CRITICAL ANALYSIS OF COMPULSORY LICENSING UNDER INDIAN PATENT LAW

Lakshana Raghavan, BBA LLB, St. Joseph's College of Law[1]

ABSTRACT

This paper critically analyzes compulsory licensing as a mechanism for balancing patent rights with public interest under the Indian Patents Act, 1970. A patent, as an exclusive right granted for an invention, is intended to provide a technical solution for a period of 20 years. However, this paper explores the concept of a 'compulsory license,' a provision embodied in Chapter XVI of the Act that acts as a government-level check on the monopoly rights of a patent holder. Rooted in the principles of non-availability and non-affordability, compulsory licensing serves as a crucial legal tool for ensuring public access to essential products, a concept reinforced by the Doha Declaration and the TRIPS Agreement.

This paper specifically analyzes the inherent legal ambiguities stemming from the Patents Act's lack of statutory definitions for 'reasonable requirements' and 'affordable prices'. It also examines the slow licensing process, a key procedural issue, and its impact on both foreign investment and new domestic research. Through a review of key provisions and an analysis of landmark judicial interpretations, including the Natco Pharma Ltd. v. Bayer Corporation case, the paper highlights the inherent conflicts between upholding patent rights and ensuring timely public access. The paper shows how the judiciary has supported compulsory licensing and its usefulness in reducing the prices of essential drugs in the interest of accessing justice in the medical field. Besides, the paper discusses the ethical issues and economic consequences associated with compulsory licensing, the effects it has on the pharmacy sector, and the stimulation of innovations. The Researcher aims to provide a comprehensive assessment of the framework's efficacy in balancing vital public health objectives with private intellectual property rights. The research paper focuses on the inherent conflicts of compulsory licensing as a mechanism for balancing public access to essential products with the rights of inventors and owners and concludes by proposing recommendations for reform to provide greater clarity and efficiency.

[1] V BBA LLB., St. Joseph's College of Law.

Keywords: Compulsory Licensing, Indian Patents Act, 1970, Intellectual Property Rights, Public Health, Natco Pharma Ltd. v. Bayer Corporation.

HYPOTHESIS:

The compulsory licensing under the Indian Patents Act, 1970, is ineffective in its objective of ensuring affordable public access to essential products due to key legal and procedural flaws.

RESEARCH PROBLEM:

Despite the Indian Patents Act, 1970, incorporating compulsory licensing as an important tool to balance patent rights with public health objectives, its practical application has significant challenges. The lack of clear statutory definitions for key terms like 'reasonable requirements' and 'affordable prices' creates legal uncertainty and procedural delays, as evidenced by the protracted judicial process in landmark cases. This ambiguity, along with a slow licensing process, not only undermines the goal of ensuring timely and affordable public access to essential products but also creates a disadvantageous situation for both foreign investment and new domestic research, thus generating a conflict between public welfare and the private incentives for innovation. The core problem is to critically assess whether the current legal and procedural structure of compulsory licensing in India law is effective in achieving its stated purpose, or if its inherent conflicts and ambiguities render it a tool that is more theoretical than practical in its efficiency.

RESEARCH QUESTIONS:

1. What is the scope and rationale of compulsory licensing under the Indian Patents Act, 1970, and how does it align with international obligations under the TRIPS Agreement and the Doha Declaration?

2. How effective is compulsory licensing under the Indian Patents Act in achieving its stated purpose of balancing public welfare with private rights, and what specific legislative amendments or procedural reforms are necessary to make it a more effective, predictable, and transparent mechanism for achieving public health objectives in India?

3. How does the fear of compulsory licensing deter foreign direct investment in India's pharmaceutical sector, and what is its measurable impact on domestic research and

development (R&D) and innovation?

SCOPE OF RESEARCH:

This paper specifically analyzes the inherent legal ambiguities stemming from the Patents Act's lack of statutory definitions for ‘reasonable requirements’ and ‘affordable prices’. It also examines the slow licensing process, a key procedural issue, and its impact on both foreign investment and new domestic research. Through a review of key provisions and an analysis of landmark judicial interpretations, including the Natco Pharma Ltd. v. Bayer Corporation case, the paper highlights the inherent conflicts between upholding patent rights and ensuring timely public access. The paper shows how the judiciary has supported compulsory licensing and its usefulness in reducing the prices of essential drugs in the interest of accessing justice in the medical field. Besides, the paper discusses the ethical issues and economic consequences associated with compulsory licensing, the effects it has on the pharmacy sector, and the stimulation of innovations. The Researcher aims to provide a comprehensive assessment of the framework's efficacy in balancing vital public health objectives with private intellectual property rights. The research paper focuses on the inherent conflicts of compulsory licensing as a mechanism for balancing public access to essential products with the rights of inventors and owners and concludes by proposing recommendations for reform to provide greater clarity and efficiency.

RESEARCH OBJECTIVES

1. To analyze the scope and legal framework of compulsory licensing under the Indian Patents Act, 1970, and its alignment with international obligations like the TRIPS Agreement and the Doha Declaration.

2. To critically evaluate the effectiveness of the compulsory licensing mechanism in balancing the public welfare of affordable medicine access against the private rights of patent holders.

3. To examine the specific legal and procedural flaws within the current framework, including the ambiguity of key terms and the impact of a slow licensing process.

4. To investigate the economic consequences of compulsory licensing on foreign direct investment and domestic research and development in India's pharmaceutical sector.

5. To propose specific legislative and procedural reforms to enhance the effectiveness, predictability, and transparency of compulsory licensing for public health purposes.

RESEARCH METHODOLOGY

This paper employs a doctrinal methodology to critically analyze the legal framework of compulsory licensing under Indian patent law. This approach is primarily non-empirical, and relies on the critical analysis of primary and secondary legal sources.The doctrinal method is chosen for this research due to the complex, interpretive nature of compulsory licensing. It relies heavily on the construction and application of statutory provisions, multiple reports, and extensive existing research papers. This type of methodology is best suited for an in-depth analysis of these existing legal sources, including specific articles and sections, which are necessary to assess the validity of the hypothesis & to suggest for reform.

The research will begin with a close reading of key statutory provisions within the Indian Patents Act, 1970. This will be followed by review of landmark judicial precedents, including the case of Natco Pharma Ltd. v. Bayer Corporation, to understand how courts have interpreted and applied these provisions in practice. The analysis will incorporate relevant international legal principles, such as the TRIPS Agreement and the Doha Declaration, to understand India's legal position on compulsory licensing within global intellectual property norms. The researcher aims to critically evaluate these sources to showcase the existing legal ambiguities, procedural inefficiencies, and conflicts between public welfare and private intellectual property rights.

EXISTING LEGAL SITUATION

The law for compulsory licensing in India is mainly governed by the Indian Patents Act, 1970, which provides a government check on a patent holder's ownership. This provision allows for a compulsory license to be granted if the patented product is not available at a reasonably affordable price, is not meeting the public's reasonable requirements, or is not manufactured in the country. The existing legal situation aims to establish a balance in private rights with public welfare through the following key provisions:

- **Section 84:** This is the primary section that governs the grant of compulsory licenses after three years from the sealing of a patent.

- **Section 90:** This section details the specific terms and conditions imposed on the grant of a compulsory license, particularly focusing on ensuring that the invention is worked efficiently and that the public interest in access is prioritized.

- **Section 92:** This section provides for the issuance of compulsory licenses in situations of **national emergency, extreme urgency, or public non-commercial use**, allowing the government to bypass the three-year waiting period under Section 84.

- **Section 83:** This section sets out the overarching general principles of the patent system in India, emphasizing that patent rights must not be exercised to the detriment of public health or to impede the public's access to the invention.

The law is aligned with international obligations under the TRIPS Agreement and further supported by the Doha Declaration, which affirms a country's right to use this flexibility for public health.

INTRODUCTION

Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. IP is protected in law by, for example, patents, copyright and trademarks, which enable people to earn recognition or financial benefit from what they invent or create. By striking the right balance between the interests of innovators and the wider public interest, the IP system aims to foster an environment in which creativity and innovation can flourish.[2] One of the most significant types of intellectual property is a Patent, wherein the law grants an inventor exclusive rights & protection for a set duration in exchange for their innovation. According to patent law, an invention must be new or unique, entail an inventive step, and have the potential for industrial use in order to qualify for patent rights. The goal of patent law is to facilitate industrial advancement, foster scientific research, foster technical innovation, and create new technologies. As a result, patent law encourages inventors to balance their rights and responsibilities with those of society.

The concept of licensing can be divided into two forms – voluntary licensing, which promotes

[2] WIPO (n.d.) *About Intellectual Property*. Available at: https://www.wipo.int/en/web/about-ip (2nd October 2025).

commercial exploitation by granting licensing by the patent holder to third party and Non-voluntary or compulsory licensing which is granted by government on the reason of non-availability, non- affordability, national emergency, extreme urgency or in case of public non-commercial use.[3] The owner of the rights, known as the patentee, has the only authority to exploit the innovation for a period of 20 years, during which time he can restrict anybody else from making any use of his patented goods.[4] However, there is also a clause that allows the patent office to grant a third party a "compulsory license" to use this patented invention in specific situations. Chapter XVI of the Indian Patents Act of 1970 embodies the idea of "compulsory licensing." As per the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement , Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.[5] It is one of the flexibility in the field of patent protection included in the WTO's agreement on intellectual property.

The foundational principles of patent protection and access are deeply rooted in global trade and public health mandates. The Compulsory Licensing framework is formally established by the World Trade Organization's (WTO) TRIPS Agreement in Article 31 (titled 'Other Use Without Authorization of the Right Holder'), which sets minimum standards while allowing Member States flexibility. This right was unequivocally reaffirmed and strengthened by the Doha Declaration on TRIPS and Public Health (2001), which granted nations the specific right to utilize Compulsory Licensing to protect public health.[6] Aligning with these international obligations, the Indian legal system, particularly the Indian Patents Act, 1970, explicitly emphasizes (under Section 83) that patent rights must not be exercised to the detriment of public health.[7] Consequently, India utilizes Section 84 (for failure to meet public requirements,

[3] IJCRT (2025) *Compulsory Licensing in India: A Legal and Economic Analysis*. *International Journal of Creative Research Thoughts (IJCRT)*, Vol. 13, Issue 3, Paper ID: IJCRT2503075. Available at: https://ijcrt.org/papers/IJCRT2503075.pdf (Accessed: 2 October 2025).
[4] JETIR (2019) *A Study on Compulsory Licensing under the Indian Patent Law*. *Journal of Emerging Technologies and Innovative Research (JETIR)*, Vol. 6, Issue 3, Paper ID: JETIR1903730. Available at: https://www.jetir.org/papers/JETIR1903730.pdf (Accessed: 2 October 2025).
[5]Basheer, S. and Mani, A. (2006) *The "Compulsory Licence" Regime in India: Past, Present and Future*. *ResearchGate*. Available at: https://www.researchgate.net/publication/228173575_The_'Compulsory_Licence'_Regime_in_India_Past_Present_and_Future (Accessed: 2 October 2025).
[6] Liu, K. (2012) *Compulsory Licensing and the Public Health Exception to Patent Protection in the TRIPS Agreement*. *Harvard International Law Journal*, Vol. 53, No. 2, pp. 561–589. Available at: https://journals.law.harvard.edu/ilj/wp-content/uploads/sites/84/561Liu.pdf (Accessed: 2 October 2025).
[7] IIPRD (2020) *How Bayer Lost Its Monopoly: The Story Behind India's First Compulsory License*. *IIPRD Blog*. Available at: *https://www.iiprd.com/how-bayer-lost-its-monopoly-the-story-behind-indias-first-compulsory-license/* (Accessed: 2 October 2025).

non-affordability, or non-working in India) and Section 92 (for national emergency or extreme urgency) as its primary domestic mechanisms for issuing a Compulsory License.[8]

While the *rationale* behind Compulsory Licensing is thus legally sound and firmly ingrained in international and domestic law, its practical efficiency remains disputed in the Indian context, giving rise to the central problem of this research. The statute, though progressive, suffers from a critical lack of clarity that undermines its main objective of ensuring affordable public access. The Patents Act lacks clear definitions for fundamental terms that focus on Compulsory Licensing, such as 'reasonable requirements of the public' and 'reasonably affordable price'.[9]This legal ambiguity creates uncertainty and prolonged judicial decision making which directly defeats the goal of ensuring timely public access to essential products and raises concerns regarding its impact on foreign investment and new domestic research.[10] This conflict is showcased by landmark judicial cases, such as the Natco Pharma Ltd. v. Bayer Corporation case, which, while supporting the *use* of Compulsory Licensing, also showcased the legal vagueness that can hinder its utility.[11]

THE SCOPE AND RATIONALE OF COMPULSORY LICENSING UNDER THE INDIAN PATENTS ACT, 1970, AND THE INTERNATIONAL OBLIGATIONS UNDER THE TRIPS AGREEMENT AND THE DOHA DECLARATION.

The scope and rationale of compulsory licensing (CL) under the Indian Patents Act, 1970, are comprehensively defined by a public health and economic welfare mandate, establishing a crucial check on the exclusivity granted to a patent holder. The core purpose, articulated in the overarching Section 83, is to ensure that patent rights do not obstruct public access to essential technologies and are worked commercially in India to the fullest extent (Indian Patents Act, 1970, Sec 83). The CL provisions in Chapter XVI activate this mandate under specific remedial

[8]IJIRL (2023) *Compulsory Licensing in India: Natco vs Bayer Case and Its Impact in India*. *International Journal of Indian Research Law (IJIRL)*. Available at: *https://ijirl.com/wp-content/uploads/2023/12/COMPULSORY-LICENSING-IN-INDI-NATCO-VS-BAYER-CASE-IMPACT-IN-INDIA.pdf* (Accessed: 2 October 2025).

[9] Jensen, E. (2015) *Balancing Innovation and Access: Compulsory Licensing in International Patent Law*. *Brigham Young University Prelaw Review*, Vol. 29, Article 3. Available at: *https://scholarsarchive.byu.edu/cgi/viewcontent.cgi?article=1303&context=byuplr* (Accessed: 2 October 2025).

[10]Manupatra (2018) *Compulsory Licensing in India: An Overview*. *Manupatra Newsline*. Available at: *http://docs.manupatra.in/newsline/articles/Upload/93092AEC-D7C8-4C1E-9219-3B4CB5DAE8F9.pdf* (Accessed: 19th November 2025).

[11] iPleaders (2021) *Bayer Corporation vs. Natco Pharma Ltd: A Case Analysis*. *iPleaders Blog*. Available at: *https://blog.ipleaders.in/bayer-corporation-vs-natco-pharma-ltd-a-case-analysis/* (Accessed: 21st Novemver 2025).

circumstances, primarily detailed in Section 84. This section allows an "interested person" to apply for a license after three years from the patent grant if the patented product is not available at a "reasonably affordable price," is not meeting the "reasonable requirements of the public," or is "not worked in the territory of India"[12]. Furthermore, Section 92 expands this scope by allowing the Central Government to grant a CL immediately, bypassing the three-year wait, in situations of "national emergency," "extreme urgency," or for "public non-commercial use," demonstrating the system's inherent prioritization of national crises over private monopoly rights.[13]

This domestic framework is highly consistent with, and fundamentally supported by, international intellectual property agreements. The basis for India's flexibility lies in Article 31 of the TRIPS Agreement, which permits Member States to authorize "other use without the authorization of the right holder," provided the country's national laws establish certain procedural safeguards, such as requiring prior attempts to negotiate a voluntary license. Crucially, Article 31 recognizes that CL can be employed to prevent the abuse of patent rights or address anti-competitive practices, directly aligning with India's rationale of preventing a patent from becoming a mere import monopoly.[14]

The alignment of the Indian Act with international obligations was unequivocally reinforced by the Doha Declaration on TRIPS and Public Health (2001). This landmark declaration affirmed that the TRIPS 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".[15] The Doha Declaration explicitly confirmed a country's right to utilize the CL flexibilities and to determine what constitutes a national emergency, thereby validating India's robust, health-centric provisions like Section 92. The Indian Patents Act serves not merely as a compliant mechanism but as a powerful assertion of a sovereign nation's right to leverage patent law to safeguard its citizens' welfare, with the international

[12]Radhi Shah, "Compulsory License: India," *Kluwer Patent Blog* (Aug. 16, 2021), available at *https://legalblogs.wolterskluwer.com/patent-blog/compulsory-license-india/* (accessed Dec. 1, 2025).
[13] *Compulsory Licensing & Public Interest in India*, Brainiac), available at https://brainiac.co.in/compulsory-licensing-and-public-interest-in-india (accessed Dec. 2, 2025).
[14] Deli Yang, "Compulsory Licensing: For Better or For Worse — the Done Deal Lies in the Balance," 17 *J. Intell. Prop. Rights* 76 (Jan. 2012), available at *http://docs.manupatra.in/newsline/articles/Upload/76691AEF-0A18-46A4-9CA8-84E09668D815.pdf* (accessed Dec. 2, 2025).
[15]WTO, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at *https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm* (accessed Dec. 4, 2025).

community's explicit backing.[16]

The practical strength of India's compulsory licensing framework was judicially tested and affirmed in *Bayer Corporation v. Natco Pharma Ltd.* (2012), the first and, so far, only compulsory license granted in India. Natco's application under Section 84 highlighted Bayer's failure to make the life-saving cancer drug Sorafenib Tosylate (Nexavar) accessible and affordable to Indian patients. Bayer's limited imports and exorbitant pricing, ₹2,80,000 per month, effectively excluded the vast majority of patients, prompting Natco to seek authorization to produce a generic version at ₹8,800 per month.

The Controller of Patents upheld Natco's claim, holding that Bayer's practices violated all three conditions of Section 84(1). The Controller's interpretation of "reasonably affordable price" was pivotal—it emphasized that affordability must be assessed in the context of the Indian public's purchasing power, not the patentee's global R&D expenditures. The decision underscored that patent protection cannot override the constitutional and statutory imperative of public access to essential medicines. Further, the Controller ruled that mere importation did not amount to "working" of the patent in India, reaffirming the Act's policy preference for domestic manufacturing and technological dissemination. The case established a jurisprudential benchmark by operationalizing the statutory objectives of Section 83 through a case-based interpretation. The decision clarified that the "working requirement" serves as an industrial policy tool to ensure technology transfer and local production rather than allowing patentees to exploit the Indian market through imports. This approach balances India's TRIPS obligations with its domestic developmental priorities, demonstrating how intellectual property rights can coexist with equitable access and industrial growth. The case further entrenched India's position as a champion of public health within the global IP regime. By translating the abstract principles of the Doha Declaration into enforceable domestic outcomes, Indian authorities demonstrated that international compliance and national welfare need not be in conflict. The compulsory license framework thus acts as a dynamic mechanism activated only in exceptional situations ensuring that patent monopolies do not hinder the right to health.

India's legislative innovation extends beyond its borders through Section 92A, which enables the manufacture and export of pharmaceutical products to countries lacking manufacturing

[16]Aggarwal, M., *[Title of the Paper]* (2004), available at *https://dr.ddn.upes.ac.in/bitstream/123456789/2004/1/Madhu%20Aggarwal.pdf* (accessed Dec. 4, 2025).

capabilities. This provision operationalizes the "Paragraph 6 Solution" under the Doha Declaration, allowing developing countries to meet urgent health demands through licensed generic production. It has transformed India into a critical supplier of affordable medicines to the Global South, reflecting the humanitarian dimension of its patent policy.

Effectiveness of compulsory licensing in Indian Patents Act in Balancing Public Welfare With Private Rights, and Specific Legislative Amendments Necessary

The Indian compulsory licensing (CL) mechanism, enshrined in the Patents Act, 1970, has shown mixed effectiveness in achieving its stated purpose of balancing public welfare with private rights. On one hand, its existence, bolstered by the landmark 2012 grant to Natco Pharma for the generic production of Bayer's anti-cancer drug Nexavar[17], serves as a critical deterrent against patent abuse, successfully demonstrating its potential to prioritize public health and ensure drug affordability. This single case proved the law's ability to correct market failure when a patented invention is neither accessible at a reasonable price nor worked in India to adequately meet public demand. However, the mechanism's overall effectiveness is limited by its low utilization rate (only one CL granted) and its unpredictable application, leading to subsequent rejections of CL applications (like those by BDR Pharmaceuticals and Lee Pharma) due to strict and arguably ambiguous procedural requirements.[18] This creates a perception of an effective tool that is paradoxically difficult to invoke, leading to legal uncertainty and limiting its utility as a predictable means to achieve public health objectives.

To enhance the effectiveness, predictability, and transparency of compulsory licensing in achieving public health objectives, specific legislative amendments and procedural reforms are necessary. A key reform involves clarifying the subjective criteria in Section 84(1). Specifically, the government should establish clear, quantifiable guidelines or a formula for determining a "reasonably affordable price," moving beyond merely comparing it to expensive substitutes. This would increase transparency and make the ground of unaffordability easier to prove. Procedurally, the mechanism for submitting Form 27 (Statement of Working of the Patented Invention) needs a radical overhaul. The current self-declaration format should be replaced with a system requiring audited, granular, and verified data on actual production,

[17] IJCRT (2025) Compulsory Licensing in India: A Legal and Economic Analysis. Available at: https://ijcrt.org/papers/IJCRT2503075.pdf (Accessed: 1 November 2025).

[18] **JETIR (2019)** *[Article Title Not Provided — JETIR1903730]*. Journal of Emerging Technologies and Innovative Research. Available at: *https://www.jetir.org/papers/JETIR1903730.pdf* (Accessed: 8 November 2025).

imports, and sales quantities, and the prices at which the product is made available to the public. Non-compliance or furnishing false information should incur severe, non-discretionary penalties, making the data in Form 27 a more reliable and transparent basis for assessing the patentee's failure to meet the "reasonable requirements of the public."

Legislative clarity is required for the application process itself. The requirement for a potential licensee to make "reasonable efforts to obtain a license" from the patentee before applying for a CL should be clarified with statutory timelines and defined parameters for what constitutes a genuine, good-faith negotiation attempt. This would reduce the current burden of proof that has led to the rejection of applications on procedural grounds. Finally, to leverage India's position as a global pharmaceutical manufacturer and align with the Doha Declaration on TRIPS and Public Health, the use of Section 92A (CL for export to countries with insufficient manufacturing capacity) should be actively facilitated by the government through clear administrative guidelines and a streamlined process for accepting notifications from importing countries.[19] These combined reforms, clarifying key definitions, increasing transparency in reporting, and streamlining procedures, would transform compulsory licensing from a strong, but rarely used, deterrent into a predictable and transparent mechanism for public health intervention.

Compulsory Licensing And Foreign Direct Investment

India’s compulsory licensing (CL) framework, detailed within the Patents Act, 1970, acts as a definitive policy instrument designed to reconcile intellectual property (IP) rights with the crucial public health objective of ensuring access to affordable medicines. The very existence of this policy, reinforced by its successful application most notably in the landmark 2012 *Natco v. Bayer* case—introduces significant regulatory uncertainty, which fulfills the theoretical mechanism for deterring Foreign Direct Investment (FDI) aimed at deep, high-risk New Chemical Entity (NCE) discovery. This perceived risk of IP erosion diminishes the expected Return on Investment (ROI) for global innovative firms, which rely on predictable market exclusivity to recoup massive development costs. The foundation of this system is India’s utilization of public health safeguards permitted under TRIPS flexibilities, particularly those

[19] **WTO (2001)** *Doha Declaration on the TRIPS Agreement and Public Health.* World Trade Organization. Available at: *https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm* (Accessed: 9th November 2025).

reaffirmed by the Doha Declaration on Public Health, ensuring that patent exclusivity is conditional upon national welfare objectives.

The Indian framework positions CL not merely as a tool for emergencies, but as an integral mechanism of market regulation codified in Chapter XVI of the Indian Patents Act.2 Any person, including a competitor, may apply for a CL after three years from the patent grant date if any of three conditions are fulfilled: the reasonable requirements of the public have not been satisfied; the invention is not available at a reasonably affordable price; or the invention is not "worked" in the territory of India. This relatively short three-year period and the broad socio-economic criteria signal to multinational corporations (MNCs) that IP rights are discretionary and conditional upon meeting public welfare obligations. This powerful regulatory threat, known as the "fear of CL," often coerces drug majors into strategic adaptations such as entering into Voluntary Licensing (VL) arrangements to preempt a government-mandated CL, thereby increasing efficiency and lessening the gestation period for access to affordable drugs .

The 2012 decision concerning *Bayer Corporation vs. Natco Pharma Ltd.* represents the most consequential application of these CL provisions, establishing a critical precedent. The dispute centered on Nexavar (Sorafenib tosylate), an expensive kidney cancer drug patented by Bayer, for which Natco Pharma sought a CL, citing Bayer's failure to meet the requirements of Section 84. In granting the CL, the Controller and the Intellectual Property Appellate Board (IPAB) firmly adopted a public health perspective, ruling that the price was unaffordable for the majority of the public, thereby confirming that the reasonable requirements of the public were not being met. Crucially, the ruling also established that mere importation does not satisfy the requirement for the patented invention to be adequately "worked in the territory of India," thereby making local manufacturing and affordable pricing structural prerequisites to avoid a CL grant. Natco was ordered to pay a royalty of 7% of its net sales to Bayer while selling the drug at a drastically reduced, affordable price. This ruling sent a definitive policy signal: the state's constitutional obligation to improve public health must prevail, and patent protection cannot be exercised at the cost of human lives.

However, the measurable impact on aggregate Foreign Direct Investment (FDI) inflows into the pharmaceutical sector has been complex and notably non-catastrophic, suggesting that deterrence is selective rather than absolute.The pharmaceutical sector was the fifth biggest sectoral recipient of FDI between 2000 and 2013, attracting US$9.225 billion, with over

US$4.5 billion invested in the three years immediately leading up to and including the *Natco* CL ruling, demonstrating that India's large market size and growth potential outweigh the specific CL risk for many investments.[20] The deterrence manifests primarily as a shift in the *type* of foreign investment: MNCs are compelled toward strategic collaborations and brownfield (existing) Mergers and Acquisitions (M&A) to acquire local manufacturing capacity, which satisfies the "working in India" requirement and mitigates CL risk. [21]MNCs continue to utilize India for substantial clinical trial activities, citing compelling operational advantages such as cost savings, the large pool of potential subjects, and the country's disease profile, confirming that high IP regulatory hurdles do not deter all forms of R&D-related investment.

Regarding domestic Research and Development (R&D) and innovation, the CL mechanism, paired with the Bolar Exemption (Section 107A(a)), structurally reinforces India's comparative advantage in *process R&D* (generic manufacturing) by allowing generic companies to prepare products for immediate launch upon patent expiry or CL grant. This dual strategy has solidified India's role as the "pharmacy of the developing world". [22]Yet, this strategy comes at a measurable cost: India's total national R&D expenditure (Gross Expenditure on R&D, GERD) remains persistently low at only 0.70% of GDP, making it the lowest among major BRICS nations (e.g., China at 2.20%), quantifying the structural innovation gap in high-cost NCE development . While R&D investment among Indian pharmaceutical companies (IPCs) increased post-2005, analysis shows that R&D intensity and export revenues for IPCs have not increased significantly from 2012 to 2019, confirming that domestic firms utilize the favorable legal environment to reinforce their established, generic-focused business model rather than undertake the high-capital, high-risk pivot toward NCE discovery. In sum, the measured impact of CL is a trade-off where access is prioritized and generic capacity thrives, but foundational R&D investment for novel drugs is structurally constrained by the inherent regulatory uncertainty surrounding the interpretation of CL criteria. To foster sustainable, high-value growth, regulatory predictability regarding the specific conditions for CL must be significantly enhanced.

---

[20] **MeitY (2024)** *Report, Ministry of Electronics and Information Technology.* Available at: *https://www.meity.gov.in/static/uploads/2024/02/24rpr.pdf* (Accessed: 16 November 2025).

[21] **PhRMA (n.d.)** *Compulsory Licensing: A Misused and Abused International Trade Law.* PhRMA. Available at: *https://phrma.org/blog/compulsory-licensing-a-misused-and-abused-international-trade-law* (Accessed: 16 November 2025).

CONCLUSION

Compulsory licensing in India represents a carefully constructed attempt to balance patent exclusivity with public health imperatives. Although the legislative framework under Sections 84, 92, and 100 is robust and aligned with TRIPS flexibilities, its practical impact has remained limited. The experience since the 2012 Natco–Bayer case demonstrates that compulsory licensing continues to function more as an exceptional remedy than a regularly accessible tool for ensuring affordable medicines. Procedural delays, ambiguous statutory language, institutional hesitation, and diplomatic pressures have collectively constrained its effectiveness. As a result, the mechanism has not yet fulfilled its full potential as a reliable instrument of public health governance.

However, the limitations observed are not structural flaws but **gaps that can be addressed through targeted reforms**. Clarifying legislative ambiguities, streamlining administrative procedures, improving transparency in governmental decision-making, and bolstering institutional capacity would substantially enhance the system's ability to protect public interest without undermining innovation. **Therefore through this paper it is proved that compulsory licensing under the Indian Patents Act, 1970, is ineffective in its objective of ensuring affordable public access to essential products due to key legal and procedural flaws.**

Hence, a strengthened compulsory licensing regime supported by broader public health initiatives can reinforce India's longstanding commitment to affordable healthcare while maintaining a stable and predictable patent environment. With these reforms, compulsory licensing can evolve from a rarely used legal provision to a meaningful, balanced, and effective tool for achieving both public welfare and sustainable innovation.

RECOMMENDATION

- Introduce Precise Statutory Definitions: The Patents Act must be amended to include precise statutory definitions for key terms, specifically "reasonable requirements of the public" and "reasonably affordable price," to eliminate inconsistent interpretations by authorities and courts.

- Define Parameters for Key Terms: These precise definitions (from point 1) must be based on public health needs, income profiles, and market access indicators to provide clear

parameters that reduce litigation and expedite decision-making.

- Implement Strict Procedural Timelines: The CL process must be strengthened by introducing strict, time-bound procedural timelines at both the Patent Office and the appellate stage before Commercial Courts to address the urgency of public health situations.

- Strengthen Technical Expertise and Benches: Delays should be reduced by introducing statutory deadlines, fast-track benches for pharmaceutical matters, and by significantly improving the technical expertise among patent officials.

- Proactive Policy for Emergency Provisions: The government should adopt a more proactive and transparent policy framework for invoking Section 92 (national emergency/extreme urgency) and Section 100 (government use).

- Specify Activation Triggers for Sections 92: This proactive policy must clearly specify the conditions under which these mechanisms may be activated, such as during pandemics, essential drug shortages, or situations of exploitative pricing, ensuring predictable use.

- Establish Uniform Royalty Guidelines: Royalty determination under Section 90 must be governed by clear and uniform guidelines that successfully balance fair compensation to the patentee with the core objective of public affordability.

- Clarify the Patent Working Requirement: The "working requirement" must be strengthened by clarifying what constitutes adequate local manufacturing or technology transfer to encourage patentees to improve domestic availability of the patented invention.

- Integrate CL Policy with Public Health Strategy: India must integrate the compulsory licensing policy with broader public health strategies, including incentivizing voluntary licensing, improving procurement systems, and promoting domestic R&D capacity, for long-term structural improvement in access to medicines.

REFERENCES

WIPO (n.d.) About Intellectual Property. Available at: https://www.wipo.int/en/web/about-ip (2nd October 2025).

IJCRT (2025) Compulsory Licensing in India: A Legal and Economic Analysis. International Journal of Creative Research Thoughts (IJCRT), Vol. 13, Issue 3, Paper ID: IJCRT2503075. Available at: https://ijcrt.org/papers/IJCRT2503075.pdf (Accessed: 2 October 2025).

JETIR (2019) A Study on Compulsory Licensing under the Indian Patent Law. Journal of Emerging Technologies and Innovative Research (JETIR), Vol. 6, Issue 3, Paper ID: JETIR1903730. Available at: https://www.jetir.org/papers/JETIR1903730.pdf (Accessed: 2 October 2025).

Basheer, S. and Mani, A. (2006) The "Compulsory Licence" Regime in India: Past, Present and Future. ResearchGate. Available at: https://www.researchgate.net/publication/228173575_The_'Compulsory_Licence'_Regime_in_India_Past_Present_and_Future (Accessed: 2 October 2025).

Liu, K. (2012) Compulsory Licensing and the Public Health Exception to Patent Protection in the TRIPS Agreement. Harvard International Law Journal, Vol. 53, No. 2, pp. 561–589. Available at: https://journals.law.harvard.edu/ilj/wp-content/uploads/sites/84/561Liu.pdf (Accessed: 2 October 2025).

IIPRD (2020) How Bayer Lost Its Monopoly: The Story Behind India's First Compulsory License. IIPRD Blog. Available at: https://www.iiprd.com/how-bayer-lost-its-monopoly-the-story-behind-indias-first-compulsory-license/ (Accessed: 2 October 2025).

IJIRL (2023) Compulsory Licensing in India: Natco vs Bayer Case and Its Impact in India. International Journal of Indian Research Law (IJIRL). Available at: https://ijirl.com/wp-content/uploads/2023/12/COMPULSORY-LICENSING-IN-INDI-NATCO-VS-BAYER-CASE-IMPACT-IN-INDIA.pdf (Accessed: 2 October 2025).

Jensen, E. (2015) Balancing Innovation and Access: Compulsory Licensing in International Patent Law. Brigham Young University Prelaw Review, Vol. 29, Article 3. Available at: https://scholarsarchive.byu.edu/cgi/viewcontent.cgi?article=1303&context=byuplr (Accessed:

2 October 2025).

Manupatra (2018) Compulsory Licensing in India: An Overview. Manupatra Newsline. Available at: http://docs.manupatra.in/newsline/articles/Upload/93092AEC-D7C8-4C1E-9219-3B4CB5DAE8F9.pdf (Accessed: 19th November 2025).

iPleaders (2021) Bayer Corporation vs. Natco Pharma Ltd: A Case Analysis. iPleaders Blog. Available at: https://blog.ipleaders.in/bayer-corporation-vs-natco-pharma-ltd-a-case-analysis/ (Accessed: 21st Novemver 2025).

Radhi Shah, "Compulsory License: India," Kluwer Patent Blog (Aug. 16, 2021), available at https://legalblogs.wolterskluwer.com/patent-blog/compulsory-license-india/ (accessed Dec. 1, 2025).

Compulsory Licensing & Public Interest in India, Brainiac), available at https://brainiac.co.in/compulsory-licensing-and-public-interest-in-india (accessed Dec. 2, 2025).

Deli Yang, "Compulsory Licensing: For Better or For Worse — the Done Deal Lies in the Balance," 17 J. Intell. Prop. Rights 76 (Jan. 2012), available at http://docs.manupatra.in/newsline/articles/Upload/76691AEF-0A18-46A4-9CA8-84E09668D815.pdf (accessed Dec. 2, 2025).

WTO, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed Dec. 4, 2025).

Aggarwal, M., [Title of the Paper] (2004), available at https://dr.ddn.upes.ac.in/bitstream/123456789/2004/1/Madhu%20Aggarwal.pdf (accessed Dec. 4, 2025).

IJCRT (2025) Compulsory Licensing in India: A Legal and Economic Analysis. Available at: https://ijcrt.org/papers/IJCRT2503075.pdf (Accessed: 1 November 2025).

JETIR (2019) [Article Title Not Provided — JETIR1903730]. Journal of Emerging Technologies and Innovative Research. Available at: https://www.jetir.org/papers/JETIR1903730.pdf (Accessed: 8 November 2025).

WTO (2001) Doha Declaration on the TRIPS Agreement and Public Health. World Trade Organization. Available at: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (Accessed: 9th November 2025).

MeitY (2024) Report, Ministry of Electronics and Information Technology. Available at: https://www.meity.gov.in/static/uploads/2024/02/24rpr.pdf (Accessed: 16 November 2025).

PhRMA (n.d.) Compulsory Licensing: A Misused and Abused International Trade Law. PhRMA. Available at: https://phrma.org/blog/compulsory-licensing-a-misused-and-abused-international-trade-law (Accessed: 16 November 2025).