# ACCESS TO MEDICINES IN CRISIS: A CRITICAL ANALYSIS OF COMPULSORY LICENSING UNDER TRIPS WITH SPECIAL REFERENCE TO COVID-19

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**ABSTRACT**

This article explores the intricate relationship between the right to health and the international intellectual property regime, particularly focusing on the TRIPS Agreement and the mechanism of compulsory licensing. Recognizing health as a fundamental human right, the study examines how patent laws, while incentivizing innovation, can also create barriers to the availability and affordability of essential medicines. Through detailed analysis of Article 31 of the TRIPS Agreement and the flexibilities it offers, such as compulsory licensing, parallel importation, and research exceptions, the article underscores the legal avenues available to member states to prioritize public health over private patent rights. The Doha Declaration of 2001 is highlighted as a pivotal moment that reaffirmed countries' sovereign rights to issue compulsory licenses in the face of public health emergencies. The article also surveys significant international case studies from countries like Canada, Thailand, Israel, and India, demonstrating the practical application of these flexibilities. Additionally, it reflects on the COVID-19 pandemic to illustrate the critical role of compulsory licensing and the push for a TRIPS waiver to ensure global access to life-saving technologies. Concluding with a rights-based and utilitarian approach, the article argues for a balanced framework that ensures equitable access to healthcare without undermining the innovation ecosystem. It calls for a reimagined global IP regime that aligns with humanitarian values and public health imperatives.

**Keywords:** Compulsory Licensing, COVID - 19, TRIPS, TRIPS Flexibilities

## INTRODUCTION

Under international law, the state is granted a number of socioeconomic rights, including the right to health. It becomes a social, economic, and political right when the human rights component is fixed to the health component. Therefore, in order for people to develop generally and have a respectable quality of life, they must be granted the fundamental human right to health.

According to the World Health Organization's Constitution, being healthy means having the best possible health. The WHO preamble states that health is not the absence of illness or disability but rather the state of being physically, mentally, and socially well. This has also been fully recognized by a number of international agreements and conventions. The United Nations Universal Declaration of Human Rights aims to establish health as a fundamental human right in addition to the indivisible and interdependent economic, political, social, and cultural rights. The World Health Organization's concept of health is suitably included into Article 12 of the International Covenant on Economic, Social, and Cultural Rights.

As a result, health is a fundamental human right that is required in order to fulfill other rights. Every person has the right to the healthiest possible state so they can live in dignity. Due to the interdependence of the human right to health, disregarding this right would result in grave human rights abuses. At the same time, Violations of human rights may have dire repercussions. major detrimental effects on a person's health. WHO works to achieve "health security" for everyone by integrating human rights elements into the Universal Declaration of Human Rights in order to advance the implementation of human rights to health.[1]

When drafting or revising their laws and regulations, Members are permitted to take the necessary actions to protect public health and nutrition and further the public interest on issues of public concern in accordance with the principles set forth in Article 8 of TRIPS. Vital to their scientific and social advancement, so long as their actions align with the terms of this agreement. These terms denote criteria to be used in order to identify and incorporate the scenario and conditions that would require Compulsory Licensing in the nation's laws and regulations. This is the core idea of TRIPS. Each signatory has the authority to determine the

[1] Saroj Choudhary, Judicial Approach in Realising Health Rights: Indian Perspective (July 17, 2014), https://ssrn.com/abstract=2467601 (last visited on June 5, 2025, 4:00 PM).

exceptional nature of the circumstance and qualify it for an extraordinary resolution, such as the implementation of compulsory licensing.

## COMPULSORY LICENCE

An inventor receives a patent as compensation for reporting their invention. The public is the invention's ultimate beneficiary, aside from the patent holder, hence it is imperative that the invention be made accessible to the general public. The risk that a patent holder will misuse the monopoly that has been granted to him has always existed. Refusing to give licenses, placing unreasonably onerous requirements on the licensee, or placing restrictions on the use of the patented products are all examples of patent rights abuse. This circumstance is avoided by the Patents Act's requirement of compulsory licencing. A compulsory license is a legal authorization granted by an authority to provide a license for the exploitation of a patent-protected subject matter, either with or without the title holder's approval. The UK Statute of Monopolies, which was introduced in 1623, is credited with giving rise to the idea of compulsory licenses.

Government issued licenses to use patents or other forms of intellectual property are known as compulsory licenses. To accomplish a variety of public goals, governments impose mandatory licenses to increase access to information and technologies. Compulsory licencing is required in many countries if the patent owner refused to make the idea available for the general public.[2]

Government policy is the source of patents and other intellectual property rights. Currently, countries have the authority to grant compulsory licence. The Paris Convention, a generally recognized international agreement safeguarding intellectual property rights, and the TRIPS Agreement both include compulsory licensing for patented inventions. The "working obligation" was approved at the 1883 conference that ratified the Paris Convention. According to the Paris Agreement for the Protection of Industrial Property it states that:

“To address any misuses of the exclusive rights conferred by the patent, such as failure to work, each member state of the Union may pass legislation permitting the issue of compulsory licenses.”

[2] Junaid Subhan, Scrutinized: The TRIPS Agreement and Public Health, 9 McGill J. Med. 152 (2006)

## COMPULSORY LICENCES UNDER THE TRIPS AGREEMENT

The compulsory licences are set out in the TRIPS agreement under Article 31. Compulsory Licence are issued with the intention to strike a balance between public interest and legitimate interest of the patent holder. The TRIPS agreement Article 31 contain subparagraph a to k. It states that:

(a) The approval of such use will be evaluated on a case-by-case basis.

(b) Such use may only be allowed if the prospective user has attempted to get permission from the right holder on acceptable commercial terms and conditions before the use, and if those attempts have failed within a reasonable amount of time. In the event of a national emergency, other extremely urgent situations, or in cases involving public non-commercial use, a member may waive this provision.

(c) The extent and duration of such usage must be restricted to the intended use, and in the case of semiconductor technology, this can only be for public non-commercial use or to address a practice that has been found to be anti-competitive via a legal or administrative process;

(d) This use will not be exclusive.

(e) with the exception of the portion of the business or goodwill that benefits from such usage, such use must not be transferable;

(f) Any such use must be approved primarily for the purpose of supplying the Member's domestic market;

(g) Permission for such use may be revoked if and when the conditions that gave birth to it cease to exist

(h) The economic value of the authorization must be taken into consideration when determining the appropriate compensation for the right holder in each case.

(i) a clear higher authority in that Member shall evaluate the legality of any decision pertaining to the authorization of such use by judicial review or other independent

review;

(j) A clear higher authority in that Member shall subject any decision pertaining to the compensation offered for such usage to judicial review or other independent review

(k) Where such use is allowed to address a practice found to be anti-competitive via a judicial or administrative process, members are not required to implement the requirements outlined in sub-paragraphs (b) and (f). In certain situations, the amount of compensation may be determined by the need to rectify anti-competitive activities. If and when the circumstances that led to the authorization are likely to reappear, competent authorities will have the power to refuse to terminate it;

Additionally, the TRIPS Agreement limits the use of compulsory licence in a number of ways. According to this rule, compulsory licenses must be given out on an individual basis. In particular, it mentions a number of justifications for issuing compulsory licenses, including emergency and urgency, anti-competitive behavior, public non-commercial usage, and dependent patents.

For purposes other than those expressly mentioned in the agreement, the TRIPS Agreement does not limit the members' authority to enforce compulsory licensing. Article 31 of the TRIPS Agreement outlines a comprehensive set of requirements, including the requirement to grant them on a case-by-case basis, although it does not limit the grounds for granting. According to Article 31(b) of the Agreement, a compulsory license does not need to be requested in advance for emergency or public non-commercial use. As soon as it is practically feasible after the usage has taken place, the patent holder may be informed when the innovation is used for public non-commercial reasons. Special consideration is given to licenses intended to address anti-competitive behavior.

The TRIPS Agreement's specifically in Articles 1.1 and 8.1—indicates that compulsory licenses may be granted to protect public health and nutrition or to further the public interest in areas that are essential to the nation's socioeconomic and technological advancement, even though it does not define what is a public non-commercial use.

## POST TRIPS AND DOHA DECLARATION

Through less stringent enforcement of patent laws, the member states of the tripartite alliance

between Brazil, India, and South Africa have decided that their nations are capable of producing, acquiring, and distributing generic medications required to fight the epidemic during a health emergency. The Doha Declaration on the TRIPS Agreement and Public Health was the result of these countries' efforts. The use of required permits for the export of pharmaceuticals to developing nations was included in the Doha Declaration of 2001. The Declaration confers certain rights and lays out certain broad guidelines. It acknowledges the necessity of addressing the public health problems that many developing nations face. States' rights to safeguard public health and advance universal access to medications must be upheld in the interpretation and application of the TRIPS Agreement. Every member has the authority to award required permits and is allowed to choose the criteria for doing so. Every member is entitled to decide what qualifies as a significant emergency, public health crisis, or national emergency.

As acknowledged in paragraph 6 of the Declaration, nations with limited or no pharmaceutical manufacturing capability may find it challenging to effectively utilize the licenses mandated by the TRIPS Agreement, and the Council is directed to TRIPS looks for a fast solution. The WTO announced its decision to implement paragraph 6, which permits the waiver of the "inner market" limit in Article 31(f) provided that favorable conditions are met. It has enabled any member country to negotiate an obligatory license for the production of standard tablets for export to the least developed countries as well as other countries that believe they no longer have enough or the capacity to manufacture pharmaceuticals.[3]

One significant milestone is the Doha Declaration. It raised public awareness of the topic, significance, and extent of compulsory licensing. It made the formal and legal method of restricting exclusive patent rights known to the world. Mainly to encourage access to reasonably priced medications for those without sufficient industrial infrastructure. According to the Doha Declaration, signatories' top priority is public health. It is a commendable global effort to address health-related issues. Although it is not a perfect answer, it did offer a formal way to deal with the public health issue. It is a limited approach that will only be useful if medications are developed eight years later. Even while many nations continue to rely on imports for little items, the world is still waiting for a gradual solution to non-medical problems

[3] Raadhika Gupta, Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations, Journal of Intellectual Property Rights, Vol 15, September 2010, pp 357-363

after 16 years. internalization of crucial Technologies is still beyond the far end of the dark intellectual tunnel, like a far-off dream.[4]

After Doha declaration the first compulsory licence was issued to the Canadian company called Apotex for the production and export of HIV drug TriAvir to Rwanda. Apotex tried to get an authorization from the patent holder but the negotiation was unsucessful. Later on Canada issued a compulsory licence, authorising Apotex to use nine patented inventions to manufacture and export TriAvir to Rwanda.

## TRIPS FLEXIBILITIES

According to the Doha Declaration, member nations are free to take action to safeguard public health under the TRIPS Agreement. At Doha it reaffirmed that each member has the right to use the provisions of TRIPS which provide some flexibility for protecting public health. There are number of flexibilities which developing countries can use to address some of the negative consequences of pharmecutical patents. They are:

- **Compulsory Licence**

The compulsory Licence are set out in TRIPS agreement under Article 31. Compulsory Licence are issued with the intention to strike a balance between public interest and legitimate interest of the patent holder.

- **Parallel Importation**

Parallel importation is an economic and legal term that describes the importation of authentic, trademarked or patented products into a nation without the intellectual property (IP) rights holder's permission, but with the products having been sold legitimately elsewhere—usually in another country or market.

- **Patentable Subject Matter**

Under Article 27 of TRIPS Agreement sets out the exception to the patentable subject matter. It states that patent shall be available for all inventions whether product or process. But Article 27 does not define what is an invention. It allows the member states to define the scope of

[4] Milind V Sathe, Compusory Licensing in Knowledge Economy (2012) Satyam Law International.

invention under their laws. Under Article 27 of the TRIPS Agreement it mentions exceptions to patentability. They are :

- ✓ inventions that have been shielded from commercial development in order to save the health or lives of people, animals, or plants.
- ✓ Diagnostic, therapeutic, and surgical methods for treating humans or animals.
- ✓ Certain plant and animal invention.

- **Research Exception**

Article 30 of TRIPS Agreement mentions Research Exception. This allow researchers to use a patented invention for scientific studies without infringing the patents. This exception is crucial in the pharmaceutical industry. It enables scientists to conduct experiments or patented drugs to improve exsisting medicines. Sec 47 (3)of patent Act also mentions this.

- **Early Working Exception (Bolar Exemption)**

This allows manufactures to start preparing generic version of patented drugs before the patent expires. so that when the patent expires, they can go on sale. This helps in ensuring faster access to affordable medicines after patent expires.

- **Limitation of Test data protection**

Article 39 of TRIPS Agreement provides protection for undisclosed test data submitted to regulatory authorities for drug approvals. The extent of this protection can be limited for preventing undue monopolization.

- **Control of Anti Competitive Practices**

Article 40 of the TRIPS Agreement specifically establishes a regime for the control of Anti Competitive practices in contractual licences. It allow member countries to take measures to control anti competitive practices related to IPR. Member countries can issue Compulsory

Licence as measures to control anti competitive practices.[5]

## INTERNATIONAL SCENARIOS IN NEXUS TO TRIPS & COMPULSORY LICENSES

Globalization has made developing and least developed nations more susceptible to outside political pressures, threats, and claimed arrests or restrictions on foreign direct investment—things that they should actually learn to resist. The United States cannot place itself under inspection if it invokes the Compulsory License.[6]

- **United States v. Besser Mfg. Co.**[7]The Supreme Court in this case explained the term Compulsory licence. The court defined it as a well recognized remedy for patent abuse.

- **Voda v. Cordis corp**[8] In this case Dr. Jan Voda have patent on angioplasty catheters, medical devices for performing angioplasty. Johnson & Johnson the proposed user applied to Dr. Jan Voda for getting authorization for the use of this angioplasty catheters. They maked a negotiation to Dr. Jan Voda. But it was unsuccessful. Then Government issued Compulsory Licence to Johnson & Johnson. Here Dr. Jan Voda approached the federal circuit court. The court upheld the decision of the government by considering the public interest and for the easily availability of this medical device.

- Bio-Technology General (BTG) of Israel was granted a compulsory license by the Israeli Registrar of Patents in 1995 on Biogen's patent for a genetically engineered hepatitis B vaccine. Because Biogen was importing the vaccine at high prices rather than producing it domestically, making it unavailable and unaffordable for the majority of Israelis, BTG requested the license. The Registrar found that the public interest required local, cost-effective vaccine production and that the patent was not being adequately worked in Israel. The use of forced licensing as a legitimate strategy to prioritize public health requirements over exclusive patent rights—particularly with regard to access to essential, life-saving medications—makes this case noteworthy.

- In 2004 Malayasian Minister of International Trade and Consumer Affairs issued a

[5] Elizabeth Varkey, *Law of Patents* 563 (2d ed. 2012).
[6] Understanding Compulsory Licensing: A Global Overview, IAM, Lexology (Apr 23, 2025, 1:20 pm), https://www.lexology.com/library/detail.aspx?g=a7f2ec22-a596-4c6a-9991-09c5fbd7fab0 (last visited on June 5, 2025 4:40 Pm)
[7] 343 U.S. 444 (1952).
[8] Voda v. Cordis Corp, 122 Fed.Appx. 515 (Fed.Cir.2005)

compulsory licence for two years for importing generic version of didanosine, zidovudine and lamivudine + zidovudine (combivir) from India. Because Malayasia was purchasing the patented version of this drugat higher price from MNC. The Malayasia's action aligns with Article 31 of TRIPS agreement and Doha declaratiom on TRIPS and public health.

- In 2006, the Thai government issued a compulsory Licence for the import of generic version of the drug called Effavirenz which is used to treat HIV. The patent holder was Merck & Co. This was issued due to the public health emergency because Thailand has one of the highest HIV infection in India.

- **Taiwan Tamiflu Case** Taiwan had two rounds of negotiations with Roche and Gilead representatives in Taipei in 2005 after submitting an application to Roche for a sublicense to manufacture its version of Tamiflu. Ultimately, Taiwan plants were granted compulsory licence to produce a generic version, which were valid until December 31, 2007. The Intellectual Property Office (IPO) gave Taiwanese pharmaceutical businesses a compulsory license following the breakdown of negotiations with Roche and Gilead Science, the U.S. company that developed Tamiflu. The first nation to issue a compulsory license for the production of Tamiflu was Taiwan.

- In order to address an alleged abuse of a dominant market position and making the medication easily accessible to the general public, the Italian Competition Authority requested in March 2007 that Merck & Co. Inc. grant free, non-exclusive licenses for generic versions of the imipenem combination of antibiotic cilastatin used for curing bacterial infection.

- Ghana attempted to purchase low-cost AIDS drugs from the generic manufacturer Cipla. The patent holder, GlaxoSmithKline, warned that the product was under patent in Ghana and, while government officials disagreed, the deal was dropped. GlaxoSmithKline eventually conceded that it had made an error and they are not well aware about the situation in Ghanna. After this confession by GSK Ghanna imported generic version of HIV drug from India.

- In 2006, Pfizer sued the Philippines government for damages for importing a drug patented by the Philippine government before the patent expired. The case involves Norvasc, in which the active ingredient group is amlodipine, which is used to treat high blood pressure,

one of the main reasons for heart problems. Cardiovascular disorders are mainly in the Philippines, and many people have died. It has been sold for several times about 2 times higher than its price in other countries. This patent was set to expire in 2007. With the intention of selling the drug after the patent expired, the Philippine government imported the consignments from India. Such an action was subsequently authorized by national regulations. The same goes for storage. The refusal to allow generic manufacturers to process patented products before the patent expires even if these products do not access the market extends patent exclusivity.[9]

## COVID 19 INITIATIVES & TRIPS WAIVER

In response to the COVID-19 epidemic, a number of nations have taken steps to modify their legal frameworks. A plan submitted by a group of Brazilian politicians during Covid 19 period that helped the government to temporarily halt all patents on medical devices that are helpful in battle COVID-19. In order to ensure that everyone has access to free and affordable medical technology and pharmaceuticals, the Ecuadorian National Assembly's Committee on Education, Science, and Technology passed a resolution asking the government to declare a health emergency and implement mandatory licenses and other measures. The idea of a compulsory patent license is also taken into consideration by many other legal systems, however it is rarely used in practice outside of Israel. The first nation to obtain mandatory license to import a patented HIV/AIDS medication (Kaletra) is Israel from India in order to treat COVID-19.[10]

During the COVID-19 pandemic period compulsory licensing was a crucial instrument for gaining access to COVID-19 medical devices and technologies. Many nations have changed their legal frameworks to make it simpler and faster to get government usage licenses or mandatory licenses during the pandemic.

There is no conflict between the TRIPS waiver and the current compulsory licensing regulations. Every nation has the authority to decide under what circumstances a compulsory license may be granted, and in situations other than emergencies, it may be an effective and even sufficient instrument. According to the Paris Convention for the Protection

[9] Federico, P. P. (1948). Compulsory Licensing in Other Countries. Law and Contemporary Problems, 13(2), 295-319.
[10] Supra note 7

of Industrial Property and the TRIPS Agreement, the patent office, the ministry of health, or competition authorities should issue a compulsory license. When a global health disaster like the COVID-19 pandemic strikes and pharmaceutical companies refuse to participate in non-exclusive global licenses, countries should be able to quickly and automatically address intellectual property issues. This should include trade agreements related to the granting and enforcement of intellectual property rights in technology, materials, and items that are important for good health, as well as the suspension of certain TRIPS Agreement criteria to permit the free exchange of health advances. In the event of an intellectual property dispute during the pandemic, the temporary TRIPS exemption for COVID-19, spearheaded by South Africa and India, offers a vital legal option to handle intellectual property monopolies and gives nations a chance to come together. However, a few nations persisted in using delay tactics to thwart the plan seven months after it was initially put forth.[11]

## CONCLUSION

Health is a right and medicines and vaccines should be seen as a global public good, rather than a market good available only to countries and those who can afford it. The right to health care, the right to development, and the right to profit from scientific advancements and their applications all depend on the availability of vaccines, medications, medical technologies, and medical therapies. Everybody has the same right to access all the best applications of scientific advancement that are required to achieve the best possible level of health.[12]

The right to health is fundamental human right, relevant and constitutional like any other fundamental right. This right to health is broad enough to include access to medicine. Lack of access to medicine is an inequality that can be measured by a very conspicuous criterion in statistical analysis of mortality due to denial of access to medical care and treatment. Such a refusal certainly constitutes a flagrant violation of human rights.

The benefits of scientific and medical advancements are denied to an estimated 2 billion individuals who lack access to necessary medications. For unjustified reasons, such as social

[11] Médecins Sans Frontières (MSF), *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies*, Briefing Document (May 2021), https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf (Last visited on June 5, 2025, 3:55 PM).

[12] 26 Committee on Economic Social and Cultural Rights (CESCR), General Comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the Covenant), para. 70.

or economic ones, people shouldn't be refused access to essential or health-promoting facilities.

However, unequal access to medicinal technologies, treatments, vaccines, etc, jeopardizes this goal, and our national regulators have properly put in place Vaccine Maitri initiative to stop that inequality by implementing the very idea behind the Alma Atta Declaration on Primary Health Care, ICESCR and other international conventions on human rights and thus becomes a perfect quintessence for other countries.

Adopting a utilitarian perspective implies that there must be a perfect moment when mandatory licensing should be implemented—something that maximizes the well-being of both current and future generations. Since the current legal system already requires compulsory licensing, any effort to guarantee that its use will be carried out more effectively would need to take welfare or utilitarian factors into account. This argument supports the claim that, rather than being inherent or natural, intellectual property rights are functional in nature. In order to increase access to innovative medications and advance overall societal welfare, patent rights are granted, particularly for essential treatments. However, using this method comes with a number of practical obstacles. Even from a utilitarian standpoint, one significant issue is that we won't know if the level of mandatory licensing was more than ideal until after the fact. Due to the lack of knowledge regarding pharmaceutical R&D expenditures and potential payback, this creates uncertainty. These gaps make choosing a policy more challenging. However, it's unlikely that the patent system itself will experience a significant fundamental shift anytime soon.

Thus, along with the remarkable progress in science it is very much expedient to accommodate our fellow human beings in benefiting from the fruits of such advancement and if not, it will result not only gross human rights violation with legally, politically, and morally unacceptable injustice but also sabotage the entire humanity.