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COMPULSORY LICENSING IN INDIA: BALANCING PATENT RIGHTS AND PUBLIC HEALTH

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Summary

This paper examines compulsory licensing (CL) in India as a cloistered legal tool to balance patent rights and public health concerns, particularly for medicines. The paper suggests that, far from being anti-patent, Indian law employs CL as a moderating measure when exclusivity causes severe access, affordability or supply issues. The Indian model primarily relies on Section 84, 92 and 92A of the Patents Act to be read with the underlying public-interest principles in Section 83 and the terms of licenses in Sections 89 and 90.[1]

Overall, the statutory model is welfare oriented. The Act does not consider patents as sacrosanct private rights separated from public ends. Rather, it associates patent rights with public good, reasonable access and reasonable availability, while ensuring compensation to the patentee through royalty and other licence conditions.

In practice, however, pharmaceutical CL has been used rarely in India. The conventional wisdom in legal and policy literature is that only one Section 84 pharmaceutical compulsory licence has been issued: the 2012 licence for sorafenib. Subsequent applications have typically failed because applicants have been unable to meet the evidentiary, procedural or negotiating requirements of the statute.[2]

The sorafenib decision is important because it provided flesh for the main statutory tests under Section 84. It demonstrated that the Controller would scrutinise the question of whether patients were served, the question of whether the patented product was reasonably affordable in the Indian market and the question of whether the patentee's working in the country could be justified. It further demonstrated that licence terms can be set to lower price while maintaining remuneration.

[1] The Patents Act, No. 39 of 1970, 84, 92, 92A (India); Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31bis, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[2] The Patents Act, No. 39 of 1970, S 83 (India).

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The takeaway from this paper is that India considers CL to be an extraordinary, evidence-based remedy, rather than a first-line remedy for price regulation. The post-2012 denials suggest that Indian authorities require specific evidence, genuine attempts to obtain a voluntary licence and the ability to produce and supply before interfering with patent rights.

The experience of COVID-19 confirmed this. Courts noted that India's law provides for emergency measures such as compulsory licensing and government-use provisions, but also that their invocation largely depends on executive decisions and the capacity to act. So, law availability doesn't necessarily translate into deployment.[3]

In contrast, India's conservative approach stands in contrast with more aggressive use of public-health licensing. Brazilian and Thai experiences indicate that non-voluntary licensing can impact prices and procurement if it is supported by administrative commitment and implementation considerations. Similarly, discussion of South African policy highlights the importance of procedure and institutional design for accessibility.[4]

The innovation debate remains mixed. Some commentators argue that compulsory licensing weakens incentives, but the available literature does not support a single universal conclusion. Much depends on the sector, timing, market structure, and the way the measure is implemented. The stronger view is that CL should be assessed as a context-specific regulatory tool rather than through abstract assumptions alone.

So, the policy implication for India is not to broaden the text of the law (the grounds are already very wide). Instead, it is the operational details that are important: clearer criteria on affordability, working, disclosure and evidence; more reliable guidance on royalties; and a crisis-proof process for accessing the Section 92/100 provisions when access crises arise.[5]

[3] Natco Pharma Ltd. v. Bayer Corp., Compulsory Licence Application No. 1 of 2011 (Controller of Patents, Mumbai Mar. 9, 2012) (India); Bayer Corp. v. Natco Pharma Ltd., OA/35/2012/PT/MUM (Intell. Prop. App. Bd., Chennai Mar. 4, 2013) (India); In re Distribu tion of Essential Supplies & Services During Pandemic, Suo Motu W.P. (C) No. 3 of 2021 (Sup. Ct. India Apr. 30, 2021).

[4] Natco Pharma Ltd. v. Bayer Corp., Compulsory Licence Application No. 1 of 2011 (Controller of Patents, Mumbai Mar. 9, 2012) (India); Bayer Corp. v. Natco Pharma Ltd., OA/35/2012/PT/MUM (Intell. Prop. App. Bd., Chennai Mar. 4, 2013) (India).

[5] In re Distribution of Essential Supplies & Services During Pandemic, Suo Motu W.P. (C) No. 3 of 2021 (Sup. Ct. India Apr. 30, 2021); Lok Sabha Unstarred Question No. 1738, Domestic Production of COVID Vaccines (answered Aug. 3, 2021) (India).

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Abstract

This paper examines compulsory licensing in India as a legal mechanism through which patent law responds to public health concerns. Using the Patents Act, leading administrative and judicial materials, and selected comparative examples, it asks how Indian law structures CL, how the framework has been applied in practice, and what this reveals about access, pricing, and innovation policy. The paper argues that Indian law contains substantial flexibility on paper, but actual use has been cautious and heavily conditioned by proof, procedure, and institutional choice. It concludes that the effectiveness of CL in India depends less on formal statutory breadth on consistent standards, administrative preparedness, and credible implementation.[6]

Introduction

Pharmaceutical patent law sits at the intersection of incentive and access. Patent protection is meant to reward invention and disclosure, yet the same exclusivity may also enable high prices or restricted availability when medicines are urgently needed. Compulsory licensing emerged as one of the legal responses to this tension. It allows use without the patentee's consent, but only within a regulated framework that preserves compensation and limits the intervention to defined public purposes.

In India, this balancing function is not implicit; it is written into the structure of the Patents Act itself. Section 83 signals that patents should serve technological progress and public benefit together. As a result, Indian patent law is better understood as a public-regulatory statute with private-right dimensions, rather than as a purely exclusionary property regime.[7]

The Indian framework must also be read alongside international law. TRIPS permits non-voluntary use under specified conditions, and "the Doha Declaration confirmed that members retain policy space to protect public health. These instruments do not eliminate patent rights, but they make clear that patent protection may be limited where access concerns justify intervention and procedural safeguards are respected.[8]

[6] The Patents Act, No. 39 of 1970, S 84, 92, 92A, 100 (India); Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001)
[7] The Patents Act, No. 39 of 1970, S 83 (India).
[8] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; World Trade

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India's later amendments to patent law reflect this dual commitment. Compliance with the post-TRIPS order required India to strengthen parts of its patent regime, but the law also preserved flexibilities relevant to medicines, including compulsory licensing, export-oriented licensing, and related public-interest mechanisms. The resulting framework is therefore a negotiated balance rather than a one-sided shift toward stronger exclusivity.

This debate remains significant because access to essential treatment continues to be uneven, particularly where patented therapies are expensive, and public or insurance coverage is limited. In such settings, the legal question is not whether innovation matters; it is how a patent system should respond when the social cost of exclusivity becomes too high. That is the question of compulsory licensing forces into the open.[9]

This paper addresses the following research questions:
First, what is the operative legal framework for compulsory licensing in India, and how do procedural requirements and statutory grounds structure the Controller's discretion?
Second, how have Indian institutions applied these rules in landmark matters, particularly the 2012 sorafenib licence and subsequent refusals?
Third, what does the empirical evidence suggest about CL's effects on access and innovation, and how should India refine its approach in routine and emergency contexts?

A brief timeline provides historical orientation:

(Timeline) **Title Key milestones shaping compulsory licensing in India and global public health flexibilities**	
1970	Patents Act enacted (CL and working framework)
1995	TRIPS Agreement enters into force
1999	Patents (Amendment) Act introduces mailbox/EMR transition
2001	Doha Declaration on TRIPS and Public Health
2002	Patents (Amendment) Act revises CL architecture
2005	Patents (Amendment) Act introduces product patents and inserts

Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001); Protocol Amending the TRIPS Agreement, Dec. 6, 2005, entered into force Jan. 23, 2017.
[9] Nat'l AIDS Control Org., Ministry of Health & Family Welfare, Gov't of India, India HIV Estimates 2023: Technical Report (2024); Int'l Agency for Research on Cancer, India Fact Sheet (GLOBOCAN 2022) (2024)

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	Section 92A (export CL)
2012	First widely documented pharma CL granted (sorafenib/Nexavar)
2014	Bombay HC upholds CL and clarifies aspects of "working
2017	TRIPS Article 31bis (Paragraph 6 system) enters into force
2021	Supreme Court highlights Sections 92/100/102 in COVID-19 context

This timeline is drawn from primary legislation and recognised international instruments, as well as widely cited case material.

Literature Review

The literature on compulsory licensing in India can be grouped into several recurring debates. One body of writing focuses on statutory interpretation, especially the meaning of affordability, working, and unmet public requirements. A second examines CL through the lens of TRIPS and the Doha framework. A third looks at the political economy of patent enforcement", including trade pressure and industry reaction. A fourth evaluates whether CL actually improves access or affects innovation in measurable ways.[10]

Writings in the first group generally treat Section 83 as central to understanding Indian patent law. The provision is often read as more than a prefatory statement: it guides how later provisions should be understood, particularly where the statute requires the Controller to balance exclusivity against broader public need. This helps explain why debates on affordability and local working carry unusual weight in Indian scholarship.[11]

The international-law literature places India's regime within the broader system of TRIPS flexibilities. Here the key point is not merely that compulsory licensing is allowed, but that its legitimacy depends on how domestic law translates international conditions into workable procedures. Section 92A, for example, is frequently discussed as India's legislative response to the post-Doha export mechanism, showing how global access problems shaped national patent design.[12]

[10] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001); Eduardo Urias & Sveta Ramani, Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence, 3 J. Int'l Bus. Pol'y 367 (2020)
[11] The Patents Act, No. 39 of 1970, S 83, 84, 90 (India)
[12] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001); Protocol Amending the TRIPS Agreement, Dec. 6, 2005, entered into force Jan. 23, 2017

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A separate strand emphasizes politics and regulatory signaling. After the sorafenib licence, industry groups and some foreign policy actors portrayed Indian CL as a threat to the innovation environment. In contrast, health-focused commentators argued that India's actual practice was too restrained to justify such alarm. The disagreement is therefore not just about doctrine, but about what message compulsory licensing sends to markets and governments.

Empirical writing offers a more nuanced picture than either side of the policy debate often admits. Studies generally suggest that CL can lower prices or improve access under some conditions, but they also show that outcomes depend on procurement systems, manufacturing capacity, timing, and supporting regulation. Put differently, a licence on paper does not by itself ensure therapeutic access.[13]

Indian commentary repeatedly returns to the Natco-Bayer matter because it translated broad statutory language into applied standards. Scholars use it to discuss the meaning of affordable pricing, the role of patients needs evidence, and the extent to which importation can satisfy the working requirement. Subsequent refusals are equally important because they indicate that the first license did not normalize routine intervention.

COVID-era writing re-opened these themes in a more urgent setting. Courts, policy commentators, and public health advocates all highlighted compulsory licensing and government-use powers, but many also noted the limits of patent-based solutions where manufacturing know-how, raw materials, and administrative coordination are missing. This literature is useful because it shifts attention from legal possibility to practical capacity.

Taken together, the literature does not support either extreme claim: that compulsory licensing is a complete answer to access problems, or that it is inherently destructive of innovation. The more defensible conclusion is that CL is a contingent policy instrument whose value depends on legal clarity, fair procedure, credible remuneration, and the state's ability to translate authorization into actual supply.

[13] Joerg Baten, Nicola Bianchi & Petra Moser, Does Compulsory Licensing Discourage Invention? Evidence from German Patents After WWI, NBER Working Paper No. 21442 (2015); Petra Moser & Alessandra Voena, Compulsory Licensing: Evidence from the Trading with the Enemy Act, 102 Am. Econ. Rev. 396 (2012).

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Method and Analytical Framework

This paper uses a mixed legal-policy method combining doctrinal, comparative, and secondary empirical analysis.

The doctrinal component is centered on the text and structure of the Patents Act. It examines the main compulsory licensing provisions, related public-interest principles, and adjacent mechanisms such as government use and parallel importation. The purpose is to identify how Indian law allocates discretion, what conditions must be met, and how the statute channels decision-making.[14]

The case-study component then tests that framework against practice. The sorafenib licence serves as the principal reference point because it is the clearest example of an actual grant. Later refusals, along with COVID-era judicial discussion, are used to show how the statutory grounds operate under pressure and where institutional hesitation appears.

The comparative element is selective rather than exhaustive. Brazil, Thailand, and South Africa are used as reference jurisdictions because each illustrates a different institutional model for dealing with access-related patent conflict. The comparison is aimed at implementation lessons, not at claiming that these systems can be transplanted directly into India.

The empirical material used here is documentary and secondary. It includes publicly reported price differences, government and international materials, and peer-reviewed scholarships on access and innovation effects. The paper uses these materials cautiously, mainly to support bounded policy inferences rather than broad causal claims.[15]

The analysis is guided by a proportionality-based understanding of patent limitations. On this view, compulsory licensing is justified where it responds to a legitimate public objective and is structured no more broadly than necessary. This approach fits both the architecture of Indian law and the conditional nature of TRIPS Article 31.

The method has obvious limits. Public data on applications, outcomes, and royalty calculations

[14] The Patents Act, No. 39 of 1970, S 83–94, 100, 107A(b) (India)
[15] Robert Steinbrook, Thailand and the Compulsory Licensing of Efavirenz, 356 New Eng. J. Med. 544 (2007); Adun Mohara et al., Impact of the Introduction of Government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand, 15 Value Health S95 (2012).

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is incomplete, especially outside the best-known pharmaceutical matters. In addition, price and innovation effects are difficult to isolate with precision. For that reason, the paper focuses on reasoned legal and policy analysis rather than strong claims of universal economic impact.

Findings and Discussion

Legal architecture in India: multiple pathways, one core design principle:

India's compulsory licensing regime is concentrated in Chapter XVI of the Patents Act, but its meaning becomes clearer only when read together with the statute's public-interest provisions. Section 84 creates the ordinary route through which a person interested may seek a licence after the prescribed time on grounds connected to public need, affordability, or working. The design is significant because it does not assume that patent exclusivity should end merely because a product is expensive; instead, it requires a structured showing that the statutory balance has broken down.[16]

Section 92 operates differently. It is intended for situations in which the Central Government considers the circumstances serious enough to justify accelerated access to patented subject matter, such as emergency, urgency, or public non-commercial use. The provision therefore reduces some of the timing barriers that exist under Section 84, but it makes executive activation the central trigger.[17]

Section 92A extends the logic of compulsory licensing beyond domestic access by permitting manufacture and export of certain patented pharmaceutical products to countries lacking sufficient manufacturing capacity. This provision matters symbolically and legally because it places India within the international access framework developed after Doha, while also demonstrating that cross-border CL is more document-heavy and procedurally demanding than it may appear in abstract discussion.[18]

Alongside these provisions, the Act also contains government-use and acquisition of powers in Chapter XVII. Section 100 is especially important because it allows state-authorized use for governmental purposes subject to compensation. In policy terms, this can operate as a faster access mechanism than ordinary market-initiated litigation, particularly when the government itself is coordinating procurement or supply.[19]

[16] The Patents Act, No. 39 of 1970, S 84 (India).
[17] The Patents Act, No. 39 of 1970, S 92 (India)
[18] The Patents Act, No. 39 of 1970, S 92A (India); Protocol Amending the TRIPS Agreement, Dec. 6, 2005, entered into force Jan. 23, 2017
[19] The Patents Act, No. 39 of 1970, S100 (India); In re Distribution of Essential Supplies & Services During Pandemic, Suo Motu W.P. (C) No. 3 of 2021 (Sup. Ct. India Apr. 30, 2021)

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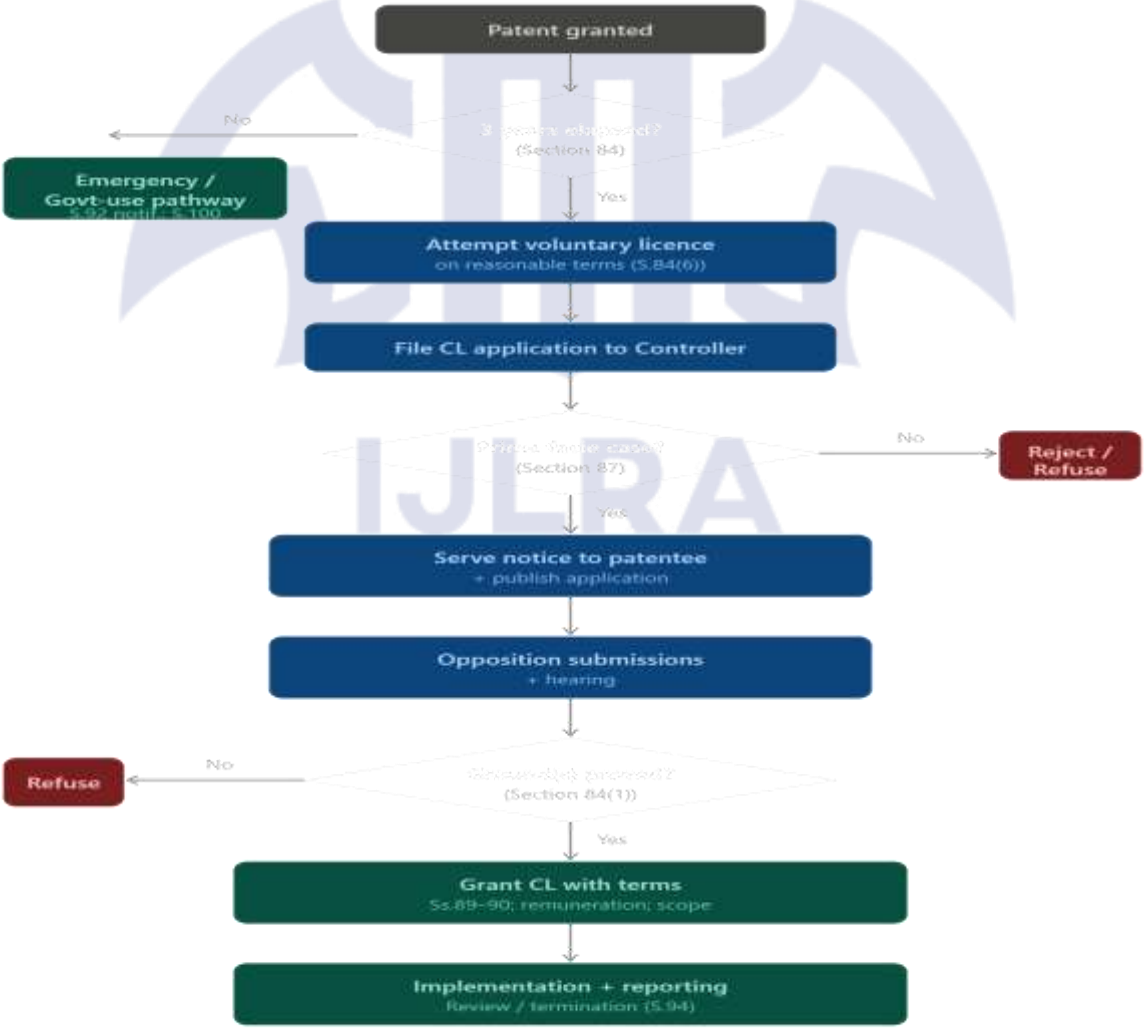
Indian law also includes measures that do not amount to compulsory licensing but can still affect access, such as parallel importation. These tools matter because they show that the access debate is not binary. Compulsory licensing is only one part of a broader regulatory toolkit for responding to monopoly pricing or supply constraints.

Process design: structured, adversarial administrative proceedings.

The Section 84 process is best understood as a controlled administrative adjudication. The Controller does not move directly to a licence merely because an application is filed; there is an initial screening stage, followed by notice, opposition, and reasoned determination if a prima facie case is made out. This process protects patentees from casual disruption while also requiring applicants to come forward with concrete material rather than broad assertions.

A simplified procedural map is set out below:



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This flow reflects the statutory sequencing built into Sections 84 and 87 and the emergency/govt-use alternatives reflected in Sections 92 and 100.

Landmark Indian experience: the 2012 sorafenib CL as doctrinal anchor:

The best-known Indian compulsory licensing decision concerns sorafenib. Its importance lies not only in the result, but in the way it gave practical content to terms that otherwise remain open-ended in the statute. The matter became the reference point for later debate precisely because it showed what sort of access failure could justify intervention under Indian law.

The pricing issue was central. Publicly reported figures showed a very large gap between the originator price and the price permitted under the license. That contrast became a concrete illustration of how the Controller might assess affordability in the Indian market, not as an abstract economic concept but as a question tied to real therapeutic access.

Royalty was equally significant because it demonstrated that compulsory licensing does not mean confiscation. Even while intervening to improve access, the licensing authority preserved payment to the patentee. The dispute over the appropriate rate also revealed why remuneration remains one of the most contested aspects of CL design.

The decision also shaped later understanding of Section 84's grounds. It highlighted the relationship between public requirements, affordability, and working, and showed that these issues are often analyzed together rather than in complete isolation. For that reason, the case became a practical benchmark against which later applicants were measured.[20]

More broadly, the sorafenib matter showed that Indian compulsory licensing is framed as a corrective mechanism rather than a punitive one. The intervention was justified through structured statutory reasoning, and the license terms were tailored to access needs while preserving the patentee's entitlement to remuneration.

[20] Natco Pharma Ltd. v. Bayer Corp., Compulsory Licence Application No. 1 of 2011 (Controller of Patents, Mumbai Mar. 9, 2012) (India).

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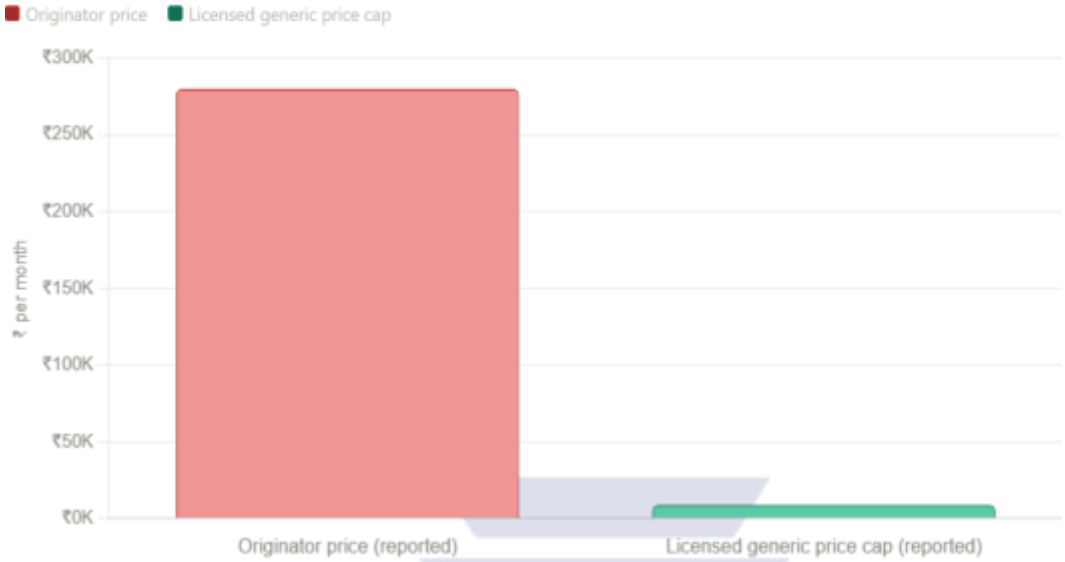
A simple visualization of the indicative price differential (as reported in public materials) is below.



The price figures are widely reported in civil society and commentary materials discussing the first Indian CL.

Subsequent applications: a pattern of high evidentiary and procedural thresholds:

The cases that followed the first license are important because they reveal the limiting side of the Indian model. Once the initial symbolic case had passed, later applicants faced a much stricter practical question: could they actually prove the factual and procedural basis for disturbing patent exclusivity? In most cases, the answer was no.

The dasatinib matter is commonly cited for the idea that compulsory licensing is a remedy of last resort. The reported reasoning places substantial weight on prior efforts to obtain a voluntary licence and on the quality of the applicant's preparation. This shows that the statute expects negotiation and evidence, not simply dissatisfaction with price.

The saxagliptin matter reinforces the same trend. The refusal is often discussed as an example of strict scrutiny at the threshold stage, particularly where the applicant could not convincingly establish unmet public need, contextual unaffordability, or the absence of viable alternatives in the market.

Taken together, these refusals suggest that the statutory grounds may be independent in theory but intertwined in practice. Weakness in proving one aspect of the case often affects the persuasiveness of the others, especially where the Controller is not convinced that intervention

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will produce meaningful public benefit.[21]

Attempts and "near misses": Herceptin controversy and export CL hurdles:

The Herceptin debate illustrates a different problem: not every high-profile access concern matures into formal compulsory licensing. Even where pricing controversy exists, the emergency-style route depends on governmental willingness to activate it, and that additional political step can prevent the process from moving forward.

The legal lesson is straightforward. Section 92 is potentially powerful, but it cannot function autonomously. Unlike Section 84, it requires prior executive action, and without that action the emergency pathway remains unavailable regardless of the seriousness of the underlying access concern.

Export-oriented licensing under Section 92A presents another set of constraints. Commentaries on early attempts show that legal availability does not remove documentary and coordination burdens. For exporting CL to work, domestic procedure must align with the regulatory position of the importing state, which makes the mechanism slower and more technical than ordinary rhetoric suggests.

Public-health emergencies: COVID-19 and the gap between legal tools and implementation:

The COVID-19 second wave brought the distance between legal power and implementation into sharp focus. The Supreme Court referred to compulsory licensing and government-use provisions as part of the legal toolbox available to the state, but the episode also made clear that courts would not themselves operationalize those provisions in place of executive policy.

That moment is important because it exposed a recurring weakness in access debates: legal authority is often discussed as though it was self-executing. A public-health response requires administrative decisions, procurement planning, manufacturing capacity, and sometimes technology transfer. Without those elements, even a legally valid licence may have limited practical value.[22]

[21] BDR Pharms. Int'l Pvt. Ltd. v. Bristol-Myers Squibb Co., C.L.A. No. 1 of 2013 (Controller of Patents, Mumbai Oct. 29, 2013) (India); Lee Pharma Ltd. v. AstraZeneca AB, C.L.A. No. 1 of 2015 (Controller of Patents, Mumbai Jan. 19, 2016) (India).

[22] In re Distribution of Essential Supplies & Services During Pandemic, Suo Motu W.P. (C) No. 3 of 2021 (Sup. Ct. India Apr. 30, 2021); Lok Sabha Unstarred Question No. 1738, Domestic Production of COVID Vaccines (answered Aug. 3, 2021) (India).

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Remuneration: Section 90, TRIPS Article 31(h), and royalty methodology:

Remuneration sits at the center of the legitimacy of debate. TRIPS requires adequate remuneration, and Indian law likewise expects royalty and related terms to reflect both the patentee's interests and the public purpose behind the authorization. This means that royalty design is not a side issue; it is part of the legal justification for compulsory licensing itself.

Section 90 reflects this balancing approach by directing the authority to shape licence terms in a way that encourages supply, preserves affordability, and ensures payment to the right holder. The sorafenib experience is therefore useful not just because a rate was fixed, but because it shows how access and compensation must be calibrated together.

From a policy perspective, the absence of more formal royalty guidance creates uncertainty for all sides. Patentees may fear unpredictable intervention, while applicants may struggle to assess whether a license is commercially workable. Greater transparency in methodology could therefore improve both fairness and credibility.

Compulsory licensing should also be viewed alongside other access mechanisms. Voluntary licenses may sometimes be faster or less contentious, while the possibility of CL can still influence bargaining positions in the background. The relationship is therefore strategic rather than oppositional.

Parallel importation offers a further route for reducing prices where lawful lower -priced supply exists elsewhere. It is not a substitute for compulsory licensing in every case, but it shows that Indian patent law contains multiple pressure points through which access problems may be addressed.

Government use under Section 100 reinforces this broader toolkit. In situations where the state is centrally involved in procurement or distribution, government-authorized use may be institutionally simpler than a contested private application under Section 84. Its significance lies in speed and administrative control.

Industry perspective and external pressure: OPPI and USTR materials:

A balanced analysis must also acknowledge industry concerns. Critics of compulsory licensing often argue that unpredictable intervention may affect investment incentives or the broader innovation climate. These concerns cannot be dismissed outright, but neither should they be accepted without examining India's actual practice, which has been notably restrained.

What emerges is that compulsory licensing in India functions not only as a legal doctrine but also as a signal in trade and regulatory politics. This makes transparency especially important. The more predictable the standards and reasoning, the easier it becomes for India to preserve

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public-health flexibility without creating an appearance of arbitrariness.

Comparative lessons: Brazil, Thailand, and South Africa:

Comparative experience suggests that the effectiveness of compulsory licensing depends heavily on institutional design. The formal existence of a legal power matters less if procedures are slow; activation is politically costly, or implementation is detached from procurement and supply planning.

Brazil and Thailand are often cited because they show that non-voluntary licensing can have stronger practical effects when public authorities are willing to use it as part of a broader health strategy. South African policy materials, by contrast, highlight how procedural complexity can weaken usability. These examples do not map perfectly onto India, but they illustrate how structure and administrative posture shape outcomes.[23]

A structured comparison is set out below.

Dimension	India	Brazil	Thailand	South Africa
Core legal route(s) for access-related non-voluntary use	Section-84 (market-initiated CL); Section 92 (notification-based); Section 92A (export); Section 100 (government use)	Public-interest CL used in HIV programmed (efavirenz)	Government-use licenses for medicines; multiple products in 2006–08	Policy notes CL subject to judicial process; proposes more efficient system
Institutional decision-maker	Patent Controller + judicial review; emergency route depends on Central Government notification	Executive/public health authorities (documented in case narratives)	Ministry of Public Health (government-use practice)	Courts (Commissioner of Patents) per policy description

[23]Robert Steinbrook, Thailand and the Compulsory Licensing of Efavirenz, 356 New Eng. J. Med. 544 (2007); Adun Mohara et al., Impact of the Introduction of Government Use Licenses on the Drug Expenditure on Seven

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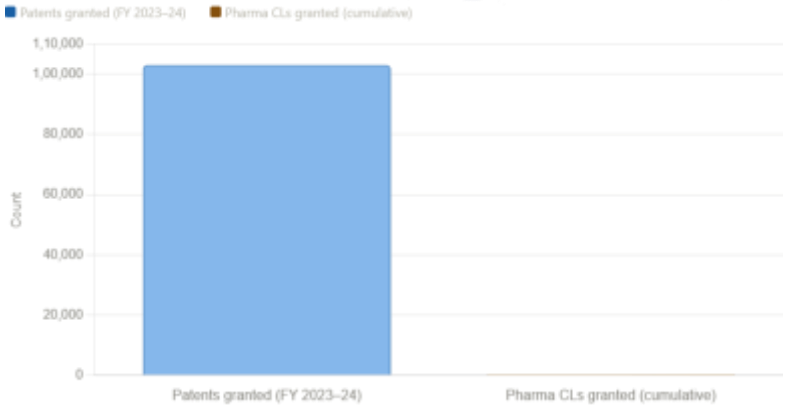
Documented practice intensity (health sector)	One widely documented pharma CL; later refusals; emergency discussions without issuance	Major CL episode in HIV; used strategically in negotiations	Multiple government-use licenses; studied budget impact	Policy indicates underutilization due to process constraints
Key implementation lesson	High evidentiary thresholds can preserve certainty but weaken leverage; crisis tools require executive activation and coordination	Credible threat + willingness to issue CL can strengthen negotiation position	Integration with procurement and health budgets is critical for measurable access gains	Court-driven processes can slow access; administrative reforms may improve responsiveness

Scale disparity: patents granted versus CL granted.

To contextualize how rare CL is in India relative to the patent system's overall scale, consider patent grants. A Government of India release reports 103,057 patents granted in FY 2023–24. Against this backdrop, multiple sources emphasize that India has granted only one widely documented pharmaceutical CL to date.



This chart is not a like-for-like annual comparison; it is an illustration of rarity and institutional restraint.

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Landmark cases table (India): holdings most relevant to CL and public-interest balancing:

The following table consolidates key holdings and relevance. Case names are provided for clarity; the operative legal significance is drawn from available judicial/administrative material.

Matter (forum; year)	Core issue	Holding / outcome (public-interest relevance)	CL relevance
Sorafenib (Controller; 2012)	Section 84 grounds: unmet need, affordability, working	CL granted with price cap and royalty; access rationale foregrounded in reporting	First widely documented pharma CL; template for affordability/need analysis
Sorafenib (Bombay HC; 2014)	Judicial review of CL decision; "working" interpretation	CL upheld; appellate reasoning reported to nuance local working (import may satisfy in some contexts) and increased royalty on appeal in summaries	Clarifies standard of review and interpretation of "working"
Dasatinib (Controller; 2013)	Prima facie case; voluntary license efforts	Application rejected/failed at threshold for insufficient negotiation/evidence in reported materials	Demonstrates CL as last resort; high procedural burden
Saxagliptin (Controller; 2016)	Evidence of unmet need, affordability, substitutes	Application rejected; failure to establish Section 84 grounds at prima facie stage	Demonstrates strict evidentiary scrutiny and market-context analysis
COVID-19 suo motu proceedings	Emergency legal levers for	Court identified Sections 92/100/102 as possible tools;	Confirms legal availability of emergency tools;

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(Supreme Court; 2021)	vaccines/essential drugs	acknowledged executive policy discretion	highlights implementation gap
Erlotinib litigation (Delhi HC; 2008–2015)	Injunctions in life-saving drugs and public interest	Materials show public interest considered in interim relief analysis; later findings on infringement/relief varied across stages	Not a CL case, but shapes "public interest" narrative in pharma patent enforcement
Glivec patentability (Supreme Court; 2013)	Patentability standards and access implications	Patent refused under Section 3(d); illustrates design of India's patentability gatekeeping in pharma	Not CL, but part of broader access architecture and innovation debate

Conclusion and Policy Implications

Conclusion:

India's compulsory licensing regime is legally substantial and normatively defensible as a public-interest limitation within patent law. The statute provides more than one route for responding to access concerns, and its internal design shows that Indian patent protection was never intended to operate without social constraints.

At the same time, the practical record is one of caution. The sorafenib licence remains the clearest example of actual intervention, while later refusals and the COVID-era experience show that doctrinal flexibility does not automatically become administrative action. India's model is therefore strong in principle but selective in use.

This pattern can be read in more than one way. Supporters of restraint may see it as evidence of institutional discipline and investment sensitivity. Critics may see it as proof that procedural and political barriers have made an important public-health mechanism too difficult to deploy. The better conclusion is that India's framework has real legal capacity, but its success depends on clearer standards and stronger implementation pathways.

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Recommendations and Policy Implications:

The recommendations below aim to preserve TRIPS consistency, reduce arbitrariness perceptions, and improve responsiveness-especially for emergencies-while maintaining incentives through predictable remuneration and process fairness.

First, India should adopt a transparent affordability assessment framework for Section 84. The phrase "reasonably affordable price" is inherently contextual; however, predictability can be improved by requiring applicants (and patentees in response) to submit structured evidence on (i) disease burden and eligible patient pool, (ii) out-of-pocket burden under prevailing coverage conditions, (iii) price benchmarks across comparable markets, and (iv) availability of patient assistance or procurement discounts. A standard evidentiary template would reduce litigation by assertion and make decisions more reviewable.

Second, India should clarify "working in India" through guidance rather than ad hoc adjudication. The sorafenib appellate record is often cited for nuanced interpretation (import may count in some contexts), but uncertainty remains when local manufacturing is expected. Sector-specific guidance-especially biologics and complex therapies-could help balance industrial policy and access goals while respecting feasibility constraints.

Third, India should publish royalty/remuneration guidance aligned with TRIPS Article 31(h) and informed by WHO/UNDP methodologies. A presumptive royalty range with defined adjustment factors (therapeutic value, public financing of R&D, scale of market, and urgency) would improve confidence for both patentees and applicants and reduce perceptions of arbitrariness. The aim is not rigid tariffs but reasoned baselines that satisfy "adequate remuneration" with case-specific tailoring.

Fourth, for emergencies, India should develop an operational "Section 92/100 rapid-response protocol". The COVID-19 litigation demonstrates that courts recognize these tools but defer to executive choice. A protocol should specify trigger criteria for notification; timelines; coordination with drug regulators; procurement commitments; pathways for technology transfer where needed; and post-crisis review. Without such preparation, legal powers may remain unused in the moment of need.

Fifth, India should integrate CL policy with voluntary licensing and parallel importation strategy. In many cases, VL may be faster and less contentious; credible CL availability can strengthen VL bargaining, but only if the CL process is administratively credible and timely. Parallel importation, where feasible, can discipline prices without manufacturing. A health-access strategy should specify a hierarchy of tools-VL first, then parallel importation where possible, then CL/government use when necessary-with clear criteria for escalation.

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Sixth, India should enhance transparency and data infrastructure relevant to access decisions. Public reporting on availability, utilization, and patents' working status affects evidentiary quality in CL proceedings. Even without expanding grounds, better data would reduce contested factual uncertainty and enable more consistent adjudication and policy evaluation.

Finally, India's global role should inform Section 92A policy. Export CL is legally aligned with Doha/31bis, but early experience shows documentary hurdles. India could support capacity-building and standardized documentation channels with importing countries (especially least developed countries) so that the export mechanism becomes practically usable in global health contingencies.

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