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COMPULSORY LICENSING IN GLOBAL HEALTH EMERGENCIES: BALANCING PATENT RIGHTS AND PUBLIC INTEREST

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Abstract

In the context of global health emergencies, such as pandemics and widespread outbreaks, access to essential medicines and medical technologies becomes a critical public health priority. Compulsory licensing — a legal mechanism that allows governments to authorize the production or use of patented products without the consent of the patent holder has emerged as a powerful tool for improving access to life-saving treatments. This paper explores the complex interplay between patent rights and the public interest during health crises, with a focus on how compulsory licensing can serve as a strategic response to urgent medical needs while respecting international legal frameworks, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration. The analysis evaluates key case studies, including the use of compulsory licenses during the HIV/AIDS crisis and the COVID-19 pandemic, to illustrate the practical implications and challenges of implementing such measures. The paper argues that while compulsory licensing is not a panacea, it is a vital policy option that should be more effectively integrated into global and national health emergency preparedness plans. The paper recommends a balance between protecting intellectual property rights and ensuring equitable access to medical innovations among others.

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1.0 Introduction

The right to health is a universal human right, and access to medicines and health technologies is a core element of this right. According to a 2011 UN Human Rights Council resolution, access to medicine is essential for realizing the highest attainable standard of health.[1] However, patent protections and regulatory exclusivities often limit access to essential medicines, particularly in low-income countries.[2] Before the WTO's TRIPS Agreement came into effect in 1995, nearly 50 countries did not grant patents on pharmaceuticals.[3] TRIPS made 20-year patent protection mandatory in all technological fields, including drugs.[4] This shift has had serious implications for global health. The HIV/AIDS crisis of the 1990s, which caused over 32 million deaths, exposed how intellectual property rights (IPRs) restricted access to affordable, life-saving treatments in developing countries.[5] More recently, the COVID-19 pandemic, which claimed over 1.35 million lives by late 2020, has once again brought these tensions to the forefront.[6]

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[1] World Health Organisation, 'TRIPS, intellectual property rights and access to medicines' https://iris.who.int/bitstream/handle/10665/258915/TRIPS.pdf Accessed on 2nd June 2025

[2] Ibid.

[3] Ibid.

[4] Article 33 of the Agreement provides that The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

[5] UNAIDS, 'Intellectual property and access to health technologies https://www.unaids.org/sites/default/files/media_asset/JC2820_en.pdf Accessed 2nd June 2025.

[6] Reliefweb, 'With More Than 1.5 Million Lives Lost to COVID-19, World Leaders in General Assembly Demand Urgent Action to Guarantee Equitable Distribution of Life-Saving Vaccines' (4th December 2020) https://reliefweb.int/report/world/more-15-million-

Patent monopolies limit collaboration and sharing of research, discourage the use of pre-patent knowledge, and restrict global manufacturing capacity.[7] These barriers have led to inflated prices for treatments for diseases like HIV/AIDS, tuberculosis, and cancer, delaying the availability of affordable options in low- and middle-income countries.[8] The COVID-19 pandemic has further stressed health systems and reduced governments' ability to subsidize treatments.[9] Although companies pledged not to enforce their COVID-19 vaccine patents during the pandemic, such voluntary actions are rare and insufficient.[10] A broader waiver proposed by South Africa and India at the WTO failed to gain consensus, highlighting ongoing resistance to reducing IPR protections even in emergencies.[11] It is worthy of note that relying solely on voluntary measures is inadequate. Mechanisms like compulsory licensing are essential to balance patent rights with the urgent need for equitable access to health technologies in global health crises.

However, while access to medicines is undeniably a critical component of the right to health, the protection of patent rights is equally important in sustaining the innovation ecosystem that makes life-saving technologies

lives-lost-covid-19-world-leaders-general-assembly-demand-urgent-action Accessed 5th June 2025.

[7] Riccardo Cappelli , Marco Corsino , Keld Laursen & Salvatore Torrisi, 'Technological Competition and Patent Strategy: Protecting Innovation, Preempting Rivals and Defending the Freedom to Operate' (2023) 52(6) *Research Policy*

[8] Ibid.

[9] Ibid.

[10] ibid

[11] Bryan Mercurio and Pratyush Nath Upreti, 'From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments (2022) 21(5) *Cambridge University Press*

possible in the first place.[12] Patents provide inventors and pharmaceutical companies with a limited period of exclusivity, which incentivizes substantial investments in research, development, and regulatory approval—an inherently costly, risky, and time-consuming process.[13] Developing a new drug or vaccine can take over a decade and cost billions of dollars, with no guarantee of success.[14] Patents enable companies to recover these investments and fund future innovations.[15] Without the assurance of patent protection, private sector engagement in health R&D—particularly for complex biologics and cutting-edge technologies—would significantly diminish, leading to fewer breakthroughs in global health.[16]

In health emergencies, patent holders are not necessarily obstacles to access. Many pharmaceutical companies have engaged in voluntary licensing, tiered pricing, and donations to improve access in low- and middle-income countries.[17] For example, during the COVID-19 pandemic, firms like Pfizer and AstraZeneca entered into manufacturing partnerships to scale up global vaccine production.[18] Moderna temporarily waived enforcement of its patents to facilitate access, illustrating that companies can act responsibly

[12] Jennifer Heaven Mike, 'A Re-Evaluation of the Framework for the Protection of Patents, Women's Health in Nigeria and the Issue of Accessing Pharmaceutical Innovation in Africa Designing Strategies for Medicines (2019) 2022(2) *The Journal of World Intellectual Property*

[13] Nina Yin, 'Pharmaceuticals, incremental innovation and market exclusivity' (2023) 87 *International Journal of Industrial Organization*

[14] Ibid.

[15] Ibid.

[16] Ibid.

[17] Gore C, Morin S, Røttingen JA & Kieny MP. 'Negotiating public-health intellectual property licensing agreements to increase access to health technologies: an insider's story'. (2023) *BMJ Glob Health.* <Sep;8(9): e012964.doi: 10.1136/bmjgh-2023-012964. PMID: 37669799; PMCID: PMC10496684.> Accessed 7th June 2025.

[18] Michael L. King, 'How Manufacturing Won or Lost the COVID-19 Vaccine Race' (2024) 42(5) *Vaccine* 1004-1012

without undermining intellectual property norms.[19] Moreover, suspending or weakening patent rights, especially through sweeping waivers, may create legal uncertainties, deter investment, and discourage future collaborations.[20] Thus, rather than dismantling IP systems, a balanced approach is needed, one that encourages innovation while promoting equitable access through mechanisms like public-private partnerships, voluntary licenses, and targeted use of compulsory licensing when absolutely necessary.[21] It is on this basis that this article, seeks to examine the implication of Compulsory Licensing on global health emergencies and seeks to undertake a study of how the rights of patent holders can be advanced and protected while ensuring that there is global access to health.

2.0 CONCEPTUAL CLARIFICATION OF TERMS

a. Intellectual Property

Intellectual Property is a branch of law that protects some of the beautiful manifestation of human imagination.[22] It is described as the rights that a person has over an invention, an innovation, a copyright, a patented product or design, a trademark and all other such incorporeal hereditaments that are recognized in law as property. It includes the rights relating to literary, artistic and scientific works, performances and performing artists, photographs and broadcasts, inventions in all fields of endeavour, scientific discoveries, industrial designs, trademarks, service marks and commercial

[19] Ibid.
[20] Ted M. Sichelman, 'Patents as Hedges' (2023) 38 *Berkeley Technology Law Journal* 515-574
[21] Ibid.
[22] WR Cornish, *Intellectual Property* (7th edn, Butterworth& Co 1995) 3.

names.[23] It is on the basis of such creations we have the intellectual property rights (IPR). Intellectual property rights are those rights that are granted to protect human creation from an indiscriminate or unfair use. The rights are preventive in nature in that they allow the owner to preclude others from carrying out acts in relation to the subject matter without his consent.[24]

Intellectual property gives rise to rights and duties. It establishes property rights, that gives the owner the right to do certain things in relation to the subject matter. Intellectual Property Law is that area of law concerning legal rights associated with creative effort or commercial reputation and goodwill. The subject matter of intellectual property is very wide and includes literary and artistic works, films, computer programmes, invention, designs and marks used by traders for their goods or services.[25] By way of a working definition, intellectual property is that aspect of law that seeks to protect the product of human ingenuity and creativity in whatever form they may appear. It seeks to protect the creator from unfair use of his ideas and creations. The concept of intellectual property is very important to this work because it is the root of all Intellectual Property Rights (IPR), which includes patent. It is comprised of those rights that are granted to protect human invention and innovation from indiscriminate and unfair use. Basically, it is the underlying reason for this research.

b. Patents

In simple terms, a patent is a right granted to the creator of an invention, by a government or government institution, which confers on the creator a

[23] Article 2, Para VIII, World Intellectual Property Organization (WIPO) Convention 1967.
[24] David Bainbridge, Intellectual Property (6th edn,Pearson Education Limited 2007) 3.
[25] RK Bera, 'The Global Importance of Patents' [2009] (96)(5) *Current Science Journal* https://www.jstor.org/stable/24104555 accessed 29 June 2025.

legal monopoly on the subject matter of the invention. It is a right given to a person for an invention for a fixed period of time to prevent any other person from exploiting or using such an invention without the consent of the person.[26] A patent is a legal document that grants an exclusive right on the patented invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. A patent is granted under the law to protect an invention that is new or essentially better in some way than what was made before, or for a better way of making it.[27] The Nigerian Patent and Designs Act[28] does not define patent. It only provides the type of invention that will be protected by patent. Thus, it provides that an invention will only be patentable if it is new or if it is an improvement on a patentable invention. It results from an inventive activity and is capable of industrial application.[29] It is of great importance to technologists, scientists, engineers, technicians, pharmacists, doctors, academics; etc.[30] The justification for a patent system is that inventors and investors are rewarded for their time, work and risk of capital by the grant of a limited, though strong, monopoly.[31] In Nigeria, the right to patent for an invention is granted to the first person that files an application for the patent and it does not matter if the applicant is not the true inventor. Section 2(1) of the Patents and Designs Act provides thus:

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[26] Chudi Nwaba chili, Intellectual Property Law and Practice in Nigeria (1st edn, Malthouse Press Limited 2017) 145
[27] Ibid. 139.
[28] Nigerian Patent and Designs Act, CAP P2,LFN 2004
[29] Section 1(1) of the Patents and Designs Act Cap.P2, LFN 2004.
[30] FO Babafemi, Intellectual Property, The Law and Practice of Copyright, Trademarks, Patents and Industrial Designs in Nigeria (1st edn, Justinian Books 2006) 342.
[31] David Bainbridge, (n 24) 346.

> Subject to this section, the right to a patent in respect of an invention is vested in the statutory inventor, that is to say, the person who, whether or not is the true inventor, is the first to file, or validly claim a foreign priority for a patent application in respect of the invention.

By way of working definition, a patent is a legal term used to describe a limited right that is conferred by the government, on a person who has engaged in an inventive activity to bring about an invention. A patent will only be granted to such a person where he has fulfilled the conditions laid down by the statute creating such right.

c. Compulsory Licensing

A compulsory license can be understood as a legal mechanism through which a government compels a patent holder to permit the use, manufacture, or sale of their patented invention by another party despite the patent holder's unwillingness under terms set and enforced by the state. In effect, it creates an involuntary agreement, where the state acts as an intermediary to balance the interests of public need against the rights of the patent owner.[32] While the original patent holder maintains ownership of the intellectual property, they are required to accept compensation usually in the form of royalties from the licensee, even though the agreement is not made voluntarily.[33] Section 11 of the Nigerian Patent & Designs Act Act provides that "the provisions of the First Schedule to this Act shall have

[32] Hilary Wong, 'The case for compulsory licensing during COVID-19' (2020) 15(10) *Journal of Global Health*

[33] Gianna Julian-Arnold, ' International compulsory licensing: the rationales and the reality' (1992) 33 *IDEA: The Journal of Law and Technology* 33.

effect in relation to compulsory licenses and the use of patents for the Service of government agencies."

The Act stipulates that the principles which apply to the patents as provided in the 1st schedule of the Act shall apply in instances of compulsory licensing and where the use of patent will be required for the service of the government. In other words, whenever a compulsory licence is granted or a government agency uses a patent, the procedures, conditions, or limitations described in the First Schedule of the Act will govern how those situations are handled. This is an implied recognition of the applicability of Compulsory licensing in Nigeria. At the international level, the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) makes provisions which allow member states to make laws which allows for other use without the authorisation of the right. However, certain conditions apply. Article 31 of the Agreement provides that where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, certain provisions shall be respected such as prior efforts to obtain authorization on reasonable terms are generally required unless waived in urgent situations. Such use must be limited, non-exclusive, and mainly for domestic supply. Patent holders must be paid adequate remuneration, and decisions are subject to judicial review. Use involving dependent patents must involve significant technical advancement and require cross-licensing. Authorization ends when justifying circumstances cease, unless there's a risk they may recur.

d. Public Interest

Public interest refers to the well-being and general welfare of the public, encompassing what benefits society as a whole rather than specific

individuals or groups.[34] It is a foundational concept in law, government policy, journalism, ethics, and social justice. Public interest serves as a guiding principle in making decisions that promote collective health, safety, economic security, education, and civil rights. In a democratic society, public interest helps justify government action and legislation. Laws and regulations are often evaluated based on their alignment with public interest. [35]In the field of intellectual property, particularly patent law, the concept of public interest plays a crucial role in balancing the rights of inventors with the broader needs of society.

Patents grant inventors exclusive rights to make, use, and sell their inventions for a limited period, incentivizing innovation by providing economic rewards. [36] However, these exclusive rights can, in some circumstances, hinder access to essential products or technologies—particularly in sectors like healthcare, agriculture, and public infrastructure. This is where the principle of public interest intersects with mechanisms like compulsory licensing.[37] Compulsory licensing allows a government to authorize the use of a patented invention without the consent of the patent holder, typically in situations of urgent public need.[38] This legal tool is often justified on public interest grounds, especially when it comes to ensuring access to life-saving medicines, medical technologies, or critical services.

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[34] Chukwuemeka Orji, Alom Anselem Chukwuma & Ebenezer Ngene, 'The Concept Of Public Interest In Planning Theory And Practice: A Review' (2024) 10(2) *International Journal of Advance Research and Innovative Ideas in Education*

[35] Ibid.

[36] Ibid.

[37] Ibid.

[38] Justin Culbertson & Jason J Jardine, 'Compulsory Patent Licensing in the Era of Pandemic' (2021) https://www.ibanet.org/article/36a60309-5a33-4891-8624-86a6d89a251e. Accessed 12 June 2025.

For instance, during public health emergencies such as the HIV/AIDS crisis or the COVID-19 pandemic, compulsory licenses have been used or proposed to facilitate the production of generic drugs that might otherwise be unaffordable or unavailable due to patent restrictions.[39] The public Interest in this context is primarily about ensuring equitable access to essential goods. Patent holders may charge high prices due to the monopoly granted by the patent, making their products inaccessible to large segments of the population, especially in low- and middle-income countries. Governments, acting in the public interest, can override these rights under international agreements like the WTO's TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement, which permits compulsory licensing under specific conditions.[40]

However, invoking the public interest through compulsory licensing is not without controversy. Patent holders often argue that such actions undermine the patent system and disincentivize innovation. They contend that if innovators cannot rely on exclusive rights, they may be less likely to invest in research and development. Therefore, governments must carefully balance the public interest in accessibility with the need to maintain a robust innovation ecosystem.[41]

3.0 OVERVIEW OF COMPULSORY LICENSING UNDER THE TRIPS AGREEMENT AND THE IMPLICATION OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

[39] Ibid.
[40] Ibid.
[41] Ibid.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is one of the most controversial international intellectual property agreements that have entered into force.[42] Its negotiations were highly contentious, and the perspectives of developed and less developed countries on the role of intellectual property protection and enforcement remain far apart.[43] The TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement negotiations began at the 1986 GATT Ministerial Conference in Punta del Este, Uruguay. This occurred during a deadlock at WIPO over revising the Paris Convention. While the conference aimed to address trade-related issues, developing countries—led by India and Brazil—initially believed discussions would focus only on counterfeit goods.[44] They argued that only WIPO had the authority to handle substantive intellectual property (IP) matters. However, this interpretation underestimated the broader intent to create binding global IP rules. By the early 1990s, most countries accepted that minimum IP standards would be part of the GATT framework.[45] This shift resulted from U.S. pressure tactics, lobbying by global IP industries, economic crises in developing countries, and fear of exclusion from a new trade body. Canada's 1990 proposal for a multilateral trade organization further cemented GATT's role in TRIPS. To move negotiations forward, the GATT Secretariat and Chairman Lars Anell produced the "Anell Draft," a composite text combining proposals from both developed and developing countries. Industrialized nations—like the U.S., EU, and Japan—submitted detailed legal drafts covering all IP rights and enforcement under the

[42] K Yu Peter, 'The objectives and Principles of the TRIPS Agreement' (2009) Houston Law Review 46.
[43] Ibid.
[44] Ibid.
[45] Jerome H Reichman, 'Enforcing the enforcement procedures of the TRIPS agreement' (1996) 37 Va. J. Int'l L 335.

GATT/WTO dispute system.[46] In contrast, developing countries offered a more flexible alternative. Ultimately, the final agreement mirrored the developed countries' "A" text, with developing country concerns mainly appearing in Articles 7 and 8. GATT Director-General Arthur Dunkel later issued the "Dunkel Draft" as a final, non-negotiable version. Despite criticism, it succeeded in concluding the negotiations.[47] In April 1994, TRIPS was adopted as Annex 1C of the Marrakesh Agreement, creating the WTO.As a WTO member since 1995, Nigeria is legally bound to implement the provisions of the TRIPS Agreement, which sets minimum standards for the protection and enforcement of intellectual property rights, including patents.

The objective of TRIPS is to promote innovation and technology transfer while protecting IP rights across member states.[48] However, critics argued that the strict enforcement of IP rights, especially patents on pharmaceuticals, limited access to affordable medicines in developing countries. This concern became more prominent with the rise of global health crises such as the HIV/AIDS epidemic. In response to these concerns, the Doha Declaration on the TRIPS Agreement and Public Health was adopted by WTO members in November 2001.[49] The declaration affirmed that the TRIPS Agreement should not prevent members from taking measures to protect public health and promote access to medicines for all.[50]

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[46] Ibid.
[47] Ibid.
[48] B.N. Pandey and **Prabhat Kumar Saha, Technology Transfer in Trips Agreement: Implications for Developing Countries Developing Countries, (2011) 3(1) *Dehradun Law Review* 38-59
[49] Ibid.
[50] Frederick M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 *Journal of International Economic Law* 469

The declaration recognized the right of WTO members to use flexibilities in the TRIPS Agreement, such as compulsory licensing and parallel imports, to ensure access to affordable medicines.[51] It confirmed that countries have the right to issue compulsory licenses and determine the grounds upon which such licenses are granted. It stated that the TRIPS Agreement should be implemented in a manner supportive of WTO members' right to protect public health.[52] The Declaration reflects a principle that the WHO has consistently supported : that WTO Members have the right to fully use the safeguard measures in the TRIPS Agreement to protect public health and improve access to medicines.[53] For instance, according to Article 31(f) of the TRIPS Agreement, a compulsory license must primarily be used to supply the domestic market of the country that issues it. As a result, many countries lacking a strong pharmaceutical manufacturing industry have been unable to benefit from this provision. While TRIPS does allow countries to issue compulsory licences to import medicines, they are limited to importing from countries where the medicines are not under patent protection or where those patents have expired.

Article 31 of the TRIPS Agreement further outlines other provisions that must be respected when member states allow for other use of the patent without the authorisation of the patent holder. These include:

a) Authorization of such use shall be considered on its individual merits;

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[51] Ibid.
[52] Ibid.
[53] Carlos María Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and public health' (2002) *World Health Organization, Essential Drugs and Medicine Policy*.

b) Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
c) The scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public noncommercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
d) Such use shall be non-exclusive;
e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have

the authority to review, upon motivated request, the continued existence of these circumstances;

h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
i) The legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f)where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be considered in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
    i. the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;(

ii. he owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
iii. the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

In light of the above, Compulsory License is not granted as an absolute right conferred on the member states to the TRIPS Agreement as it subject to the above conditions as stipulated in the Agreement. It can be gleaned that while the above Article recognizes the need to protect public interest in situations where there is limited access to patented inventions, it also seeks ensure that the legal and economic rights of the Patent holder is protected. This underscores the limited applicability and use of compulsory licensing. Thus, it is imperative for member states to ensure that a comprehensive framework for compulsory license is created domestically to prevent an annihilation of the rights of patent holders.

4.0 JUSTIFICATION FOR COMPULSORY LICENSING IN GLOBAL HEALTH EMERGENCIES; A CASE STUDY OF HIV/AIDS & COVID 19

In the context of global health emergencies such as pandemics, epidemics, or widespread health crises compulsory licensing becomes a critical tool to ensure access to life-saving medicines, vaccines, and medical technologies.[54] The justification for its use lies in balancing intellectual property rights with public health needs, particularly when lives are at stake. One of the primary justifications for compulsory licensing is the urgent need to overcome barriers to access. During health emergencies, patented

[54] Lowri Davies, 'Compulsory licensing: an effective tool for securing access to Covid-19 vaccines for developing states?' (2023) 43(1) *Legal Studies* 86-103

drugs or vaccines may be available only from a single supplier, often at high prices or in insufficient quantities.[55] This situation can severely limit access in low- and middle-income countries, exacerbating inequality and prolonging crises. Compulsory licensing enables governments to authorize domestic production or importation of generic versions, significantly reducing costs and improving availability.[56]

The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), especially the Doha Declaration on the TRIPS Agreement and Public Health (2001), explicitly supports this approach.[57] The Declaration affirms that the TRIPS agreement should not prevent members from taking measures to protect public health and that each country has the right to grant compulsory licenses and determine the grounds for doing so[58]. This international legal backing strengthens the moral and legal justification for compulsory licensing in emergencies. Public health emergencies also demand swift and scalable responses. In situations like the COVID-19 pandemic, time is of the essence. While voluntary licensing agreements and patent pools are helpful, they are often time-consuming and subject to the patent holder's discretion. Compulsory licensing bypasses these delays, allowing governments to act decisively in the public interest. By enabling local production or bulk imports, countries can scale up response efforts without being bottlenecked by proprietary restrictions.[59]

[55] Ibid.
[56] Ibid.
[57] Ibid (n 50)
[58] Ibid.
[59] Anastasia Lupasco and Ioana-Teodora Stanciu, 'The Impact of Compulsory Licensing on Access to Life-saving Medicines in Low-income Countries under the WTO's TRIPS

Furthermore, compulsory licensing encourages pharmaceutical companies to engage in fairer pricing and more equitable access. The potential of governments to issue such licenses creates a form of negotiation leverage.[60] In several historical cases, the mere threat of compulsory licensing has led patent holders to reduce prices or expand access to medicines in developing countries. Ethically, the justification for compulsory licensing is grounded in the principle of health equity. In global health emergencies, prioritizing human lives over corporate profits is not only a moral imperative but also a pragmatic one.[61] Containing the spread of diseases and ensuring treatment access globally is essential for global health security. Since the founding of the World Trade Organization (WTO), approximately twenty countries either issued or publicly considered issuing compulsory licenses for one or more pharmaceutical products.[62]

In many cases, governments did not ultimately issue a license. However, merely announcing or discussing the possibility of a compulsory license often prompted patent holders to voluntarily lower drug prices or offer voluntary licenses.[63] Historically, compulsory licensing, whether resulting in actual implementation or leading to price negotiations, was predominantly used in the context of HIV/AIDS treatment.[64] During the

Agreement' (Being a Master's Thesis in European and International Trade Law submitted at the School of Economics & Management, Lund's University)

[60] Ibid.

[61] Ibid.

[62] Beall R, Kuhn R. 'Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: A database analysis.' (2012) <PLOS Medicine. 2012;9: e1001154.Medline:22253577 doi: 10.1371/journal.pmed.1001154 > Accessed 30th June 2025

[63] Ibid.

[64] Ford N, Wilson D, Costa Chaves G, Lotrowska M, Kijtiwatchakul K. Sustaining Access to Antiretroviral Therapy in the Less-Developed World: Lessons from Brazil and Thailand.

2000s, countries such as Brazil, Ecuador, Ghana, Indonesia, Malaysia, Mozambique, Thailand, Rwanda, Zambia, and Zimbabwe issued compulsory licenses for one or more antiretroviral (ARV) drugs. These licenses aimed to increase access to lifesaving therapy for HIV-infected citizens who could not afford patented treatments. While most of these licenses targeted specific drugs, Ghana and Zimbabwe went further, issuing broad compulsory licenses covering all ARV drugs.[65]

Thailand and Brazil stood out in the mid-2000s for successfully reducing the prices of ARV medications. Both nations had publicly committed to providing free ARV therapy to all HIV-positive citizens, motivating them to seek affordable supply chains. Specifically, they pursued two key patented drugs: efavirenz (marketed as Sustiva by Merck) and lopinavir/ritonavir (marketed as Kaletra by AbbVie, previously Abbott Laboratories).[66]

In light of the implications of compulsory licence during the HIV/AIDs pandemic, several countries publicly considered using compulsory licensing as part of their response to COVID-19. On March 24, 2020, Israel became one of the first to issue a compulsory license, allowing the import of generic versions of lopinavir/ritonavir (marketed as Kaletra by AbbVie). The Israeli Ministry of Health identified the drug as a potential treatment for COVID-19 patients. Unlike previous cases in Thailand and Brazil, Israel's action was not driven by pricing concerns but by supply shortages. AbbVie was unable to meet the demand, prompting Israel to source generic

AIDS. (2007) 21 <Medline:17620749doi: 10.1097/01.aids.0000279703. 78685.a6> Accessed 30th June 2025.
[65] Ibid.
[66] Ibid.

alternatives from India. In response, AbbVie announced that it would not enforce its patent during the pandemic.[67]

To enable the use of compulsory licensing for COVID-19-related treatments or technologies, countries needed to ensure their domestic laws allowed for such measures. By March 2020, several nations had already taken legislative steps to streamline the process. In Canada, the government passed the COVID-19 Emergency Response Act, amending the Canadian Patent Act.[68] This amendment allowed the government to issue compulsory licenses more quickly on public health grounds and negotiate payment to the patent holder later.[69] In Chile, the Chamber of Deputies approved a resolution stating that the COVID-19 pandemic justified the issuance of compulsory licenses for relevant technologies. Similarly, Ecuador's National Assembly Committee passed a resolution urging the President and Minister of Health to ensure free or affordable access to COVID-19-related medicines, diagnostics, and preventive technologies through the use of compulsory licensing. These proactive legal steps demonstrated how countries could create a framework for issuing compulsory licenses if needed.[70] While compulsory licensing might not ultimately be necessary—for instance, if effective treatments turned out to be off-patent or made available through donations or voluntary licensing—it was important for countries to be prepared.[71]

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[67] Kass D. Israel Defies AbbVie IP To Import Generic Drugs For COVID-19. March 19, 2020. Available: https://www.law360.com/articles/1255079?scroll=1&related=1. Accessed 30th June 2025.
[68] Ibid n 32.
[69] Ibid.
[70] Ibid.
[71] Ibid.

In Africa, the HIV/AIDS crisis illustrated how the continent leveraged compulsory licensing to overcome the prohibitive costs of patented antiretroviral (ARV) drugs. Countries such as Zimbabwe, Zambia, Ghana, and Mozambique issued compulsory licenses to import or produce generic versions of ARVs, significantly lowering treatment costs and expanding access. Ghana and Zimbabwe notably issued broad licenses covering all ARVs, a bold move driven by public health necessity.[72] For many African nations, compulsory licensing became a legal and moral instrument to protect their citizens' right to health, especially when pharmaceutical companies offered little price relief voluntarily.

During the COVID-19 pandemic, the threat of inequitable vaccine and therapeutic distribution reignited the relevance of compulsory licensing. While few African nations formally issued such licenses for COVID-19 treatments, several including South Africa advocated for broader patent waivers to facilitate access. Legal frameworks, technical capacity, and fears of trade retaliation remained significant barriers. Nonetheless, the continent's prior use of compulsory licensing during the HIV/AIDS epidemic provided both precedent and justification.[73]

5.0 IMPLICATION OF COMPULSORY LICENSING ON PATENT HOLDERS

a) One of the most direct implications is the loss of exclusive rights. Patents are granted on the premise of exclusivity, giving inventors the legal right to prevent others from making, using, or selling their invention for a certain period.[74] Compulsory

[72] Ibid.
[73] Ibid.
[74] WIPO, *An Introduction to Patents for Small and Medium-sized Enterprises in Nigeria* (Series Number 3, Intellectual Property for Business, WIPO 2023)

licensing overrides this exclusivity, thereby weakening the patent holder's ability to control the distribution and pricing of their invention. This can significantly reduce expected profits, especially in high-demand markets.[75]

b) Another major impact is the potential discouragement of innovation. The rationale behind patent protection is to reward innovation by offering a temporary monopoly in exchange for disclosure of the invention.[76] If patent holders believe their rights can be easily overridden through CL, particularly in markets with weak rule of law or political instability, they may be less inclined to invest in research and development (R&D). This chilling effect could have broader implications for industries such as pharmaceuticals and biotechnology, where R&D costs are high and success rates are low. Financially, compulsory licensing can result in revenue loss or reduced licensing income. Although international agreements like the TRIPS Agreement mandate that patent holders receive "adequate remuneration" under a compulsory license, the compensation is often significantly less than what would be earned through market-based negotiations or voluntary licensing.[77] This gap can especially affect smaller companies or research institutions that rely on licensing fees to fund ongoing innovation.

c) In terms of legal and reputational risks, compulsory licensing can sometimes be seen as a form of state intervention or expropriation, especially by foreign investors. This may trigger

[75] Ibid.
[76] Ibid.
[77] Article 31(h) of the TRIPS Agreement

legal disputes under bilateral investment treaties (BITs) or investor-state dispute settlement (ISDS) mechanisms. The uncertainty surrounding how "adequate remuneration" is calculated or what constitutes a "national emergency" can expose patent holders to prolonged litigation or damage their relationships with key markets.

However, it's important to note that not all implications are negative. In some cases, compulsory licensing can serve as a negotiation tool. The threat of issuing a CL may push patent holders toward more favorable voluntary licensing agreements or tiered pricing models, especially in low- and middle-income countries. Additionally, when structured fairly, compulsory licensing can still protect core patent interests while advancing broader public health goals.

6.0 CONCLUSION

The COVID-19 pandemic starkly highlighted the deep fault lines in global health governance, particularly the tension between patent rights and public health imperatives. Compulsory licensing, as a legal mechanism that allows governments to override patent protections in the interest of public health, emerged as a critical—albeit controversial—tool for expanding access to life-saving medicines and technologies during global emergencies. While it does not dismantle the framework of intellectual property rights, compulsory licensing temporarily recalibrates it to prioritize human life, especially in contexts where monopolies restrict affordability and accessibility. This legal provision, enshrined in the WTO's TRIPS Agreement and reaffirmed by the Doha Declaration on TRIPS and Public Health, underscores the recognition that patent rights must not come at the expense of basic health needs. In times of crises, such as pandemics, when

speed, equity, and scale of access are paramount, compulsory licensing offers countries—particularly low- and middle-income nations—a vital tool to overcome the barriers posed by exclusive rights. It fosters local production or importation of more affordable generics, enabling broader public access to essential treatments. However, compulsory licensing is not without its challenges. Procedural complexities, diplomatic pressures, fear of trade retaliation, and lack of manufacturing capacity often dissuade countries from invoking it. To this end, a more collaborative and transparent global framework is needed—one that facilitates timely use of compulsory licensing without stigmatization or punitive backlash. Mechanisms like patent pooling, voluntary licensing, and technology transfer agreements can complement compulsory licensing, helping build trust among stakeholders and promoting shared responsibility. Multilateral cooperation, capacity building, and stronger institutional support are also essential to empower countries to use compulsory licensing effectively and responsibly.

7.0 RECOMMENDATIONS

i. Governments should review and update national laws to ensure that compulsory licensing mechanisms are clearly defined, transparent, and operationally ready during public health emergencies. This includes simplifying procedural requirements, reducing bureaucratic delays, and ensuring alignment with the flexibilities allowed under the TRIPS Agreement. Developing countries often face difficulties in utilizing compulsory licenses due to limited domestic production capacity or lack of access to quality-assured imports. Investments in local pharmaceutical infrastructure, regulatory agencies, and regional partnerships—such as through pooled procurement or shared manufacturing—

can help countries better exercise their rights and respond quickly in emergencies.

ii. Global health crises demand coordinated responses. Regional bodies should facilitate joint licensing strategies, collective bargaining, and knowledge sharing. At the multilateral level, institutions like the WHO and WTO should strengthen support mechanisms, including providing technical assistance and creating platforms for transparent negotiations between governments and patent holders. Voluntary and compulsory licensing efforts must be accompanied by greater transparency in drug pricing, licensing terms, and patent landscapes. Open access to this information will empower countries to make informed decisions, identify barriers early, and avoid legal or diplomatic disputes.

iii. While compulsory licensing remains an important legal option, proactive strategies such as voluntary licensing agreements, patent pools (e.g., Medicines Patent Pool), and technology-sharing platforms should be promoted. Governments and international donors can provide incentives (e.g., funding, regulatory fast-tracking, or market assurances) to encourage private companies to engage in more equitable partnerships. Institutions such as the WHO, WTO, and WIPO should take a more active role in supporting countries in invoking and implementing compulsory licenses. This includes providing legal guidance, dispute resolution support, and monitoring compliance with international norms. The creation of an emergency-use IP waiver mechanism could also be explored for future pandemics.