INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 5 AND ISSUE 13 OF 2025

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

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COMPULSORY LICENSING IN INDIA: A CRITICAL ANALYSIS POST–NOVARTIS V. UNION OF INDIA

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BEST CITATION - SHAMBHAVI SINGH, COMPULSORY LICENSING IN INDIA: A CRITICAL ANALYSIS POST–NOVARTIS V. UNION OF INDIA, *INDIAN JOURNAL OF LEGAL REVIEW (IJLR)*, 5 (13) OF 2025, PG. 218-225, APIS – 3920 – 0001 & ISSN - 2583-2344.

ABSTRACT:

This research paper examines the balance between patent protection and public health through the lens of compulsory licensing (CL) under the Indian Patents Act, 1970. It explores how CL serves as a legal mechanism to ensure affordable access to essential medicines while preserving incentives for innovation. The study traces the historical evolution of India's CL framework, its alignment with international norms under the TRIPS Agreement and the Doha Declaration, and its practical application in landmark cases such as Bayer v. Natco and Novartis v. Union of India. It further analyzes the post-Novartis landscape, highlighting trends, challenges, and India's cautious yet principled stance amid global trade pressures. The paper concludes with policy recommendations aimed at strengthening transparency, defining affordability standards, and enhancing institutional capacity. Ultimately, it argues that compulsory licensing remains a vital policy tool ensuring that the patent system functions not only to reward innovation but also to uphold the public's right to health and equitable access to life-saving medicines.

Keywords: *compulsory licensing, TRIPS, Patent act, Doha declaration, commercial, Public health, Patents,*

INTRODUCTION

Patents provide inventors with a temporary monopoly in return for revealing an invention; this exclusivity aims to encourage innovation by allowing inventors and companies to recover their investment in research and development. Simultaneously, a strict or complete monopoly can hinder access to vital products — particularly medications — by maintaining high prices or restricting availability. The principle of compulsory licensing (CL) is a clear legal tool aimed at balancing these conflicting public interests: it maintains motivation for innovation while guaranteeing that patent rights do not prevent the public from obtaining affordable access to essential technologies and medicines[374].

According to Indian law, mandatory licensing is outlined in Section 84 of the Patents Act, 1970. Section 84 permits any "interested person" to request a compulsory licence from the Controller of Patents three years after the patent is granted, provided the Controller determines that (among other reasons) (1) the reasonable needs of the public regarding the patented invention remain unmet, (2) the patented invention is not offered to the public at a reasonably affordable cost, or (3) the invention is not being utilized (i.e., manufactured or otherwise employed) in India. The Controller's examination under Section 84 specifically allows for the evaluation of both

[374]. (*WTO | Intellectual Property (TRIPS) - Agreement Text - Standards*, n.d.)

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availability and affordability, and the law thereby establishes CL as a means of addressing publicinterest issues when the patent holder's exclusivity leads to intolerable societal effects[375].

The TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) serves as the international legal foundation for compulsory licensing. Article 31 of TRIPS acknowledges that Members can allow "other use without the permission of the right holder" (i.e., compulsory licensing) provided certain procedural protections are in place (like adequate compensation and, in numerous cases, prior discussions with the right-holder). Significantly, the Doha Declaration on TRIPS and Public Health (2001) specified that TRIPS "can and should be construed and executed in a way that supports WTO Members' entitlement to safeguard public health" and clearly reasserted Members' right to utilize TRIPS flexibilities (such as compulsory licensing) to enhance access to medicines. Consequently, although CL disrupts exclusive rights, it is a recognized internationally acceptable solution when applied in line with TRIPS protections[376].

Two significant developments in India illustrate how CL exists at the crossroads of statutory law, judicial interpretation, and public health policy. Initially, the Natco–Bayer compulsory license (Controller's order dated 9 March 2012, subsequently confirmed on appeal) represented India's first significant use of the CL authority: the Controller authorized Natco to produce Bayer's anticancer medication Nexavar after determining that the drug was unavailable in India at a reasonable cost and was insufficiently "worked" domestically — and established a royalty rate and pricing terms to safeguard both public interest and the rights of the patentee. That order set practical standards for implementing Section 84 (accessibility, cost-effectiveness, and functionality in India). Moreover, the Supreme Court's ruling in ***Novartis v. Union of India***[377] — while not a CL case — strengthened India's stance against "evergreening" (patents on minor modifications that fail to demonstrate improved therapeutic efficacy) as outlined in Section 3(d). Novartis indicated the judiciary's readiness to interpret patentability and patent scope in a way that protects public interest in accessing medicines, influencing the legal landscape where CL is created and defended. Collectively, these authorities demonstrate that India's CL framework is not merely a legal instrument but also an element of a wider jurisprudential and policy strategy that prioritizes public health, which would otherwise be compromised by patent exclusivity[378].

Legal Framework of Compulsory Licensing in India

India's Patents Act, 1970 (as amended to implement TRIPS in 2005) expressly permits compulsory licensing and other state-use mechanisms to balance patent exclusivity with public health and access imperatives, chiefly through Sections 84, 92, 100, 102, and the Form 27 working requirement under Section 146, consistent with TRIPS Article 31 and the Doha Declaration on TRIPS and Public Health.

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Statutory backdrop (post-TRIPS 2005)

- India moved to a product-patent regime in 2005 for pharmaceuticals and agrochemicals, while retaining robust public-interest safeguards like compulsory licensing

[375] . (*Indian Patent Act 1970-Sections*, n.d.-b)
[376] .*supra*
[377] . Novartis AG v. Union of India is (2013) 6 SCC 1
[378] . *Bayer Corporation v. Natco Pharma Limited, 2014(60) PTC 277 (BOM).* (n.d.). Drishti Judiciary. https://www.drishtijudiciary.com/landmark-judgement/intellectual-property-rights/bayer-corporation-v-natco-pharma-limited-2014-60-ptc-277-bom

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under Chapter XVI (Sections 84–94) and government-use/acquisition under Chapter XVII (Sections 100–102).

- Section 83 articulates general principles (e.g., patents are not to enable monopoly importation) that guide licensing decisions, interfacing with Section 84 grounds and Section 92 emergencies.

Section 84[379] — general grounds

- Any "person interested" may apply for a compulsory licence after three years from the patent grant if any of the following are established: (a) reasonable requirements of the public are not met; (b) the patented invention is not available at a reasonably affordable price; or (c) the invention is not worked in India.

- Section 84(6) mandates the Controller to consider factors such as the nature of the invention, time elapsed since grant, steps taken to work the patent, the applicant's ability to work the invention, risk capacity, and whether reasonable efforts to obtain a voluntary licence were made within a reasonable period (ordinarily within six months).

- Section 84(7) elaborates when "reasonable requirements of the public" are deemed unmet, including inadequate supply, restrictive licensing conditions, non-commercial working in India, or hindrance due to importation practices[380].

Section 92[381] — emergencies and public non-commercial use

- Upon Central Government notification of a national emergency, extreme urgency, or public non-commercial use, the Controller shall grant compulsory licences on terms that secure availability at the lowest prices consistent with the patentee deriving a reasonable advantage.

- In such cases, Section 87's ordinary pre-grant procedures (e.g., hearing steps) can be dispensed with, and the provision expressly includes public health crises relating to AIDS/HIV, tuberculosis, malaria, or other epidemics.

Sections (100 and 102)[382]— government use and acquisition

- Section 100 authorizes the Central Government (or an authorized person) to use an invention for governmental purposes any time after filing or grant; if the invention was already recorded or tested by/for the Government before priority, use may be royalty-free; otherwise, terms (including remuneration) are set by agreement or, failing agreement, by the High Court.

- Government authorization under Section 100 can be granted before/after grant and to persons not otherwise licensed by the patentee; except in emergencies or extreme urgency or for non-commercial use, the patentee must be notified as soon as practicable with information on the extent of use; non-commercial sales by the Government are allowed and pass ordinary purchaser rights.

- Section 102 empowers the Central Government to acquire an invention or a patent for a public purpose by Gazette notification; rights vest in the Government, with compensation payable as agreed or determined by the High Court, considering costs, term, working, and profits, among other relevant factors.[383]

Section 146 [384] — working statements (Form 27)

- Section 146 and Rule 131 require patentees/licensees to file annual "working statements" (Form 27) on the extent of commercial working of the invention in India; non-compliance can attract penalties under Section 122(1)(b).[385]

[379] . (*Indian Patent Act 1970-Sections*, n.d.-c)
[380] . Reddy, P. (2010, April 22). *'Working' a Patent under the Indian Patent Act, 1970 – Does importation of a patented invention count?* SpicyIP. https://spicyip.com/2010/04/working-patent-under-indian-patent-act.html
[381] . (*Indian Patent Act 1970-Sections*, n.d.-c)
[382] . (*Indian Patent Act 1970-Sections*, n.d.-c)
[383] . Hub, L. (2022, October 7). *Section 102 Indian Patents Act*. LawGlobal Hub. https://www.lawglobalhub.com/section-102-indian-patents-act/
[384] . (*Indian Patent Act 1970-Sections*, n.d.-c)
[385] . Nishith Desai Associates. (2020, November 6). *Patent (Amendment) Rules, 2020: Streamlining Form 27 filings*. https://nishithdesai.com/default.aspx?id=4470

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- The Patent (Amendment) Rules, 2020 streamlined Form 27: filings align with the financial year; multiple related patents can be reported together; disclosures distinguish working vs. not-working and provide brief details, aiding transparency for CL considerations (e.g., "worked in India" under Section 84)[386].

TRIPS Article 31 and Doha Declaration (2001)

- TRIPS Article 31 permits use of patented subject matter without authorization (including compulsory licences) subject to conditions such as prior efforts to obtain authorization on reasonable commercial terms (waivable in national emergencies or extreme urgency), scope/duration limits, non-exclusivity, predominantly domestic supply, and adequate remuneration reflecting economic value[387].

- The Doha Declaration affirms that TRIPS "does not and should not prevent Members from taking measures to protect public health," and should be interpreted to promote access to medicines for all, reaffirming Members' right to use TRIPS flexibilities, including compulsory licensing; it also led to the Paragraph 6 System and TRIPS Article 31bis for exports to countries with insufficient pharmaceutical capacity[388].

Practical interface and policy considerations

- Section 84 operates as the default, evidence-based route after three years, with the Controller applying Section 83 principles and Section 90 terms (e.g., adequate remuneration, non-exclusivity), while Section 92 provides expedited licensing in emergencies/public non-commercial use settings via Government notification.

- Sections 100 and 102 offer parallel state powers: immediate government use (with post-use notice/terms) and outright acquisition for public purposes, respectively, which can be more direct than a third-party CL when the State needs assured supply or control.

Historical Context: Compulsory Licensing in India

India's patent rules were created in the decades following independence with consideration for both national development and medication accessibility. Patent law should guarantee that "food and medicine… are made available to the public at the cheapest price commensurate with reasonable compensation to the patentee," according to early policy reports (such as the Bakshi Tek Chand Committee). The Patents Act, 1970, which went into effect in April 1972, fundamentally changed India's patent system to reflect these aims. In order to facilitate the development of generic drugs, it eliminated foreign-held product patents in the pharmaceutical and agrochemical industries, leaving only process patents in those domains. Crucially, compulsory licensing measures were included in the 1970 Act from the beginning. After three years of a patent's issuance, any "person interested" may petition to the Patent Controller for a compulsory license under Section 84 if the innovation is not adequately developed in India, the reasonable criteria of the patent are not satisfied, or the invention is not reasonably priced. The Act essentially required patent holders to develop their ideas and satisfy consumer demand. Unless there is a national emergency, a public non-commercial use, or anti-competitive behavior, applicants must additionally show that they requested a voluntary license on acceptable conditions, as required by Section 84 and related laws. These compulsory-licensing regulations set the stage for future use after India started permitting product patent protection, even though the 1970

[386] . (*Patent Working Statement – the New Law – the New Form – S. Majumdar & Co*, n.d.)

[387] . Desai, M. A., PhD & Eli Lilly and Company. (2016). Compulsory licensing: Procedural requirements under the TRIPS agreement. In *Pharmaceuticals Policy and Law* (Vol. 18, pp. 31–44) [Journal-article]. IOS Press. https://doi.org/10.3233/PPL-160430

[388] . International Institute for Sustainable Development. (n.d.). Insights from the International Institute for Sustainable Development. In *TRIPS and Public Health*. https://www.iisd.org/system/files/publications/investment_sdc_dec_2003_9.pdf

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Act did not allow for product patents in pharmaceuticals[389].

TRIPS Requirements and Amendments to Patents

India joined the WTO in 1995 and ratified the TRIPS Agreement, which mandated that by 2005, member governments grant patents in all technological domains. India was given a grace period to implement pharmaceutical product patents; nonetheless, this shift necessitated a revision to its patent legislation. Following findings by WTO panels (1997–2000) that India had violated TRIPS (for example, the United States contested India's denial of product patents)[390], Several amendments were passed by Parliament. In addition to introducing an interim exclusive marketing rights framework, the Patents (Amendment) Act, 1999 (which went into force on January 1, 1995) created a "mailbox" method for product patent applications in pharmaceuticals and agrochemicals, which would not grant patents until 2005. By extending the patent term to 20 years, expanding the lists of non-patentable subject matter, and codifying the Bolar-type exemption, the Patents (Amendment) Act, 2002 (which went into effect on May 20, 2003) and its supporting Rules increased patentability. Importantly, the 2002 Amendments introduced further protections. For instance, if the patented innovation "is not worked in the territory of India[391]," there is now a specific basis for mandatory license (nishithdesai.com). Pharmaceutical product patents were then completely implemented by the Patents (Amendment) Act, 2005 (which went into force on January 1, 2005), bringing Indian law into accordance with TRIPS. Additionally, this Act amended licensing regulations and included Section 3(d), which prohibits patents on novel versions of well-known pharmaceuticals in the absence of improved efficacy. The 2005 Act specifically added Section 92A, which permits mandatory licenses for the export of patented medications to nations with limited manufacturing capacity. This is a direct application of the TRIPS "Paragraph 6" mechanism that was agreed upon in Doha[392].

Public Health and the Compulsory-Licensing Framework

Several compulsory licensing mechanisms are currently included in Indian patent law. According to Section 84(1) (first adopted in 1970), a CL may be issued after three years if it can be demonstrated that the invention has not been developed to "the fullest extent that is reasonably practicable" in India, that public demand has not been satisfied, or that it is not affordable. The Controller must consider the patentee's endeavors to implement the invention and previous license applications. When the requirements are met, the Controller has the authority to set terms and fair royalties for the license. India's public health purpose is reflected in the Patents Act, which also permits broader grounds. In cases of national emergency, extraordinary urgency, or public non-commercial use, Section 92 gives the government the authority to award or revoke licenses on its own initiative. Public health emergencies (such as HIV/AIDS, TB, and malaria outbreaks) are among the situations that need mandatory licenses, according to the 2002 modifications. nishithdesai.com. A patented medication may be "used" by the government for its own purposes (such as the military or railroads) under Section 100. A license "shall be available for manufacture and export of patented pharmaceutical products" to any nation with inadequate manufacturing capacity to meet public health needs, provided that nation has also authorized the importation of such generics, according to Section 92A (added

[389] . (*History of Indian Patent System - Intellectual Property India | Government of India*, n.d.)
[390] . *An international Guide to patent Case Management for Judges*. (n.d.). https://www.wipo.int/patent-judicial-guide/en/full-guide/india/6.1.4
[391] . Nishith Desai Associates. (2003, May 26). *Patents Amendment Act, 2002 and Patents Rules, 2003 come into force.* https://nishithdesai.com/default.aspx?id=5793#:~:text=,works%20and%20television%20productions%3B%20a
[392] . (*Compulsory License: India*, n.d.)

2005), which, last but not least, permits the export of CLs[393].

International Flexibilities and the Doha Declaration

The TRIPS flexibilities must be taken into consideration when analyzing India's CL regime. The TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health," according to the WTO's Doha Declaration on TRIPS and Public Health (2001). Doha confirmed that each member is free to identify national emergencies or other extremely urgent situations, as well as to decide the basis for mandatory licensing. Additionally, it acknowledged that many underdeveloped nations lack the capacity to manufacture pharmaceuticals, which is why Article 31bis, the Paragraph 6 solution, was created for export CLs. India made strong use of these flexibilities. For example, the export license clause of Article 31bis legalblogs is clearly implemented by the addition of Section 92A. In general, India has argued that its patent laws, which include stringent patentability requirements, are compliant with TRIPS as amended; it frequently cites Doha to support policies such as parallel imports and forced licensing. Indian authorities have stressed in WTO talks that patents must not be exploited to subvert public health objectives.

Landmark Cases: *Bayer v Natco* and *Novartis v Union of India*

A turning point came in Bayer Corporation v. Natco Pharma Ltd. (2012–13), India's first post-TRIPS compulsory licence. Natco applied for a CL on Bayer's patent for sorafenib tosylate (Nexavar), an expensive cancer drug, arguing the price was unaffordable and demand unmetwipo.int. On 9 March 2012, the Controller granted Natco a licence (with 6% royalty to Bayer), a decision upheld by the IP Appellate Board in March 2013wipo.int. The IPAB explicitly found that Natco satisfied Section 84's criteria: the public requirements were not being met and the patented drug was priced unreasonably highwipo.int. In dismissing Bayer's appeal, the Board noted this was "the first compulsory license granted in India under the Patents Act"wipo.int. This case thus firmly established India's willingness to use CLs for access to medicines. (Bayer's further appeal to the Supreme Court was ultimately dismissed, leaving the licence in force.)

By contrast, Novartis AG v. Union of India (2013) dealt with patentability, not licensing per se, but had major implications for access. Novartis had challenged the refusal of a patent on its leukemia drug Glivec under Section 3(d). The Supreme Court unanimously upheld the denial, holding that the new form of imatinib mesylate lacked "enhanced therapeutic efficacy" over the known form and therefore was not patentable. While not a CL ruling, Novartis *effectively barred trivial "evergreen" patents on drugs* and was hailed as a victory for public health interests. Observers noted that Novartis confirmed India's interpretation of TRIPS as allowing such safeguards in favor of access. In practical terms, the Glivec case meant generic competition (and cheaper drugs) could continue, reducing the scenarios in which compulsory licences might be needed. Together, Bayer v Natco and Novartis v Union illustrate how India's courts and patent office have balanced patent rights against public health: applying CL flexibly when necessary, and demanding real innovation for patent protection, in line with the Doha Declaration's spirit.

Post–Novartis Landscape: Trends and Challenges

Following the *Novartis v. Union of India* (2013) judgment, India emerged as a global example of balancing intellectual property rights with public health imperatives. However, the post-*Novartis* period has been marked by both progress and restraint. Since the landmark *Bayer v. Natco* compulsory licence (2012), India has issued very few CLs, signaling a cautious approach influenced by trade diplomacy and

[393] . (*Compulsory License: India*, n.d.)

global pressure, particularly from the United States and the European Union. The Indian government has often preferred encouraging voluntary licensing, as seen in Gilead's licensing of Hepatitis C drugs to Indian generic manufacturers, which allowed broader access without invoking compulsory powers.

Despite its progressive legal framework, India faces several challenges. Internationally, the country continues to be criticized as "IP unfriendly" due to its strong public health safeguards. Domestically, the Patent Office struggles with administrative bottlenecks, including lack of transparency in decision-making and inadequate publication of Form 27 (working statements). Furthermore, data deficiency on drug prices and patent utilization hampers effective implementation. From an innovation perspective, pharmaceutical corporations argue that frequent use of CL could discourage foreign investment and research and development in the Indian market. Even during the COVID-19 pandemic, while India led the call at the WTO for a global IP waiver for vaccines, it did not issue domestic CLs—reflecting a preference for negotiation and diplomacy over direct compulsion.

International Perspective and TRIPS Flexibilities

Globally, India's restrained use of compulsory licensing contrasts sharply with countries like *Thailand and Brazil*, which invoked CLs extensively to lower the cost of HIV/AIDS medications in the 2000s. Even developed nations such as the *United States* have historically used government-use provisions akin to compulsory licensing to safeguard public interest. *China*, too, incorporated public health–oriented CL provisions in its 2008 patent law reforms. India, in comparison, has chosen a middle path—using CL sparingly and strategically—balancing its domestic health priorities with international trade relations and TRIPS obligations. This cautious yet principled stance demonstrates India's commitment to accessibility and equity, while maintaining its credibility in global IP diplomacy.

Critical Analysis

India's approach to compulsory licensing represents a measured compromise between protecting patent rights and ensuring public access to essential medicines. On the positive side, CL provisions uphold social justice by preventing abuse of monopoly power, reducing drug prices, and fostering the growth of a robust generic pharmaceutical industry. However, the limited number of CLs granted shows that it remains largely a law in principle rather than in practice. The absence of clear definitions for terms like "reasonably affordable price" and "public requirement" creates uncertainty in implementation. Critics also warn that the fear of compulsory licensing could deter foreign direct investment (FDI**)** and innovation in the pharmaceutical sector. Nevertheless, the *Novartis* judgment, though not directly about CL, reaffirmed India's public health–first philosophy, reinforcing its right under TRIPS to prioritize citizens' access to medicines over absolute patent monopolies. This balance continues to shape global debates on intellectual property and health equity.

8. Policy Recommendations

To strengthen India's compulsory licensing (CL) framework and ensure a fair balance between innovation and accessibility, several policy interventions are necessary. First, the government should define clear affordability standards through the Department for Promotion of Industry and Internal Trade (DPIIT) or the National Pharmaceutical Pricing Authority (NPPA). This would bring consistency to the interpretation of "reasonably affordable price" under Section 84 of the Patents Act. Second, India should encourage voluntary licensing mechanisms that ensure equitable access to patented medicines while providing fair royalty compensation to patent holders—reducing the need for contentious CL proceedings.

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Furthermore, greater transparency in Form 27 disclosures—which indicate whether and how a patent is being "worked" in India—should be mandated to ensure accountability of patent holders. In situations of public health emergencies, a fast-track mechanism for CL applications should be established to enable swift access to critical medicines and technologies. The government can also promote public–private partnerships to facilitate domestic manufacturing once a CL is granted, ensuring the country's self-sufficiency in essential drug production. Finally, capacity building within the Indian Patent Office is crucial, enabling examiners and controllers to conduct not only legal reviews but also socio-economic assessments that consider public health impact, market data, and affordability factors. These measures together would make India's CL regime more responsive, transparent, and effective.

Conclusion

Compulsory licensing remains a vital policy instrument that ensures the patent system operates in the broader interest of society. India's legal framework, particularly shaped by the *Bayer v. Natco* case and reinforced by the *Novartis v. Union of India* judgment, exemplifies how developing countries can balance innovation incentives with public health imperatives. Although used sparingly, India's CL provisions stand as a symbol of equitable access, ensuring that life-saving medicines do not remain confined to the privileged few.

As new health challenges emerge—such as pandemics and the rising cost of patented treatments—India's approach to compulsory licensing will likely play a decisive role in global intellectual property discourse. The future of patent law lies not only in rewarding inventors but also in protecting the collective right to health. As aptly stated, *"The strength of a patent system lies not merely in the rights it confers, but in the checks it imposes in the public interest — and compulsory licensing is that check."*