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SOVEREIGN POWERS AND "SHADOW LICENSING": EXECUTIVE RESTRAINT AND JUDICIAL ACTIVISM IN INDIA DURING THE COVID-19 PANDEMIC

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ABSTRACT

This research paper provides a comprehensive legal analysis of the interplay between the international intellectual property rights (IPR) regime and the sovereign obligation to safeguard public health and ensure access to medicines. The study explores the multilateral framework established by the WTO's TRIPS Agreement, emphasizing the structural flexibilities under Article 31, the permanent amendment of Article 31bis, the interpretive guidance of the 2001 Doha Declaration, and the polarizing debates surrounding the TRIPS Waiver during the COVID-19 pandemic. Furthermore, the paper systematically examines India's domestic legal landscape under the Patents Act, 1970, which serves as a global model for balancing proprietary rights with public welfare. It deeply scrutinizes statutory mechanisms such as Compulsory Licensing (Sections 84, 92, and 92A) and sovereign powers of Government Use and Acquisition (Sections 100 and 102). By evaluating the procedural guidelines of the Patent Rules, 2003, and the strategic directives of the National IPR Policy, 2016, the research highlights the practical complexities, judicial activism, and political economy such as the reliance on "shadow compulsory licensing" that influence the execution of these vital legal safeguards during global health emergencies.

Keywords: Compulsory Licensing, TRIPS Agreement, Public Health, Patents Act 1970, Access to Medicines

1.1 Introduction

The interplay between the international regime of intellectual property rights (IPR) and the sovereign obligation to safeguard public health constitutes one of the most contentious and dynamic arenas of modern legal scholarship. This research paper provides an exhaustive legal analysis of the framework governing this interface, spanning from the multilateral commitments under the World Trade Organization (WTO) to the specific statutory provisions enshrined in India's domestic legislation. The legal architecture regulating access to medicines is not a monolith but a complex, stratified system where international treaties establish minimum standards, and domestic statutes carve out essential flexibilities.

The analysis proceeds through a hierarchical examination, commencing with the foundational text of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), moving through the interpretive clarification of the Doha Declaration (2001), and

culminating in the recent, polarising debates surrounding the TRIPS Waiver proposal during the COVID-19 pandemic. Subsequently, the report pivots to the Indian domestic context, scrutinizing the Patents Act, 1970, which is widely regarded as the vanguard of legislative balancing between proprietary rights and public welfare. This section dissects the operative mechanisms of Compulsory Licensing (CL) under Sections 84, 92, and 92A, and the sovereign powers of Government Use under Sections 100 and 102. Furthermore, it evaluates the procedural nuances contained in the Patent Rules, 2003, and analyses the overarching policy directives contained in the National IPR Policy, 2016. By integrating statutory text, procedural rules, and policy instruments, this Research paper establishes the legal scaffold upon which access to medicines is negotiated in the Indian jurisdiction.

1.2 International Legal Framework

The international regime governing the protection of pharmaceutical patents is primarily anchored in the TRIPS Agreement, which entered into force on January 1, 1995. TRIPS introduced minimum standards of IP protection that all WTO members were required to adopt, fundamentally altering the global landscape for the production and trade of generic medicines. However, embedded within this regime are specific "flexibilities" legal mechanisms that allow Member States to bypass patent exclusivity to achieve public policy objectives, most notably public health.

1.2.1 The TRIPS Agreement: Article 31 and the Framework for Compulsory Licensing

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) fundamentally shifted the global economic order by mandating that all WTO Member States provide patent protection for a minimum term of twenty years for both products and processes across all fields of technology, including pharmaceuticals. This requirement, codified in Article 27, effectively closed the window for nations to exclude medicines from patentability a strategy previously employed by India under its 1970 Act to foster a domestic generic industry.

However, the drafters of TRIPS recognized that absolute exclusivity could lead to market failures, particularly where public interest was at stake. Consequently, Article 31, titled "Other Use Without Authorization of the Right Holder," creates the legal basis for what is commonly known as compulsory licensing. It is legally significant that the term "compulsory license" does not explicitly appear in the Article's text; rather, it refers to "use" by the government or third parties authorized by the government.[492] This nomenclature emphasizes the sovereign's inherent right to authorize the use of a grant it has issued.

Article 31 does not act as a prohibition on such licenses but rather functions as a conditional permission structure. It establishes a rigorous set of procedural conditions that must be satisfied before a Member State can grant such authorization. These safeguards were designed to protect the economic interests of the patent holder while permitting state intervention in specific circumstances.

1.2.1.1 The Requirement of Prior Negotiation (Article 31(b))

A fundamental prerequisite for granting a compulsory license under normal commercial circumstances is the requirement for prior negotiation. Article 31(b) mandates that:

"such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."

This provision protects patent holders from arbitrary expropriation of their market exclusivity. It essentially requires a prospective licensee to first attempt a voluntary license. Only upon the failure of these commercial

[492] TRIPS - Article 31 - CPTech, accessed December 19, 2025, http://www.cptech.org/ip/wto/trips-art31.html

negotiations can the state machinery for compulsory licensing be engaged.

However, recognizing the exigencies of health crises where time is a luxury the state cannot afford, the Article includes a critical waiver of this requirement. The text explicitly states:

"This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."

This distinction creates a bipartite legal structure for compulsory licenses within the international framework:

1. **Commercial/Competition-based Licenses:** These require a "reasonable period" of prior negotiation.
2. **Emergency/Government Use Licenses:** These allow for the immediate waiver of negotiations, permitting the state to issue the license first and notify the patent holder later. This bifurcation directly informs the structure of domestic laws, such as India's separation of Section 84 (commercial default requiring effort) and Section 92 (emergency requiring notification).

1.2.1.2 The Domestic Market Restriction (Article 31(f))

Perhaps the most contentious clause within Article 31, and the one that would eventually necessitate an amendment to the treaty itself, is paragraph (f). This clause imposes a restriction on the destination of products manufactured under a compulsory license. It states that:

"any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."[493]

This clause created a profound legal and practical asymmetry between developed and developing nations. While it allowed countries with robust domestic manufacturing capacity (like the United States, Germany, or India) to issue compulsory licenses for their own populations, it effectively disenfranchised countries with insufficient or no pharmaceutical manufacturing capacity (such as many Sub-Saharan African nations).

The logic of the restriction operates as follows: If a Least Developed Country (LDC) faced a health crisis (e.g., HIV/AIDS) but lacked the factories to produce the necessary drug, it could legally issue a compulsory license. However, the license would be useless without a manufacturer. If the LDC turned to a country with capacity (e.g., India) to produce the drug for them, the Indian manufacturer would need an export compulsory license. However, Article 31(f) prevented India from issuing a license "predominantly" for export. The Indian manufacturer would be legally barred from producing the drug primarily for the LDC market. This legislative gap became known as the "Paragraph 6 problem" (referring to Paragraph 6 of the Doha Declaration), necessitating subsequent legal amendments.[494]

1.2.1.3 Remuneration and Judicial Review (Article 31(h), (i), (j))

The Agreement maintains economic and procedural safeguards for the right holder to prevent confiscatory action by the state.

- **Adequate Remuneration (Article 31(h)):** The right holder must be paid "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization". The term "adequate" is not defined, leaving significant discretion to national authorities, though it is often interpreted in relation to the royalty rates standard in the industry (typically 2-5% in compulsory license cases).

[493] Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation - PubMed Central, accessed December 19, 2025, https://pmc.ncbi.nlm.nih.gov/articles/PMC10726804/

[494] Article 31 bis | IP-PorTal - ippt.eu, accessed December 19, 2025, https://www.ippt.eu/legal-texts/trips/article-31bis

- **Review of Validity (Article 31(i)):** The legal validity of any decision relating to the authorization must be subject to judicial or other independent review by a distinct higher authority in that Member.
- **Review of Remuneration (Article 31(j)):** Similarly, any decision regarding the remuneration provided shall be subject to judicial or other independent review.

These provisions ensure due process but also add layers of litigation risk and procedural delay to the issuance of CLs. A patent holder can challenge both the grant of the license and the royalty rate, potentially tying up the generic production in years of litigation.

1.2.2 The Doha Declaration on the TRIPS Agreement and Public Health (2001)

The implementation of TRIPS in the late 1990s coincided with the peak of the HIV/AIDS crisis in the developing world, particularly in South Africa and Brazil. The friction between the high cost of patented antiretrovirals and the desperate need for access led to a legitimacy crisis for the WTO IP regime. In response, the Fourth WTO Ministerial Conference in Doha, Qatar, adopted the seminal "Declaration on the TRIPS Agreement and Public Health" on November 14, 2001.[495]

The Doha Declaration did not amend TRIPS but provided a binding interpretive lens. It was a political assertion that rebalanced the text of the agreement, affirming the primacy of health rights.

1.2.2.1 The Supremacy of Public Health

Paragraph 4 of the Declaration articulates the core principle of the consensus:

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

This paragraph is legally significant because it serves as a rule of interpretation under international law (specifically Article 31 of the Vienna Convention on the Law of Treaties), guiding dispute settlement panels to read TRIPS provisions in light of the object and purpose of public health.

1.2.2.2 Clarifying Sovereign Freedoms

The Declaration articulated specific freedoms that had been contested by developed nations during the negotiations. It provided legal certainty on the scope of flexibilities:

- **Freedom of Grounds (Para 5(b)):** It clarified that "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." This negated the argument propagated by some pharmaceutical lobbies that CLs were restricted only to emergencies. Members could grant licenses for non-working, high prices, or public interest.
- **Determination of Emergency (Para 5(c)):** It affirmed that "Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency," expressly noting that public health crises, including HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent such conditions. This prevents second-guessing by WTO dispute panels regarding what constitutes an "emergency" for a sovereign nation.
- **Exhaustion of Rights (Para 5(d)):** It left each member free to establish its own regime for the exhaustion of intellectual property rights, thereby validating the practice of **parallel importation**. This allows a country to import legitimate patented products from international

[495] Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation - The South Centre, accessed December 19, 2025, https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf

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markets where they are sold at lower prices, bypassing the local authorized distributor.

1.2.2.3 The Paragraph 6 Mandate

The Declaration acknowledged the structural defect of Article 31(f) regarding countries with no manufacturing capacity. Paragraph 6 instructed the Council for TRIPS to "find an expeditious solution to this problem" and report to the General Council. This instruction set in motion the negotiations that eventually led to the 2003 Waiver and the permanent Article 31bis amendment.

1.2.3 Article 31bis: The Permanent Amendment

On December 6, 2005, WTO members approved a Protocol to amend the TRIPS Agreement, inserting Article 31bis, which entered into force on January 23, 2017, upon acceptance by two-thirds of the members.[496] This was the first, and remains the only, amendment to the core TRIPS text.

1.2.3.1 The Mechanism of Article 31bis

Article 31bis was designed to formalize the "Paragraph 6 solution." It allows a specific waiver of Article 31(f) for exporting countries, permitting them to produce generic medicines *exclusively* for export to a country in need.

"The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)..."[497]

To utilize this system, a complex set of notifications and procedural steps is required, detailed in the Annex to the TRIPS Agreement. The system is often criticized for its bureaucratic weight:

1. **Notification by Importing Member:** The importing country must notify the Council for TRIPS of its intention to use the system, specifying the product and quantity needed, and confirming it lacks manufacturing capacity (unless it is an LDC, where incapacity is presumed).
2. **Notification by Exporting Member:** The exporting country (e.g., India) must issue a compulsory license solely for the production of the export quantity and notify the TRIPS Council of the grant and conditions.[498]
3. **Anti-Diversion Measures:** The products produced under this system must be clearly identified to prevent re-exportation to rich markets. This involves specific labelling, colouring, or shaping of the pills to distinguish them from the commercial product.
4. **Remuneration:** The obligation to pay remuneration is waived in the importing country (to avoid double payment) if it is paid in the exporting country.

1.2.3.2 Critique and Limited Utility

Despite its intention to facilitate access, Article 31bis has been widely criticized for its procedural burdens. Critics argue that the requirements for precise quantification of demand, special packaging, and double-notification create high transaction costs that deter generic manufacturers. The system relies on a "contract manufacturing" model where a generic firm produces a specific batch for a specific country, rather than allowing economies of scale.

Prior to the COVID-19 pandemic, the system had been used only once: in 2007, when Canada authorized Apotex to export an HIV/AIDS drug (Apo-TriAvir) to Rwanda. The process took years to finalize, leading Apotex to declare they would not use the system again due to its complexity.

[496] WIPO Lex, Treaties, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), accessed December 19, 2025, https://www.wipo.int/wipolex/en/treaties/details/231
[497] TRIP-ING UP: THE FAILURE OF TRIPS ARTICLE 31BIS - Gonzaga Journal of International Law, accessed December 19, 2025, https://gjil.scholasticahq.com/article/19098-trip-ing-up-the-failure-of-trips-article-31bis/attachment/50973.pdf
[498] WIPO Lex, Treaties, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), accessed December 19, 2025, https://www.wipo.int/wipolex/en/treaties/details/231

This "fallow state" of Article 31bis [499] became a central argument for the proponents of the broader TRIPS Waiver during the COVID-19 pandemic that the existing flexibility was structurally designed to fail during a rapid-onset global emergency.

1.2.4 The WTO TRIPS Waiver Debates (COVID-19)

The emergence of the COVID-19 pandemic in 2020 presented an unprecedented stress test for the global IP framework. While TRIPS flexibilities existed on paper, the scale of the crisis prompted calls for a more radical suspension of IP rights to facilitate the rapid scaling of vaccine and therapeutic production.

1.2.4.1 The India-South Africa Proposal (IP/C/W/669)

On October 2, 2020, India and South Africa submitted a joint proposal (Document IP/C/W/669) to the TRIPS Council.[500] The proposal requested a temporary waiver of certain provisions of the TRIPS Agreement.

- **Broad Scope:** The proposal sought to waive obligations under **Sections 1 (Copyright), 4 (Industrial Designs), 5 (Patents), and 7 (Undisclosed Information/Trade Secrets)** of Part II of the TRIPS Agreement.
- **Subject Matter:** The waiver would apply in relation to the "prevention, containment or treatment of COVID-19." This was deliberately broad, covering vaccines, therapeutics, diagnostics, and medical equipment (like ventilators and PPE).
- **Rationale:** The proponents argued that existing flexibilities like Article 31bis were insufficient because:

1. They operate on a case-by-case, product-by-product basis, which is too slow for a pandemic.[501]
2. They primarily address patents, whereas the manufacturing of modern vaccines (like mRNA) involves complex trade secrets, industrial designs, and copyright-protected data which Article 31bis does not unlock.
3. Article IX:3 and IX:4 of the Marrakesh Agreement establishing the WTO allow for waivers in "exceptional circumstances," a threshold clearly met by the pandemic.[502]

1.2.4.2 Opposition and Counter-Arguments

The proposal faced staunch opposition from the European Union, the United Kingdom, Switzerland, and initially the United States. The opposing arguments centered on the role of IP in innovation:

- **Incentives:** Opponents argued that waiving IP would undermine the incentives that allowed the rapid development of vaccines in record time.[503]
- **Manufacturing vs IP:** They contended that the bottleneck was a lack of raw materials and complex manufacturing know-how (technology transfer), not IP rights themselves. Waiving patents would not magically build bio-reactors.
- **Existing Sufficiency:** The EU maintained that the TRIPS Agreement already

[499] Access To Medicines and Pharmaceutical Patents: Fulfilling The Promise of TRIPS Article 31bis - Penn Carey Law: Legal Scholarship Repository, accessed December 19, 2025, https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=3805&context=faculty_scholarship

[500] TRIPS Waiver Proposal: A Compilation of Statements & reports, accessed December 19, 2025, https://twn.my/title2/intellectual_property/trips_waiver_proposal.htm

[501] Research Paper - The South Centre, accessed December 19, 2025, https://www.southcentre.int/wp-content/uploads/2024/01/RP191_TRIPS-Waiver-Decision-for-Equitable-Access-to-Medical-Countermeasures-in-the-Pandemic_EN.pdf

[502] World Trade Organization: "TRIPS Waiver" for COVID-19 Vaccines - Congress.gov, accessed December 19, 2025, https://www.congress.gov/crs_external_products/R/PDF/R47231/R47231.1.pdf

[503] Improving Access to COVID-19 Vaccines: An Analysis of TRIPS Waiver Discourse among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders – HHR Journal, accessed December 19, 2025, https://www.hhrjournal.org/2022/12/06/improving-access-to-covid-19-vaccines-an-analysis-of-trips-waiver-discourse-among-wto-members-civil-society-organizations-and-pharmaceutical-industry-stakeholders/

contained sufficient flexibilities (Article 31 and 31bis) to handle the crisis if countries utilized them effectively.[504]

1.2.4.3 The Ministerial Decision of June 17, 2022

After nearly 20 months of intense negotiation, the 12th WTO Ministerial Conference adopted the "Ministerial Decision on the TRIPS Agreement" on June 17, 2022. The outcome was significantly narrower than the original India-South Africa proposal, leading many civil society groups to label it a disappointment.[505]

Key Provisions of the Decision:

1. **Restricted Scope (Vaccines Only):** The waiver was limited strictly to **vaccines**. It did not cover therapeutics (like Paxlovid) or diagnostics, although paragraph 8 of the decision promised a review within six months to consider extending the scope (a deadline that passed without consensus).
2. **Clarification over Waiver:** The decision largely functioned as a clarification rather than a suspension of rights. It reiterated that an "eligible Member" (defined as all developing countries, though China voluntarily opted out) could limit the exclusive rights of the patent holder by authorizing the use of the subject matter of a patent.
3. **Waiver of Article 31(f):** The most substantive legal shift was the waiver of the requirement that production be "predominantly for the domestic market." This allows eligible members to export any proportion of the authorized vaccine production to other eligible members.[506] This theoretically enables a regional manufacturing hub model.
4. **Trade Secrets Exclusion:** Crucially, the decision **did not waive** the protection of "undisclosed information" (Section 7 of TRIPS). For mRNA vaccines, where the "recipe" and process know-how are as critical as the patent, critics argued this exclusion rendered the decision ineffective.
5. **Duration:** The mechanism applies for 5 years from the date of the decision.

The 2022 Decision represents a compromise that falls short of the full waiver sought by the Global South, reinforcing the dominance of the existing TRIPS framework even in times of global crisis.

1.3 Domestic Legal Framework: The Patents Act, 1970

India's domestic legislation, the Patents Act of 1970, serves as the operational vehicle for these international concepts. The Act has a storied history; formulated on the recommendations of the Justice N. Rajagopala Ayyangar Committee (1959), the original 1970 Act did not grant product patents for pharmaceuticals, only process patents. This regime allowed India to reverse-engineer drugs and build a massive generic industry. Following the 2005 amendment which reintroduced product patents to comply with TRIPS, India retained and strengthened a suite of safeguards designed to prevent the abuse of patent rights and ensure the availability of medicines. These provisions are viewed globally as a model for developing countries attempting to balance TRIPS compliance with public welfare.

1.3.1 Compulsory Licensing (Section 84)

Section 84 constitutes the primary mechanism for compulsory licensing in India, available to private parties. It operates as a check against the abuse of monopoly power by the patentee and is the domestic implementation of the "commercial" license envisioned in TRIPS Article 31(b).

[504] Inside the COVID-19 TRIPS Waiver - AIPPI, accessed December 19, 2025, https://www.aippi.org/news/inside-the-covid-19-trips-waiver-ongoing-discussions-on-possible-extension-to-diagnostics-and-therapeutics/
[505] The COVID-19 TRIPS Waiver and the WTO Ministerial Decision - Texas A&M Law Scholarship, accessed December 19, 2025, https://scholarship.law.tamu.edu/facscholar/2124/
[506] TRIPS Waiver - Covid-19 Response, accessed December 19, 2025, https://covid19response.org/trips-waiver/

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1.3.1.1 Statutory Triggers and Grounds

Under Section 84(1), "any person interested" may make an application to the Controller for the grant of a compulsory license on a patent. A critical temporal restriction applies: the application can be made only after the **expiration of three years** from the date of the grant of the patent.[21] This waiting period provides the patentee a reasonable opportunity to work the invention.

The application must be based on one or more of the following three grounds:

1. **(a) Reasonable Requirements of the Public:** That the reasonable requirements of the public with respect to the patented invention have not been satisfied. Section 84(7) elaborates on this, deeming requirements unsatisfied if, *inter alia*, the refusal to grant a license has prejudiced existing trade or the establishment of new trade, or if the demand is not met to an adequate extent.[507]
2. **(b) Affordable Price:** That the patented invention is not available to the public at a reasonably affordable price. This ground is unique to Indian law in its explicitness. The Act does not define "reasonably affordable," leaving it to the Controller's discretion to determine based on the purchasing power of the Indian public rather than international benchmarks.
3. **(c) Local Working:** That the patented invention is not worked in the territory of India.[508] This provision reflects the Ayyangar Committee's philosophy that patents are granted to encourage industrialization, not merely importation.

1.3.1.2 The *Natco v. Bayer* Precedent (2012)

The efficacy of Section 84 was tested in India's first (and to date, only) granted compulsory license case: *Natco Pharma Ltd. v. Bayer Corporation* (Order No. 45/2013).

- **Facts:** Bayer held a patent for the kidney cancer drug Sorafenib Tosylate (brand name Nexavar), selling it at approximately ₹2.8 lakh per month. Natco applied for a CL, proposing to sell it at ₹8,800 per month.
- **Controller's Ruling:** The Controller granted the license, finding against Bayer on all three grounds:
  - *Requirements*: Bayer supplied only 2% of the eligible patient population.
  - *Price*: ₹2.8 lakh was deemed not "reasonably affordable" for the average Indian, regardless of R&D costs.
  - *Working*: The Controller held that mere importation did not satisfy the "working" requirement of Section 84(1)(c), although this interpretation was later nuanced by the Intellectual Property Appellate Board (IPAB) to say that importation *could* constitute working if justified, but the burden of proof lies on the patentee.[509]
- **Significance:** The case established that public health interest could override patent rights when access gaps are egregious. However, the subsequent rejections of CL applications (e.g., *BDR Pharmaceuticals v. Bristol Myers Squibb*, *Lee Pharma v. AstraZeneca*) on procedural grounds (failure to prove a prima facie case or inadequate prior

[507] Understanding Compulsory Licensing in India - IIPRD, accessed December 19, 2025, https://www.iiprd.com/compulsory-licencing/

[508] Compulsory License: India | Kluwer Patent Blog, accessed December 19, 2025, https://legalblogs.wolterskluwer.com/patent-blog/compulsory-license-india/

[509] COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN INDIA: ISSUES AND CHALLENGES Dr. Payal Thaorey, accessed December 19, 2025, https://www.nlunagpur.ac.in/PDF/Publications/5-Current-Issue/1.%20COMPULSORY%20LICENSING%20OF%20PHARMACEUTICAL%20PATENTS%20IN%20INDIA.pdf

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negotiation) demonstrate the high threshold for applicants.

1.3.1.3 Procedural Requirements (Rules 96-98)

The procedure for Section 84 is governed by Chapter XIII of the Patent Rules, 2003.

- **Application:** The applicant must file **Form 17**, accompanied by a statement setting out the nature of the applicant's interest and the facts upon which the application is based.
- **Prima Facie Case (Rule 97):** The Controller first analyses whether a *prima facie* case has been made out. This is a screening mechanism. If the Controller is not satisfied, they notify the applicant, who can request a hearing. If a prima facie case exists, the Controller directs the applicant to serve a copy to the patentee.[510]
- **Opposition (Rule 98):** The patentee may file a notice of opposition under Section 87(2) using **Form 14** within two months.[511] This leads to an adversarial proceeding where both sides present evidence and expert testimony.
- **Controller's Discretion:** In making a decision, the Controller considers the nature of the invention, the time elapsed since the grant, the measures taken by the patentee to use the invention, and the ability of the applicant to work the invention to the public advantage (Section 84(6)).

Insight on Efficacy: The mandatory three-year waiting period and the adversarial nature of Section 84 render it unsuitable for immediate health crises like a pandemic. It is a tool for market correction (antitrust-like) rather than emergency response.

1.3.2 Special Provision for National Emergency (Section 92)

Recognizing that the adversarial process of Section 84 is too slow for emergencies, Section 92 provides a "fast-track" mechanism driven by the Central Government. This is the domestic implementation of the "waiver of negotiation" allowed under TRIPS Article 31(b).

1.3.2.1 Notification of Emergency

Section 92(1) empowers the Central Government to issue a notification in the Official Gazette if it is satisfied that it is necessary to grant compulsory licenses in circumstances of:

1. **National Emergency;**
2. **Extreme Urgency;** or
3. **Public Non-Commercial Use**.

The classification of what constitutes these conditions is the prerogative of the Central Government. The section is triggered *suo motu* by the government, unlike Section 84 which is triggered by a private applicant.

1.3.2.2 Effect of Notification

Once such a notification is in force, the Controller receives applications from interested persons (Form 17) and grants the license. Crucially, Section 92(3) allows the Controller to waive the elaborate procedure of Section 87 (the right of the patentee to be heard) in cases of national emergency or extreme urgency.

"In case of national emergency or other circumstances of extreme urgency... the Controller shall not apply any procedure specified in section 87 so far as it relates to the giving of notice and hearing to the interested person."

This waiver of the *audi alteram partem* (right to be heard) principle effectively transforms the license from a judicial determination to an executive order, significantly accelerating the process. The patentee is notified *after* the grant, primarily to settle the terms of remuneration.

[510] The Patents Rules, 20031, accessed December 19, 2025, https://www.indiaip.com/product_image/1398763919.pdf
[511] 1 INDIA The Patents Rules, 2003 Updated till 15-03-2024 TABLE OF CONTENTS CHAPTER I PRELIMINARY Rule 1. Short title and commence, accessed December 19, 2025, https://www.ipo.go.jp/e/system/laws/gaikoku/document/index/india-e_patents_rules.pdf

1.3.2.3 Utilization During Public Health Crises

Despite the robust nature of Section 92, it has never been successfully invoked to grant a license. During the COVID-19 pandemic, the Supreme Court of India in its *suo motu* cognizance case (*In Re: Distribution of Essential Supplies and Services During Pandemic*) in April 2021 explicitly directed the Central Government to consider invoking Section 92 for drugs like Remdesivir, Tocilizumab, and Favipiravir.[512] The Court observed:

"This is a situation which usually triggers the use of Section 92... The lives of the people take priority over everything else." [513]

However, the Central Government filed an affidavit arguing that engaging Section 92 might be "counter-productive" as it could lead to diplomatic fallout and jeopardize the supply of raw materials from countries like the US. Instead, the government preferred to use the threat of the section to encourage voluntary licensing by patent holders (e.g., Gilead licensing Remdesivir to multiple Indian manufacturers). This reflects the political economy of patent law: the *existence* of the provision often serves as a bargaining chip (shadow CL) even if the provision is not formally invoked.[514]

1.3.3 Manufacture for Export (Section 92A)

Section 92A was inserted by the Patents (Amendment) Act, 2005, specifically to implement the Paragraph 6 decision of the Doha Declaration (and subsequently Article 31bis of TRIPS). It addresses the "manufacturing capacity" gap.

Statutory Text:

"Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances. (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems..."

Condition Precedent: The section requires that the importing country has either:

1. Granted a compulsory license itself; or
2. By notification or other legal process, allowed the importation of the patented pharmaceutical products from India.

Significance: This provision establishes India as the potential "pharmacy of the developing world" under the international legal framework. It legally enables Indian generic firms to supply LDCs that cannot manufacture their own medicines, bypassing the domestic market restriction of Section 84(f) (which mirrors TRIPS Art 31(f)). In *Natco Pharma v. Bayer* (Export CL application), Natco sought a license under Section 92A to export Nexavar to Nepal. However, the application was rejected because Natco could not produce a valid notification or CL from the Government of Nepal, illustrating the procedural hurdles of the "double notification" system.

1.3.4 Government Use (Sections 100 and 102)

Distinct from compulsory licensing (which authorizes a third party to compete), the Act provides powers for the Government itself to use or acquire inventions. These are colloquially known as "Crown Use" or "Eminent Domain" provisions.

1.3.4.1 Power of Central Government to Use Inventions (Section 100)

Section 100 allows the Central Government (or any person authorized by it) to use a patented invention "for the purposes of Government".

[512] Compulsory licensing of essential drugs during the Covid-19 pandemic, accessed December 19, 2025, https://www.ibanet.org/ip-july-2021-compulsory-licensing-essential-drugs-covid-19
[513] Delhi HC: "Use provisions under Indian Patent Law to issue compulsory licenses for COVID19 drugs" - IndiaAI, accessed December 19, 2025, https://indiaai.gov.in/news/delhi-hc-use-provisions-under-indian-patent-law-to-issue-compulsory-licenses-for-covid19-drugs
[514] Balancing Intellectual Property Rights and Public Health to Cope with the COVID-19 Pandemic - eRepository @ Seton Hall, accessed December 19, 2025, https://scholarship.shu.edu/cgi/viewcontent.cgi?article=2197&context=student_scholarship

- **Broad Scope:** "Purposes of Government" is defined in Section 99 to include use for the Central Government, State Government, or a Government undertaking. This covers public procurement for government hospitals, vaccination drives, and defense needs.[515]
- **Procedure:** Unlike Section 84, this does not require a formal judicial application to the Controller. It is an executive authorization. The government must, however, notify the patentee as soon as practicable.
- **Royalty (Section 100(3)):** The patentee is entitled to "adequate remuneration" (royalty). If the amount cannot be agreed upon, it is determined by the High Court.[516] This shifts the battle from "whether to grant" to "how much to pay."
- **Utility:** This section is highly agile. During the pandemic, the Delhi High Court in *Rakesh Malhotra v. Govt of NCT* (2021) observed that the government should not hesitate to invoke Section 100 to authorize manufacturers to produce vaccines if supply shortages persisted. The Court noted that under this section, the government could simply authorize generic firms as "authorized persons" to manufacture for the state's stockpile.

1.3.4.2 Acquisition of Inventions (Section 102)

Section 102 is a more drastic measure involving the transfer of ownership. The Central Government may acquire a patent (or a pending application) for a public purpose.

- **Process:** The government issues a notification in the Official Gazette. Upon such notice, the invention/patent stands transferred to and vests in the Central Government. All rights of the original patentee are extinguished.
- **Compensation:** The government must pay compensation as agreed or as determined by the High Court. The court considers the expenditure incurred on the invention and the potential profits.[517]
- **Difference from Section 100:** Under Section 100, the patent remains with the patentee, and the government essentially forces a license. Under Section 102, the government seizes the property right entirely. Section 102 is rarely discussed for pharmaceuticals due to the high fiscal cost of compensation (acquisition value vs royalty), making Section 100 or 92 preferred for transient crises.[518]

1.4 Procedural Framework: Patent Rules, 2003

The efficacy of the substantive provisions depends heavily on the procedural rules maintained by the Patent Office. Chapter XIII of the Patent Rules, 2003 (Rules 96 to 102) governs the administration of compulsory licenses.

1.4.1 Application and Opposition Procedures

- **Rule 96:** An application for a CL under Section 84, 91, 92, or 92A must be made in **Form 17**. The application must identify the specific ground (e.g., non-working) and be accompanied by evidence.[519]
- **Rule 97:** Establishes the threshold of a *prima facie* case. If the Controller is not satisfied initially, the application can be rejected without even notifying the patentee, though the applicant has a right to be heard. This serves as a filter against frivolous applications.[520]

[515] Exceptions and Limitation of Patent Rights and its Enforcement in India - Manupatra, accessed December 19, 2025, http://docs.manupatra.in/newsline/articles/Upload/68811C66-E206-4E36-AB5A-415E9B19395B.pdf
[516] Compulsory Licensing under Indian Patent Act - R K Dewan, accessed December 19, 2025, https://www.rkdewan.com/blogs/compulsory-licensing-under-indian-patent-act/
[517] Government Acquisition of Invention - S102 (4/5) - YouTube, accessed December 19, 2025, https://www.youtube.com/watch?v=jC1IjdAQNNs
[518] Use of Inventions for purposes of Government and Acquisition of Inventions by Central Government - The Law Codes, accessed December 19, 2025, https://thelawcodes.com/article/use-of-inventions-for-purposes-of-government-and-acquisition-of-inventions-by-central-government/
[519] The Patents Rules, 20031, accessed December 19, 2025, https://www.indiaip.com/product_image/1398763919.pdf
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- **Rule 98:** If a prima facie case is found, the Controller directs the applicant to serve copies to the patentee. The patentee may oppose the grant using **Form 14** within the prescribed time (usually two months).[521]
- **Rule 102:** Provides for the termination of a compulsory license (under Section 94) if the circumstances that led to the grant cease to exist. The patentee applies using **Form 21**.[522]

1.4.2 Role of the Controller

The text places immense power in the hands of the Controller of Patents. The Controller acts as a quasi-judicial authority. The 2016 National IPR Policy's focus on "modernizing administration"[523] implies a push for efficiency, but it also raises questions about whether "efficiency" translates to faster grants of patents or more robust scrutiny of monopoly abuses. The Controller's discretion in defining "reasonably affordable price" or "working" effectively sets the boundaries of the patent bargain in India.

1.5 Policy Instruments: National IPR Policy 2016

The statutory framework operates within the broader context of the **National IPR Policy**, approved by the Union Cabinet on May 12, 2016. This policy document outlines the strategic roadmap for IPR in India, attempting to reconcile the "Make in India" economic agenda with public health obligations.

1.5.1 Objectives and Public Health

The Policy lays down seven objectives, ranging from IPR Awareness (Objective 1) to Enforcement (Objective 6).

- **Objective 4 (Legislative Framework):** This objective is critical for public health. It aims to have "strong and effective IPR laws, which balance the interests of rights owners with larger public interest."
    - **Section 4.3:** Specifically addresses the balance. It states that India will continue to utilize the legislative space and flexibilities available in international treaties (TRIPS) to protect public health and ensure access to medicines.[524]
    - **Commitment to Flexibilities:** The policy explicitly affirms the validity of provisions like Section 3(d) (preventing evergreening) and Compulsory Licensing. It resists external pressure (often from the US Trade Representative's "Special 301 Report") to adopt "TRIPS-plus" standards.[525]

1.5.2 Tension in Policy

Critiques of the policy note a tension between Objective 1 (Promoting IPR as a marketable asset) and Objective 4 (Public Interest). While the policy promotes the commercialization of IP (Objective 5), it simultaneously attempts to reassure the public health community that access to medicine remains a priority. The Policy does not recommend any amendment to the Patents Act to weaken the flexibilities, maintaining the status quo of the 1970 Act (as amended in 2005).

1.6 Government Orders and Notifications During COVID-19

The COVID-19 pandemic served as a real-world stress test for this entire legal edifice.

- **Judicial Activism:** The Supreme Court (in *In Re: Distribution of Essential Supplies*) and the Delhi High Court (in

[521] Patents Rules, 2003, accessed December 19, 2025, https://thc.nic.in/Central%20Governmental%20Rules/Patents%20Rules,%202003..pdf

[522] 1 INDIA The Patents Rules, 2003 Updated till 15-03-2024 TABLE OF CONTENTS CHAPTER I PRELIMINARY Rule 1. Short title and commence, accessed December 19, 2025, https://www.jpo.go.jp/e/system/laws/gaikoku/document/index/india-e_patents_rules.pdf

[523] 7 Objectives of India's New IPR Policy 2016 | Free Legal Advice - Lawyered, accessed December 19, 2025, https://www.lawyered.in/legal-disrupt/articles/7-objectives-indias-new-ipr-policy/

[524] NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY, accessed December 19, 2025, https://www.jetro.go.jp/ext_images/world/asia/in/ip/pdf/national_ip_20160512en.pdf

[525] Indian national IPR policy - A reality check, accessed December 19, 2025, https://twn.my/title2/health.info/2016/hi160603.htm

Rakesh Malhotra) actively engaged with the Patents Act. The courts essentially directed the government to "read" the Act, pointing out that Sections 92 and 100 were designed precisely for such moments.[526]

- **Executive Restraint:** The Central Government argued against the immediate use of CLs in the Supreme Court, citing potential diplomatic fallout and the disruption of supply chains for raw materials. Instead, the government used the *threat* of these sections to negotiate voluntary licenses with patent holders (e.g., for Remdesivir), a strategy often called "shadow compulsory licensing".

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[526] Compulsory licensing of essential drugs during the Covid-19 pandemic, accessed December 19, 2025, https://www.ibanet.org/ip-july-2021-compulsory-licensing-essential-drugs-covid-19