COMPULSORY LICENSING AS A TOOL FOR GLOBAL PUBLIC INTEREST: EVOLUTION, CHALLENGES, AND REFORM

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ABSTRACT

This paper explores the evolving role of compulsory licensing (CL) as a critical legal and policy tool for reconciling intellectual property rights with the broader public interest in the 21st century. While the TRIPS Agreement and the Doha Declaration provide member states with considerable flexibility to issue CLs in situations of national emergency and public need, practical obstacles—including procedural complexity, vague legal definitions, and geopolitical pressures—continue to limit its application. Drawing on historical development, international legal frameworks, and recent case studies, this study examines the potential of CL not only in the context of public health, but also in addressing global challenges such as climate change, digital inequality, and food insecurity. The conclusion outlines specific legal, institutional, and policy reforms at national and international levels aimed at making CL more effective, equitable, and responsive to emerging societal needs. By reframing CL as a mechanism of innovation equity, the paper argues for a renewed commitment to cooperative global governance in the management and dissemination of patented knowledge.

Keywords: Compulsory Licensing; TRIPS Agreement; Doha Declaration; Intellectual Property; Public Health; Access to Medicines; Sustainable Development; Innovation Equity; Green Technologies; Digital Access; Food Security; WTO; WIPO.

The global system of intellectual property (IP) law is built upon a fundamental balance between the exclusive rights granted to creators and inventors and the broader societal interest in disseminating knowledge, fostering innovation, and promoting equitable access to essential goods and services. Patents, in particular, serve as one of the most prominent mechanisms to reward inventors by granting them a temporary monopoly over the use, production, and commercialization of their inventions. However, this monopoly is not absolute. It is subject to limitations and exceptions designed to protect public welfare, prevent market abuse, and address instances where exclusive rights conflict with fundamental human needs. Among these legal tools, compulsory licensing represents one of the most significant, yet controversial,

regulatory interventions available to states under both international and national law.

In recent years, the Republic of Uzbekistan has undertaken comprehensive reforms in the field of intellectual property, aligning national legislation with international standards and promoting innovation-led economic development. **Under the leadership of President Shavkat Mirziyoyev**, the country adopted the **"Intellectual Property Strategy for 2022–2026"** in 2022, a landmark document aimed at enhancing the efficiency of the patent system, fostering innovation, and harmonizing legal frameworks with the norms of global intellectual property regimes such as the TRIPS Agreement and the WIPO-administered treaties. One of the most notable legislative developments within the framework of this Strategy is the Law of the Republic of Uzbekistan No. O'RQ-908, adopted on February 15, 2024. This law introduces amendments and additions to the earlier foundational legislation — the Law No. 397-II dated August 29, 2002, "On Inventions, Utility Models, and Industrial Designs." The amendments signal a significant policy shift by emphasizing the importance of compulsory licensing as a legal and economic tool to ensure the public interest is not undermined by the exclusive rights granted through patents. The revised provisions clarify the conditions under which compulsory licenses can be granted, aiming to strike a balance between protecting inventors' rights and ensuring accessibility to vital technologies, especially in areas related to public health, food security, and critical infrastructure. This aligns with global practices under Article 31 of the TRIPS Agreement, as well as the Doha Declaration on the TRIPS Agreement and Public Health (2001), which reaffirms the right of WTO member states to grant compulsory licenses in situations of national emergency or extreme urgency. Furthermore, the 2024 amendments reflect growing recognition of intellectual property as a policy instrument, not merely a legal right. By strengthening the regulatory framework for compulsory licensing, Uzbekistan positions itself among progressive jurisdictions that seek to leverage intellectual property for sustainable development and technological sovereignty. The new provisions also provide procedural clarity, outlining steps for filing, examining, and enforcing compulsory licenses, and incorporate international best practices regarding non-voluntary use of patents. These reforms are particularly timely, as the global discourse increasingly focuses on access to life-saving technologies, climate-related innovations, and equitable economic growth. In this context, Uzbekistan's updated legal approach to compulsory licensing offers a model for other developing and transition economies facing similar challenges in balancing private rights with public needs.

A compulsory licence is a legal authorization that allows a third party—typically a generic manufacturer or competitor—to use, manufacture, or sell a patented invention without the consent of the patent holder, provided that certain legal criteria are met. The mechanism does not eliminate the patent; rather, it overrides its exclusivity in

specific contexts, usually upon payment of adequate remuneration to the rights holder[1]. The rationale behind compulsory licensing is rooted in the recognition that patent protection, if left unchecked, may lead to monopolistic abuses, elevated prices, limited availability of essential products (such as medicines or green technologies), and failure to serve public interest objectives. Thus, it offers a critical corrective mechanism in the broader structure of intellectual property governance.

Historically, the use of compulsory licensing has been relatively rare, often invoked in exceptional circumstances such as public health emergencies, war, or national security threats. Yet, in the 21st century, the scope and justification for compulsory licences have considerably widened. The HIV/AIDS crisis in the late 1990s and early 2000s was a turning point that thrust compulsory licensing into the international spotlight, particularly when several developing countries began using it to obtain low-cost generic versions of life-saving antiretroviral drugs. The adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001 further solidified its status as a legitimate tool of global health policy, affirming the sovereign right of WTO member states to protect public health and promote access to medicines for all.

In recent years, the COVID-19 pandemic has once again catalyzed discussions around IP flexibility and compulsory licensing, as countries confronted the stark inequities in access to vaccines, diagnostics, and therapeutics. Additionally, the growing urgency of climate change, coupled with the need for rapid deployment of green technologies, has led to renewed calls for compulsory licensing mechanisms in sectors beyond pharmaceuticals[2]. Similarly, digital technologies, semiconductors, and artificial intelligence have emerged as new frontiers where access to critical patents may require intervention under competition or public interest doctrines. At the international level, compulsory licensing is primarily governed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), specifically Article 31 and the subsequent Article 31bis, which governs international trade in pharmaceuticals produced under compulsory licences. These provisions impose certain procedural and substantive safeguards to prevent abuse while also preserving the autonomy of states to grant licences in accordance with their national priorities. Notably, the Doha Declaration reinterpreted TRIPS provisions to give more operational flexibility to developing and least developed countries (LDCs)[3]. However, despite its legal

[1] Abbott, F.M., 2005. The WTO medicines decision: world pharmaceutical trade and the protection of public health. American Journal of International Law, 99(2), pp.317–358.

[2] Country experiences in using TRIPS safeguards: Part I // https://iris.who.int/bitstream/handle/10665/272977/Country-experiences-TRIPS-Part1.pdf?isAllowed=y&sequence=1#:~:text=A%20compulsory%20licence%20(CL)%20is,which%20is%20allowed%20under%20TRIPS.

[3] Love, J., 2007. Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies. Geneva: World Health Organization/UNDP.

legitimacy, the use of compulsory licensing remains entangled in political tensions, diplomatic pressures, and trade retaliations, often resulting in its underutilization or cautious implementation.

The legal institution of compulsory licensing is not a recent innovation, despite its contemporary resurgence in global discourse. It has deep historical roots in the evolution of patent law as a system intended not merely to reward inventors but also to serve the public interest by promoting the dissemination and practical application of knowledge. From its inception in early European legal systems to its adaptation in colonial and post-colonial national laws, compulsory licensing has developed as a legal instrument for governments to assert public control over the market behavior of private rightsholders.

Importantly, British colonial administrations transferred these mechanisms into the patent laws of their colonies, thereby diffusing the concept across Africa, South Asia, and the Caribbean. For example, colonial-era patent statutes in India, Kenya, Nigeria, and Malaya mirrored the UK law's approach to compulsory licensing, embedding it within the legal DNA of what would later become post-independence national IP systems. In these contexts, compulsory licensing became closely tied to early economic self-reliance strategies, particularly as newly independent states sought to use patent law as a tool for industrial development. The 20th century saw the use of compulsory licensing expand beyond the narrow grounds of non-working or price abuse. As states grew more involved in economic planning and industrial policy, they began to view intellectual property as a lever for directing technology transfer and stimulating domestic production capabilities. This was especially evident in Latin America, where countries like Brazil and Argentina incorporated compulsory licensing provisions into their patent laws to counterbalance foreign corporate control over key sectors such as pharmaceuticals and agriculture.

In the United States, while formal compulsory licensing statutes were rare, analogous outcomes were often achieved through antitrust enforcement and government use provisions. For example, under Section 1498 of the U.S. Code, the federal government is allowed to use patented inventions without authorization, provided that "reasonable and entire compensation" is paid to the patent holder. During wartime and national emergencies, this has served as a de facto compulsory licensing mechanism, though not labeled as such. Furthermore, several multilateral agreements during the post-World War II era allowed for exceptions to patent exclusivity. The Paris Convention for the Protection of Industrial Property (1883, revised multiple times) included in Article 5A(2) a specific allowance for compulsory licensing in cases where patents were not being worked. Although relatively weak in enforcement, it laid the foundation for later, stronger formulations in international IP law[4]. Following

[4] Stiglitz, J.E., 2008. Economic foundations of intellectual property rights. Duke Law Journal, 57(6), pp.1693–

decolonization, many developing countries retained the compulsory licensing provisions inherited from colonial legal systems, but adapted them to suit their developmental objectives. In countries such as India, Pakistan, South Africa, and Malaysia, patent law was increasingly seen as a tool to reduce dependence on foreign technology and to protect nascent domestic industries. Compulsory licences were viewed as instruments of technology transfer, industrial empowerment, and price regulation—particularly in sensitive sectors like health, energy, and food production.

The Indian Patents Act of 1970 was a seminal example of this shift. Influenced by the 1969 Hathi Committee Report, which concluded that foreign pharmaceutical firms were overcharging Indian consumers and under-supplying medicines, the Act included detailed provisions under Sections 84–92 to allow compulsory licensing based on non-working, unmet public demand, or public health needs. This law laid the groundwork for India's later leadership in the use of compulsory licences under the TRIPS regime.

In Sub-Saharan Africa, similar motivations led to the incorporation of compulsory licensing regimes, although their use remained limited due to institutional weaknesses, legal complexity, and political pressures from developed countries and multinational patent holders. However, the HIV/AIDS crisis at the turn of the 21st century triggered a renewed interest in activating these dormant provisions, particularly in South Africa, Zimbabwe, and Kenya, where legal reforms and litigation centered on access to antiretroviral medicines.

By the late 20th century, the emergence of the TRIPS Agreement (1994) under the WTO framework marked a watershed moment in the history of global patent law[5]. TRIPS aimed to standardize minimum levels of IP protection across all WTO members, which included both developed and developing countries. This shift provoked significant tension regarding compulsory licensing. On one hand, TRIPS recognized the right of countries to issue compulsory licences under Article 31; on the other hand, it introduced procedural constraints and ambiguities that critics argued could be used to chill or deter their actual implementation. In response, developing countries engaged in extensive legal and diplomatic advocacy to ensure that TRIPS would not become a straitjacket on national policy autonomy. The resulting Doha Declaration (2001) was a key moment in the modern evolution of compulsory licensing, reaffirming its legitimacy and expanding its interpretation to prioritize public health. It marked the culmination of a century-long trajectory—from a European legal safeguard against patent abuse to a global mechanism for social justice and access to innovation.

While the TRIPS Agreement provides a common international legal basis for

1724.

[5] WIPO, 2020. Patent-Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels. Geneva: WIPO.

compulsory licensing, its interpretation and implementation vary significantly across national jurisdictions. Different countries have used the mechanism based on their legal traditions, economic capacities, political will, and public policy priorities. This section presents a comparative overview of how compulsory licensing has been applied in key countries, highlighting practical examples, legal frameworks, and outcomes. These case studies offer insights into the diverse ways in which compulsory licensing has evolved as both a legal tool and a strategic instrument of innovation and public interest governance.

India is often cited as one of the most prominent users of compulsory licensing, especially in the context of pharmaceutical patents. The Indian Patents Act of 1970, as amended in 2005 to comply with TRIPS, includes several detailed provisions on compulsory licences, including their grounds, procedures, and duration. According to Section 84 of the Act, a compulsory licence may be granted if:

the reasonable requirements of the public are not being met,

the patented invention is not available at an affordable price,

or the invention is not worked in India.

The landmark case of Natco Pharma Ltd. v. Bayer Corporation (2012) marked a turning point. India's Patent Office granted Natco a compulsory licence to manufacture and sell a generic version of Bayer's cancer drug Nexavar (sorafenib tosylate)[6]. The decision was based on Bayer's excessive pricing and failure to supply the drug to a sufficient number of patients in India. The court ordered Natco to pay 6% royalties to Bayer, ensuring both access and compensation[7]. This case set a precedent for public health-oriented licensing and reinforced India's global reputation as a "pharmacy of the developing world."

Brazil's compulsory licensing experience demonstrates how the mere threat of issuing a licence can influence patent holder behavior. The Brazilian Industrial Property Law allows the government to issue a compulsory licence in cases of public interest, national emergency, or anticompetitive practices. During the early 2000s, Brazil faced severe challenges in providing affordable HIV/AIDS treatment. In response, the government strategically used the threat of compulsory licensing to negotiate lower prices with pharmaceutical companies. In 2007, Brazil issued its first compulsory licence for the antiretroviral drug efavirenz, originally patented by Merck[8]. The Ministry of Health justified the decision on the grounds of public interest and high pricing. The licence allowed Brazil to import a generic version from India, resulting in

[6] MSF Access Campaign, 2012. India upholds compulsory licence on cancer drug in Bayer case appeal. [online] Available at: https://www.msfaccess.org/india-upholds-compulsory-licence-cancer-drug-bayer-case-appeal

[7] LiveMint, 2012. Natco gets India's first compulsory licence. [online] Available at: https://www.livemint.com/Home-Page/9fjRX50WwBwTeWrfZYFYiM/Natco-gets-India8217s-first-compulsory-licence.html

[8] Financial Times, 2007. Brazil overrides Merck patent on HIV drug. Financial Times, 4 May.

significant cost savings[9]. Brazil's use of compulsory licensing demonstrates that even without frequent formal implementation, the threat of a licence can be an effective bargaining tool in global pharmaceutical pricing negotiations.

Thailand has taken a more direct and assertive approach to compulsory licensing, particularly under its government's health equity agenda[10]. Between 2006 and 2008, the Ministry of Public Health issued compulsory licences for multiple patented drugs, including Abbott's Kaletra (lopinavir/ritonavir), Sanofi's Plavix (clopidogrel), and Merck's efavirenz. These actions, grounded in Thailand's National Health Security Act and in response to high treatment costs, were met with significant international backlash. The United States placed Thailand on the Special 301 "Watch List," and multinational pharmaceutical companies publicly condemned the move. Nonetheless, the Thai government maintained its stance, emphasizing its constitutional obligation to protect the right to health. Thailand's experience underscores the legal legitimacy and political risks associated with compulsory licensing, especially when used by middle-income countries with growing health burdens and limited resources.

Canada is notable for being the only country to use TRIPS Article 31bis, which allows countries with insufficient manufacturing capacity to import generic medicines produced under a compulsory licence. In 2004, Canada passed the Canada Access to Medicines Regime (CAMR), enabling the export of generic drugs to eligible developing countries[11]. In 2007, the Canadian generic manufacturer Apotex produced a triple-combination HIV/AIDS treatment and exported it to Rwanda under a compulsory licence. While the case was successful in principle, the process was criticized for being bureaucratically burdensome and commercially unattractive, taking over two years from licence application to delivery[12]. Apotex later announced it would not repeat the process due to regulatory obstacles. This case demonstrates the technical viability but procedural complexity of using Article 31bis, reinforcing the need for streamlined processes and stronger incentives for pharmaceutical suppliers.

Germany has provisions for compulsory licensing under its Patent Act, particularly in cases where public interest outweighs the exclusive rights of the patent holder. These provisions are rarely used but are legally sound. In 2016, the German Federal Patent Court granted a compulsory licence in the case of Merck v. Shionogi,

[9] Rodrigues, W.C.V. & Soler, O., 2009. Compulsory licensing of efavirenz in Brazil in 2007: contextualization. Revista Panamericana de Salud Pública, 26(6), pp.553–559. Available at: https://pubmed.ncbi.nlm.nih.gov/20107711/ [Accessed 3 July 2025].

[10] Chalkidou, K., 2008. Thailand's pharmaceutical cost-saving strategies: compulsory licensing and beyond. Health Affairs, 27(1), pp.247–251.

[11] Bermúdez, J., 2013. A one-time-only combination: Emergency medicine exports under Canada's access to medicines regime. Health and Human Rights Journal, 15(2), pp.116–125.

[12] Parliament of Canada, 2009. Evidence – Industry Committee on CAMR. House of Commons, 39th Parliament, 1st Session. // https://www.ourcommons.ca/documentviewer/en/39-1/NDDN/meeting-39/evidence

involving a patent on HIV treatment[13]. The licence was deemed necessary to maintain continuous supply and avoid public health disruptions. This marked one of the few times a developed country formally invoked compulsory licensing for health-related reasons[14]. Germany's approach reflects a high legal threshold and rigorous procedural standards, ensuring that compulsory licensing is applied only when absolutely necessary and justified by substantial public interest.

South Africa's experience is shaped by its historical struggle for access to HIV/AIDS medicines and ongoing reforms to align its IP laws with public health objectives[15]. While South Africa has not issued many compulsory licences formally, the 1997 Medicines and Related Substances Control Amendment Act allowed for generic substitution and parallel importation—principles aligned with compulsory licensing. South Africa's attempt to implement these provisions triggered a lawsuit by 39 multinational pharmaceutical companies in 1998. The international outcry and activism eventually forced the companies to drop the case in 2001. This political episode reaffirmed South Africa's right to prioritize health over patents and paved the way for TRIPS flexibilities in developing nations. Although South Africa has legal grounds for compulsory licensing, institutional fragmentation and private sector resistance have slowed practical implementation. However, recent reforms under the IP Policy Phase 1 (2018) signal a stronger commitment to balancing IP protection with health access[16].

National experiences with compulsory licensing reveal a complex interplay of law, politics, economics, and health policy. While some countries, like India and Thailand, have actively used the mechanism to promote access to medicines, others, such as Canada and Germany, demonstrate how procedural and political barriers can limit its use. The case studies also highlight how compulsory licensing serves multiple roles: as a legal remedy, a negotiation tactic, a health policy instrument, and a symbol of sovereignty in global IP governance. These diverse approaches show that the success of compulsory licensing depends not just on having the legal option, but on building the institutional capacity, political will, and social legitimacy to use it effectively. In this way, compulsory licensing stands as a modern and flexible mechanism — one that, if properly implemented, can support not only national health systems but broader goals of equitable and sustainable development.

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[13] German Federal Patent Court (2016). Federal Patent Court grants compulsory licence on HIV drug Isentress. [online] Bundespatentgericht. Available at: https://www.bundespatentgericht.de/EN/Decisions/Press-Releases/press-release-2016-06-27.html

[14] Bird & Bird (2017). Compulsory licensing in Germany: HIV medication case. [online] Available at: https://www.twobirds.com/en/news/articles/2017/global/compulsory-licensing-in-germany-hiv-medication-case

[15] Wired, 2001. S. Africa to Rule on AIDS Drugs. Wired, 14 April. Available at: https://www.wired.com/2001/04/s-africa-to-rule-on-aids-drugs/

[16] UNCTAD, 2018. South Africa adopts new IP policy improving access to medicine. UNCTAD, 31 May. Available at: https://unctad.org/news/south-africa-adopts-new-ip-policy-improving-access-medicine

The legal architecture of compulsory licensing at the international level is fundamentally rooted in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was adopted in 1994 as part of the World Trade Organization (WTO) framework. TRIPS represents the most comprehensive and far-reaching multilateral treaty on intellectual property (IP) to date. It established minimum standards for the protection and enforcement of IP rights—including patents—across all WTO member states. However, TRIPS also includes certain flexibilities that allow countries to limit the scope or enforcement of IP rights under specific conditions. Among these flexibilities, compulsory licensing is one of the most significant and controversial. Special emphasis is placed on how these legal instruments have affected the practical use of compulsory licences, especially in developing countries confronting urgent health crises. Article 31 of the TRIPS Agreement provides the primary legal foundation for compulsory licensing. It allows member states to authorize the use of a patented invention without the authorization of the rights holder, under certain conditions. Importantly, the article does not define the term "compulsory licence" explicitly, but outlines the procedural safeguards and substantive criteria that must be satisfied[17].

While Article 31 created a legal pathway for compulsory licensing, its restrictions—especially the domestic use limitation in Article 31(f)—posed significant challenges for countries lacking pharmaceutical manufacturing capabilities. For instance, least developed countries (LDCs) or small island states that did not have local production capacity were unable to procure cheaper medicines via compulsory licences issued elsewhere. To address this, WTO members adopted Article 31bis in 2005, following the temporary waiver agreed upon in 2003. Article 31bis allows countries to export pharmaceutical products made under a compulsory licence to countries that lack production capacity. It sets out additional procedural requirements for both exporting and importing countries, including notifications to the WTO and specific packaging and labeling requirements to prevent re-importation. Despite its well-intentioned design, Article 31bis has only been used once—by Canada to export HIV medicines to Rwanda—due to its overly complex and bureaucratic procedures. Critics argue that Article 31bis places an undue burden on generic manufacturers and importing governments, effectively rendering the mechanism impractical for emergency use. The Doha Declaration on the TRIPS Agreement and Public Health, adopted by WTO members in November 2001, marked a turning point in the global discourse on IP rights and public health. Sparked by mounting pressure from developing countries, civil society, and international health organizations, the Declaration sought to clarify ambiguities in TRIPS and reaffirm the right of governments to protect public health.

[17] World Health Organization, 2021. Guidelines on Country Use of TRIPS Flexibilities for Public Health Purposes. Geneva: WHO.

In the past ten years, the use of compulsory licences has gone beyond just HIV medicines. Governments have started to use this tool for other serious health issues too. For example, in India, a compulsory licence was granted for a cancer medicine called Nexavar. This helped reduce the price of the drug and made it more accessible to patients who could not afford it[18]. In Egypt, the government used a special strategy to get cheaper medicines for Hepatitis C. They used the idea of compulsory licensing to encourage companies to provide the treatment at lower prices, which helped treat many people across the country. There have also been discussions about using compulsory licences for diabetes treatments, especially insulin. Since insulin is essential for many people, some governments have considered this option to improve access. During the COVID-19 pandemic, the idea of compulsory licensing became more important again[19]. Countries were trying to get access to vaccines, treatments, and test kits. Some governments looked at compulsory licensing as a way to overcome the shortage of supplies and the high prices caused by patent restrictions.

These examples show that compulsory licences are now being used in more areas of healthcare, not just for emergencies, but also to make sure people can access important medicines when they need them.Although few compulsory licences were officially issued during the COVID-19 crisis, the pandemic brought renewed attention to TRIPS flexibilities, with countries such as Bolivia and Hungary invoking them in preparation. Moreover, public pressure and political discourse led to debates about global IP waivers, even if many were not realized.These developments show that compulsory licensing is now regarded as a legitimate public health strategy, not only in emergencies but also in routine health system management, especially where market failures prevent access to affordable medicines.

Compulsory licensing works best when countries work together. Although each country has the right to decide when to issue a compulsory licence, the problems they are trying to fix—like global pandemics, climate change, and lack of access to technology—are shared by many nations. These are not just local problems; they are global issues that need global solutions. To encourage stronger cooperation, international organizations like the World Health Organization (WHO), World Trade Organization (WTO), and World Intellectual Property Organization (WIPO) should work together. They can help coordinate global responses, especially during emergencies like pandemics or natural disasters, so countries are not acting alone. One useful idea is to create a global support fund for compulsory licensing. This fund could help pay patent holders fair compensation and support medicine or technology production in developing countries. That way, poorer countries could use compulsory

[18] Sell, S.K., 2003. Private Power, Public Law: The Globalization of Intellectual Property Rights. Cambridge: Cambridge University Press.

[19] KEI (Knowledge Ecology International), 2022. Use of Compulsory Licensing for Access to COVID-19 Technologies. [online] Available at: https://www.keionline.org [Accessed 1 July 2025].

licences without facing financial hardship. There should also be more support for technology-sharing platforms. For example, during COVID-19, the COVID-19 Technology Access Pool (C-TAP) was created to encourage companies to share important patents and know-how. Programs like this should be expanded and made stronger, to promote voluntary or fair-use licensing in the public interest. By working together, the world can build an intellectual property system that values solidarity, fairness, and shared responsibility, rather than profit alone[20]. Patent holders—like pharmaceutical companies and tech firms—also have a part to play in making access fairer. They should be encouraged to adopt more responsible and ethical licensing practices that balance profit with public good.

Conclusion. Compulsory licensing (CL) remains a vital yet under-utilized mechanism for balancing patent rights with public interest in the modern global economy. Throughout this paper we have traced CL's evolution from its origins in 19th-century IP law to its codification in TRIPS and clarification in the Doha Declaration. We have seen that, in principle, TRIPS provides broad flexibility: countries are explicitly free to grant CLs on any grounds they choose, including national emergencies or other urgent circumstances. TRIPS even confirms that Members may adopt measures necessary to protect public health or vital public interests.

In practice, however, CL use has been constrained by TRIPS' detailed conditions—such as the requirement of prior negotiation with patent holders and the limitation to predominantly domestic supply—as well as by additional restrictions in bilateral and regional treaties. These features have often discouraged the actual use of CLs. Even so, a number of countries have adopted CL provisions and issued licenses for essential medicines like HIV/AIDS, cancer, and heart disease treatments. The Doha Declaration reaffirmed Members' rights to determine their own emergencies and licensing grounds, while Article 31bis introduced a system allowing exports to countries without manufacturing capacity. Building on these findings, several key conclusions emerge. First, if used effectively, CL can support public health, promote access to green technologies, and foster digital inclusion. Second, the current framework—while flexible in some areas—still contains significant weaknesses, including vague definitions, high costs, and narrow applicability. Third, many countries lack the legal, institutional, and technical capacity to use CL provisions to their full potential. Fourth, multilateral cooperation mechanisms are beginning to emerge but need to be expanded and strengthened. The way forward must therefore include legal reform, institutional capacity-building, and strategic international cooperation to align CL with sustainable development and innovation equity. This

[20] WIPO, 2019. WIPO GREEN Strategic Plan: Promoting Innovation and Diffusion of Green Technologies. Geneva: World Intellectual Property Organization.

includes: Legal Reforms: TRIPS and national IP laws should be clarified and modernized to ease the use of CL. Article 31bis should be expanded to cover a broader range of goods and simplify procedures. Terms like “national emergency” and “public non-commercial use” should be clearly defined to include health, climate, energy, and food-related crises. Trade agreements should preserve, not restrict, the use of CL. An international review of TRIPS should be undertaken to bring the agreement in line with today’s global challenges. Institutional Capacity-Building: Developing countries must strengthen their legislative, administrative, and judicial infrastructure to use CL effectively. This includes clear legal procedures, training for judges and patent examiners, and support for national patent offices. International assistance should prioritize technical and legal training, as well as help in developing model CL laws and procedures.

Global challenges also require shared solutions. Patent pools, international licensing platforms, and dedicated support funds should be developed. A permanent international forum for technology access could coordinate legal and technical responses during crises. Financial mechanisms should help low-income countries cover costs related to licensing and local production.

Sector-Specific Strategies in health, CL should be integrated into national and global health strategies. Fast-track rules for emergencies, simplified procedures, and expanded patent pools should support access to essential medicines. For climate and energy, CL can be used to promote clean technologies. Governments should treat climate emergencies as valid grounds for licensing and support patent pools for green innovation. In digital and AI technologies, CL-like mechanisms can help prevent monopolies and promote access to key tools for education, health, and communication. Governments should ensure fair licensing for software, algorithms, and data. In agriculture, CL can support food security and climate resilience by enabling access to patented seeds and technologies. Countries should harmonize seed laws and ensure compatibility with plant variety protection rules. Throughout all these reforms, the guiding principle should be innovation equity and sustainable development. Compulsory licensing can help ensure that patent rights do not hinder the broader social good. When used wisely and fairly, CL enables countries to respond to public needs, protect vulnerable populations, and promote shared prosperity. In conclusion, CL is not a threat to innovation—it is a vital tool for ensuring that innovation benefits everyone. Achieving this balance will require bold reforms, stronger institutions, and coordinated international action. If the world acts now, compulsory licensing can become a cornerstone of a fairer, more resilient, and inclusive global innovation system.

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