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COMPULSORY LICENSING UNDER PATENT LAW: A BALANCING MECHANISM BETWEEN PUBLIC HEALTH AND INTELLECTUAL PROPERTY RIGHTS

AUTHORED BY - MAHRISHI BHARDWAJ
Vivekananda Institute Of Professional Studies

Abstract

This research paper critically examines the doctrine of compulsory licensing as a legal mechanism that seeks to balance intellectual property (IP) rights with public interest, particularly in the context of access to medicines and essential technologies. Recognized under Article 31 of the TRIPS Agreement and codified within Section 84 and Section 92 of the Indian Patents Act, 1970, compulsory licensing enables a government to authorize the use of a patented invention without the consent of the patent holder under specific conditions. This study delves into the conceptual foundations of compulsory licensing, tracing its evolution from early patent law jurisprudence to its codification in multilateral IP regimes. It further analyzes the international framework, including the Doha Declaration on the TRIPS Agreement and Public Health, and evaluates India's legal infrastructure, emphasizing landmark cases such as *Bayer Corp. v. Natco Pharma Ltd.*

The paper presents a critical appraisal of the effectiveness of compulsory licensing in practice, highlighting procedural complexities, political pressures, and underutilization despite legal clarity. Through comparative analysis and case studies, the research underscores how compulsory licensing, though designed as a flexibility, often faces geopolitical and trade-related resistance, especially from high-income nations and multinational pharmaceutical companies.

In the post-COVID-19 era, the doctrine has reemerged at the center of global health policy debates, prompting renewed calls for its reform and proactive use. The paper argues that compulsory licensing should evolve from being a last-resort remedy to a strategically embedded component of public health governance, covering not only medicines but also vaccines, diagnostics, and essential health technologies. Finally, the study offers policy recommendations aimed at enhancing the doctrine’s accessibility, effectiveness, and legitimacy

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in both domestic and global settings. The paper concludes that compulsory licensing, if implemented with clarity, courage, and consistency, can serve as a crucial legal bridge between innovation and equitable access, ensuring that patents do not become barriers to human survival and dignity.

I. Introduction

The architecture of intellectual property law, particularly patent law, is designed to incentivize innovation by granting exclusive rights to inventors for a limited period. This monopoly allows patentees to commercially exploit their inventions, recoup research and development costs, and maintain a competitive edge in the market. In return, they are required to publicly disclose the technical know-how of the invention, thereby contributing to the body of public knowledge and fostering future innovation.[1] However, this trade-off becomes contentious when the enforcement of patent rights impedes access to essential products, especially life-saving medications, in low- and middle-income countries (LMICs). It is in such contexts that the doctrine of **compulsory licensing** emerges as a crucial regulatory tool.

Compulsory licensing refers to the state-sanctioned authorization granted to a third party to produce, use, or sell a patented product or process without the consent of the patent holder, typically in the interest of public welfare. Though often portrayed as an exception to patent rights, compulsory licensing is in fact a **legitimate legal mechanism** recognized under both domestic statutes and international treaties, including the **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**.[2] This mechanism seeks to strike a balance between two competing objectives: promoting innovation through strong patent protection and ensuring that technological advancements, particularly in healthcare, do not remain inaccessible to those who need them most.

The global relevance of compulsory licensing was dramatically underscored during the early 2000s amid the HIV/AIDS epidemic. Countries like South Africa, Brazil, and Thailand resorted to or threatened to invoke compulsory licenses to procure affordable generic versions of antiretroviral drugs, challenging the monopoly pricing of pharmaceutical multinationals.[3] The

1 William M. Landes & Richard A. Posner, *The Economic Structure of Intellectual Property Law* 294–98 (2003).

2 Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

3 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* 62–70 (2009).

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resulting geopolitical tensions triggered intense debates within the **World Trade Organization (WTO)**, culminating in the adoption of the **Doha Declaration on the TRIPS Agreement and Public Health** in 2001. The declaration reaffirmed that TRIPS should not prevent member states from taking measures to protect public health, and emphasized the right of countries to issue compulsory licenses, especially during national health emergencies.[4]

India's approach to compulsory licensing, shaped by its socio-economic context and constitutional commitment to public health, has been particularly instructive. The **Patents Act, 1970**, amended in 2005 to align with TRIPS, contains detailed provisions for the grant of compulsory licenses under various circumstances including non-working of patents, excessive pricing, and public health crises.[5] The landmark case of **Bayer Corporation v. Natco Pharma Ltd.** (2012) marked a watershed moment in Indian IP jurisprudence, setting a precedent for balancing patent rights with access to affordable medicines.[6]

In the post-COVID era, the relevance of compulsory licensing has further expanded, with global calls for greater access to vaccines, treatments, and diagnostics. The inadequacy of voluntary mechanisms such as **COVAX** and the tepid global response to the **COVID-19 Technology Access Pool (C-TAP)** have once again spotlighted compulsory licensing as a necessary, though underutilized, policy instrument for ensuring equitable health access.[7] As nations navigate complex tensions between public health, trade obligations, and innovation incentives, compulsory licensing remains a **critical intersection of law, ethics, and global justice**.

II. Conceptual Understanding of Compulsory Licensing

Compulsory licensing occupies a unique space in the intellectual property landscape as both a legal exception and a policy safeguard. At its core, it refers to the statutory authorization granted by a government to a third party—typically a local manufacturer—to produce or use a patented product or process without the voluntary consent of the patent holder, subject to certain conditions and safeguards. It is not an expropriation of patent rights but rather a conditional override, rooted in public interest considerations such as national health, nutrition,

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

5 The Patents Act, 1970, §§ 84–92A, No. 39, Acts of Parliament, 1970 (India).

6 Bayer Corp. v. Natco Pharma Ltd., Compulsory License Application No. 1 of 2011 (Controller of Patents, Mar. 9, 2012); see also Shamnad Basheer, *India's First Compulsory License: The Breaking of a New Patent Regime*, SpicyIP (Mar. 13, 2012)

7 World Health Organization, *COVID-19 Technology Access Pool (C-TAP)*

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or technological advancement.[8]

This mechanism functions as a corrective tool against the potential abuse of patent monopolies. While patent protection is essential to incentivize innovation, unregulated monopoly power may result in excessive pricing, restricted supply, and lack of local availability, especially in low-income settings. Compulsory licensing thus,serves to recalibrate the balance between private rights and public welfare—recognizing that intellectual property is not absolute but subject to reasonable limitations in a democratic and welfare-oriented legal system.[9]

From a jurisprudential standpoint, compulsory licensing is underpinned by the doctrine of utilitarianism in patent law, which views intellectual property as a means to achieve greater societal good, rather than as a natural right.[10] By compelling patent holders to share their innovations under specific public interest circumstances, the law ensures that technological advancement does not become exclusionary or elitist. This is particularly important in the pharmaceutical sector, where patents can determine access to life-saving medicines.

Importantly, compulsory licenses are not granted arbitrarily. International treaties such as the TRIPS Agreement and domestic laws like the Indian Patents Act, 1970, outline specific grounds, procedures, and limitations under which such licenses may be issued. These include the non-working of the patent, failure to make the invention available at a reasonable price, and public health emergencies.[11] The grant of a compulsory license is also non-exclusive, meaning that multiple parties may be permitted to exploit the patent, and the patent holder is entitled to adequate remuneration, thus preserving some degree of commercial benefit.[12]

In a broader developmental context, compulsory licensing can stimulate domestic industrial growth, facilitate technology transfer, and promote economic self-reliance in developing countries. The mechanism is not anti-innovation; rather, it is pro-access and pro-equity, seeking to ensure that the fruits of innovation reach the marginalized and not just the affluent.

8 Frederick M. Abbott, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision* 1–3 (2005)

9 Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* 95–98 (2000).

10 William Fisher, *Theories of Intellectual Property*, in *New Essays in the Legal and Political Theory of Property* 168–99 (Stephen R. Munzer ed., 2001).

11 The Patents Act, 1970, § 84, No. 39, Acts of Parliament, 1970 (India); TRIPS Agreement art. 31.

12 UNCTAD–ICTSD, *Resource Book on TRIPS and Development* 471–82 (2005).

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Thus, compulsory licensing represents a constitutional, legal, and ethical reconciliation between the rights of inventors and the needs of society—particularly in areas where health, human dignity, and life itself are at stake.

III. International Legal Framework

The legal foundation for compulsory licensing in the international domain is primarily derived from the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is administered by the World Trade Organization (WTO). TRIPS sets minimum standards for the protection and enforcement of intellectual property rights, including patents, across all WTO member states. However, it also embeds certain flexibilities that allow countries to safeguard public health and promote socio-economic welfare—chief among them being the provision for compulsory licensing.

A. TRIPS Agreement: Article 31 and Flexibilities

Article 31 of the TRIPS Agreement explicitly recognizes the right of member states to authorize the use of a patented invention without the authorization of the right holder, subject to specific procedural safeguards such as prior negotiations with the patent holder (except in cases of national emergency or public non-commercial use), non-exclusivity of the license, and adequate remuneration to the patent holder.[13] This provision essentially provides the legal scaffolding for compulsory licensing while balancing the legitimate interests of patentees.

Despite these built-in flexibilities, early implementation of Article 31 faced resistance from developed nations and pharmaceutical corporations, who argued that such measures could deter innovation and violate TRIPS commitments. This tension came to a head in the late 1990s and early 2000s, when developing countries like South Africa and Brazil sought to override patents on life-saving HIV/AIDS medications to deal with the public health crisis.[14]

B. The Doha Declaration on the TRIPS Agreement and Public Health (2001)

In response to mounting global pressure and moral outrage over access to essential medicines, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and

13 Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

14 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* 62–70 (2009).

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Public Health in 2001. The Declaration marked a paradigm shift, reaffirming that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."[15] It emphasized the right of member states to grant compulsory licenses and determine the grounds upon which such licenses are issued.

Clause 5(b) of the Declaration states that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[16] This provided much-needed clarity and political legitimacy to developing countries, enabling them to prioritize public health over strict patent protection in times of need.

C. Paragraph 6 System and the August 30 Decision (2003)

One of the limitations of TRIPS Article 31 was that it restricted compulsory licenses predominantly to domestic use. This created challenges for countries with insufficient manufacturing capacity in the pharmaceutical sector. To remedy this, Paragraph 6 of the Doha Declaration called upon the WTO to find a solution that would enable such countries to import generic medicines produced under compulsory licenses.

This led to the August 30 Decision of 2003, which created a legal mechanism—often called the Paragraph 6 System—allowing WTO members to export patented medicines under compulsory licenses to countries lacking manufacturing capacity.[17] While this mechanism was later incorporated into TRIPS as Article 31bis, its complex procedural requirements have drawn criticism for being cumbersome and underutilized.[18] The only notable implementation occurred in 2007 when Rwanda imported generic HIV drugs from Canada's Apotex under the Paragraph 6 system, highlighting both the potential and procedural burden of the system.[19]

D. Compulsory Licensing and International Human Rights Law

Beyond the trade framework, compulsory licensing also intersects with international human rights instruments. The International Covenant on Economic, Social and Cultural Rights (ICESCR), ratified by over 170 countries, obligates states to ensure "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[20] The

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

16 Id. ¶ 5(b).

17 World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Sept. 1, 2003).

18 Carlos M. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*, 31 S. Afr. J. Hum. Rts. 569, 573–75 (2015).

19 Apotex Inc., *Rwanda and Canada's Access to Medicines Regime*, https://www.apotex.com/global/about/archives/2007 (last visited June 16, 2025).

20 International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.

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Committee on Economic, Social and Cultural Rights has interpreted this to mean that access to essential medicines is a core obligation, and states are expected to take steps—including issuing compulsory licenses—to ensure such access, especially for vulnerable and marginalized populations.[21]

This human rights dimension strengthens the normative legitimacy of compulsory licensing, reinforcing it as not merely a trade law exception but a humanitarian imperative.

IV. Indian Legal Regime

India's legal framework on compulsory licensing reflects a careful attempt to harmonize international obligations under TRIPS with domestic socio-economic and public health needs. India, as a developing country with a large population vulnerable to health crises and lacking in universal health coverage, has adopted a relatively progressive and access-oriented approach to compulsory licensing through its domestic legislation.

The cornerstone of this regime is enshrined in the Patents Act, 1970, which was amended significantly in 2005 to comply with TRIPS obligations after the end of the transition period provided to developing countries. While introducing product patents in pharmaceuticals and agrochemicals, the 2005 amendment also retained and strengthened public health safeguards—notably compulsory licensing provisions under Chapter XVI (Sections 84 to 92A).[22]

A. Statutory Grounds for Compulsory Licensing under Section 84

Under Section 84(1) of the Patents Act, any person interested, after the expiry of three years from the date of grant of the patent, may apply to the Controller of Patents for a compulsory license on any one or more of the following three grounds:

1. That the reasonable requirements of the public with respect to the patented invention have not been satisfied;
2. That the patented invention is not available to the public at a reasonably affordable price;
3. That the patented invention is not worked in the territory of India.[23]

21 U.N. Committee on Economic, Social and Cultural Rights, General Comment No. 14, The Right to the Highest Attainable Standard of Health, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000), ¶¶ 43–45.

22 The Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India), amended by Patents (Amendment) Act, 2005, Act No. 15 of 2005.

23 Id. § 84(1).

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These grounds reflect a rights-based framework, where the unmet needs of the public—rather than just procedural non-compliance—form the basis for intervention. The requirement of "working" a patent in India has been interpreted to mean local manufacture rather than mere importation, thereby promoting domestic production and self-reliance in essential technologies.[24]

The applicant must furnish evidence supporting their claims and is required to propose terms for the license, including royalty and other conditions. The Controller evaluates the application in light of public interest, the nature of the invention, the capability of the applicant, and existing market conditions.

B. Compulsory Licensing in Cases of National Emergency – Section 92

Section 92 of the Act empowers the Central Government to notify a national emergency or extreme urgency, or use for public non-commercial purposes, upon which the Controller may issue a compulsory license without following the procedural requirements under Section 84, such as prior negotiation with the patent holder.[25] This provision was specifically designed to enable quick intervention in times of crisis, such as pandemics, epidemics, or bioterrorism.

The flexibility under this provision was under active discussion during the COVID-19 pandemic, though no license was ultimately issued under it. However, it served as a deterrent mechanism in pricing negotiations and policy formulation during the vaccine procurement phase.

C. Export of Generic Medicines – Section 92A

India was among the first countries to legislate for the Paragraph 6 solution under the Doha Declaration by inserting Section 92A into its Patents Act. This provision allows Indian pharmaceutical companies to manufacture and export patented drugs under compulsory license to countries with insufficient or no manufacturing capacity, provided such countries have issued a compulsory license or notified their intent to do so under the TRIPS mechanism.[26]
Section 92A is vital to India's role as the "pharmacy of the developing world", facilitating access to affordable generics in Sub-Saharan Africa, Latin America, and Southeast Asia.

24 Bayer Corp. v. Natco Pharma Ltd., Compulsory License Application No. 1 of 2011 (Controller of Patents, Mar. 9, 2012).

25 The Patents Act, 1970, § 92.

26 Id. § 92A; see also WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Sept. 1, 2003).

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D. Judicial Precedent – Bayer Corporation v. Natco Pharma Ltd. (2012)

The first and most significant instance of a compulsory license in India was the case of Bayer Corporation v. Natco Pharma Ltd., decided in 2012. Bayer held a patent for Sorafenib Tosylate (brand name: Nexavar), a life-extending drug used for liver and kidney cancer. Natco Pharma applied for a compulsory license under Section 84, arguing that:

- The drug was not reasonably affordable (Bayer charged ₹2.8 lakhs per month while Natco proposed ₹8,800),
- It was not manufactured in India,
- And the public requirements were not being met.

The Controller of Patents granted the license, holding that all three statutory conditions under Section 84 were satisfied. The license allowed Natco to manufacture and sell the drug at a much lower price while paying a 6% royalty to Bayer.[27]

This landmark ruling was upheld by the Intellectual Property Appellate Board (IPAB) and later by the Bombay High Court, affirming India's commitment to balancing patent rights with public interest. It established a powerful precedent on the scope, interpretation, and implementation of compulsory licensing provisions.

E. TRIPS Compatibility and Constitutional Validity

India’s compulsory licensing provisions are TRIPS-compliant, as they conform to the requirements of Article 31 and 31bis of the Agreement. Furthermore, these provisions serve the Directive Principles of State Policy (DPSPs) enshrined in Articles 38, 39, and 47 of the Indian Constitution, which mandate the State to secure a just social order, reduce inequalities, and promote public health.[28]

Courts in India have consistently held that the right to health is integral to Article 21, the fundamental right to life. In this context, the compulsory licensing mechanism acquires constitutional legitimacy as a tool to operationalize the right to life, dignity, and healthcare for all citizens.[8]

27 Bayer Corp. v. Natco Pharma Ltd., supra note 3; see also Shamnad Basheer, *India's First Compulsory License: The Breaking of a New Patent Regime*, SpicyIP (Mar. 13, 2012), https://spicyip.com.

28 India Const. art. 38, 39, 47.

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V. Comparative Jurisprudence and Practices

A. Thailand

Between 2006 and 2008, Thailand issued multiple compulsory licenses for drugs treating HIV/AIDS and cardiovascular diseases. These actions saved the country millions of dollars and expanded healthcare access. Thailand faced backlash from pharmaceutical companies and certain Western governments but upheld its stance under the Doha Declaration.[29]

B. Brazil

Brazil leveraged the threat of compulsory licensing as a bargaining tool, pressuring companies like Abbott and Roche to reduce prices for anti-retroviral drugs. It eventually issued a compulsory license for Efavirenz in 2007.[30]

C. Canada and Rwanda: The First Use of Paragraph 6

Canada's Access to Medicines Regime (CAMR) was invoked by Apotex Inc. to supply Rwanda with TriAvir, a fixed-dose HIV drug. Though successful, the process exposed the cumbersome procedures and lack of incentives involved in utilizing Paragraph 6, highlighting the need for reform.[31]

VI. Critical Appraisal of the Regime

While compulsory licensing is hailed as a legally sanctioned humanitarian tool for promoting access to essential technologies, particularly life-saving medicines, it is not without its complexities and controversies. A critical evaluation reveals that while the mechanism theoretically strikes a balance between patent protection and public interest, its practical application is often fraught with legal, political, and procedural hurdles.

A. Effectiveness in Ensuring Public Health Access

The primary strength of compulsory licensing lies in its public health orientation. It offers countries a lawful way to override patent monopolies to address market failures, especially in the pharmaceutical sector, where access to patented medicines remains elusive for millions in low-income and middle-income countries.[32] The Indian case of Bayer v. Natco is often cited

29 World Health Organization, Regional Office for South-East Asia, *Compulsory Licensing and Access to Medicines: A South-East Asia Perspective* (2008).

30 Ellen F.M. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power* 154 (2009).

31 Amir Attaran, *Canada's Access to Medicines Regime: A Review of its First Use and Proposals for Reform*, 3 Health L. J. 51 (2010).

32 World Health Organization, *Intellectual Property and Access to Medicines: A South-East Asia Perspective* 15–19 (2010).

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as a successful example where compulsory licensing achieved its goal of reducing drug prices without compromising on legal or procedural integrity.[33]

Moreover, the mere threat of compulsory licensing has, in several cases, served as a bargaining chip to negotiate reduced prices with patent-holding corporations, even when no license was eventually issued. Countries such as Brazil and Thailand used this tactic to secure affordable access to HIV and cancer treatments in the mid-2000s.[334]B. Limited Utilization and Procedural Hurdles Despite the available legal framework, the actual issuance of compulsory licenses globally remains very rare. The cumbersome procedural requirements under both domestic laws and the TRIPS regime often disincentivize their use. For instance, under TRIPS Article 31, the obligation of prior negotiations and royalty assessment, combined with possible litigation, can delay the process considerably, even in urgent situations.[35]

India, despite having a robust legal framework, has only granted one compulsory license to date (Natco, 2012). Several applications have either been rejected or withdrawn due to the complexity of evidentiary standards, the lack of political will, or external pressure from powerful pharmaceutical lobbies and foreign governments.[36] This reveals a gap between the de jure availability of compulsory licensing and its de facto implementation.

C. International Pressure and Political Economy

The geopolitics of intellectual property often inhibit the effective exercise of compulsory licensing, particularly by developing nations. The United States Trade Representative (USTR) routinely places countries like India, Thailand, and South Africa on the Special 301 Watch List, accusing them of undermining IP rights when they consider issuing compulsory licenses—even when such actions are TRIPS-compliant.[37] This has had a chilling effect on many nations, making them reluctant to issue compulsory licenses even in situations of public need.

Furthermore, the influence of multinational pharmaceutical companies and bilateral free trade agreements (FTAs) often includes TRIPS-plus provisions, which restrict the flexibility provided under TRIPS, making compulsory licensing more difficult.[38]

33 Bayer Corp. v. Natco Pharma Ltd., Compulsory License Application No. 1 of 2011 (Controller of Patents, Mar. 9, 2012).

34 Ellen ‘t Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* 56–60 (2009).

35 Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299.

36 Shamnad Basheer, *India's Compulsory Licensing Regime: A De Facto Dead Letter?*, SpicyIP (Apr. 3, 2015).

37 Office of the United States Trade Representative, *2023 Special 301 Report*, at 55–59.

38 UNDP, *The Impact of Free Trade Agreements on Public Health* 20–24 (2015).

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D. Innovation vs. Access: A False Dichotomy?

Critics of compulsory licensing often argue that it disincentivizes innovation by undermining the exclusive commercial benefits granted to patent holders. While this concern may have some merit in niche, high-risk R&D areas, empirical studies suggest that the use of compulsory licensing has not significantly deterred investment or research in countries that have implemented it responsibly.[39] On the contrary, ensuring access can stimulate local innovation, generic production capacity, and even technological transfer in the long run.

Thus, the supposed conflict between innovation and access is, in many cases, a false dichotomy. A well-regulated system of compulsory licensing can complement innovation by ensuring that it serves human needs over market exclusivity.

E. Underutilization of Section 92A in India

India's Section 92A provides a powerful tool to export generics under compulsory licensing to countries with insufficient manufacturing capacity. However, its usage has been negligible. The reasons include complex compliance protocols, fear of retaliation under trade agreements, and the lack of legal and institutional readiness in recipient countries.[40] The only real case involved Rwanda's import of an HIV drug from Canada under the Paragraph 6 system—ironically, not from India.

This underutilization reflects a missed opportunity for India to assert its global leadership in the access-to-medicine movement, especially given its capacity for generic drug manufacturing.

VII. The Future of Compulsory Licensing in the Post-Pandemic Era

The COVID-19 pandemic brought the global intellectual property regime under unprecedented scrutiny. It reignited debates on the tension between patent exclusivity and public health needs, casting a spotlight on compulsory licensing as a crucial, yet underutilized, legal mechanism. Moving forward, the post-pandemic world is likely to reshape the scope, relevance, and application of compulsory licensing across both domestic and international jurisdictions.

39 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, 935 (2007).

40 Carlos Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*, 31 S. Afr. J. Hum. Rts. 569 (2015).

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A. A Shift Towards Public Health Sovereignty

The pandemic demonstrated the vulnerability of global supply chains, especially in the realm of essential medical supplies and vaccines. Many developing and least-developed countries found themselves at the periphery of vaccine access, with wealthy nations engaging in vaccine hoarding and pharmaceutical companies enforcing tight patent controls.[41] This experience has intensified calls for greater self-reliance, with compulsory licensing emerging as a key instrument of public health sovereignty.

Countries such as India, South Africa, and Indonesia are revisiting domestic patent laws to streamline compulsory licensing procedures in preparation for future pandemics. The increased willingness of states to assert TRIPS flexibilities may signal a revival of compulsory licensing not only for medicines but also for vaccine technology, diagnostics, and manufacturing know-how.[42]

B. Beyond Pharmaceuticals: A Broader Technological Scope

The future of compulsory licensing is not confined to pharmaceuticals alone. As technology becomes more interdisciplinary and essential, especially in healthcare, climate adaptation, and artificial intelligence, there is increasing discussion about extending compulsory licensing to medical devices (e.g., ventilators), diagnostic kits, mRNA technology platforms, and even software used in epidemiological modeling.[43]

For example, during the COVID-19 crisis, the lack of access to diagnostic kits and ventilator designs prompted countries like Chile and Israel to consider broader forms of patent waivers and compulsory licensing. The World Intellectual Property Organization (WIPO) has also noted that in future emergencies, non-pharmaceutical patents may be critical to address public needs.[44]

C. TRIPS Waiver and Global Solidarity Measures

One of the most significant developments during the pandemic was the joint proposal by India and South Africa at the WTO for a temporary waiver of TRIPS obligations for COVID-19-

41 World Health Organization, *COVID-19 Vaccine Global Access Inequity Report* (2021)

42 Médecins Sans Frontières, *Overcoming Intellectual Property Barriers in the Pandemic Response* (2022).

43 Frederick M. Abbott, *The Scope of Compulsory Licensing in the COVID Era*, 18 J. Intell. Prop. L. 1, 22–27 (2021).

44 WIPO, *Intellectual Property and COVID-19: Policy Considerations* (2020),

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related technologies. Although the final outcome was watered down at the WTO Ministerial Conference in 2022, it has laid the groundwork for more robust discussions on permanent reforms to the TRIPS framework.[45]

The proposal brought widespread attention to the inadequacy of the current IP regime in responding to global health emergencies. Moving forward, compulsory licensing may serve as a bridge between patent waivers and full exclusivity, providing a middle path that respects innovation while ensuring access. It also reinforces the Doha Declaration's affirmation that the TRIPS Agreement should be interpreted in a manner supportive of public health and access to medicines for all.[46]

D. Digital Infrastructure and Regulatory Readiness

A major bottleneck in the past has been the lack of digital infrastructure and regulatory frameworks to support swift issuance of compulsory licenses. In the post-pandemic world, countries are investing in e-governance mechanisms that allow for online application, evidence submission, and expedited hearings in patent disputes, including compulsory licensing applications.

For example, the Indian Patent Office is now increasingly digitalized, allowing for faster responses. Coupled with judicial precedents like *Natco v. Bayer*, the stage is being set for a more responsive and rights-based administrative system.[47]

E. Challenges Ahead: Political Economy and Innovation Ethics

Despite growing momentum, compulsory licensing in the post-pandemic world will still face considerable resistance from pharmaceutical lobbies, geopolitical actors, and trade treaty obligations. The Special 301 Reports by the U.S. continue to act as diplomatic tools to discourage nations from invoking TRIPS flexibilities.[48]

Moreover, questions around innovation ethics—such as whether inventors should be compelled to share their work without adequate compensation—continue to dominate policy debates. A

[45] WTO, *Ministerial Decision on the TRIPS Agreement*, WT/MIN(22)/30 (June 17, 2022).
[46] WTO, *Doha Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 14, 2001).
[47] Bayer Corp. v. Natco Pharma Ltd., Compulsory License Application No. 1 of 2011 (Controller of Patents, Mar. 9, 2012).
[48] Office of the United States Trade Representative, *2023 Special 301 Report*, at 55, https://ustr.gov.

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possible future direction may involve pre-negotiated licensing pools or automatic trigger mechanisms for emergencies to balance ethical and legal concerns.

VIII. Conclusion

Compulsory licensing stands at the confluence of two pivotal yet often conflicting imperatives: the protection of intellectual property rights and the preservation of public interest, especially in the domain of access to essential healthcare technologies. As a legal instrument enshrined in both international treaties like the TRIPS Agreement and domestic statutes such as the Indian Patents Act, 1970, it reflects the normative understanding that patent rights, while essential for incentivizing innovation, must not become barriers to life-saving interventions or technological dissemination in times of crisis.

The jurisprudence and policy landscape surrounding compulsory licensing have evolved through landmark cases like *Bayer v. Natco*, multilateral negotiations such as the Doha Declaration on TRIPS and Public Health, and more recently, the global response to the COVID-19 pandemic. These developments have collectively underscored the doctrine's relevance not merely as a theoretical flex of sovereign power, but as a practical tool of global equity in matters of health, technology, and innovation.

However, the underutilization of compulsory licensing—despite its legal availability—exposes structural, political, and economic barriers that often obstruct its implementation. Issues such as complex procedural requirements, international political pressure, fear of trade retaliation, lack of administrative readiness, and limited awareness among potential applicants have rendered compulsory licensing an exception rather than a norm. The reluctance of many countries to invoke this mechanism, despite facing urgent public health crises, highlights the gap between legal potential and practical enforcement.

The post-pandemic era presents an opportunity to reimagine the contours of compulsory licensing. As the global community grapples with future pandemics, antimicrobial resistance, and climate-induced health emergencies, there is a growing recognition that IP flexibility mechanisms must be integrated into national preparedness strategies. Future directions may include: simplification of domestic procedures; development of regional frameworks for pooled procurement and licensing; introduction of pre-negotiated compulsory licenses in emergency protocols; and the establishment of international legal norms to insulate states from

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coercive trade diplomacy when exercising their lawful rights.

Ultimately, compulsory licensing is not an affront to innovation but a guardrail against monopolistic excesses that threaten the right to life and health. If harnessed effectively, it can serve as a cornerstone in the global architecture of equitable access to knowledge, technology, and medicines—a vision that is both constitutionally grounded and ethically indispensable. As India and other nations contemplate their role in the future of global health governance, compulsory licensing must no longer remain a reactive tool of emergency relief, but a proactive legal strategy of developmental justice and human dignity.