



## Proposal for a TRIPS waiver from intellectual property protections for COVID-19-related medicines, vaccines, diagnostics and other health technologies

Briefing Document  
Updated 27 May 2021

### Table of Contents

<b>Introduction .....</b>	<b>1</b>
<b>Questions &amp; Answers .....</b>	<b>2</b>
1. What is in the ‘TRIPS waiver’ that has been proposed? .....	2
2. Is it legal to request a waiver from obligations under the TRIPS Agreement? .....	3
3. Is the waiver permanent? .....	4
4. Does the waiver proposed apply only to developing countries? Will every country have to implement the waiver if adopted? .....	4
5. How will the decision to adopt a waiver be made? .....	4
6. What would it mean if the waiver was adopted? .....	4
7. Has a consensus been reached by WTO members to grant waivers in the past? .....	4
8. What developments have happened since the proposal was introduced at the WTO? .....	5
9. Besides WTO members, who else supports the TRIPS waiver? .....	6
10. What does it mean for the process since the US changed its position in May 2021? .....	6
11. What are the next steps in the process? .....	6
12. What is a text-based negotiation? Why is it important? .....	7
<b>Examples of Article IX waivers .....</b>	<b>8</b>

### Introduction

In a landmark move, India and South Africa made a proposal to the World Trade Organization (WTO) to allow all countries the legal right under international trade rules to choose not to grant or enforce patents and other intellectual property (IP) related to COVID-19 drugs, vaccines, diagnostics and other technologies and materials for the duration of the pandemic, until global herd immunity is achieved. This proposal has gained momentum, and 63 countries have co-sponsored the draft as of May 2021.

This briefing document provides further details related to this important development, including a Q&A and examples of waivers that have been granted with respect to provisions under the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) in the past (Article IX waivers).

# Questions & Answers

## 1. What is in the ‘TRIPS waiver’ that has been proposed?

On 2 October 2020, India and South Africa submitted a [joint communication](#) to the TRIPS Council at the WTO titled, “Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19.”

The proposal requests that a waiver to be granted to WTO members so that they do not have to implement, apply or enforce certain obligations related to COVID-19 products and technologies under Sections 1 (copyrights and related rights), 4 (industrial design), 5 (patents) and 7 (protection of undisclosed information) of [Part II of the TRIPS Agreement](#).

On 21 May 2021, in order to move forward with text-based negotiations, the governments co-sponsoring the proposal have submitted [a revised proposal](#) to WTO (see Table 1). The revised proposal includes the draft decision text and an explanation of the rationale for a waiver.

### Scope of technologies

The revised May 2021 proposal specifies the scope of the proposal. The October 2020 proposal, while extending to the prevention, containment and treatment of COVID-19, did not explicitly specify the nature and extent of the technologies that the waiver would cover. The revised proposal presented on 21 May 2021 clarifies this. The waiver shall be applicable to health products and technologies for the prevention, treatment or containment of COVID-19. These include, but are not limited to, diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture.

On 5 May 2021, [the US announced](#) its support to the waiver but only mentioned vaccines for COVID-19 and did not mention other technologies for treatment, prevention and containment.

With a frightening increase in infections and deaths in developing countries, and with potentially promising treatments in the pipeline, it is crucial that all member states support the proposal to cover not just vaccines, but also therapeutics, diagnostics and other health technologies.

### Types of IP

The waiver proposal, both the version from October 2020 and the version from May 2021, covers four types of IP under the TRIPS Agreement: patents, undisclosed information, industrial design and copyrights.

The [statement made by the US](#) on 5 May 2021 expresses its support for the waiving “intellectual property protections,” not only patents, corresponding to the scope of the proposal which covers four types of IP relevant to production and supply of diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture.

### Duration

The October 2020 proposal did not specify a specific time duration and recommended in the introduction that the waiver should continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity.

The revised proposal specifies *a minimum* duration of three years during which the waiver shall be applicable, beginning from the date of decision of the General Council. The new proposed text requires the General Council to review the exceptional circumstances justifying the waiver and determine the date of termination of waiver *only if* such circumstances cease to exist. The

introduction to the May 2021 draft proposal clarifies that the complexities involved with the novel pathogen suggests the need for a practical and flexible duration.

**Table 1: Comparison of the October 2020 and May 2021 versions of the TRIPS waiver proposal decision text**

October 2020 proposal decision text	May 2021 revised proposal decision text
<p>1. The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to prevention, containment or treatment of COVID-19, for [X] years from the decision of the General Council.</p>	<p>1. The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to <b>health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.</b></p> <p><b>2. This waiver shall be in force for at least 3 years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver.</b></p>
<p>2. The waiver in paragraph 1 shall not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement.</p>	<p>3. The waiver in paragraph 1 shall not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement.</p>
<p>3. This decision is without prejudice to the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.</p>	<p>4. This decision is without prejudice to the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.</p>
<p>4. This waiver shall be reviewed by the General Council not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement.</p>	<p>5. This waiver shall be reviewed by the General Council not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement.</p>
<p>5. Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism</p>	<p>6. Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism.</p>

## 2. Is it legal to request a waiver from obligations under the TRIPS Agreement?

Yes. Paragraphs 3 and 4 of Article IX of the Marrakesh Agreement Establishing the WTO ([WTO Agreement](#)), affirm that in exceptional circumstances, a waiver from certain obligations under WTO treaties, such as the TRIPS Agreement is possible. Waivers can be adopted by following Article IX of the Marrakesh Agreement.

### **3. Is the waiver permanent?**

The revised text submitted by the co-sponsors on 21 May suggests that the waiver should remain valid for *at least* three years from the date of the decision. After that, the WTO General Council will be reviewing the exceptional circumstances justifying the waiver, and whether such circumstances cease to exist.

### **4. Does the waiver proposed apply only to developing countries? Will every country have to implement the waiver if adopted?**

No. The proposal calls for a waiver to be applicable for all WTO members. The waiver is an option for countries to implement at their discretion.

### **5. How will the decision to adopt a waiver be made?**

According to the decision-making rules of WTO (Article IX of WTO Agreement), the application for a waiver must be submitted to the TRIPS Council first and then decided at the Ministerial Conference or the General Council of WTO that functions on behalf of the Ministerial Conference (Article IV.2 of the WTO Agreement).

To reach a decision, proposals for such waivers are negotiated by WTO members at informal and formal meetings of the TRIPS Council. Once consensus is reached, a formal decision can be made at the WTO General Council during the interval of the Ministerial Conferences.

The decision to grant the waiver will be reached based on consensus of all WTO members. According to WTO rules, if consensus cannot be reached, a decision on a waiver can be made by voting. A three-fourths majority is needed for a decision to be made through voting.

### **6. What would it mean if the waiver was adopted?**

If the waiver was adopted, it would allow WTO member states the legal rights under international trade rules to not grant and/or enforce patents and other IP related to health products and technologies, including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19. This would provide countries with the policy space to address IP barriers to increase collaboration in research and development (R&D), manufacturing, scaling up, and supplying COVID-19 vaccines, medicines and other health technologies.

The waiver, once adopted, could immediately exempt WTO members from the risk of being sued by others before the WTO dispute settlement body for not fully implementing the TRIPS Agreement for choosing to waive certain obligations of IP during the pandemic. When countries implement the waiver, it could also offer guidance to national IP offices, policy makers and courts to de-prioritize IP protection and enforcement, reduce litigation risks for alternative producers and suppliers, so that they gain greater certainty and freedom to operate. The waiver could also mitigate some of the critical limitations of the existing rules regarding overcoming IP barriers product-by-product in a pandemic.<sup>1</sup>

### **7. Has a consensus been reached by WTO members to grant waivers in the past?**

Yes, many waivers have been adopted by WTO members. See Table 2 for examples of Article IX waivers under TRIPS Agreement.

---

<sup>1</sup> For a more detailed discussion of the challenges of using existing TRIPS rules to address IP barriers in a pandemic, see MSF's technical brief: "[Compulsory licenses, the TRIPS Waiver, and access to COVID-19 medical technologies.](#)"

For example, in 2003, WTO members reached a consensus for a [waiver related to Paragraph 6 of the Doha Declaration](#) on the TRIPS Agreement and Public Health. The waiver established a mechanism to allow countries producing generic medicines under a compulsory license to supply the medicines to other countries that lacked the manufacturing capacity required to produce the medicines themselves.

#### **Transition periods and waivers granted to least-developed countries (LDCs)**

LDCs enjoy special exemptions from implementation of the TRIPS Agreement under Article 66.1 of the Agreement. LDC members do not have to implement any aspect of the TRIPS Agreement until July 2021.<sup>2</sup> As this transition period is coming to an end, the LDC Group in WTO has submitted a request to extend the period for as long as a country remains an LDC, plus an additional period of 12 years once they graduate from the LDC status. This request (IP/C/W/668) was discussed at the 15-16 October 2020 TRIPS Council meeting and will be discussed at subsequent sessions. The request [should be supported](#) by all members.

In addition, more specifically with respect to pharmaceutical products, LDCs do not have to implement, apply or enforce Section 5 (on patents) and Section 7 (on protection of undisclosed information) of TRIPS until 1 January 2033. Linked to this decision, LDCs have been granted waivers under Article IX of the WTO Agreement from obligations pertaining to [exclusive marketing rights and mailbox obligations](#) (Articles 70.8 and 70.9 of the TRIPS Agreement).

### **8. What developments have happened since the proposal was introduced at the WTO?**

The waiver proposed by India and South Africa has been presented and discussed at the WTO TRIPS Council meeting multiple times since October 2020.<sup>3</sup> In the last [meeting of the TRIPS Council](#) on 30 April 2021, WTO members agreed to continue consideration of the proposal.

On 5 May 2021, Ambassador Katherine Tai, the United States Trade Representative (USTR), made [a public announcement](#) supporting the proposal and expressing willingness to engage in text-based negotiation.

On 5-6 May 2021, the Chair of the TRIPS Council reported to the WTO General Council that members shall continue the discussion on the proposal.

On 17 May 2021, the co-sponsors of the proposal issued [a joint statement](#) welcoming the US support and change of position and expressed the urgency for text-based negotiation to start, calling for all WTO members to work in solidarity to conclude the process. In the statement, the co-sponsors suggested that a revised proposal will be put forward to initiate text-based negotiation.

As of 18 May 2021, the proposal has been co-sponsored by Kenya, Eswatini, Mozambique, Pakistan, Bolivia, Venezuela, Mongolia, Zimbabwe, Egypt, Maldives, Fiji, Namibia, the [African Group](#), the [Least Developed Countries \(LDC\) Group](#), and most recently Vanuatu, Indonesia and Jordan. In total, 63 countries are co-sponsoring the waiver and more than 100 countries, mostly developing countries, showed support overall for the waiver.

There is a small group of countries that continues, along with Big Pharma, to oppose or stall the TRIPS waiver. This group includes European Union countries, Japan, Switzerland and the United Kingdom.

---

<sup>2</sup> Under [Article 66](#) of the TRIPS Agreement, LDC members still need to follow Articles 3 and 4 concerning the obligations of providing national treatment and most-favoured nation treatment to all WTO members, and Article 5 on retaining obligations under other international treaties on IP.

<sup>3</sup> South Africa's opening and closing statements can be found [here](#); India's opening statement can be found [here](#).

On 21 May 2021, the co-sponsors submitted [revised proposal](#) text elaborating on the scope and duration of the waiver proposal with the objective of progressing to text-based negotiations.

## **9. Besides WTO members, who else supports the TRIPS waiver?**

Notably, the Director-General of WHO, Dr Tedros Adhanom Ghebreyesus, has repeatedly called on countries to support the waiver and make a bold move to end the pandemic. The new [Director-General of the WTO](#) at the General Council meeting on 5 May 2021 expressed the urgency of the issue of responding to COVID-19 and appealed to move towards the conclusion of the proposal.

Since October 2020, supporting the TRIPS waiver has been central to a global movement asking to remove monopolies in a pandemic. Across the globe, hundreds of organizations and individuals have voiced their support and urged governments to stop stonewalling the proposal and to work in solidarity for its adoption. Supporters of the waiver include but not limited to: the [African Commission of Human and Peoples' Rights](#); [Amnesty International](#); [Drugs for Neglected Diseases initiative \(DNDi\)](#); [frontline health workers](#); [Health Action International](#); [Human Rights Watch](#); [MSF](#); [Nobel Prize laureates and former heads of states](#); [Oxfam](#); [parliamentarians](#); [People's Health Movement](#); [Public Citizen](#); [public health associations](#); [religious leaders](#); [Section 27](#); [South Centre](#); [Third World Network](#); [trade unions](#); the [Joint United Nations Programme on HIV/AIDS \(UNAIDS\)](#); [Unitaid](#); [experts of the UN Office of the High Commissioner for Human Rights](#); the [United National Conference on Trade and Development \(UNCTAD\)](#); the [World Health Organization \(WHO\)](#); and [more than 400 civil society organisations](#).

## **10. What does it mean for the process since the US changed its position in May 2021?**

The United States on 5 May 2021 [expressed willingness](#) to participate in text-based negotiations at the WTO and expressed support to waive IP protections on COVID-19 vaccines. Ambassador Tai's [statement](#) at a WTO meeting on TRIPS and COVID-19 expressing support for the waiver also recognizes that WTO rules may need to be adapted in order to meet the demands during this time of unprecedented global need. This comes after [more than 400 US organisations](#) and [170 former heads of state and Nobel laureates](#) called on President Biden to support the WTO IP waiver.

The US's change of position is a significant step towards breaking the seven-month stalemate over the proposal thanks to a handful of countries holding up the text-based negotiation and will accelerate the process towards the adoption of the waiver.

Since the US expressed support for the waiver, New Zealand and Ireland have also expressed their willingness to support the waiver, and [Canada will actively participate in the negotiations](#). Australia, Japan, Switzerland and the United Kingdom, who have stonewalled the discussions, now must take action too. They must decide to put people's health before pharmaceutical profits and agree to text based negotiations on the proposal.

## **11. What are the next steps in the process?**

The next informal session of the TRIPS Council takes place on 31 May 2021 when WTO members will meet for the first time after the monumental step taken by the US to support the waiver and after the revised proposal has been submitted by the co-sponsoring countries. The next formal session of TRIPS Council shall take place on 8-9 June 2021, where members will continue to discuss the proposal. After that, informal and formal sessions of TRIPS Council meetings may continue to be scheduled.

The outcome of these TRIPS Council meetings will be reported to the WTO General Council on 21-22 July 2021. The [WTO Director-General estimates](#) that the negotiation could be concluded before the WTO Ministerial Conference in November 2021. However, several months have passed, and WTO members should reach a decision to adopt the waiver rapidly to facilitate better access to COVID-19 medical tools.

## **12. What is a text-based negotiation? Why is it important?**

Since a waiver is a legal instrument allowed by the WTO framework, countries need to engage in text-based negotiation, a formal negotiation with the focus on the waiver itself, in order to conclude the process. The text-based negotiation means that countries will concretely negotiate and work on the text of the proposal to reach an agreement on its scope, duration and other language as necessary to implement the waiver.

In the past seven months, countries who continue to oppose the waiver have mostly stalled the process by engaging in [delay tactics](#) and preventing the TRIPS Council members from performing the concrete task of working on the text of the proposal itself.

On 6 May 2021, the Director General of WTO also [urged countries to start text-based negotiation](#) of the TRIPS waiver proposal. The Director General estimates that the negotiation process may conclude before the WTO Ministerial Conference in November 2021. However, if members reached consensus earlier, the waiver can also be adopted by an earlier event of the WTO General Council.

The revised proposal aims to ensure that the TRIPS waiver is tailored to meet the needs of this pandemic. With the TRIPS waiver proposal having first been put forward nearly eight months ago, we cannot afford to lose any more precious time: the virus continues to claim millions of lives around the world.

## Examples of Article IX waivers

Many waivers adopted according to [Article IX of the WTO Agreement](#) on various trade issues have been granted at the WTO benefiting different members including developed and developing countries and LDCs (see, for example, the list of waivers granted [1995-2015](#) and [2019](#)). Table 2 below presents a non-exhaustive list of Article IX waivers granted with respect to provisions under the TRIPS Agreement.

**Table 2. Examples of Article IX waivers granted with respect to provisions under the TRIPS Agreement**

Table developed with the support of [Third World Network \(TWN\)](#)

Decision number	Provisions waived	Beneficiaries	Grounds of the waiver	Duration
<a href="#">WT/L/478</a>	TRIPS Agreement Article 70.9 with respect to pharmaceutical products	LDC members	In accordance with <a href="#">Paragraph 7</a> of the Doha Declaration on the TRIPS Agreement and Public Health, LDC members do not have to implement, apply or enforce Section 5 (on patents) and Section 7 (on protection of undisclosed information) of the TRIPS Agreement.	Until 1 January 2016 (about 13 years)
<a href="#">WT/L/540</a>	TRIPS Agreement Paragraph 6 decision waiving Paragraphs (f) and (h) of Article 31	All WTO members except those who opted out	The need to implement <a href="#">Paragraph 6</a> of the Doha Declaration on the TRIPS Agreement and Public Health to find a rapid solution to help countries with insufficient or no manufacturing capacities in the pharmaceutical sector make effective use of compulsory licenses.	Until the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that member
<a href="#">WT/L/971</a>	TRIPS Agreement Article 70.8 and 70.9 with respect to pharmaceutical products	LDC members	In line with the waiver decision WT/L/478, reaffirm that LDC members do not have to implement, apply or enforce obligations under Article 70.8 and 70.9 of the TRIPS Agreement with respect to <a href="#">exclusive market rights and mailbox obligations</a> .	Until 1 January 2033, or until a country graduates from LDC status (about 17 years)