts as "new " " step," or "capable of industrial application." This gives WTO members room to set their rules. For example countries can use standards like Section 3(d) to shape patentability rules in their ways.

Article 7 makes clear the main goals of the Agreement. It says that protecting and enforcing intellectual property rights should help promote innovation. It should also support the transfer and sharing of technology. This should benefit both creators and users of technology. The process should support economic welfare. It should also balance rights and responsibilities.

Article 8(1) adds that members can make laws or change existing ones to protect health and nutrition.. These measures must not go against the rules in the Agreement.

On a level Article 31 allows for the use of a patent without the owner's permission. It sets up procedures for licenses and government use. Later Article 31bis created a system. This system allows countries with no manufacturing capacity to get licenses. These licenses are for producing and exporting medicines. These rules show that intellectual property protection, under law is not absolute. It fits within a framework that includes social needs and public health.

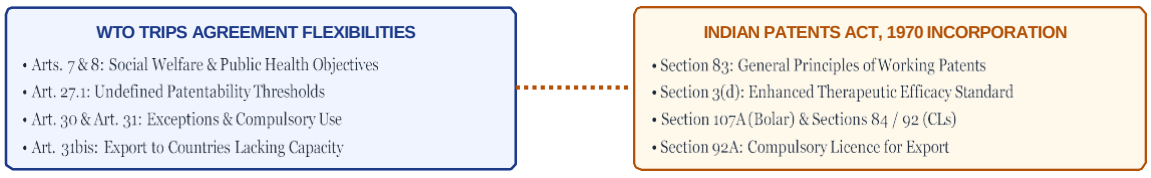



Figure 6.1 : Statutory Concordance Between Multilateral TRIPS Flexibilities and the Indian Patents Act, 1970

## 6.2 The Doha Declaration on TRIPS and Public Health

The **Doha Declaration on the TRIPS Agreement and Public Health** (WT/MIN(01)/DEC/2, also archived at **WTO Ministerial Declarations, 2001**), adopted unanimously on 14 November 2001 at the Fourth WTO Ministerial Conference, authoritatively clarified the legal relationship between international intellectual property obligations and public-health protection. Adopted amidst global concern over the affordability of patented treatments for HIV/AIDS, tuberculosis, malaria, and other epidemics, the Declaration explicitly recognised both the importance of intellectual property protection for the development ofnewmedicines and the gravity ofconcerns about its effects on medicine prices.

In Paragraph 4, the Declaration affirmed that the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health, and emphasised 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. In Paragraph 5, it specifically enumerated key TRIPS flexibilities: requiring that each provision of the Agreement be read in light of the object and purpose expressed in Articles 7 and 8; confirming that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; and affirming that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency.

For India, the Doha Declaration reinforces the international legal legitimacy of using statutory flexibilities —such as Section 3(d), Section 84, and Section 92—to address genuine public-health concerns. It does not, however, automatically invalidate pharmaceutical patents or exempt India from the procedural conditions attached to the exercise of those flexibilities under TRIPS. The appropriate policy approach is therefore neither unrestricted exclusivity nor indiscriminate compulsory licensing, but rather the lawful, transparent, and evidence-based exercise of the flexibility available under international and domestic law.

> **NORMATIVE SYNTHESIS: DOHA PARAGRAPH 4 & PARAGRAPH 5**
>
> The Doha Declaration functions as an authoritative interpretive instrument under international law, confirming that sovereign determination of compulsory licensing grounds (Section 84) and national health emergencies (Section 92) is fully consistent with WTO membership when procedural safeguards are respected.

| Articles 7 & 8 | Paragraph 5(b) | Article 31 bis |
|---|---|---|
| Purposive Public Health Reading | Freedom to Set CL Grounds | Export Licence Operationalisation |

# 7. Critical Challenges in the Indian Framework

## 7.1 The Affordability Problem Extends Beyond Patent Law

Although drug patents can have an impact on medicine costs by limiting competition from generic drugs while the patent is active not all costly medicines are expensive just because of patents. The difficulty of making the medicine for things like biologics and similar drugs the way medicines are sold and distributed how concentrated the market is, how hospitals buy medicines, not enough money from public health systems high costs patients pay out of their own pockets and the availability of other treatments that work also play a big role in how affordable medicines really are.

Also, just because there are companies that make generic drugs in the country doesn't mean every medicine that is no longer under patent or licensed will be available to every patient who needs it. A generic drug has to be made to quality standards get the needed approval from rules and regulations quickly be delivered in a good way and be available through supply chains that work in both big cities and small towns. This means that changing patent rules needs to be part of a complete plan for public health. A good patent system can take away legal problems that stop competition but it can't alone make sure everyone has access, to health care.

## 7.2 The Practical Limits of Compulsory Licensing

Compulsory licensing is a statutory remedy but in India it is used rarely. The reasons are many. Patent litigation is complex. It is expensive to gather clinical evidence. There is uncertainty about the decisions of the courts. It takes a long time to prove that compulsory licensing applies in higher courts. Furthermore, a future licensee must have the ability to make the medicine, the money, factories that meet GMP standards and the knowledge of regulations needed to produce and supply the medicine in amounts. Compulsory licensing that lacks production and distribution power has little practical value. On the hand if procedures are too random it could disturb real investment choices. Clear rules for evidence thoughtful decisions, predictable payment rules under Section 90 and quick court work are essential. They keep licensing a credible and fair remedy, not just a goal, in itself.

| Constraint Category | Manifestation in Patent & Health System | Consequence for Patient Access |
|---|---|---|
| **Evidentiary & Litigation Burden** | Proving total patient demand, working status, and reasonable negotiation under S. 84 across multi-year appeals. | Deters generic applicants from filing compulsory licence petitions for lower-margin therapeutics. |
| **Manufacturing & Regulatory Capacity** | Need for active pharmaceutical ingredient (API) synthesis, bioequivalence studies, and regulatory clearance. | Legal permission to manufacture does not translate into immediate bedside availability without industrial readiness. |
| **Healthcare Financing & Procurement** | Predominance of out-of-pocket spending and fragmented state-level drug procurement systems. | Even off-patent or discounted generic treatments can remain financially catastrophic for low-income households. |

## 7.3 Patent Opposition and Procedural Transparency

Pre-grant and post-grant opposition under Section 25 can really make a difference in the quality of patents. This is because it gives people a chance to share information like old research, health data and legal concerns with the person in charge. This is especially important in cases involving medicine, where it is hard to find the right chemical information and decide if a new idea is truly new or if it works better than what already exists. These cases need experts who understand science well.. The rules for opposition must be made carefully. They need to make sure that everyone can take part in a way without making everything too slow. If the rules are not set up properly they can cause delays. Also if there are many costs or rules that stop people from joining in then important concerns from the public might not get a fair chance to be heard.

The Patents Rules, 2003 have had some changes in years. One of these changes is the Patents (Amendment) Rules, 2024. This updated the rules about when people can challenge a patent before it is approved. It changed the rules about the money people have to pay. How often they need to fill in a special form called Form 27. Now of having to fill it in every year people do it once every three years. Also some of the details about prices and amounts are no longer needed. These changes should be checked properly by looking at what they do in practice. They should be judged based on how they affect people sharing information how many people take part in the process and how well the system works. They should not be thought to help or hurt access, to medicines just because some rules have changed.

## 7.4 Innovation Incentives and Incremental Research

A balanced critical study of access to medicines must also recognise the economic case for pharmaceutical innovation. Developing therapeutics involves large scientific uncertainty and financial risk and patents give incentives for private research, clinical trials and commercialisation. At the time biomedical research is not done only by private companies nor are patents the only incentive: public research funding, universities, public-sector laboratories, collaborative groups and advance purchase agreements also play key roles. The policy question is therefore about how to design institutions—rewarding inventions that meet standards while adding public funding and procurement when access, to medicines and pharmaceutical innovation needs are bigger than what commercial buying can cover.

**PRE-GRANT SCREENING QUALITY**

Enables civil society, patient groups, and generic researchers to assist examiners in identifying prior art and testing Section 3(d) claims prior to grant.

**PROCEDURAL EFFICIENCY BALANCE**

Requires clear timelines and reasoned threshold orders so that valid applications are not indefinitely delayed while meritorious oppositions are fully heard.

**FORM 27 WORKING TRANSPARENCY**

Highlights the importance of accessible working information following the 2024 Patent Rules amendments for evaluating domestic supply and licensing needs.

**PLURALISTIC INNOVATION INCENTIVES**

Recognises that patent exclusivity operates alongside public research grants, academic laboratories, and pooled procurement in driving drug development.

## 7.5 Patent Law and Constitutional Values

The Indian constitutional framework sets the rules and principles that guide public-health policy and how laws are understood. Article 21 of the Constitution of India as the Supreme Court of India has repeatedly explained protects the right to life and personal liberty. This includes the right to health and access to care. Because of this courts often look to Article 21 when deciding whether the government is meeting its duties in health matters.

At the time the Directive Principles of State Policy especially Article 47 make it clear that the State has a key responsibility. That responsibility is to improve health raise nutrition levels and increase the standard of living for all people. These principles are not legally enforceable in the way as fundamental rights but they shape how laws are made and interpreted.

In terms these constitutional provisions do not automatically cancel a validly granted pharmaceutical patent.. Do they create an unconditional right for individuals to demand every patented medicine from a private company at any price. The law still allows for government regulation and price controls. However Articles 21 and 47 are important because they give courts and lawmakers a framework. This framework helps in understanding the purpose behind laws like the Patents Act, 1970. For example it helps interpret provisions such as Section 3(d) which deals with patentability, Section 83 which covers licensing and Section 84 which allows for revocation of patents under certain conditions.

The connection, between values and patent rights is not one of conflict. It is one of balance and shared responsibility. Lawmakers, patent examiners, courts, price regulators and health agencies all have their roles.. Each must consider how their decisions affect real people—especially those who need essential medicines. The law must work in a way that supports health without undermining innovation. This means that every decision, whether made by Parliament or an agency must respect both the spirit of the Constitution and the needs of the people.

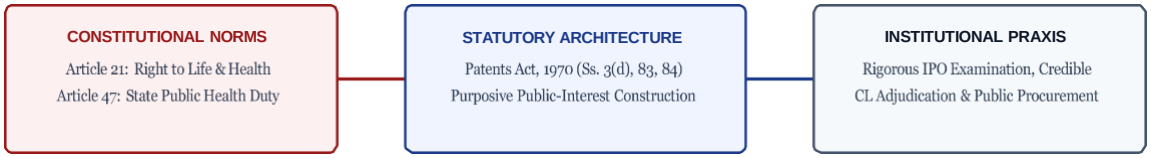



**Figure 7.1: Normative Transmission from Constitutional Health Principles to Statutory Patent Interpretation and Institutional Action**

**CONSTITUTIONAL PRINCIPLE**

Articles 21 and 47 guide courts and administrators to interpret statutory patent flexibilities purposively so that commercial exclusivity remains harmonised with public health responsibilities.

# 8. Recommendations for Reform

The following six institutional and legal proposals aim to strengthen the practical effectiveness of India's existing patent framework without presuming that every pharmaceutical patent is contrary to public health.

## 8.1 Strengthen Evidence-Based Patent Examination

The Indian Patent Office (IPO) should keep expanding and deepening its work on pharmaceutical and chemical patents. Patent examination reports and the final orders issued by Controllers must clearly explain the analysis of prior art the assessment of the inventive step as defined in Section 2(1)(ja) and when needed the exact application of the statutory rules in Section 3(d) and Section 3(e). When examiners look at pharmaceutical claims they must first find the base "known substance" and then insist on solid peer-reviewed evidence if a claim says the new drug works better.

Scientific and clinical evidence must be judged the way in all four branches of the patent office guided by newly updated Pharmaceutical Patent Examination Guidelines that follow solid appellate case law. Also, the written reasoning that backs a grant or a refusal of a patent as well as the orders that handle Section 25 oppositions must be detailed and clear enough, for a fair appellate review.

This way legal certainty and predictability grow for innovators and secondary patents will not be granted if the statutory conditions are not met.

## 8.2 Improve Access to Patent Information

Comprehensive patent records and all relevant procedural information should be made available to the public in a way. They should be easy to search and use and presented in form. Public access to patent prosecution histories, International Nonproprietary Name (INN) mapping, pre-grant and post-grant opposition filings working statements and reasoned administrative decisions helps academic researchers, generic manufacturers, patient organizations, procurement agencies and legal practitioners. It allows them to assess freedom to operate and understand health implications. Disclosure requirements, including Form 27 statements of working must be enforced according to current laws and regulations. Any changes to procedures should be tested through real-world evidence. We need to evaluate the impact of those changes, on public transparency and administrative burden. We should not assume that either full disclosure or minimal disclosure is automatically better.

> **REFORM PRIORITY I: ADMINISTRATIVE RIGOUR & DIGITAL TRANSPARENCY**
>
> Institutionalising structured Section 3(d) evidentiary checklists alongside INN-indexed digital patent databases reduces examination inconsistency and lowers search costs for generic manufacturers and public health authorities.

## 8.3 Make Compulsory Licensing Procedurally Credible

Compulsory licensing must stay an usable legal solution under Section 84 and Section 92 of the Patents Act, 1970. When people apply the process should use predictable rules for evidence and well-thought-out decisions that look at every rule that applies. Judges and officials should not give a denial just because the evidence is too hard to gather nor should they give a quick yes without proof that meets the law.

In a Section 84 case useful evidence should show how many people in the country need the medicine how affordable the treatment is compared to incomes and insurance how much the country can make the medicine whether parties have tried to negotiate a fair license as the law says in Section 84(6)(iv) and the real facts, about how the invention works in India. Setting time limits and open royalty rules under Section 90 will keep health care safe and also give patent holders a fair payment.

## 8.4 Strengthen Generic Competition and Public Procurement

Patent law safeguards must be supported by fast-moving generic competition right after a patent ends or when legal exceptions like Section 107A allow it or when compulsory licences are granted. For these opportunities to truly help patients drug control authorities must have strong review power. They must enforce bioequivalence rules and good manufacturing practices to ensure quality. Competitive markets and reliable supply chains are also essential to turn permission into access for patients. At the time public health procurement can greatly improve affordability. This can be done through tendering combining national and state demand into one large pool and choosing essential medicines based on solid evidence. These steps must follow the law. Still keep the highest standards, for medicine quality and patient safety.

| Operational Stage | Patent Law Instrument | Complementary Health & Regulatory Action |
|---|---|---|
| **Pre-Expiry Preparation** | Section 107A regulatory exception (Bolar safe harbour). | Streamlined bioequivalence review and regulatory dossier approval for day-one generic launch. |
| **Licensed Intervention** | Sections 84, 90, and 92 compulsory licensing mechanisms. | Clear evidentiary standards, structured royalty bands, and verified GMP production capacity. |
| **Market Delivery** | Post-expiry public domain or multi-source generic entry. | Pooled public procurement, transparent tendering, quality surveillance, and supply-chain distribution. |

## 8.5 Expand Public Funding and Alternative Innovation Incentives

Public research institutions, universities and government-funded biomedical programmes have a role to play in creating treatments for neglected tropical diseases, rare disorders and health issues that are specific to certain regions. These areas often do not attract private investment because they offer limited financial returns under a market-driven patent system. When public money helps discover or develop a medicine it is important that the results benefit society. This means that when public funding is used the resulting inventions should be shared in ways that're fair and accessible to all.

Better coordination between labs, clinical trial systems and local drug manufacturing can help turn scientific discoveries into real medicines that people can actually use. This kind of teamwork can speed up the process of turning research into treatments that reach patients.

When public funds help in the discovery or testing of a drug it makes sense to include rules about licensing and access. These rules should be built into the agreements that govern how technology is transferred from research to production. Such provisions ensure that medicines developed with support remain available, to the public especially in low-income areas.These approaches do not oppose the patent system. Instead they work alongside it. They show that intellectual property protection and public health goals are not enemies. They can exist together in a way that supports both innovation and justice.

## 8.6 Improve the Evidence Base for Patent and Access Policy

Finally, Indian legal and health policymakers would benefit substantially from systematic, interdisciplinary empirical research examining the real-world relationship between patent status, generic entry timelines, medicine prices, public procurement volume, and patient access outcomes. Such empirical research must carefully distinguish between patented and off-patent products, across diverse therapeutic categories (such as oncology, cardiovascular, and anti-infective medicines), and isolate the effects of non-patent supply-chain and financing factors. It should also evaluate whether specific statutory interventions
—such as Section 3(d) refusals, Section 25 oppositions, or procedural rule amendments—result in measurable changes in price, availability, and treatment continuity. A stronger empirical evidence base allows legislators and regulators to design legal interventions proportionately, rather than relying exclusively on theoretical assumptions.

| Reform Pillar | Primary Institutional Actor | Expected Policy & Access Outcome |
|---|---|---|
| **8.1–8.2 Examination & Data** | Indian Patent Office (CGPDTM) & DPIIT. | Consistent, reasoned S. 3(d) orders and searchable INN-linked patent status/working records. |
| **8.3 Credible CL Procedure** | Controller of Patents & High Courts (IP Divisions). | Timely, evidence-based adjudication under Ss. 84/92 with predictable S. 90 royalty metrics. |
| **8.4 Generic & Procurement** | Drug Regulatory Authorities & Public Health Agencies. | Rapid post-expiry generic approval, assured quality, and pooled public purchasing leverage. |
| **8.5–8.6 Public R&D & Data** | Public Research Councils, Universities & Policy Bodies. | Socially licensed public inventions and empirical tracking ofpatent-to-price pathways. |

## 9. Discussion: Towards a Balanced Model of Pharmaceutical Governance

The previous doctrinal and policy analysis shows that the standing disagreement between patent protection and getting medicines cannot be fixed by making either side completely right. A patent system that gives drug companies control without checking if the invention is real can create barriers for generic medicines and make healthcare more expensive. On the hand a system that ignores real hard-earned medical inventions can stop people from doing important research, testing and sharing new ideas. Neither side is good enough for a long-term plan for medicines.

India’s rules under the Patents Act 1970 have a set of tools to help. Section 3(d) deals with a kind of problem where a known substance is changed a little. Section 25 lets people check patent applications and approved rights before and after they are given. Compulsory licensing in Section 84 and Section
92 helps in cases where the public needs medicine but can't afford it or when theres a health emergency. Section 107A helps prepare for medicines to come in when patents end.

It is very important to use these rules the way they are meant to be used. Section 3(d) is about whether a patent's allowed, not about setting medicine prices. Compulsory licensing is for situations not for fixing big issues like buying medicine or making healthcare available to all. Stronger patents alone can't make medicines in areas where companies don't have enough reason to invest. The main goal should be a working system, for medicines. The Indian experience shows that getting medicines is better when patent rights are used correctly and follow the law and public health needs.




Figure 9.1: Integrated Four-Stage Governance Continuum Reconciling Patent Law and Patient Access

## 10. Conclusion

The relationship between pharmaceutical patent protection and access to medicines is an issue in Indian intellectual property law and global health policy. Patents for medicines can help drive investment in research and development which's often expensive and risky.. These same patents can also block generic versions from entering the market making treatments more expensive and harder to get—especially when no other treatments exist.

India's Patents Act, 1970 was adjusted during the TRIPS transition to balance innovation and public health. Section 3(d) prevents patents for forms of known drugs unless they show real therapeutic benefits. This stops companies from extending patents through changes that don't improve the medicine. Section 84 allows the government to issue licenses when a medicine is not available at a fair price or when its not being produced locally. Section 92 and Section 92A are used during health emergencies. When other countries cannot make their own medicines. These tools help ensure that people can get life-saving drugs when they need them.

The law also includes procedures that help keep the patent system fair. Section 25 allows anyone to challenge a patent before it is granted or after it is granted. Section 107A gives an exception that lets generic makers produce medicines for personal use or research without breaking patent rules. These steps help maintain the quality of the patent review process and support competition.

Important court decisions have shown how these laws work in practice. In Novartis AG v. Union of India (2013) the Supreme Court refused a patent on a modified version of a cancer drug saying it didn't meet the standard of therapeutic efficacy. This decision confirmed that patent laws must not be used to extend monopolies. In Bayer Corporation v. Union of India (2014) the court allowed a license for a hepatitis C drug showing that public health needs can override patent rights when necessary.

Having good laws on paper is not enough. Real access, to medicines depends on how these lawsre applied. Strong implementation means procedures, trained patent examiners, low-cost legal access, a strong generic drug industry and public policies that support medicine affordability. Without all these parts working the system cannot deliver the health benefits it is meant to.

> **CONCLUDING DOCTRINAL PROPOSITION**
>
> India should continue to pursue a balanced legal and institutional approach that protects genuine pharmaceutical innovation while ensuring that patent rights do not extend beyond the strict limits established by Parliament. Ultimately, the success of Indian patent law should be assessed not merely by the gross volume of patents granted or compulsory licences issued, but by the scientific and legal quality of patent decisions, the predictability of the regulatory framework, the incentives available for genuine biomedical innovation, and the tangible contribution of the broader pharmaceutical system to equitable access to life-saving treatment.

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## Submission Note and Publication Protocol

This manuscript is structured as a comprehensive doctrinal research treatise, not a completed primary econometric or clinical study. Prior to formal submission to a peer-reviewed law review or policy journal, the author should complete the following verification steps:

| Verification Domain | Pre-Submission Action Required by Author |
|---|---|
| **1. Statutory & Judicial Currency** | Verify the current statutory text of the Patents Act, 1970, all recent procedural amendments to the Patents Rules (including 2024 rules), and the latest High Court Intellectual Property Division authorities. |
| **2. Citation Formatting** | Convert all in-text references and bibliographic entries into the target journal's prescribed citation style (e.g., OSCOLA, Bluebook, ILI, or Chicago), including full pinpoint paragraph and page citations. |
| **3. Secondary Literature Review** | Expand the secondary-literature dialogue using peer-reviewed scholarship on Section 3(d), compulsory licensing, pre-grant/post-grant opposition, and pharmaceutical access in LMICs. |
| **4. Original Contribution** | Strengthen the paper's distinct contribution by integrating a clearly bounded comparative, empirical (e.g., IPO disposal data), or administrative case-study component. |
| **5. Publication Ethics** | Verify the target journal's policies concerning originality, plagiarism screening, AI-assisted writing disclosure, conflicts ofinterest, and ethical declarations. |
| **6. Author Metadata** | Insert the author's full name, institutional affiliation, ORCID identifier, contact details, and funding acknowledgements in accordance with the journal's anonymisation rules. |

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Submit to a peer-reviewed journal specialising in intellectual property law, health law, pharmaceutical regulation, or law and public policy (such as the *Journal of Intellectual Property Rights*, *Indian Law Review*, *Journal ofWorld Intellectual Property*, or *IIC – International Review of Intellectual Property and Competition Law*). A particularly strong submission will focus on the practical administrative effectiveness of India's patent safeguards, supported by a verified review of recent High Court IP Division jurisprudence and Patent Office practice.

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