

# Not Tripping over TRIPS: An Analysis of Necessity and Legality of the COVID-19 TRIPS Waiver Proposal



Ahan Gadkari, Sofia Dash

**Abstract:** *The availability of vaccinations against COVID-19 provides hope for containing the epidemic, which has already claimed over 2.84 million lives. However, inoculating millions of individuals worldwide would need large vaccine manufacturing followed by fair distribution. A barrier to vaccine development and dissemination is the developers' intellectual property rights. India and South Africa have jointly sought to the World Trade Organization that certain TRIPS rules of COVID-19 vaccines, medicines, and treatments be waived. This piece argues for such a waiver, highlighting the unique circumstances that exist. It believes that TRIPS's flexibilities are inadequate to cope with the present epidemic, particularly for nations without pharmaceutical manufacturing competence.*

**Keywords:** *Intellectual Property Rights, COVID-19 Vaccines, TRIPS Agreement, WTO*

## I. INTRODUCTION

*"With a fast-moving pandemic, no-one is safe until everyone is safe."*

- World Health Organization

On October 2, 2020, South Africa and India jointly submitted to the Council on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS Council) to waive the intellectual property (hereinafter IP) protection given to COVID-19 vaccines. On February 23, 2021, the TRIPS Council convened to debate this idea. However, the meeting produced no productive outcomes. The members simply chose to advocate for increased international collaboration and to demonstrate their commitment via "actions rather than words." It seems a little ironic that such a statement would be made immediately following the TRIPS council meeting. The very same meeting during which members were supposed to take "action." Although other countries, including the United States of America (hereinafter US), have jumped on the waiver bandwagon, there does not appear to be a fruitful conclusion. It is also worth mentioning that a movement openly opposes the IP waiver's efficacy or applicability. Some have expressed concern that the waiver could spell the end of pharmaceutical development in the future.

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As a result, the question arises as to whether the IP waiver is necessary and legal? This piece will first examine the role of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS) and the World Trade Organization's (hereinafter WTO) decision-making processes. This piece will also examine the waiver's legality under IP and WTO law. Finally, this piece will discuss the necessity of the IP waiver and whether it will have any practical benefit.

## II. ROLE OF TRIPS

TRIPS is a crucial legislative instrument that harmonizes IP protection by requiring member countries to ensure that IP rights are protected and enforced at a minimum level in their territories. TRIPS also controls the enforcement of IP rights through an obligatory and enforceable dispute settlement procedure, which is part of the WTO legal regime. In the Uruguay Round of negotiations, which took place from 1986 to 1994 and resulted in the formation of the WTO in 1995, the TRIPS agreement was a source of contention. Developed countries, particularly the US, aggressively pushed for the TRIPS agreement, backed by their transnational pharmaceutical corporations. These countries reasoned that better cross-border IP protection, which a multilateral agreement might appropriately manage, would result in higher rents for national pharmaceutical companies. Developing countries, on the other hand, were not excited about a WTO deal on IP. Predictably, the wealthy nations triumphed, forcing poor countries to concede to include IP in the Uruguay round of talks by threatening trade sanctions and offering concessions in agriculture and textiles trade. The contention over TRIPS' effect on individuals' right to health has not stopped since then. Proponents argue that IP protection encourages innovation and should be strengthened through a network of national and international legislation. Meanwhile, opponents argue that IP rights, particularly patent rights, prevent the introduction of affordable vaccinations and medications in developing countries, as well as people's right to health. Today, with the world struggling with COVID-19, this debate is front and centre. The TRIPS agreement protects the IP of the vaccinations, and other medicines developed to combat COVID-19. For the course of the patent's 20-year term since the date of filing, patent holders have exclusive rights to produce, use, and sell the vaccine or medicine. Such protection could obstruct wider access to vaccines, thereby prolonging the pandemic.

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The pandemic will be ended by the vaccination campaign as a whole, rather than the vaccinations themselves, and the task will be to achieve their universality. The challenge is mammoth in view of growing worries over vaccine nationalism, in which wealthier countries prioritize vaccine procurement for their own populations, threatening the two billion vaccine dose's objective for middle- and low-income countries.

### III. WTO DECISION MAKING PROCESS:

To know how the TRIPS waiver might be used, it is necessary to understand how the WTO operates. This section will analyze the WTO's operations and then how the waiver could be implemented within this framework. The WTO does not follow the World Bank's financial contribution model, nor does it follow the United Nations' one-state, one-vote approach. Instead, the WTO operates on the premise of consensus-based decision-making. Ministerial Conferences have previously failed to reach an agreement due to the resistance of a single state, such as India, at the Cancun Ministerial Conference in 2003. As established in Article IX of the WTO Agreement, certain decisions, such as granting a waiver individually or collectively, require a three-fourths majority. If a member state wants an extension of its transition period with less restrictions, the decision must be made by agreement, according to Article IX (4). In relation to the treatment, prevention and containment of COVID-19, the TRIPS Council has already reviewed a proposal by India and South Africa to waive enforcement of IP rights such as copyrights, patents, industrial designs and trade secrets. However, the phrase "containment" must be interpreted broadly to include vaccines. The proposed waiver would be in place until universal vaccination has been achieved and a major part of the world's population develops immunity. As expected, the debate was intense, with some expressing fear that the waiver request would jeopardize efforts to combat the pandemic by eroding cooperation. After that, Australia proposed a "Trade And Health" Initiative. Brazil, Chile, and Kenya also endorsed Australia's proposal. According to the WTO, all waiver petitions must be examined within ninety days and then presented to the General Council. This stipulation applies to all WTO members. In December 2020, the WTO General Council directed the TRIPS Council to continue working on the waiver proposal. While it is true that the WTO system has significant inequities, it must also be acknowledged that, at least in some circumstances, the interests of economically weaker states may override the interests of economically powerful governments. India and South Africa's combined request to the WTO for a temporary waiver of IP rights on the COVID-19 vaccines and pharmaceuticals must be viewed in this light. IP rights, according to the theory, might stifle the affordable supply of vaccines and pharmaceuticals. As a result, India and South Africa have requested that the WTO's TRIPS Council recommend a waiver of certain TRIPS Agreement implementation, application, and enforcement responsibilities to the General Council. In order to prevent, contain, or treat COVID-19, IP rights like as patents, copyright, and trademarks would have to be waived. If the waiver is granted, WTO members will be spared of the

obligation to award or enforce patents and other IP rights on COVID-19 vaccines, medicines, and other therapies for a limited time. This will protect countries' vaccination policies against charges of inconsistency under WTO rules. Numerous developing countries have since co-sponsored the initiative, recognizing the enormous benefits that would accrue if the concept became a reality. The TRIPS Council has considered this topic within its formal and informal meetings. Many economically superior countries are hesitant to give up their IP rights, so a consensus is improbable. They claim that maintaining IP rights encourages research and innovation and that suspending them will not result in an increase in COVID-19 vaccine production. They also contend that the TRIPS Agreement contains flexibility that allows for a balance between patent holder rights and the public's right to health. However, are these arguments valid, or are they merely lip service? The following two sections of this piece will address this question.

### IV. LEGALITY

Article IX (3) of the WTO Agreement provides the legal basis for the TRIPS waiver. This provides that commitments imposed by the WTO Agreement and linked multilateral trade agreements may be waived in extraordinary situations. Therefore, the proposal must also be presented to the Council for Trade in Goods, the Council for Trade in Services, and the TRIPS Council if the waiver is for a multilateral agreement included in Annex 1A, 1B, or 1C. In addition, because this is a TRIPS waiver, the proposal must be made to the TRIPS Council. An article IX waiver can be granted individually or collectively to WTO members. There are two instances in which the WTO system has granted collective waivers in the past. To begin, in 2003, some countries were granted a derogation from certain GATT agreements in order to put in place measures to restrict the import and export of raw diamonds or "blood diamonds" to non-Kimberley Process Certification Scheme non-member countries (hereinafter KPCS). Second, in 2003 there were concerns raised regarding about the accessibility of certain pharmaceutical products in least developed countries (hereinafter LDCs) and other developing nations without manufacturing capacity. In this case, the General Council exempted the TRIPS Agreement's Articles 31(f) and 31(h) provisions in 2003. Article 31(f) had been waived for exporting countries, which mandates compulsory licenses (hereinafter CL) for patented drugs to be issued primarily for domestic market supply. This waiver was only granted to the extent required to manufacture and export a pharmaceutical product to an eligible importing country. Furthermore, the product's manufacture and subsequent export are subject to further limitations. To begin, a non-LDC eligible importing country must notify the TRIPS Council that it lacks manufacturing capabilities or is unable to manufacture the product (or medication) in contention, as well as the expected names and quantities. Second, if the pharmaceutical product is patented in the eligible importing country, the government must have secured or be planning to grant a CL.

Similarly, the eligible importing country is excluded from the duty to reimburse the patent holder under Article 31(h). For the waiver to take effect, three more conditions had to be met. To begin, the generic pharmaceutical manufacturer must only produce the amount required to meet the importer's requirements. Second, any medications developed under the CL must be transported in their whole to the eligible importing country. Finally, products developed under the CL must bear a visible generic label. As a result, all WTO member countries that met the requirements outlined in the 2003 Declaration were eligible for this waiver. The COVID-19 worldwide pandemic is the most deadly disease to strike the world in the last century, killing millions of people and causing havoc on the economy and society. A pandemic of this magnitude on a worldwide scale clearly qualifies as an unusual circumstance under the WTO Agreement's article IX. As the pandemic spreads, nations must work together to devise new ways to expand vaccine production and ensure timely and low-cost distribution. In this instance, following the TRIPS Agreement's stringent IP standards may be impossible. A collective waiver, similar to the one given to participants in the KPCS, has a solid legal case to be made. Compulsory licencing, as implemented in 2003, may not be sufficient to address the COVID-19 pandemic's challenges. This will be discussed further in the section on the TRIPS waiver's necessity. WTO members' IP commitments would be suspended under the waiver, allowing those with manufacturing capabilities to develop COVID-19 vaccines and export them to countries that do not have them. The core of this waiver is that all of the actions listed above can be carried out without fear of a WTO legal challenge. The COVID-19 pandemic is constantly changing. The waiver can even be granted for a one-year period and then extended based on the circumstances.

## V. NECESSITY

Some academics believe that the TRIPS waiver is superfluous and that other flexibilities included in the TRIPS agreement can be used instead. The TRIPS Agreement does, in fact, include flexibility. One such crucial flexibility is CL. CL refers to the government's right to grant a license to use a patent without the patent holder's consent during the patent's term. TRIPS article 31 governs CL, which also provides for non-commercial public use. A government may allow the use of a patent for its own purposes under this article. However, implying that this flexibility would be sufficient to address all public health concerns, let alone one as large as the current pandemic, is like a whiteboard with erroneous written all over it. TRIPS flexibilities, such as CL, are of varying utility in various nations. While countries with competence in pharmaceutical production can execute CL efficiently, a considerable percentage of LDCs cannot. Moreover, even underdeveloped countries that are capable of issuing CL to manufacture patented medications are under constant pressure from developed countries not to do so. For example, when India granted a CL to produce a generic version of Bayer's cancer medication in 2012, the US government launched a long-running campaign of opposition. CL as previously indicated, is not a beneficial flexibility for countries lacking manufacturing competence. A CL may be given primarily for the issuing nation's internal market, according to Article 31(f) of the TRIPS Agreement. As a

result, generic medications produced under a CL are not exportable. While this reasoning makes sense for granting a CL waiver, it does not apply to nations with insufficient manufacturing skills. As a result, countries with limited pharmaceutical manufacturing capabilities will be unable to profit from the TRIPS Agreement's CL provision. In 2001, the World Trade Organization (WTO) recognized the problem, noting it in paragraph 6 of the Doha Declaration on TRIPS and Public Health. It was addressed, and the WTO General Council approved a waiver on article 31(f) and 31(h) commitments in August 2003, allowing countries to export pharmaceuticals created under a CL to countries without manufacturing competence. Further, in 2005, the TRIPS agreement was revised, which took effect on January 23 2017, to add Article 31 bis, which permanently codified the 2003 waiver. The requirement for a waiver first, followed by a TRIPS Agreement modification, shows that the TRIPS flexibilities were insufficient to meet all cases of drug scarcity. Whilst this change has been lauded as alleviating the issue of developing countries without manufacturing capability having access to affordable drugs, issues remain about the lengthy process that countries must go through in order to obtain and export such medications. For example, suppose a government gives a CL to export medications to another country that lacks manufacturing capability. In that case, the exporting country must ensure that the drugs produced are solely for that country. Furthermore, the pharmaceuticals must be easily identifiable by their characteristic colour or shape, and just the quantity necessary to meet the requirements of the qualified importing country is manufactured. These conditions act as a deterrent to generic pharmaceutical producers developing drugs for CL export. Furthermore, because countries without manufacturing expertise are generally smaller in size, they lack economies of scale. Making it harder to persuade countries with generic manufacturing facilities to send drugs to such countries. In their suggestion, India and South Africa point out that Article 31 bis is unable to solve the issues raised by COVID-19. Because many countries lack pharmaceutical manufacturing skills and would need COVID-19 vaccines for their people, the lengthy and costly procedures outlined in Article 31 bis would stymie their efforts to achieve universal vaccination. Furthermore, using the requirements outlined in Article 31 bis for a significant number of countries at the same time would drastically restrict vaccine exports. This would make the process prohibitively expensive in cases where countries require these products urgently in this pandemic. As a result, TRIPS flexibility is no longer possible due to the magnitude of the problem and the tremendous demand for vaccines from all countries. This emphasizes the vital importance of India and South Africa's proposed TRIPS waiver.

## VI. CONCLUSION AND WAY FORWARD

States themselves would benefit from promoting equitable access to vaccines, given that the COVID-19 is a worldwide concern, and the world is becoming increasingly globalized.

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However, vaccine nationalism may jeopardize the global pharmaceutical supply chain. Perhaps the most serious worldwide consequence of vaccine nationalism would be virus mutation in countries lacking vaccines, rendering current vaccines ineffective against such mutations. The issue over the TRIPS waiver also highlights the practical and procedural difficulties inherent in today's IP environment, notwithstanding the flexibilities in existence. It emphasizes the significance of reflecting on and updating the system in order to make it more resilient to future pandemics. Thus, precautions should be taken to prevent vaccine nationalism and IP encumbrances that obstruct equal access.

In the year 2021, the international community set out with the primary goal of putting a stop to the COVID-19 outbreak. This will only be possible if a growing number of people around the world get immunized as soon as possible. Given the enormous demand, vaccine production must be boosted exponentially, followed by more equitable distribution. This cannot be accomplished just through the surrender of IP rights. In order to increase vaccine production and ensure fair access, certain countries would need to develop institutional capacity, overcome systemic obstacles, and execute appropriate administrative and legislative reforms. A TRIPS waiver, on the other hand, might be a crucial step toward increasing vaccine production. Voluntary efforts like COVAX, which tries to speed vaccine development and production, may not be enough given the magnitude of the task. Nations with manufacturing capabilities can employ TRIPS flexibilities such as CL, whereas countries without manufacturing capabilities, especially LDCs in Africa and Asia, cannot. Additionally, developed countries must exert a greater push. During Indian Prime Minister Narendra Modi's recent visit to the US, members of the Quadrilateral Security Dialogue (hereinafter Quad) reviewed urgent global issues such as COVID-19. This would have provided an excellent opportunity for the Quad to demonstrate their support for the TRIPS waiver. Regrettably, this did not occur. All possible options, including a temporary TRIPS waiver, must be explored by the international community and efforts should be taken to avoid vaccine nationalism and IP restrictions that block equal access to vaccines.

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