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A STUDY ON THE COMPULSORY LICENSING MECHANISM UNDER THE PATENT SYSTEM

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Abstract: Compulsory licensing is a pressure-release valve in patent law: it protects incentives to invent while making sure people can actually get the technologies they need—especially life-saving medicines when it matters most. Anchored in article 31 of trips and underscored by the 2001 doha declaration on public health, it lets governments authorize use of a patent without the owner's consent, but only under clearly defined safeguards. This paper maps the global rules that shape compulsory licensing and shows how india puts them to work through the patents act, 1970—focusing on sections 84, 92, and 92a—using a doctrinal lens alongside comparative insights. Drawing on touchstone examples like natco pharma ltd. V. Bayer corporation and the canada–rwanda apotex route, it demonstrates how india and other countries leverage trips flexibilities to bring medicine prices within reach. The takeaway is straightforward: compulsory licensing isn't a loophole in patent law—it's a built-in flexibility—and it works best when processes are transparent, royalties are fair, and countries coordinate across borders to balance innovation with equitable access.

Index Terms – Compulsory licensing, Patent law, TRIPS agreement, Innovation, Affordable drugs.

I. Introduction

Compulsory licensing refers to a precisely designed limitation on patent exclusivity, which allows the use of a patented invention without the right holder's consent under particular statutory conditions. A balance between two conflicting goals has to be struck: providing incentives for innovation while ensuring that public interests in access, affordability, and sufficient supply are not compromised by the stringency of the absolute protection of a patent. At the international level, its legal basis exists under Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, which allows "other use without authorization of the right holder" on the condition of defined safeguards such as prior negotiation where possible, proportionate limits on scope and duration, and the payment of adequate remuneration[1]. These provisions institute a structured rules-based mechanism for exceptional access within the multilateral intellectual property regime. The Doha Declaration on the TRIPS Agreement and Public Health of 2001 reemphasized that TRIPS should be interpreted and implemented in a way that supports public health policies and the promotion of access to medicines, acknowledging each member state's discretion to determine grounds for compulsory licensing and to treat health emergencies as circumstances of extreme urgency[2].Acknowledging that some countries lack domestic manufacturing capacity, the 2005 TRIPS Amendment (Article 31bis) introduced an export mechanism that allows the production and supply of pharmaceuticals under a compulsory license to eligible importing countries. This system is governed by procedural safeguards, including notification, anti-diversion measures, and coordinated remuneration to the patent holder[3].

[1] *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[2] *World Trade Organization*, *Ministerial Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 14, 2001).
[3] *Protocol Amending the TRIPS Agreement*, WTO Doc. WT/L/641 (Dec. 6, 2005) (introducing TRIPS art. 31bis); see also TRIPS art. 31bis (export mechanism).

India has operationalized these international principles through its Patents Act, 1970. Section 84 provides a general route for compulsory licensing when public requirements remain unmet, prices are not reasonably affordable, or the patented invention is not sufficiently worked in India[4]. Section 92 enables expedited action in circumstances of national emergency or for public non-commercial use, while Section 92A incorporates the TRIPS Article 31bis mechanism by authorizing export-only licenses to supply essential medicines to countries lacking manufacturing capacity[5].Conceptually, India's framework positions compulsory licensing as a proportionate policy instrument to address market failures in life-saving technologies. By combining statutory grounds, time-bound triggers, and royalty-based remuneration within the broader multilateral framework, it seeks to harmonize the goals of equitable access and innovation incentives[6]. Accordingly, this research adopts that perspective to examine the doctrinal and procedural dimensions of Sections 84, 92, and 92A of the Patents Act in light of TRIPS Articles 31 and 31bis and the Doha Declaration[7]. It explores when, how, and on what terms compulsory licenses should be activated to address affordability gaps, unmet demand, and manufacturing constraints, without eroding the long-term incentive structures essential to innovation[8]. By situating India's practice within the treaty framework, the study investigates how a rules-based compulsory licensing regime can reconcile patent-driven innovation with equitable access—both domestically through calibrated statutory limitations and internationally through export solidarity mechanisms consistent with TRIPS and Doha principles.[9]

II.International Architecture — TRIPS and DOHA

The article 31 of the TRIPS offers a legal basis for compulsory licenses under the WTO, giving the member countries to regulate the use of a patented invention without the consent of the patent holder thus ensuring that the rights of the patentee are not abused by the public[10]. In fact, the right of the members to obtain compulsory licenses was confirmed again in 2001 when the Doha Declaration provided that each country might determine the grounds for issuing a compulsory license at its own discretion including in cases of public health crisis declared a national emergency or extreme urgency. Article 31bis authorizes the export of patented medicines produced under compulsory licensing to countries with insufficient manufacturing capacity thus promoting access to medicines in developing and least developed countries.

A. TRIPS 31

Article 31 of the TRIPS Agreement allows compulsory licensing only under conditions that are tightly circumscribed, with procedural safeguards designed to balance public interest needs with the legitimate interests of the patent holder and to ensure independent review of the decisions and remuneration[11].

The need for prior efforts to obtain authorization: Except in specified exceptional circumstances, a prospective user must first seek a voluntary license from the right holder on reasonable commercial terms and conditions and allow a reasonable period for negotiation before any non-authorized use is permitted[12]. The prior-negotiation requirement may be waived in a national emergency, other circumstances of extreme urgency, or for public non-commercial use, although right holders must be promptly notified in the latter categories[13]. These TRIPS flexibilities have been central to public health responses and are framed to let Members determine the facts and timing that justify waiver, subject to their treaty obligations[14].Article 31 of the TRIPS Agreement provides that any authorization of use without the right holder's consent must be

[4] The Patents Act, No. 39 of 1970, India, sec 84, 92, 92A.
[5] The Patents Act sec 92A (compulsory license for manufacture and export of patented pharmaceutical products to eligible countries).
[6] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], art. 31 (providing conditions for use without authorization of the right holder).
[7] TRIPS Agreement, arts. 31, 31bis; Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Declaration]; Patents Act, sec 84, 92, 92A (India).
[8] TRIPS Agreement, art. 31; Doha Declaration, ¶¶ 4–6 (affirming Members' right to determine grounds for compulsory licences and to address public health crises).
[9] TRIPS Agreement, art. 31bis (establishing export mechanisms for countries with insufficient manufacturing capacity); Patents Act, § 92A (India) (implementing India's export-oriented compulsory licensing regime).
[10] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, art. 31 [hereinafter *TRIPS Agreement*].
[11] World Trade Organization (WTO), *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, Article 31, 1994.
[12] WTO, *TRIPS Agreement*, Article 31(b); see also World Intellectual Property Organization (WIPO), *Compulsory Licensing of Patents and Access to Medicines*, WIPO Publication No. 489(E), 2020.
[13] WTO, *Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), WT/MIN(01)/DEC/2, 2001, para. 5(b)–(c).
[14] Correa, Carlos M., *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, Zed Books, 2000; see also WTO, *TRIPS and Public Health: Frequently Asked Questions*, 2021.

narrowly tailored to the stated objective, with its scope and duration confined to what that purpose requires[15].Licenses issued under Article 31 must also be non-exclusive and non-assignable, meaning they cannot confer exclusive rights or be transferred except with that part of the enterprise or goodwill that enjoys such use. These limitations ensure that compulsory measures remain targeted, time-bound, and proportionate, thereby preventing over-broad or indefinite interference with patent rights.

A right holder must be paid adequate remuneration in each case, having regard to the economic value of the authorization. Although TRIPS provides no fixed formula, the adequacy of remuneration must be determined on a case-by-case basis, reflecting the economic value of the authorization while allowing Members flexibility consistent with treaty obligations[16].Decisions regarding remuneration are subject to judicial or other independent review, thereby ensuring protection of the right holder's interests.

Procedural review and legitimate interests: Article 31 further requires that all decisions authorizing use without the patent holder's consent be reasoned, decided on the merits of each case, and open to judicial or other independent review, including review of remuneration terms. In doing so, Members must balance the legitimate interests of patent owners in safeguarding innovation incentives against the public needs that may justify such use, embodying the equilibrium envisioned by TRIPS[17].

B. Doha Declaration

The 2001 *Doha Declaration on the TRIPS Agreement and Public Health* reaffirmed the sovereign right of Members of the World Trade Organization (WTO) to utilize the flexibilities provided under TRIPS to protect public health, particularly to ensure access to medicines, by reaffirming Members' rights to grant compulsory licenses and to determine the grounds upon which such licenses may be issued[18]. The Declaration further recognized Members' authority to declare, for themselves, a "national emergency" or "other circumstances of extreme urgency," including those arising from HIV/AIDS, tuberculosis, malaria, or other epidemics, and to establish national procedures for the issuance of compulsory licenses in accordance with their domestic health needs and TRIPS obligations[19].

The *Doha Declaration* also emphasizes public health flexibilities, asserting that TRIPS "should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for allIt specifically guides the interpretation of Article 31 of TRIPS concerning compulsory licensing and related measures. Paragraph 5(b) of the Declaration explicitly provides that "each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted," reaffirming the national policy space to invoke non-voluntary use when necessary[20].

Paragraph 5(c) of the *Doha Declaration on the TRIPS Agreement and Public Health* provides that each Member may determine what constitutes a "national emergency or other circumstances of extreme urgency," and specifically notes that public health crises — including HIV/AIDS, tuberculosis, malaria, and other epidemics — may qualify as such[21].This clarification confirms that, in these situations, Members may waive the requirement of prior negotiation with patent holders under TRIPS Article 31(b), enabling governments to act promptly when urgent public health measures are necessary. The provision thus ensures that rapid action to address public health emergencies can occur without necessitating reinterpretation of TRIPS, while procedural safeguards continue to govern such measures[22].

The *Doha Declaration* also affirms Members' procedural autonomy to establish equitable, transparent domestic mechanisms for compulsory licensing consistent with their public health needs and local health systems, provided that TRIPS obligations — including independent review and adequate remuneration — are maintained[23].Furthermore, Paragraph 6 of the Declaration, which led to the insertion of Article 31bis into the

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[15] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31(a), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

[16] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* 210 (Zed Books 2000).

[17] RIPS Agreement, supra note 4, art. 31(i)–(j); see also WTO, *Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), WT/MIN(01)/DEC/2, ¶¶ 5(b)–(c) (Nov. 14, 2001).

[18] World Trade Organization (WTO), *Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), WT/MIN(01)/DEC/2, ¶ 4 (Nov. 14, 2001).

[19] Id. ¶ 5(c).

[20] Doha Declaration, supra note 1, ¶ 5(b).

[21] World Trade Organization (WTO), *Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), WT/MIN(01)/DEC/2, ¶ 5(c) (Nov. 14, 2001).

[22] Id.; see also Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* 314–18 (Oxford Univ. Press 2007).

[23] Doha Declaration, supra note 6, ¶ 5(b)–(c).

TRIPS Agreement, encourages Members to devise practical solutions for addressing implementation challenges, particularly for countries lacking sufficient pharmaceutical manufacturing capacity[24].Scholarly commentary has observed that this explicit interpretative guidance enhances the legitimacy, predictability, and accessibility of TRIPS flexibilities for public health purposes, especially in developing and least-developed countries[25].

C. Article 31bis – Mechanism for Exporting to Countries Lacking Manufacturing Capacity

Article 31bis of the *TRIPS Agreement* introduces an export mechanism that waives the Article 31(f) requirement that use under a compulsory license be "predominantly for the supply of the domestic market[26]." This provision enables Members with pharmaceutical manufacturing capacity to issue compulsory licenses permitting the production and export of patented medicines to eligible importing Members that lack sufficient domestic manufacturing capacity. The amendment, together with its Annex and Appendix, provides the legal and procedural framework for implementing this waiver.

Features and Scope

Under this system, an exporting Member may issue a compulsory license specifically for the manufacture and export of pharmaceutical products to an eligible importing Member that has notified the WTO of its needs and confirmed that it possesses insufficient or no manufacturing capacity in the relevant pharmaceutical sector. Least-developed country (LDC) Members are deemed eligible by default, without the need for individual confirmation. The remuneration required under Article 31(h) is to be paid in the exporting Member, calculated in light of the economic value to the importing Member. Where the importing Member also grants a compulsory license for the same products, its obligation to provide remuneration under Article 31(h) does not apply to those units, thus avoiding double compensation.

Procedural Safeguards

The Annex to Article 31bis prescribes several procedural safeguards. Both the importing and exporting Members must notify the WTO of the product names, quantities, and relevant details.The export license must limit production strictly to the notified quantity and require that the entire output be exported to the notified Member. To prevent diversion of medicines into unauthorized markets, anti-diversion measures include special labeling or marking, distinctive packaging or coloring/shaping, and publication of product details, quantities, and distinguishing features online. Importing and other Members must ensure effective domestic legal mechanisms exist to prevent diversion of these medicines into their own markets.

Practical Significance

Article 31bis operationalizes the *Doha Declaration's* public health objectives by creating a legal pathway for Members with manufacturing capacity to assist those without it[27]. In practice, however, the mechanism has been rarely used, largely due to its administrative complexity and procedural burdens. The most notable example is the 2007 *Canada–Rwanda* case, in which the Canadian generic company Apotex exported antiretroviral drugs to Rwanda under Canada's Access to Medicines Regime (CAMR)[28]. Although the mechanism remains available for public health emergencies and access initiatives, policy analyses indicate that notification, transparency, and anti-diversion requirements can be resource-intensive, prompting calls for streamlined alternatives[29].

III. India's Compulsory Licensing Regime Under the Patents Act

India's *Patents Act, 1970* establishes three complementary compulsory licensing (CL) mechanisms that align with the flexibilities permitted under the *TRIPS Agreement*: Section 84 for general compulsory licenses after three years from the grant of a patent, Section 92 for expedited compulsory licenses in cases of national emergency or public non-commercial use, and Section 92A for export-only licenses implementing Article 31bis of TRIPS[30].

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[24] Id. ¶ 6; see also WTO General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003); TRIPS Agreement, art. 31bis.

[25] Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. Int'l Econ. L. 921, 923–25 (2007).

[26] 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 [hereinafter TRIPS Agreement].

[27] World Trade Organization (WTO), *Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), WT/MIN(01)/DEC/2, ¶ 6 (Nov. 14, 2001).

[28] Government of Canada, *Canada's Access to Medicines Regime (CAMR): Apotex–Rwanda Case* (2007); see also WTO Council for TRIPS, *Annual Review of the Decision on the Implementation of Parag*

[29] Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference*, 5 J. World Intell. Prop. 15, 27–30 (2002).

[30] The Patents Act, No. 39 of 1970, §§ 84, 92, 92A, INDIA CODE (as amended by The Patents (Amendment) Act, 2005).

A. Section 84: Grounds and Assessment

Under Section 84(1), *any interested person* may apply for a compulsory license after the expiration of three years from the patent grant on any of three grounds: (a) reasonable public requirements have not been satisfied, (b) the patented invention is not available at a reasonably affordable price, or (c) the patented invention is not being worked in India[31]. In determining whether to grant a license, the Controller considers factors enumerated in Section 84(6), including the nature of the invention, measures taken to develop and work the invention in India, the applicant's capacity to undertake production, and prior efforts to obtain a voluntary license.

In *Natco Pharma Ltd. v. Bayer Corp.*, India's first compulsory license was granted in 2012 for the cancer drug *Sorafenib Tosylate* (marketed as Nexavar)[32]. The Controller General of Patents found that Bayer had failed to make the drug available at an affordable price, had not adequately worked the patent in India, and had left a substantial portion of public demand unmet. The compulsory license required Natco to pay a royalty of 6% of net sales to Bayer, to maintain quality standards, and to supply the medicine predominantly to the Indian market. The decision was upheld on appeal by the Intellectual Property Appellate Board (IPAB), which confirmed that Section 84(1) must be interpreted to balance access to medicines with the legitimate interests of patent holders[33].

B. Section 92: Emergency or Public Use

Section 92 provides for a streamlined compulsory licensing process that may be invoked following a Central Government notification in circumstances of national emergency, extreme urgency, or public non-commercial use. Once such a notification is issued, the Controller may dispense with procedural requirements such as prior negotiation with the patent holder and expedite consideration of the license. This mechanism ensures timely intervention during crises such as epidemics or health emergencies, enabling rapid availability of essential goods while maintaining the obligation to provide adequate remuneration to the patent owner[34].

C. Section 92A: Export-Only Licenses

Section 92A, inserted by the *Patents (Amendment) Act, 2005*, enables the grant of compulsory licenses solely for the manufacture and export of patented pharmaceutical products to countries with insufficient or no manufacturing capacity in the pharmaceutical sector. This provision operationalizes India's commitment to implement the *Doha Declaration on the TRIPS Agreement and Public Health* and Article 31bis of TRIPS[35]. It underscores India's position as a major supplier of affordable generic medicines to least-developed and developing countries facing public health crises. Although actual use of Section 92A has been limited, its existence strengthens the legal framework supporting equitable global access to essential medicines[36].

D. Procedure, Standards, And Remuneration

Under **Section 84** of the *Patents Act, 1970*, a compulsory licence may be sought only after three years from the grant, by any person interested, with the Controller assessing both procedural preconditions—such as disclosure of the applicant's interest and bona fide efforts to obtain a voluntary licence within a reasonable period—and substantive capacity to work the invention to the public advantage, alongside the patentee's own steps to make the invention available in India[37]. Substantively, a licence can issue if at least one ground is shown: unmet reasonable public requirements, unreasonably high pricing relative to reasonable affordability, or non-working in the territory of India; **Section 84(7)** elaborates deeming situations for unmet public requirements, including refusals to license on reasonable terms, unmet demand on adequate terms, prejudice to industry or trade including export markets, restrictive licensing practices, failure to commercially work, or undue hindrance of imports by the patentee or persons in concert.[38]

When settling terms under **Section 90**, the Controller strives to secure reasonable royalty and remuneration having regard to the invention's nature and patentee expenditures, ensure working to the fullest extent with

[31] Id. § 84(1)(a)–(c).
[32] *Natco Pharma Ltd. v. Bayer Corp.*, Compulsory Licence Application No. 1 of 2011, Decision of the Controller of Patents (Mar. 9, 2012).
[33] *Bayer Corp. v. Natco Pharma Ltd.*, OA/35/2012/PT/MUM, Intellectual Property Appellate Board (Mar. 4, 2013).
[34] World Trade Organization (WTO), *Declaration on the TRIPS Agreement and Public Health* (Doha Declaration), WT/MIN(01)/DEC/2, ¶ 5(c) (Nov. 14, 2001).
[35] 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; see also Doha Declaration, supra note 43, ¶ 6.
[36] Frederick M. Abbott, *Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health*, 13 J. World Intell. Prop. 1, 5–7 (2010).
[37] *The Patents Act, 1970*, § 84(1); see also *Natco Pharma Ltd. v. Bayer Corporation*, Compulsory Licence Application No. 1 of 2011, Order dated 9 March 2012 (Controller of Patents).
[38] *Id.*, § 84(7); see also *Intellectual Property Appellate Board, Bayer Corporation v. Union of India* (2014) 60 PTC 277 (IPAB).

reasonable licensee profit, mandate availability at reasonably affordable prices, and impose non-exclusive, non-assignable licences typically for the balance of the patent term, with directions possible regarding supply to the Indian market and limited import/export as permitted[39]. In emergencies, extreme urgency, or public non-commercial use notified by the Central Government, **Section 92** authorizes streamlined compulsory licences without the Section 87 procedure to ensure rapid availability at the lowest reasonable price consistent with a reasonable return to the patentee, while otherwise **Sections 83** and **87–90** govern the terms and conditions[40].

V. Comparative Analysis

Brazil, Thailand, Germany, and Canada exemplify distinct institutional pathways for compulsory licensing that operate within TRIPS safeguards on prior efforts, scope/duration, and adequate remuneration, while advancing the *Doha Declaration*'s access-to-medicines objective: Brazil's *Presidential Decree No. 6,108* (May 4, 2007) authorized a public non-commercial compulsory licence for efavirenz with remuneration set at 1.5% of the government purchase price, initially relying on Indian generics before shifting to local production at *Farmanguinhos/Fiocruz*, reflecting *Article 31* compliance on public supply and payment criteria[41]. Thailand's *Ministry of Public Health* issued government-use licences under *Section 51* for efavirenz (2006), lopinavir/ritonavir (2007), and clopidogrel (2007), justified through public-interest and affordability data to secure broader access, consistent with *Article 31(b)*'s waiver of prior negotiation in emergencies or urgent public need[42]. Germany's courts used a judicial channel to grant a compulsory licence by preliminary injunction for raltegravir (*Isentress*), later affirmed by the *Federal Supreme Court (Bundesgerichtshof)*, emphasizing continuity of care and public health as sufficient public interest within the *German Patentgesetz* framework aligned to TRIPS[43]. Canada's *Access to Medicines Regime (CAMR)* enabled export to Rwanda under the Paragraph 6/*Article 31bis* system, with the *Apotex–Rwanda* case illustrating protracted sequencing of voluntary-licence talks, notifications, tendering, and shipment timing, even as the legal mechanism ultimately functioned to deliver medicines under the TRIPS waiver architecture[44].

VI.Conclusion

The current paradigm, viewed in its entirety, demonstrates that compulsory licensing is not some sort of exceptional departure from the patent system but an integral flexibility created to make certain that protection of innovation serves the interest of societal welfare in general, especially when facing health emergencies or market failures that impede affordability and supply[45]. *TRIPS* Article 31 contains procedural and substantive safeguards—prior efforts where appropriate, limits on scope and duration, and adequate remuneration—that channel non-voluntary use toward targeted, proportionate interventions rather than blunt expropriation[46]. While the *Doha Declaration* clarifies Members' sovereign space to deploy these tools for public health, and Article 31bis extends the regime across borders in support of countries without manufacturing capacity, real-world utilization shows both promise and friction[47].

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[39] *The Patents Act, 1970*, § 90(1); and Department for Promotion of Industry and Internal Trade (DPIIT), *Manual of Patent Office Practice and Procedure*, 2020, Chapter 15 (Compulsory Licensing).

[40] *The Patents Act, 1970*, §§ 92, 83–90; see also WTO, *TRIPS Agreement*, Art. 31; and Ministry of Commerce & Industry, *Statement on Compulsory Licensing and Access to Medicines in India* (2013).

[41] *Presidential Decree No. 6,108*, de 4 de Maio de 2007 (Braz.); see also World Trade Organization (WTO), *Council for TRIPS, Notification IP/N/1/BRA/P/1* (2007); Ellen 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* 183–85 (AMB Publishers 2009).

[42] Ministry of Public Health (Thailand), *The Government Use of Patents on the Drugs "Efavirenz", "Lopinavir+Ritonavir", and "Clopidogrel" in Thailand* (White Paper, 2007); WTO, *Notification under Article 63.2 of the TRIPS Agreement: Thailand IP/N/1/THA/P/2* (2007); Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions*, 10 J. Int'l Econ. L. 921, 940–43 (2007).

[43] *Merck Sharp & Dohme Corp. v. Shionogi & Co. Ltd.*, Compulsory Licence (Raltegravir/Isentress Case), Decision of the Federal Patent Court (BPatG), 31 August 2016, upheld by *Bundesgerichtshof*, Case X ZB 2/17 (11 July 2017); Jens Schovsbo, *Compulsory Licensing in Germany: A Landmark Decision in the Isentress Case*, 48 IIC 115 (2017).

[44] WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 and Corr.1 (Sept. 1, 2003); Apotex Inc., *Press Release: Shipment of Apo-TriAvir to Rwanda under Canada's Access to Medicines Regime* (Sept. 2008); Amir Attaran, *Assessing Canada's Access to Medicines Regime: Lessons for Compulsory Licensing and Access to Medicines*, 8 Global Health 5 (2012).

[45] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], art. 7.

[46] *Id.*, art. 31; Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* 211–14 (Zed Books 2000).

[47] *World Trade Organization, Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 14, 2001); *WTO General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003).

Empirical and case-study evidence show that compulsory licensing can lower prices and expand access, yet administrative complexity, political pressure, and production bottlenecks can blunt its timeliness—especially under the export pathway, which has seen limited uptake despite urgent need[48]. Policy scholarship therefore converges on two complementary priorities: streamline domestic and cross-border procedures, including clearer remuneration benchmarks and simplified notifications, while investing in regional manufacturing capacity so that compulsory licences translate swiftly into supply[49]. For countries such as India, the tripartite architecture (Sections 84, 92, and 92A of the *Patents Act, 1970*) attests to how calibrated national rules can make *TRIPS* flexibilities operational while keeping innovation signals through case-specific remuneration and judicial or independent review.

The most effective compulsory-licensing regimes going forward are those embedded within robust health-system planning and industrial policy—conducted with transparent criteria, measured against access outcomes, and linked with fair compensation—so that the patent system's objectives and principles find application in reality: promoting technological innovation and the transfer and dissemination of technology to the mutual advantage of producers and users, in a manner conducive to social and economic welfare[50].

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[49] Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP*, 18 J. Intell. Prop. L. 447, 455–57 (2011); Antony Taubman, *Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing*, 11 J. Int'l Econ. L. 927, 943–45 (2008).

[50] TRIPS Agreement, supra note 1, art. 7; Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 Hous. L. Rev. 979, 1004–09 (2009).