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COMPULSORY LICENSING IN INDIA: A CRITICAL ANALYSIS OF THE LEGAL FRAMEWORK, JUDICIAL INTERPRETATION, REGULATORY CHALLENGES AND FUTURE REFORMS

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Abstract

India's Patents Act, 1970 offers one of the broadest compulsory licensing regimes permitted by the TRIPS Agreement, including affordability as an independent ground. Yet since the 2005 amendments only one license has been granted under Section 84, and the emergency powers in Section 92 have never been invoked, even during the COVID-19 pandemic. Existing scholarship usually attributes this disuse to political caution or to procedural rigidity. This article asks whether the design of Chapter XVI itself explains the gap between availability and use. Using doctrinal analysis of the statute, rules and decisions of the Controller, the Appellate Board and the Bombay High Court, with a functional comparison with the United States, Brazil and Canada, it advances a structural thesis. Chapter XVI frames what is in substance a public-interest determination as a private list. The procedure must be started by a rival commercial organization which will provide all the required evidence. The Controller has no option for carrying out investigations which entail that the patentee possesses most of the relevant information. The example of shifting burden by the Bombay High Court can be seen in Bayer after the prima facie concept is applied and the following negative decisions on dasatinib and saxagliptin applications confirm that it is impossible to achieve success without the provision of patentee's information. The transformation introduced in 2024 implying the introduction of triennial simplified working statements has expanded this gap. The aim of this article is to connect

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adjudication processes and information with the outcome of the case by proposing the so-called graded approach to public inquiry. This approach will involve the method of balanced private inquiry with the possibility of shifting a burden along with the indication of the time limits of an inquiry and public inquiry for health authorities.

Keywords: compulsory licensing; Patents Act 1970; Section 84; Natco v. Bayer; TRIPS flexibilities; access to medicines; burden of proof

1. Introduction

1.1 Background and Context of Compulsory Licensing

A patent is a bargain struck in public. The State confers a temporary right to exclude, and in exchange the patentee discloses the invention and, in India at least, undertakes that the invention will be worked for the benefit of those who live under the grant. Compulsory licensing is the clause in that bargain which allows the State to step in when the exchange has visibly failed. Chapter XVI of the Patents Act, 1970 permits the Controller of Patents, on application by "any person interested", to license a patented invention without the patentee's consent where the reasonable requirements of the public are unmet, where the invention is not available at a reasonably affordable price, or where it is not worked in the territory of India.[2] Further provisions allow licences on government notification in national emergencies, extreme urgency or public non-commercial use, and licences for export to countries without pharmaceutical manufacturing capacity.[3]

On paper, few legal systems offer a more generous menu. The scope of grounds for compulsory licensing in India is wider than what is mandated under TRIPS agreement, the government has altered its laws and regulations on compulsory licencing following the Doha Declaration of 2002, and the judiciary has been using clear expressions concerning public health.[4] In practice, the regime has produced a single licence under Section 84: the 2012 license granted to Natco Pharma for Bayer's anti-cancer drug sorafenib tosylate,

[2] The Patents Act, 1970, N0. 39 of 1970 (India)[hereinafter Patents Act].
[3] *Id.* §§ 92, 92A.
[4] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health ¶ 5(b), WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

marketed as Nexavar.[5] Subsequent applications of note have been unsuccessful, and at no time has a license been issued by the government under Section 92, even during the COVID-19 pandemic, at which time the Supreme Court wondered why the government has not used this power.[6]

2. Conceptual and Theoretical Foundation of Compulsory Licensing

2.1 Meaning Nature and Legal Character of Compulsory Licensing

A compulsory license refers to an obligatory authorization given by a state to a rights holder, allowing a third party to use a patent subject to a certain fee. The legal nature of such a license is often misinterpreted. It does not invalidate a patent; a license does not transfer ownership; and in practice, no authorization is given for importation from abroad.[7] Under Indian law the order operates as if it were a deed of license executed by the patentee on terms settled by the Controller.[8] Thus, the statute provides a substitute for consent: instead of having to provide it, the law has its own agreement. This framing is significant as it explains why the statute requires attempts at voluntary licensing and why the payment is calculated as if there were negotiations.

In addition, the term also encompasses other legal mechanisms.

The applicant-initiated license under Section 84 differs from the notification-based license under Section 92, and both differ from government use under Section 100 and from revocation in the public interest under Section 66.[9] Comparative work on India, Brazil and China has argued that these mechanisms ought to be classified separately, since an adjudicated license between private parties raises different questions from an executive decision to use an invention in the public interest.[10] That distinction is central to the argument of this article.

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[5] Natco Pharma Ltd. v. Bayer Corp., Compulsory License Application No. 1 of 2011 (Controller of Patents, Mumbai, Mar. 9, 2012) (India); see also Payal Thaorey & Anushree Mukte, Compulsory Licensing of Pharmaceutical Patents in India: Issues and Challenges, 1 MNLU Nagpur IPR J. 1, 11 (2023).
[6] *In re* Distribution of Essential Supplies and Services During Pandemic, Suo Motu Write Petition (Civil) No. 3 of 2021, Order (S.C. Apri 30, 2021) (India).
[7] Patents Act § 90(1)(iv)–(vi), (2).
[8] *Id.* § 93.
[9] *Id.* §§ 66, 100.
[10] A.V. Latyntsev, *Prinuditel'noe litsenzirovanie i inye formy ispol'zovaniya izobretenii bez soglasiya*

2.2 The Justification for Patent Exclusivity

The dominant justification for patents is economic. Inventions are costly to develop and low cost to copy; without exclusivity, competitors could benefit from the inventor's investment and under-investment in research would follow.[11] This problem is resolved with the help of the patent which permits the price to exceed the marginal cost for a short span of time. The unnecessary cost that arises in this situation is static inefficiency: some individuals who would have purchased the good at a competitive price are unable to buy it at monopoly price.[12] The patent system agrees to take this loss as an acceptable price for future innovations. According to the theory of disclosure, there is another rationale behind the system: a patent helps acquire public knowledge of the creation which otherwise would remain a secret. Indian law additionally presents an obligatory requirement that relates to the operational duty of the patent. According to the High Court of Bombay, the working obligation is implicit in the grant of the patent, and the invention should not.[13] On this view the patentee's privilege is conditional from the outset; it is not a natural right that compulsory licensing subtracts from.

2.3 Public Interest, Access to Medicines and the Right to Health

Where the patented product is a medicine, the static loss is measured in untreated illness. The Supreme Court has interpreted Article 21 of the Indian Constitution as encompassing the right to health and medical treatment while 47 places a responsibility on the state to ensure access to essential medicines as part of its public health obligation.[14] At the international level, the Committee on Economic, Social and Cultural Rights has identified access to essential drugs as a core obligation of the right to health.[15] Section 83(d) and (e)

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[11] Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention, in* The Rate and Direction of Inventive Activity: Economic and Social Factors 609, 609–26 (Richard R. Nelson ed., Princeton Univ. Press 1962).

[12] William M. Landes & Richard A. Posner, *The Economic Structure of Intellectual Property Law* 20 (2003).

[13] *Bayer Corp. v. Union of India*, Writ Petition No. 1323 of 2013, ¶ 8(a) (Bombay High Ct. July 15, 2014) (India).

[14] *Paschim Banga Khet Mazdoor Samity v. State of W.B.*, (1996) 4 SCC 37 (India); *Vincent Panikurlangara v. Union of India*, (1987) 2 SCC 165 (India).

[15] U.N. Comm. on Econ., Soc. & Cultural Rts., General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant), ¶ 43(d), U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

of the Patents Act incorporate this concern directly, directing that patents should not impede public health and should not prevent the government from taking measures to protect it.[16]

These constitutional commitments do not, however, create a right to a compulsory license. They operate as interpretive weight. The Bombay High Court gave them that weight when it held that, for medicines, the "adequate extent" of supply means supplies to every patient who needs the drug.[17]

2.4 Innovation Incentives, Competition and Consumer Welfare

Compulsory licensing also serves competition policy. A patent confers a lawful monopoly, but conduct beyond its scope, such as refusals to license, tying, grant-back clauses or restraints on validity challenges, can harm competition without serving innovation. Section 84(7) lists several of these practices as deemed failures to meet the reasonable requirements of the public, and TRIPS Article 31(k) relaxes the usual conditions where a license remedies anti-competitive conduct.[18] The objection against incentives works in reverse, if licenses are given too easily, expected returns from research will diminish and resources reallocated elsewhere. There is an ongoing debate among researchers on the validity of this claim, and there is good reason to believe that the risk increases for products designed for markets such as India rather than for those products which act as global blockbusters and for which the recovery of research costs occurs in wealthy markets.[19] A mechanism that is predictable and well calibrated addresses the incentive concern better than one that is either dormant or unpredictable.

2.5 Theoretical Tension between Private Patent Rights and Public Welfare

The theoretical tension is often presented as a binary choice between innovation and access. A better way to frame it is as a problem of calibration under uncertainty. The legislature cannot know in advance which patents will be priced beyond reach or left unworked, so it

[16] Patents Act § 83(d)–(e).
[17] *Bayer*, W.P. No. 1323 of 2013, ¶ 13(f).
[18] Patents Act § 84(7)(b)–(c); TRIPS Agreement art. 31(k).
[19] *See* Jerome H. Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA* (UNCTAD-ICTSD Project on IPRs & Sustainable Dev., Issue Paper No. 5, 2003).

grants rights broadly and corrects them case by case. Compulsory licensing is that corrective mechanism. Its value depends on more than whether it is used. It depends on whether patentees believe it *could* be used. Like Chekhov's gun, a remedy displayed on the wall of the statute must be capable of being fired; if it never can be, it shapes no one's conduct. The deterrent value of the mechanism therefore depends on its credibility, and credibility depends on procedure, evidence and institutional capacity rather than on the breadth of the statutory grounds. The rest of this article tests Indian law against that standard.

3. Evolution of Compulsory Licensing in India

3.1 Historical Development of Indian Patent Law

Compulsory licensing came to India with the colonial patent statutes. The Indian Patents and Designs Act, 1911 contained provisions for compulsory licenses and revocation to prevent abuse, modelled on contemporary British law.[20] After independence, two committees reviewed the system. A committee under Justice Bakshi Tek Chand was constituted in 1949, and Justice N. Rajagopala Ayyangar's Report of 1959 became the intellectual foundation of the 1970 Act.[21] Ayyangar found that foreigners held roughly ninety per cent of Indian patents, that many were not worked in India, and that the system was raising the price of medicines without building domestic industry.[22]

3.2 The Patents Act, 1970 and Its Original Objectives

The 1970 Act accepted Ayyangar's diagnosis. It allowed only process patents for food, medicines and chemicals, shortened the term for those processes, and retained compulsory licensing alongside revocation for non-working.[23] The original Chapter XVI also deemed the reasonable requirements of the public unmet where the patentee failed "to manufacture

[20] Indian Patents and Designs Act, 1911, No. 2 of 1911 (India); *see* Muhammad Z. Abbas, *Patent Laws and the Public Health Puzzle: Comparing India's Patent Opposition Model with the US and EU Model*, 13 Indian J. Intell. Prop. L. 1, 7 (2023).
[21] *Bayer*, W.P. No. 1323 of 2013, ¶ 8(b); N. Rajagopala Ayyangar, Report on the Revision of the Patents Law (1959).
[22] Abbas, *supra* note 22, at 12.
[23] Abbas, *supra* note 22, at 14–16.

in India to an adequate extent".[24] The Act's working philosophy was clear: a patent was a license to industrialize in India, not a privilege to import.

3.3 The TRIPS Agreement and the 1999, 2002 and 2002 and 2005 Amendments

TRIPS obliged India to grant product patents in all fields of technology and to apply the rule that patent rights are enjoyable "without discrimination as to whether products are imported or locally produced".[25] India used the transitional periods available to developing countries and amended the Act in three stages. The 1999 amendment created the "mailbox" for pharmaceutical product applications and exclusive marketing rights. The 2002 amendment, in force from 20 May 2003, substituted Chapter XVI almost entirely and introduced the present structure of Sections 82 to 94.[26] The 2005 amendment introduced product patents for pharmaceuticals from 1 January 2005 and, in the same breath, added Section 92A, the six-month explanation to Section 84(6)(iv), and the export-related terms in Section 90(1)(vii)–(ix).[27]

3.4 The Development of India's Public-Interest-Oriented Patent Framework

The 2005 settlement was not merely compliance. Parliament paired product patents with a set of safeguards designed to keep generics in the market: the restriction on patenting new forms of known substances in Section 3(d), pre-grant and post-grant opposition, and the strengthened compulsory licensing chapter.[28] The Supreme Court's decision in *Novartis* confirmed that Section 3(d) would be read as a substantive public-interest filter.[29] Scholarship comparing India's opposition model with those of the United States and European Union credits these upstream filters with doing much of the access work that compulsory licensing was once expected to do.[30] This observation is relevant for this paper

[24] *Bayer*, W.P. No. 1323 of 2013, ¶ 15(b) (quoting former Patents Act § 90(a)).
[25] TRIPS Agreement art. 27(1).
[26] The Patents (Amendment) Act, 1999, No. 17 of 1999 (India); The Patents (Amendment) Act, 2002, No. 38 of 2002 (India); *Bayer*, W.P. No. 1323 of 2013, ¶ 9.
[27] The Patents (Amendment) Act, 2005, No. 15 of 2005, §§ 52–55 (India).
[28] Patents Act §§ 3(d), 25; *see* Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 Indian J.L. & Tech. 15 (2005).
[29] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[30] Abbas, *supra* note 22, at 1–3.

since in India compulsory licensing has now assumed the role of a corrective mechanism in a system that aims at preventing the issuance of weak patents altogether.

3.5 Contemporary Legal and Policy Developments

"Three recent developments shape the current framework. First, the Tribunals Reforms Act, 2021 abolished the Intellectual Property Appellate Board, and appeals against compulsory licensing orders now lie to the High Court."[31] "Second, the Jan Vishwas (Amendment of Provisions) Act, 2023 replaced criminal sanctions for failing to file working information with monetary penalties of up to one lakh rupees, plus a daily amount for continuing default."[32] Third, the Patents (Amendment) Rules, 2024 changed the working statement in Form 27 from an annual filing to one filed once for every period of three financial years, and simplified its contents.[33] The pandemic years also tested the system, with no compulsory license emerging despite a judicial prompt. That record is examined in Part 6.

4. Statutory Framework Governing Compulsory Licensing in India

4.1 Section 83: General Principles Applicable to Working of Patented Inventions

Section 83 is not itself a ground for relief. It sets out the "general considerations" to which regard must be had whenever powers under Chapter XVI are exercised.[34] Patents are granted to encourage invention and to secure working in India "on a commercial scale and to the fullest extent that is reasonably practicable without undue delay"; they are not granted merely to enable a monopoly over importation; they should promote technology transfer, should not impede public health, and should make the benefit of the invention available "at reasonably affordable prices".[35] The Bombay High Court used Section 83 as

[31] The Tribunals Reforms Act, 2021, No. 33 of 2021, § 13 (India); Patents Act § 117A(2).
[32] The Jan Vishwas (Amendment of Provisions) Act, 2023, No. 18 of 2023, sch. (India); Patents Act § 122(1).
[33] Patents (Amendment) Rules, 2024, r. 131 (India); U.S. Pat. & Trademark Off., India IPR Toolkit: A Guide to Protecting and Enforcing Intellectual Property Rights in India 24 (2026).
[34] Patents Act § 83.
[35] *Id.* § 83(a)–(c), (g).

the lens through which "worked in the territory of India" must be read which gives this hortatory provision real interpretive force.[36]

4.2 Section 84: Grounds and Conditions for Grant of Compulsory Licenses

Under section 84(1), any interested may seek a compulsory license after three years from the grant of a patent if the public's reasonable requirement remains unmet, the patented invention is not available at a reasonable affordable price, or the invention is not worked in India.[37] The grounds are disjunctive; one suffices. An existing licensee may apply, and no admission in a license estops the applicant.[38]

"Two features deserve emphasis. First, the deeming provision in Section 84(7) gives content to the first ground. The reasonable requirements of the public are deemed unmet where, by reason of the patentee's refusal to license on reasonable terms, demand "has not been met to an adequate extent or on reasonable terms", where an Indian industry or export market is prejudiced, where restrictive license conditions are imposed, or where the invention is not worked on a commercial scale to an adequate extent."[39] Second, "Section 84(6) lists four matters the Controller "shall take into account": the nature of the invention, the time elapsed and the patentee's measures to use it; the applicant's ability to work the invention to the public advantage; the applicant's capacity to bear the risk of capital and working; and whether the applicant made efforts to obtain a voluntary license that failed within a reasonable period, ordinarily not exceeding six months."[40] The last requirement does not apply in cases of national emergency, extreme urgency, public non-commercial use or established anti-competitive practice.[41] The Controller need not consider any developments occurring after the application's filing date, thereby establishing the filing date as the cutoff for assessing evidence.[42]

The unique aspect about affordability is that it is the distinguishing element that makes India stand out in world. The TRIPS agreement does not either demand it or forbid it and

[36] *Bayer*, W.P. No. 1323 of 2013, ¶ 15(b).
[37] Patents Act § 84(1).
[38] *Id.* § 84(2).
[39] *Id.* § 84(7)(a)–(e).
[40] *Id.* § 84(6)(i)–(iv) & expl.
[41] *Id.* § 84(6)(iv) proviso.
[42] *Id.* § 84(6).

hardly any patent law provides affordability as a separate basis for granting license. It embodies the commitment made in Section 83(g) and makes way for the granting of licenses directly to ensure affordability instead of relying on local production.

4.3 Sections 85–89: Revocation, Procedure, Powers and General Purposes

Section 85 allows a patent to be revoked for non-working only after two years have elapsed from the grant of the first compulsory license, with such applications ordinarily to be decided within one year.[43] Section 84 applications are exempt from any effective time limitations; hence this gap is very apparent. Evoking Section 86 entails the possibility of postponement for a maximum of a year provided the time elapsed since sealing was not sufficient for the commencement of work, only if the patentee acted with "promptitude adequate or reasonable measures."[44] According to Section 87, the procedure consists of a three-step process: 1st, it must be established by the Controller that there exists "a prima facie case"; 2nd, the application must be published and served; and 3rd, the oppositions must be filed.[45] Section 88 gives ancillary powers, including the power to license related patents held by the same patentee and to revise terms that prove onerous after twelve months of working.[46] Section 89 states the purposes the Controller must pursue: commercial working in India without undue delay and the avoidance of unfair prejudice to those already working the invention.[47]

4.4 Section 90: Terms and Conditions of Compulsory

"Section 90 directs the Controller to "endeavor to secure" a reasonable royalty that takes account of the nature of the invention and the patentee's expenditure in making, developing, patenting and maintaining it; working to the fullest extent with reasonable profit to the licensee; availability at reasonably affordable prices; non-exclusivity; non-assign ability; and duration for the balance of the term unless a shorter term suits the public interest."[48] While the license has to be mainly granted with the intention of making supplies

[43] *Id.* § 85(1), (4).
[44] *Id.* § 86(1)–(2).
[45] *Id.* § 87(1)–(4).
[46] *Id.* § 88(3)–(4).
[47] *Id.* § 89.
[48] *Id.* § 90(1)(i)–(vi).

to the Indian market, exports are also allowed in certain cases.[49] However, the license does not allow imports, except if the Central Government otherwise orders for it in the interest of the public.[50] In accordance with section 94 of the Act, cancellation is allowed in case of circumstances not being continued or being unlikely to recur, but the license holder can protest.[51]

4.5 Section 91: Licensing of Related Patents

"Section 91 deals with blocking patents, specifically allowing the holder of a subsequent patent to apply for a license under an earlier patent if he is unable to use that subsequent patent effectively on his own, as long as the applicant offers a license on reasonable terms and the later patent has significantly contributed to the commercial or industrial activity in the country."[52] The provision tracks TRIPS Article 31(l), although the Indian test of "substantial contribution" to Indian commerce differs in wording from the treaty's standard of "an important technical advance of considerable economic significance".[53] It has no reported use, but it is the provision most relevant to cumulative innovation outside pharmaceuticals, for example in telecommunications and biotechnology.

4.6 Section 92: Special Provisions in Circumstances of National Emergency , Extreme Urgency or Public Non- Commercial

Section 92 creates a two-stage procedure. The Central Government must first declare, by notification, that compulsory licenses are necessary in a national emergency, extreme urgency or public non-commercial use. Thereafter the Controller "shall" grant a license to any interested applicant on terms that make the articles available "at the lowest prices consistent with the patentees deriving a reasonable advantage".[54] The three-year waiting period does not apply, and in public health crises "relating to Acquired Immune Deficiency Syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics" the Controller must dispense with the Section 87 procedure, informing the patentee as soon as

[49] *Id.* § 90(1)(vii), (ix).
[50] *Id.* § 90(2)–(3).
[51] *Id.* § 94.
[52] *Id.* § 91(1)–(2).
[53] TRIPS Agreement art. 31(l)(i).
[54] Patents Act § 92(1)(i)–(ii).

practicable.[55] Section 92 resembles the *brahmastra* of the epics: a weapon of decisive force, held in reserve, and in practice never used. No notification has been issued under it. In 2014, the Health Ministry reportedly supported a request by Cipla for a Section 92 license over indacaterol, but the Department of Industrial Policy and Promotion did not act on it.[56]

4.7 Section 92A: Export of Pharmaceutical Products to Countries with Insufficient or No Manufacturing Capacity

"Section 92A implements the 2003 WTO waiver. It makes a license available for manufacture and export of patented pharmaceutical products to a country with insufficient or no manufacturing capacity, provided that country has granted a compulsory license or has, "by notification or otherwise", allowed importation from India."[57] The license is "solely for manufacture and export", and "pharmaceutical products" include ingredients and diagnostic kits.[58] The provision was tested in 2008, when Natco applied for licenses to export erlotinib and sunitinib to Nepal. The Controller held, on an interlocutory question, that although Section 92A was silent on hearing the patentee, nothing prevented him from doing so.[59] Contemporary reports indicate that the Patent Office also questioned whether Nepal's letter satisfied the statutory requirement of permission to import.[60] No Section 92A license appears to have been granted.

4.8 Relevant Procedural Rules and Regulatory Requirements

Chapter XIII of the Patents Rules, 2003 governs procedure. Applications are made in the prescribed form with a statement of the applicant's interest and the facts relied on.[61] Under Rule 97, if the Controller considers that no prima facie case is made out, the applicant is notified and the application is refused unless a hearing is requested within one month.[62] This prima facie stage became the decisive filter in practice. The sources of information

[55] *Id.* § 92(3).
[56] Jishnu, *supra* note 6.
[57] Patents Act § 92A(1).
[58] *Id.* § 92A(2) & expl.
[59] Swarup Kumar, *Compulsory Licensing Provision under TRIPS: A Study of Roche vs Natco Case in India vis-à-vis the Applicability of the Principle of Audi Alteram Partem*, 7 SCRIPTed 135, 141–43 (2010).
[60] *Natco vs Pfizer: Joe Mathew Reports on Compulsory Licensing Decision*, SpicyIP (July 2008), https://spicyip.com/2008/07/natco-vs-pfizer-joe-mathew-reports-on.html.
[61] Patents Act § 84(3); Patents Rules, 2003, rr. 96–102 (India).
[62] Patents Rules, 2003, r. 97(1)–(2).

utilized by applicants and the Controller can be summarized as Section 146, which permits the Controller to acquire information about commercial usage, making it necessary for patentees and licensees to make periodic filings, and Rule 131 and Form 27.[63] As of 2024, Form 27 shall be submitted for every period of three financial years and not later than six months after the last day of the period, with the possibility of extension by not more than nine months in total.[64] The new version of the form asks only such questions as whether the invention has been implemented, what are the reasons for non-working, and if it is licensed for use.[65]

4.9 Critical Assessment of Statutory Ambiguities and Implementation Challenges

The issues in the passage can be listed as follows: In the first place, the act does not state who is supposed to bear the burden of proof concerning every reason and when that burden is supposed to be shifted. Section 87 only speaks of a "prima facie case" and does not elaborate how the burden of proof is going to be settled. Secondly, the term "reasonably affordable" is not defined in the act, and the Controller is not given any power to investigate prices and costs. The Bombay High Court states exactly that.[66] Third, the relationship between Section 84(1)(c) and importation is left to case-by-case judgment, which gives patentees no clear standard of compliance. Fourth, the export license under Section 92A is procedurally incomplete. It is silent on hearing the patentee, it provides no time limit, and it is absent from the list of appealable orders in Section 117A (2), which leaves a refused applicant with writ review alone.[67] Beyond these textual gaps lies the structural point developed below. Section 84 is drafted as an inter partes proceeding initiated by "any person interested". Public-interest concerns enter the analysis only through a private applicant's commercial decision to file, its capacity to gather evidence, and its appetite for

[63] Patents Act § 146(1)–(3).
[64] U.S. Pat. & Trademark Off., *supra* note 35, at 24; Off. of the Controller Gen. of Pats., Designs & Trade Marks, Frequently Asked Questions (FAQs) on Form 27, FAQs 3–4 (Aug. 26, 2024).
[65] *Navigating India's Form 27 Triennial Regime: A Comprehensive Compliance Guide for Patent Holders*, Conventus Law (2026), https://conventuslaw.com/report/navigating-indias-form-27-triennial-regime-a-comprehensive-compliance-guide-for-patent-holders-for-working-statement-requirements-in-2026/ (the precise fields should be confirmed against the gazetted form).
[66] *Bayer*, W.P. No. 1323 of 2013, ¶ 14(a).
[67] Patents Act § 117A(2); Kumar, *supra* note 61, at 144–45.

litigation against a patentee who may also be a supplier, partner or plaintiff in infringement proceedings.

5. Compulsory Licensing Under International Intellectual Property Law

5.1 Article 31 of the TRIPS Agreement

"TRIPS does not list permitted grounds for compulsory licenses. Article 31 instead regulates "other use" without authorization through procedural and substantive conditions. Authorization must be considered on individual merits; the proposed user must first seek a voluntary license on reasonable commercial terms, except in national emergency, extreme urgency or public non-commercial use; scope and duration are limited to the authorized purpose; use is non-exclusive and non-assignable; supply must be "predominantly" for the domestic market; the right holder must receive "adequate remuneration ... taking into account the economic value of the authorization"; and decisions on authorization and remuneration must be subject to independent review."[68] Article 31(k) relaxes the prior-negotiation and domestic-market conditions where the license remedies anti-competitive conduct.[69] "The Paris Convention, incorporated through TRIPS Article 2, continues to permit licenses "to prevent the abuses which might result from the exercise of the exclusive rights", such as failure to work, but bars applications for non-working before four years from filing or three years from grant, whichever expires last."[70] Section 84(1)'s three-year bar mirrors this limit.

5.2 Article 31bis and the Export Mechanism for Pharmaceutical Products

"Article 31(f) created a problem the Doha Declaration acknowledged in paragraph 6: countries without manufacturing capacity could not use compulsory licenses effectively, because producing countries could license only predominantly for domestic supply."[71] The General Council's 2003 decision waived Article 31(f) for exports to eligible importing members, and the waiver became Article 31*bis* when the Protocol Amending the TRIPS

[68] TRIPS Agreement art. 31(a)–(j).
[69] *Id.* art. 31(k).
[70] Paris Convention for the Protection of Industrial Property art. 5A(2), (4), Mar. 20, 1883, as revised July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305; TRIPS Agreement art. 2(1).
[71] Doha Declaration ¶ 6.

Agreement entered into force on 23 January 2017.[72] Remuneration is paid in the exporting country, taking into account the economic value of the use to the importing member, so that the right holder is not paid twice.[73] The system has been used only once, for Canada's export of an antiretroviral combination to Rwanda, a record discussed in Part 8.

5.3 The Doha Declaration on the TRIPS Agreement and Public Health

"The Doha Declaration states that TRIPS "does not and should not prevent members from taking measures to protect public health" and should be interpreted "in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all"."[74] "It confirms that each member "has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted", and the right to determine what constitutes a national emergency, including public health crises relating to HIV/AIDS, tuberculosis, malaria and other epidemics."[75] Its legal status is debated. Many commentators treat it as a subsequent agreement relevant to interpretation under Article 31(3)(a) of the Vienna Convention on the Law of Treaties, though others treat it as political guidance only. The Bombay High Court relied on it as an interpretive guide to municipal law.[76] Section 92(3) repeats the Declaration's list of epidemics almost word for word, a sign of how closely Parliament followed it.

5.4 Policy Space Available to WTO Members

In summary, the combination of TRIPS and Doha affords members extensive freedom concerning the reasons but strict control over the process. The reason for the license may vary from affordability to failure of exploitation or generally public interest and to eliminating anti-competitive actions. It must, however, observe individual consideration, prior negotiation outside emergencies, adequate remuneration and independent review.

[72] Decision of the General Council of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/L/540 (Sept. 2, 2003); General Council, Amendment of the TRIPS Agreement, WTO Doc. WT/L/641 (Dec. 8, 2005); World Trade Organization, WTO Analytical Index: TRIPS Agreement – Article 31 (Practice) ¶ 5 & n.5.
[73] TRIPS Agreement art. 31*bis*(2); WTO Analytical Index, *supra* note 74, ¶ 7.
[74] Doha Declaration ¶ 4.
[75] *Id.* ¶ 5(b)–(c).
[76] *Bayer*, W.P. No. 1323 of 2013, ¶ 8(e); Vienna Convention on the Law of Treaties art. 31(3)(a), May 23, 1969, 1155 U.N.T.S. 331.

The 2022 Ministerial Decision on COVID-19 vaccines went further for eligible members, clarifying that the "law of a Member" includes executive orders, emergency decrees and administrative orders, and dispensing with prior negotiation for the vaccines covered.[77] The decision was narrower than the waiver India and South Africa had proposed in 2020, which would have suspended several sections of TRIPS for COVID-19 health products.[78]

5.5 India's Obligations and Discretion under International Law

India's compliance with Article 31 has been questioned on two fronts. First, the accusation regarding the affordability basis and emphasis on local production discriminating against imported products is against Article 27(1).[79] To this concern, the Bombay High Court stated that the Articles 30 and 31 restrict the applicability of Article 27 and that importation can be considered as working if there is justification for it.[80] The better view is that Doha paragraph 5(b) authorizes the grounds, while the case-by-case approach to working avoids a per se rule against imports. The unresolved Brazil–United States dispute over Brazil's local working rule ended in a mutually agreed solution in 2001, leaving the question without a panel ruling.[81] Second, the absence of a statutory remuneration methodology makes it harder to demonstrate "adequate remuneration" in a given case, though the reasoned royalty in *Natco* suggests the requirement can be met in practice.

5.6 Critical Assessment of the Relationship between International Standards and Indian Law

Indian law uses most of the policy space TRIPS allows on grounds, but surprisingly little of the space it allows on procedure. TRIPS do not require that a compulsory license be adjudicated as a private dispute, that the applicant bear the burden of proving the public's need, or that the authority lack investigatory power. Since 2022, the WTO has also

[77] Ministerial Decision on the TRIPS Agreement of 17 June 2022, ¶¶ 2, 3(a), WTO Doc. WT/MIN(22)/30, WT/L/1141 (June 22, 2022).
[78] Communication from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, WTO Doc. IP/C/W/669 (Oct. 2, 2020).
[79] *See* Sunil Kumar Yadav & Saurabh Verma, *Whether Indian Patent Act Is TRIPS Compliant for Pharmaceutical Businesses: A Case-Based Approach*, 28 J. Intell. Prop. Rts. 224, 224–25 (2023).
[80] *Bayer*, W.P. No. 1323 of 2013, ¶ 15(b).
[81] Brazil – Measures Affecting Patent Protection, WTO Doc. WT/DS199/4 (July 19, 2001) (notification of mutually agreed solution).

expressly recognized administrative and executive instruments as legitimate vehicles for authorization in the vaccine context. The binding constraints on Indian reform are therefore domestic and institutional rather than international. This finding shapes the reform proposals in Part 9.

6. Judicial Interpretation and Practical Application in India

6.1 Bayer Corporation v. Union of India: Background and Legal Issues

Bayer's patent over sorafenib tosylate, used in advanced kidney cancer (renal cell carcinoma) and liver cancer (hepatocellular carcinoma), was granted in India on 3 March 2008.[82] Bayer sold the drug at about ₹2,80,428 for a month's therapy. On 6 December 2010 Natco requested a voluntary license, proposing a price below ₹10,000 per month. Bayer refused on 27 December 2010, inviting Natco to revert within fourteen days if it had anything further to add.[83] Natco applied under Section 84(1) on 29 July 2011, after the three-year window had opened, relying on all three grounds and offering to sell at ₹8,800 per month.[84] The litigation raised five questions: whether Natco had made adequate efforts at voluntary licensing, how the reasonable requirements of the public should be measured, what "reasonably affordable" means and who must prove it, whether importation counts as working, and how the royalty should be fixed.

6.2 Analysis of the Controller's Decision in the Natco–Bayer Compulsory Licensing Dispute

The Controller granted the license on 9 March 2012, finding all three grounds established.[85] The license was non-exclusive, non-assignable and for the balance of the patent term, with royalty at six per cent of net sales and the price capped at ₹8,800 for 120 tablets.[86] Natco also undertook to supply the drug free of charge to a number of needy patients each year.[87] Two parts of the Controller's reasoning were later modified. He read "worked in the

[82] *Bayer*, W.P. No. 1323 of 2013, ¶ 3(a)–(c).
[83] *Id.* ¶ 3(e).
[84] *Id.* ¶ 3(f).
[85] *Natco Pharma*, Compulsory License Application No. 1 of 2011, *supra* note 4.
[86] *Bayer*, W.P. No. 1323 of 2013, ¶ 3(g).
[87] *Apex Court Dismisses Bayer's SLP Against Compulsory License for Anti-Cancer Drug*, LiveLaw (Dec. 12, 2014), https://www.livelaw.in/apex-court-dismisses-bayers-slp-compulsory-license-anti-cancer-drug.

territory of India" as requiring manufacture in India, and he fixed the royalty by starting from the four per cent benchmark in guidelines published under UNDP and WHO auspices and adjusting it upward.[88]

6.3 Subsequent Appellate Proceedings and Their Legal Significance

The appeal followed three stages. The IPAB refused a stay on 14 September 2012 and dismissed the appeal on 4 March 2013. It raised the royalty to seven per cent and rejected the Controller's view that working always required local manufacture, holding instead that working must be judged case by case.[89] Bayer then petitioned the Bombay High Court under Article 226. The Division Bench (Shah C.J. and Sanklecha J.) noted that its review was supervisory rather than appellate. On 15 July 2014 it dismissed the petition while giving its own reasons on each issue.[90] The Supreme Court dismissed Bayer's special leave petition on 12 December 2014.[91] A dismissal *in limine* does not amount to an affirmation of the High Court's reasoning under Article 141. The authoritative statement of law is therefore the Bombay High Court's judgment, binding within its jurisdiction and highly persuasive elsewhere, together with the IPAB order that merged into it.

The Court's first holding concerned voluntary licensing. It held that Natco had satisfied Section 84(6)(iv). Bayer's letter had refused outright, and the offer to consider anything "further" was "illusory".[92] The Court treated Section 84(6)(iv) as a condition precedent to considering the application. That reading is stricter than the text, which lists it among matters the Controller "shall take into account". Later Controllers followed the stricter reading.

6.4 Judicial Interpretation of Reasonable Requirement of the Public

The High Court's treatment of Section 84(1)(a) contains three important holdings. First, on burden, the applicant must make out a prima facie case under Section 87, after which the

[88] *Bayer*, W.P. No. 1323 of 2013, ¶¶ 3(i), 17; *see* James Love, Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies (WHO & UNDP, Health Econ. & Drugs TCM Series No. 18, 2005).
[89] Bayer Corp. v. Natco Pharma Ltd., OA/35/2012/PT/MUM (Intell. Prop. App. Bd. Mar. 4, 2013) (India); *Bayer*, W.P. No. 1323 of 2013, ¶ 3(h)–(i).
[90] *Bayer*, W.P. No. 1323 of 2013, ¶¶ 6(a), 20–21.
[91] *Apex Court Dismisses Bayer's SLP*, *supra* note 89.
[92] *Bayer*, W.P. No. 1323 of 2013, ¶ 12.

patentee must "aver and thereafter lead evidence" that the public's requirements are met, because "the best evidence" of supply "is within the knowledge of the patent holder".[93] Second, on measurement, the Court said the exercise "can never be carried out on a mathematical basis". On Bayer's own figures, about 8,842 patients needed the drug, while Bayer supplied about 200 patients in 2011, and even adding Cipla's infringing supplies did not close the gap.[94] Thirdly, according to the patent statute, the supply of products by the illegal supplier cannot be covered under public requirement as they can be stopped at any point of time. It is the duty of the patentee and his licensee to ensure supply.[95] The Court then added that for medicines "the adequate extent test has to be 100%", because medicine must be made available to every patient.[96] Read in context, this observation explains why a two per cent supply rate could not be adequate. It is better treated as a strong interpretive principle than as a rule that any shortfall triggers a license.

6.5 Assessment of Reasonably Affordable Price and Patent Working

On affordability, the Court made a choice that shaped later practice. It held that the Act gives the Controller no power to investigate prices and that the proceeding is "a lis" in which "it is not open to an adjudicator to become a participant". The reasonably affordable price must therefore be found from the competing prices placed in evidence. On those facts, Natco's offer "by itself establishes" that Bayer's price was not reasonably affordable.[97] Bayer's refusal to produce its accounts and its research costs, including the reimbursement it received under United States orphan-drug rules, attracted an adverse inference.[98] Its patient assistance programme did not set a public price, because the discounted price was conditional, discretionary and, on Bayer's own description, charity. The Court reasoned that differential pricing bears on whether requirements are met "on reasonable terms" under Section 84(7)(a)(ii), not on affordability under Section 84(1)(b).[99]

[93] *Id.* ¶ 13(a).
[94] *Id.* ¶ 13(b)–(c).
[95] *Id.* ¶ 13(d)–(e).
[96] *Id.* ¶ 13(f).
[97] *Id.* ¶ 14(a).
[98] *Id.* ¶ 14(b)–(c).
[99] *Id.* ¶ 14(d)–(e).

On working, the Court rejected both extremes. It refused the Union's argument that working always means local manufacture, but it also refused Bayer's argument that any importation is enough. Read through Section 83, working by import is acceptable only where the patentee shows why manufacture in India is impossible or prohibitive. The burden of that explanation rests on the patentee, all the more so where, as here, it already had Indian manufacturing facilities.[100] Adjournment under Section 86 was rightly refused, because Bayer led no evidence of prompt steps to work the patent locally.[101] The seven per cent royalty stood, Bayer having offered no evidence of its development costs.[102]

6.6 The Evidentiary and Procedural Burdens on Applicants

The two applications that followed show how the *Bayer* framework operates when the facts are less stark. BDR Pharmaceuticals sought a license for Bristol-Myers Squibb's dasatinib, a leukaemia drug, and applied in March 2013. BDR had requested a voluntary license in February 2012. BMS replied with queries about BDR's manufacturing capacity, quality systems and regulatory compliance, and BDR did not respond for about a year. On 29 October 2013 the Controller refused the application at the prima facie stage. BDR's silence was treated as a failure to make efforts on reasonable terms, and its lack of regulatory approval to manufacture the drug was held to show that it had not acquired the ability to work the invention.[103]

Lee Pharma's application concerned AstraZeneca's saxagliptin, an anti-diabetic. The Controller rejected it prima facie under Rule 97(1) in August 2015 and, after a hearing, confirmed the rejection on 19 January 2016.[104] The Controller accepted that Lee was a person interested and that it had negotiated. The application failed on evidence. Lee had to

[100] *Id.* ¶ 15(b).
[101] *Id.* ¶ 16.
[102] *Id.* ¶ 17.
[103] Compulsory License Application by BDR Pharm. Int'l Pvt. Ltd. in Respect of Indian Patent No. 203937 (Controller of Patents, Oct. 29, 2013) (India), *as reported in Indian Patent Office Rejects Compulsory Licensing Application: BDR Pharmaceuticals Pvt. Ltd. vs Bristol Myers Squibb*, Khurana & Khurana (Nov. 13, 2013), https://www.khuranaandkhurana.com/2013/11/13/indian-patent-office-rejects-compulsory-licensing-application.
[104] Compulsory License Application by Lee Pharma Ltd. in Respect of Indian Patent No. 206543 (Controller of Patents, Jan. 19, 2016) (India), *as reported in* Balaji Subramanian, *Examining the Rejection of Lee's Saxagliptin CL Application*, SpicyIP (Jan. 22, 2016), https://spicyip.com/2016/01/examining-the-rejection-of-lees-saxagliptin-cl-application.html.

quantify demand for saxagliptin specifically, not for anti-diabetics or for the drug class as a whole. It relied on assumptions rather than "authentic data", and other drugs of the same class were available. With regard to the price, saxagliptin is priced similarly to its therapeutic equivalents, thus in effect making it so that Lee would need to demonstrate that the entire class was not affordable. With regard to the concept of the working, the duty to produce locally was taken to depend on local demand from India, which was not proven.[105]

The pattern is the same in each instance. In every case, the issue is factual, and in each case, the burden has been assigned during the beginning phase under Section 87 and Rule 97.

6.7 The Significance and Limitations of India's Compulsory Licensing Jurisprudence

The Natco-Bayer case has been pivotal for several reasons. The case showed how price itself could provide justification for the issuance of a license, that charitable access schemes are insufficient to mitigate the problem of affordability that the provision of infringing supplies does not extinguish the responsibilities of the patentee, and that justification comes with the requirement of working by import. Its limitations are less often noticed. The burden-shifting in paragraph 13(a) is conditional on the applicant first clearing the prima facie threshold. The "lis" characterization in paragraph 14(a) confines the Controller to whatever evidence the parties choose to produce. *Bayer* succeeded because the gap between ₹2.8 lakh and ₹8,800, and between roughly two hundred patients served and nearly nine thousand in need, was so large that rough evidence sufficed. *Lee* shows what happens in harder cases: when substitutes exist and the price gap is narrower, the applicant must produce product-specific epidemiological and market data that it is poorly placed to obtain. Jurisprudence built on a single, exceptionally clear case is unlikely to provide guidance for harder ones. The ambiguity this leaves behind discourages future applications.

6.8 Other Relevant Indian Decisions and Regulatory Developments

Three further episodes complete the picture. First, in *Shamnad Basheer v. Union of India*, a public interest petition about the poor quality of and non-compliance with Form 27 filings, the Delhi High Court recorded the government's commitment to review Section

[105] *Id.*

146, Rule 131, Form 27 and the enforcement of Section 122. On April 23, 2018, the Supreme Court ruled the petition after approving time for the process of modifying the regulations.[106] The changes made in 2020 and 2024 simplified the working statement. However, since these changes were not meant to make the working statement more efficient, and after 2024 the working statement seems to have been filed less. In the second wave of COVID-19, the SC also asked the Union to consider sections 92 and 100 for remdesivir etc.[107] In its response, the Union stated in an affidavit that use of the Patents Act could be "counter-productive," and that supply was limited by raw-material constraints and not by patents.[108] In 2014, the government did not approve Cipla's application for a Section 92 license for the drug indacaterol and thus the conflict shifted to the courts.[109] These events confirm that the executive route is seen as a last resort.

7. Critical Challenges in the Existing Framework

7.1 Affordability and Access to Essential Medicines

Price is the most immediate access barrier, and Section 84(1)(b) addresses it directly. Yet the statutory text gives no benchmark, the Controller has no power to compute one, and the Drugs (Prices Control) Order, 2013 now exempts a new drug patented under the Patents Act from price control for five years from commercial marketing.[110] The result is a regulatory gap. Ordinary price regulation does not reach a new patented medicine during its early years on the market, and compulsory licensing reaches it only if a private applicant chooses to litigate. Scholarship in law and economics has rightly treated price control and compulsory licensing as interdependent instruments that India has failed to coordinate.[111]

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[106] Shamnad Basheer v. Union of India, W.P.(C) 5590/2015, ¶¶ 1–8 (Del. H.C. Apr. 23, 2018) (India).
[107] *In re* Distribution of Essential Supplies & Services During Pandemic, *supra* note 5.
[108] *Invoking Patents Act for Production of Covid Vaccines, Drugs Can Have 'Consequences': Govt to SC*, ThePrint (May 10, 2021), https://theprint.in/judiciary/invoking-patents-act-for-production-of-covid-vaccines-drugs-can-have-consequences-govt-to-sc/655863.
[109] Jishnu, *supra* note 6.
[110] Drugs (Prices Control) Order, 2013, ¶ 32 (India) (as amended 2019); K.M. Gopakumar, *India: No Price Control on New Patented Drugs for Five Years*, Third World Network Info. Serv. on Health Issues (Feb. 18, 2019), https://twn.my/title2/health.info/2019/hi190202.htm.
[111] Shyamal M. Dave & Aditi Dave, *An Analysis of the Government Policies Related to Access to Essential Medicines in India: A Law and Economics Analysis of Drug Pricing Controls, Patent Policy, and the DPCO Framework*, 16 Int'l J. Drug Delivery Tech. 1906, 1906 (2026).

7.2 The Meaning and Assessment of Reasonable Requirements of the Public

Bayer and *Lee* together reveal a definitional uncertainty. If demand is measured product by product, the patentee of one member of a crowded therapeutic class will rarely fail the test, even if the whole class is priced beyond the means of most patients. When demand is defined as therapeutic need, the patentee in first-in-class cases has responsibilities from which those entering later can escape. The language in the Act and the decisions does not solve this problem. The requirement of authentic data shown in Lee has a good basis in theory, but in practice India does not have public registries of treatments and prescriptions, so it may be impossible for the applicant to satisfy the requirement.

7.3 Patent Working Requirements and the Role of Local Manufacturing

The Bayer compromise stands on legitimate grounds. Importation is an acceptable practice if the owner of the patent proves it is appropriate to do so. However, this compromise relies on correct data on how much is imported, what price is paid and how many patients are involved. The purpose of Section 146 is to deliver the required data, and the High Court based its decision on Bayer's Form 27 to dismiss its arguments about unlawful supply.[112] A working statement filed every three years, with simplified contents, offers far less to an applicant trying to build a prima facie case or to a Controller trying to assess it.[113] The legal standard for working has become more demanding, while the information needed to apply it has thinned.

7.4 Procedural Delays, Administrative Capacity and Regulatory Uncertainty

Natco's application took a little over seven months to decide, and the litigation then ran for a further thirty-three months through three forums.[114] That was swift by Indian standards, but there is no statutory deadline for Section 84 applications, unlike the one-year norm for revocation applications under Section 85(4).[115] After 2021, appeals lie to High Courts, many of which have created dedicated intellectual property divisions. That improves

[112] *Bayer*, W.P. No. 1323 of 2013, ¶ 13(e).
[113] U.S. Pat. & Trademark Off., *supra* note 35, at 24.
[114] *Bayer*, W.P. No. 1323 of 2013, ¶ 3(f)–(i); *Apex Court Dismisses Bayer's SLP*, *supra* note 89.
[115] Patents Act § 85(4).

expertise but scatters precedent across courts.[116] For an applicant planning an investment in manufacturing, the uncertainty about timing itself is a cost.

7.5 Balancing Public Health Needs against Patent Holders' Legitimate Interests

Patentees have legitimate grievances too. The statute gives no structured method for setting the royalty, and the "adequate remuneration" required by TRIPS Article 31(h) is left to judgment that varies with the evidence produced.[117] The *Bayer* royalty was reasoned, but it rested largely on an adverse inference from Bayer's refusal to produce its costs.[118] A patentee that does disclose may find its confidential cost data exposed in a public proceeding. A fair system must protect such data and give patentees a predictable remuneration framework, if only to make it reasonable to expect disclosure from them.

7.6 Commercial Viability, Technology Transfer and Manufacturing Capacity

A licence is useful only if the licensee can make the product. Section 84(6)(ii) and (iii) require the applicant to show ability and capacity, and *BDR* shows that regulatory approval may be treated as part of that ability.[119] Complex medicines, especially biologics, depend on know-how, cell lines and regulatory data that a patent license does not transfer. A compulsory license can remove the legal barrier to manufacture without removing the technical one. This limits the mechanism's reach precisely where future access concerns are likely to concentrate.

7.7 The Limited Use of Compulsory Licensing and Its Policy Implications

India's record is not unusual internationally, but its causes deserve precise statement. Political caution plays a part, as shown by the Union's 2021 affidavit and the 2014 inaction on indacaterol. Structural causes play a larger part. The applicant must be a commercial competitor willing to litigate against a patentee who may control its future licensing and partnership opportunities. It must assemble evidence that lies largely with the patentee. It must clear a threshold before disclosure is compelled and then wait an uncertain time for

[116] *Id.* § 117A(2); U.S. Pat. & Trademark Off., *supra* note 35, at 51–52.
[117] TRIPS Agreement art. 31(h); Patents Act § 90(1)(i).
[118] *Bayer*, W.P. No. 1323 of 2013, ¶ 17.
[119] Patents Act § 84(6)(ii)–(iii); *see BDR*, *supra* note 105.

an outcome. A private applicant rationally files only when the case is as clear as *Bayer*. Disuse is therefore a predictable consequence of the regime's design, not evidence that access problems have been solved.[120]

7.8 Risks of Overreliance on Compulsory Licensing as a Public Health Instrument

The opposite risk also deserves attention. Compulsory licensing is slow, product-specific and adversarial. This method is not a replacement for public procurement, collective buying, price negotiations or voluntary licensing. Relying solely on this method as the access mechanism would lead to perpetual conflict without making progress. In addition, it would divert attention from upstream strategies like Section 3(d) and opposition, which have done much for access in India.[121] The purpose of reform should be to create a credible background threat, rather than a large number of licenses. An effective mechanism can work precisely when it is used rarely, which is because it promotes negotiated prices and voluntary licenses.

8. Comparative Analysis of Selected Jurisdictions

8.1 Selection of Jurisdictions and Comparative Methodology

Three jurisdictions are analyzed, each selected to highlight distinct institutional differences rather than to serve as a universal model.

The United States represents a high-protection system that has no general compulsory licensing statute but retains powers of state use. Brazil, like India a large developing country with a domestic generic industry, uses an executive, *ex officio* public-interest model. Canada offers two lessons: a long history of compulsory licensing of pharmaceuticals before 1993, and the only completed use of the WTO export mechanism, which bears directly on India's Section 92A. The comparison asks three questions of each system: who may trigger the mechanism, who carries the evidentiary burden, and who holds the information.

[120] *Cf.* Thaorey & Mukte, *supra* note 4, at 11 (questioning whether the rarity of licences reflects adequate access).
[121] Abbas, *supra* note 22, at 1–3.

8.2 Compulsory Licensing in the United States

United States law has no provision equivalent to Section 84. It nonetheless contains three functional substitutes. First, the federal government may use any patented invention, or authorize a contractor to use it, subject only to the patentee's claim for "reasonable and entire compensation" in the Court of Federal Claims.[122] Second, under the Bayh-Dole Act a funding agency may "march in" and require licensing of a federally funded invention where, among other grounds, action is necessary to alleviate health or safety needs not reasonably satisfied by the contractor.[123] Third, after *eBay*, courts may deny injunctions and award ongoing royalties, which in effect creates judicially imposed licenses.[124]

The march-in experience is instructive for India. In December 2023 the National Institute of Standards and Technology proposed a framework that would have allowed price to be considered in march-in decisions.[125] As of December 2025 that framework had not been finalized, and the Government Accountability Office reported in 2026 that agencies "have never exercised march-in rights" despite about a dozen petitions.[126] The lesson is that a power in executive hands, without criteria, deadlines or an obligation to give reasons, can lie as dormant as a private remedy hedged with evidentiary burdens. By contrast, Section 1498 works routinely because it requires no prior permission. Government use is lawful, and only compensation is litigated.

8.3 Compulsory Licensing In Brazil

Brazil's Industrial Property Law provides for licenses on grounds of abuse, insufficient local working and dependency between patents. Its Article 71 allows the executive to grant temporary, non-exclusive licenses *ex officio* in national emergencies or in the public interest.[127] In 2007 Brazil used Article 71 for Merck's antiretroviral efavirenz after

[122] 28 U.S.C. § 1498(a).
[123] 35 U.S.C. § 203(a).
[124] eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391–94 (2006).
[125] Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85,593 (Dec. 8, 2023).
[126] U.S. Gov't Accountability Off., GAO-26-107885, Intellectual Property: Information on Draft Guidance to Assert Government Rights Based on Price (2026).
[127] Lei No. 9.279, de 14 de maio de 1996, arts. 68–71, Diário Oficial da União [D.O.U.] de 15.05.1996 (Braz.).

negotiations over price failed, initially importing generic versions from India.[128] In 2021, during the pandemic, Law 14.200 amended Article 71. It recognized international health emergencies and national calamities as triggers, extended the mechanism to patent applications, and required the government to publish within thirty days a list of patents potentially relevant to the emergency, after consultation, together with remuneration parameters.[129]

The Brazilian approach has its trigger and evidentiary probe conducted by the executive, normally the Ministry of Health, rather than by a competitor in the private sector. Its drawbacks are also apparent. Brazil's previous local content requirement attracted a complaint from the US in the WTO, which was eventually resolved.[130] In 2026, bills in the Brazilian Congress sought to declare tirzepatide, a medicine used for obesity, to be of public interest, even though the government opposed a license and there was no demonstrated shortage. That episode shows how an executive-led mechanism can become a vehicle for legislative signaling rather than reasoned decision.[131]

8.4 Compulsory Licensing in Canada

Canada is the jurisdiction most often cited for the economic effects of pharmaceutical compulsory licensing. From 1969 until 1993, the Patent Act allowed compulsory licences to import, as well as to manufacture, patented medicines on payment of a royalty, a regime credited with building a Canadian generic industry. It was dismantled in 1993 under trade and industry pressure.[132] Canada's Access to Medicines Regime later implemented the WTO export system. Apotex used it once, to supply an antiretroviral combination to Rwanda. Apotex committed to the project in December 2004, but the license was granted only in September 2007, and shipments followed in 2008 and 2009. Its chief executive afterwards described the requirements as "impossible to navigate".[133] The procedural steps

[128] Decreto No. 6.108, de 4 de maio de 2007, D.O.U. de 07.05.2007 (Braz.); Eduardo Hallak, Juliana Neves & Juliana Libman, *Compulsory Licensing in Brazil (2026): The Mounjaro Case*, Chambers & Partners (Apr. 2, 2026), https://chambers.com/articles/compulsory-licensing-in-brazil-2026-the-mounjaro-case.
[129] Lei No. 14.200, de 2 de setembro de 2021, D.O.U. de 03.09.2021 (Braz.); Hallak et al., *supra* note 130.
[130] Brazil – Measures Affecting Patent Protection, *supra* note 83.
[131] Hallak et al., *supra* note 130.
[132] Harry C. Eastman, Report of the Commission of Inquiry on the Pharmaceutical Industry (1985); Patent Act Amendment Act, 1992, S.C. 1993, c. 2 (Can.); *see* Reichman & Hasenzahl, *supra* note 21.
[133] Patent Act, R.S.C. 1985, c. P-4, §§ 21.01–21.2 (Can.); Arianna Schouten, *Canadian Experience with*

that made the regime so difficult to use included product-specific schedules, separate notifications by the importing and exporting countries, and repeated voluntary-license requests.

8.5 Comparative Judicial, Legislative and Administrative Approaches

Three contrasts emerge. On the trigger, India relies mainly on private applicants. Brazil relies on the executive, and the United States relies on the government acting as user or funder. On burden, India places the initial burden on the applicant and shifts it only after a prima facie showing. Brazil's executive builds its own record, and under Section 1498 the government acts first and litigates compensation later. On information, Brazil's 2021 reform makes the State responsible for identifying relevant patents and publishing them, while India's 2024 reform reduced the information patentees must supply. The comparison also shows a shared failure. Executive powers without published criteria, deadlines or duties to give reasons, such as American march-in and Indian Section 92, tend to remain unused. Regimes with too many procedural steps, such as Canada's export mechanism, defeat their own purpose.

8.6 Lessons for India and Limits of Legal Transplantation

It is not advisable for India to adopt Section 1498 in its entirety. It operates in the USA's Court of Federal Claims system under the government as a very important purchaser of patented goods. Furthermore, India lacks a counterpart for either of the two supposed features. Brazil's ex officio model is more suitable for Indian public health institutions but weakens the possibility for legislative signal recognition. Public authorities should have the right to bring cases. The government should be accountable for facts. The executive should operate with certain criteria and deadlines. Section 92A export licenses should eliminate unnecessary procedures. These lessons provide the foundations for the proposals outlined below.

Compulsory Licensing under the Canadian Access to Medicines Regime 3–6 (Knowledge Ecology Int'l, Briefing Note 2021:2, Mar. 31, 2021).

9. Reform Proposals and Policy Recommendations

9.1 Clarifying Statutory Standards and Evidentiary Requirements

The approach on burden of proof devised in Bayer should be enacted into law. Section 87 could be amended to provide for the situation whereby once a complainant demonstrates a prima facie case based on information available publicly on price, delivery or manufacturing, the patent-holder must provide data on volumes sold, prices and any schemes allowing patients to get the treatment, as well as reason for any non-manufacturing. Section 84(6)(iv) should be amended to clarify that the issue is to be considered in weighing rather than as a jurisdictional bar. The rules should clear up the content of a reasonable request for a compulsory license so as to ensure that disputes like that in the BDR are based on substantive grounds rather than correspondence.

9.2 Improving Procedural Efficiency and Institutional Transparency

We need to apply the same one-year norm to section 84 applications as applies to revocation under section 85(4), but with a timeline that is shorter in the prima facie stage.[134] The Patent Office has to publish all compulsory licensing applications, prima facie decisions, and final orders in a searchable register. Section 117A(2) should be amended to include Section 92A, and Section 92A should specify a limited hearing on terms, which resolves the uncertainty identified in the Natco–Roche proceedings.[135]

9.3 Developing Clearer Affordability and Public-Interest Assessment Criteria

The Patent Office, in consultation with the Ministry of Health and Family Welfare and the National Pharmaceutical Pricing Authority, should issue guidelines identifying indicators of unaffordability. Such indicators might include monthly treatment cost relative to household consumption or income, the existence of public procurement at the patented price, and price differentials against comparable markets. These guidelines would serve as refutable indicators, rather than price restrictions. They would respond to the Bayer court's concern about the fact that the Controller is not a price regulator and help applicants avoid

[134] Patents Act § 85(4).
[135] Kumar, *supra* note 61, at 144–45.

the need to substantiate affordability from scratch. The guidelines should address the therapeutic classes issue raised in the Lee case by allowing evidence of classes being provided for parallel-priced substitutes.

9.4 Strengthening Patent-Working Assessment and Access to Relevant Information

The reduction of the frequency of working statements in 2024 should be reconsidered when it comes to the pharmaceutical patents and other patents in the sectors that are of importance for public health. For those patents, the annual working statements with the quantity and value of the products supplied, whether made or imported, should be reinstated. Sensitive commercial information may be provided to the Controller and the applicants under the confidentiality regulations, rather than published in full. Section 146(1) already allows the Controller to call for information "at any time". Practice should treat that power as available at the prima facie stage of a Section 84 application, so that the threshold inquiry is not conducted without the patentee's data.[136]

9.5 Improving Coordination between Patent Authorities and Public Heath Institution

A standing inter-ministerial mechanism, comprising the Department for Promotion of Industry and Internal Trade, the Ministry of Health and Family Welfare, the Department of Pharmaceuticals and the Patent Office, should be empowered to refer patients to the Controller for inquiry and to recommend notifications under Section 92 by reference to published criteria and within fixed time limits. Its recommendations, and the government's reasons for accepting or rejecting them, should be made public. Mandatory reasoned decisions would make it harder to leave Section 92 unused without explanation, as happened with indacaterol in 2014 and with the pandemic medicines in 2021.

9.6 Integrating Compulsory Licensing With Other Access-to-Medicine Measures

Compulsory licensing should be integrated with the Drugs (Prices Control) Order, public procurement and voluntary licensing rather than operated in isolation. The five-year price-control exemption for new patented drugs should be reconsidered for drugs on the National

[136] Patents Act § 146(1).

List of Essential Medicines.[137] Voluntary licences that meet published access criteria could be treated as evidence that the public's requirements are met. This would give patentees a reason to license voluntarily, which is the outcome the mechanism exists to encourage.

9.7 Protecting Legitimate Patent Incentives While Advancing Public Welfare

Reform must preserve the safeguards that make compulsory licensing defensible. These include the three-year bar, non-exclusive, a domestic-market focus outside the export provisions, termination under Section 94, and independent review. An approach for royalty calculation which involves going through the various tiers of the royalty system under the WHO–UNDP policy as applied by Natco while adapting it according to the therapeutic value and the research costs and public subsidies can be as beneficial for patent holders as it could be for the applicants.[138] Cost data confidentiality provisions will permit patent holders to use their real expenditure on research without disclosing it. Predicable remuneration mitigates the possibility that India's action will be contested as violating Article 31(h).

9.8 A Proposed Framework for More Predictable and Effective Compulsory Licensing

These proposals can be combined into what this article calls a *graduated public-interest inquiry*. It has three tiers. The first is the private-applicant track under Section 84, retained but rebalanced through a codified burden shift, information powers usable at the threshold stage, affordability guidelines and a one-year decision norm. The second is a public-referral track, under which the inter-ministerial mechanism may refer to a patent for inquiry. The Controller would then conduct an inquiry under Section 84 on the record built by public agencies, so that the process no longer depends on a commercial competitor's willingness to sue. The third is the emergency track under Sections 92 and 100, governed by published criteria, reasoned decisions within fixed deadlines and pre-agreed remuneration parameters. Brazil's 2021 duty to publish a list of relevant patents offers a model here.[139] Each tier preserves notice to the patentee, remuneration and review, and so remains within

[137] Drugs (Prices Control) Order, 2013, ¶ 32; Dave & Dave, *supra* note 113, at 1906.
[138] Love, *supra* note 90.
[139] Hallak et al., *supra* note 130.

Article 31. Each also corrects the defect identified in this article: a public-interest determination should not depend on private initiative and on information controlled by the patentee.

10. Conclusion

Compulsory licensing in India is rich in law and poor in use. This article argued that the gap is not explained by the breadth of the statutory grounds, which are generous, or by international constraints, which leave considerable room for procedural reform. It is explained by the architecture of Chapter XVI. The statute treats a public-interest inquiry as a private dispute. It utilizes a business rival to start the investigation and provide almost all proof, and it eliminates the Controller's power to conduct the inquiry. The judgment of the Bombay High Court in Bayer acknowledged that the patent holder possesses the most accurate proof and thus decided who needs to bear the responsibility but only on the condition that the applicant has passed the preliminary stage. It was seen in the refusal of the applications in BDR and Lee that without the patent holder's information, the threshold causes most applications to be rejected now. The dilution of working statements in 2024 has only increased the gap.

The solution does not lie in the frequent issuance of mandatory licenses. A system that freely grants licenses will hurt motivation, cause trade tensions, and lead to the distraction from other useful upstream mechanisms of action. The solution is to create credibility for this mechanism. Credibility entails the need to establish burden-shifting mechanisms, restate the relevant good data on patenting in the area of public health, and allow public institutions to initiate inquiries, find appropriate thresholds for activation of emergency powers, and come up with a method for the calculation of remuneration. The remedy, which is effective in real-life practice, needs not be applied often since its existence gives grounds for proper pricing and licensing. For over ten years, the remedy introduced in India has been devoid of such credibility. The proposals presented here aim to restore it while keeping the rights of patent holders secure.