



# India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies

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## INTRODUCTION

In a landmark move, India and South Africa on 2 October [asked](#) the World Trade Organization (WTO) to allow all countries to choose to neither grant nor enforce patents and other intellectual property (IP) related to COVID-19 drugs, vaccines, diagnostics and other technologies for the duration of the pandemic, until global herd immunity is achieved.

This briefing document aims to provide further details related to this important development, including a Q&A; an overview of the impact of IP barriers on access to therapeutics, vaccines and diagnostics; three case studies examining IP barriers in the context of COVID-19; and examples of Article IX waivers that have been granted with respect to provisions under the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) Agreement in the past.

## Q&A

### **What has been proposed?**

On 2 October 2020, South Africa and India 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 Council, which includes all WTO members, will meet 15-16 October 2020 at WTO headquarters in Geneva.

The proposal requests 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 Section 1 (copyrights and related rights), 4 (industrial design), 5 (patents) and 7 (protection of undisclosed information) of [Part II of the TRIPS Agreement](#).

The proposed waiver would be applicable only to COVID-19. It does not suggest a waiver from all TRIPS obligations, nor does it suggest a waiver beyond what is needed for COVID-19 prevention, containment and treatment.

### **What would it mean if the waiver was granted?**

If the waiver was granted, it would allow countries who are WTO members to choose to neither grant nor enforce patents and other IP related to all COVID-19 drugs, vaccines, diagnostics, and other technologies, including masks and ventilators. This would provide countries with the policy space needed to collaborate in research and development and manufacturing, scaling up and supplying COVID-19 tools.

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

Yes. Article IX 3 and 4 of the Marrakesh Agreement Establishing the WTO ([WTO Agreement](#)), affirm that in exceptional circumstances, a waiver from certain obligations under WTO treaties, such as TRIPS, can be decided at the WTO Ministerial Conference (during the interval of the Conferences, the WTO General Council would perform this function). The waiver needs to contain a justification based on the exceptional circumstances, the conditions and the time when the waiver terminates. Waivers longer than one year will be reviewed by the Ministerial Conference annually until its termination.

### **Does the waiver proposed apply only to developing countries?**

No. The proposal calls for a waiver to be applicable for all WTO members – including developing, developed, and least-developed countries (LDCs).

### **How is a final decision reached at WTO on a waiver?**

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.

After receiving the application for a waiver, the TRIPS Council must consider it within 90 days, and then submit a report to the Ministerial Conference – the highest decision-making body that consists of all WTO members – for a decision. The Ministerial Conference is held every two years, with [the next one planned for June 2021](#). In the interim, the General Council of WTO functions on behalf of the Ministerial Conference (Article IV.2 of the WTO Agreement).

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

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

Yes, many waivers have been adopted by WTO members.

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 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 (other than Articles 3, 4 and 5) until July 2021. 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) will be discussed at the upcoming TRIPS Council meeting on 15-16 October and 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](#) (Article 70.8 and 70.9 of TRIPS Agreement).

**Is the waiver permanent?**

The proposal submitted by South Africa and India suggests that the waiver should remain valid until the majority of the world's population has access to effective vaccines and has developed immunity to COVID-19. The actual duration of the waiver is unknown, but it will depend on negotiations by members and is time-limited based on WTO rules.

**Why is the waiver important at this moment in the pandemic?**

All governments are facing challenges ensuring timely, sufficient and affordable access to effective medicines, vaccines, diagnostics and other essential medical tools. This is especially challenging, however, for many developing countries that face limitations developing and scaling up manufacturing capacity due to IP barriers. The unprecedented situation today requires that all IP, knowledge, technology and data related to COVID-19 health technologies can be utilised by everyone to ensure uninterrupted production and supply by any competent country or manufacturer worldwide. To achieve this, governments have a collective responsibility to address IP and technology barriers.

Since the start of this pandemic, pharmaceutical corporations have continued with their 'business-as-usual' approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries heavily affected by COVID-19. The pharmaceutical industry as a whole has also chosen not to engage the World Health Organization (WHO) COVID-19 Technology Access Pool (C-TAP) initiative that aims to encourage the voluntary contribution of IP, technologies and data to support global sharing and scale up of manufacturing and supply of COVID-19 health technologies.

Despite having received [at least US\\$70.5 million of public funding](#) to develop remdesivir, one of the candidate drugs for COVID-19 treatment, pharmaceutical corporation Gilead has signed secretive bilateral deals with a few generic companies of its choosing that exclude nearly half of the world's population from its licensed territories.

These recent actions by pharmaceutical corporations show that relying on their exclusive rights and limited voluntary actions is not the solution in a global pandemic. Governments need to take back the driver's seat and fulfil their core obligations of protecting public health and ensuring access to medicines for all. The waiver proposal by India and South Africa presents an important opportunity for all governments to unite and stand up for public health, global solidarity, and equitable access through a concrete step at the international level that can provide an automatic and expedited solution to address IP and technology challenges collectively.

## **Some people say IP is not an issue for COVID-19 tools. If that is true, why is a waiver needed?**

We disagree with this claim. Both past experiences and current actions have shown concretely that IP does pose a challenge in ensuring global equitable access to the effective tools needed in response to COVID-19, including vaccines.

In the last few months, treatment providers and governments have faced IP barriers over drugs, masks, ventilator valves and reagents for testing kits. Countries are facing shortages of remdesivir, which is widely patented but licensed in a manner that allows generic supply only in a limited number of countries. In addition, multiple patents have been filed for COVID-19 vaccines in development, for example, [more than 100 patents have been filed for the mRNA technology](#) that Moderna is using to develop a vaccine. A report by MSF found that [patents pose a serious threat](#) to access to affordable versions of newer vaccines like pneumococcal conjugate vaccines (PCV) and human papillomavirus (HPV) vaccines.

## **Why do countries need a waiver when they can already use TRIPS flexibilities for public health?**

The waiver and existing TRIPS flexibilities are not mutually exclusive.

The proposal for a waiver on certain IP provisions offers an expedited, open and automatic global solution that allows for uninterrupted collaboration in development and scale up of production and supply and that collectively addresses the global challenge facing all countries.

Countries should continue to use TRIPS flexibilities to safeguard public health, including issuing compulsory licenses and placing limitations on or making exceptions to exclusive rights. However, the “case by case” or “product by product” approach required when using flexibilities to address IP barriers at the national level could be limiting during the pandemic. Some countries also face limitations with respect to their national laws, face pressures from their trading partners, or lack the practical and institutional capacity required to exercise TRIPS flexibilities during the pandemic quickly and effectively.

Given these common challenges, and the pharmaceutical industry’s refusal to routinely offer non-exclusive licenses with worldwide coverage to facilitate global access, it is critical for governments to address this global crisis as they did nearly 20 years ago under the Doha Declaration on the TRIPS Agreement and Public Health amidst the HIV/AIDS epidemic and support this landmark move by India and South Africa.

### **Limitations of relying on a “case by case” and “product by product” approach to address IP barriers:**

1. The development of COVID-19 medicines, vaccines and diagnostics is evolving rapidly, and it is challenging for countries to select one or two specific products to target.
2. There is a practical need for countries to collaborate and share manufacturing and supply capacities to achieve a truly global response. When countries lack immediate manufacturing capacity for any of the essential parts for a product, including raw materials, components or packaging materials, removing IP barriers on one product in one country alone will not be sufficient. Other countries who can produce the required materials and parts need to ensure that they are monopoly free so that they can support other countries by freely exporting the materials based on need. Likewise, countries who have the capacity to produce a finished product would need to ensure that there are no restrictions for them to export the product to any other countries in need. Responding to COVID-19 effectively requires a collective and global solution that overcomes the restrictions of addressing IP barriers on a national level so that countries can collaborate and freely share manufacturing and supply capacities.

3. The existing mechanisms for compulsory licenses under Article 31 and Article 31*bis* of the TRIPS Agreement contain territorial and procedural restrictions that make the practice of issuing product-by-product compulsory licenses a complex process, making it difficult for countries to collaborate.
  - a. Article 31 requires that compulsory licenses are issued on a case-by-case basis and used predominantly to supply domestic markets, thereby limiting the ability of manufacturing countries to export to countries in need.
  - b. [Article 31\*bis\*](#) requires that any product produced and exported under a compulsory license be identified with specific packaging and quantities, which can lead to unnecessary delays in the context of COVID-19 where countries need urgent access to medical tools.

[MSF's experience](#) trying to buy drugs under this mechanism showed that the rules are prohibitively complex and offer neither an expedited nor global solution.

## **IMPACT OF IP BARRIERS ON ACCESS TO THERAPEUTICS, VACCINES AND DIAGNOSTICS**

### Therapeutics

The example of remdesivir reveals a typical example of how IP barriers affect global access to COVID-19 therapeutics. The primary patent on the base compound of remdesivir has been granted to Gilead in more than 70 countries, which means that when countries are not covered by a voluntary license or do not use other measures to overcome the patents, they may be blocked from getting access to generic alternatives until [2031](#). After ignoring [demands](#) calling for non-enforcement of its patents on remdesivir, Gilead proceeded to secretly sign voluntary licensing agreements with only a few manufacturers of its choosing. The [voluntary licensing agreements](#) excluded nearly half of the world's population from accessing more affordable generics, including most South American countries and many countries with manufacturing capacity, some of which have supported COVID-19 related clinical trials. Today many countries are facing shortages of remdesivir in their health systems. This dangerous precedent set by Gilead must alert governments that voluntary actions of companies are not reliable.

In addition, there is an emerging cluster of biologic medicine candidates, including a group of repurposed monoclonal antibodies, such as sarilumab and tocilizumab, and a group of specific new antiviral monoclonal antibodies that are currently being investigated as potential COVID-19 treatments in clinical trials. Many of these monoclonal antibody candidate therapeutics are still [under patent protection](#) in many developing countries such as Brazil, South Africa, India, Indonesia, China and Malaysia. This means that if some of these therapeutics show clear efficacy, production and supply by diverse manufacturers in different countries would be challenging unless governments take early actions to address these barriers.

### Vaccines

Since the start of the pandemic, there has been a constant denial or avoidance by some institutions and lobby groups of the pharmaceutical industry stating that IP is not an issue in the context of addressing the possible scarcity of vaccine supplies. Such a statement is at odds with what MSF has documented with other essential vaccines prior to COVID-19.

In 2017, MSF published a [report](#) documenting the effects of patents in hindering the introduction of affordable vaccines in developing countries, with a focus on pneumococcal conjugate vaccines (PCV) and the human papillomavirus (HPV) vaccine. The report summarises that patents have been applied for or granted across the entire process of vaccine development, production and use. Patents were identified on vaccine-production materials such as chemical reagents, host cells, vectors, and DNA/RNA sequences; vaccine compositions; process technologies; vaccination age groups; methods of using vaccines; and vaccine schedules and presentations. These patents increase uncertainty and costs,

delay competition and keep prices high for low- and middle-income countries, hindering people's access to important vaccines.

In 2016-2017, MSF filed a patent opposition and later a writ petition to [challenge Pfizer's vaccine composition patent](#) that has blocked India from developing alternative versions of Pfizer's PCV13 vaccine. The equivalent patent has been granted in South Korea, which compelled a Korean vaccine developer to close their production of PCV13.

In the context of COVID-19, IP barriers have been [reported](#) in vaccine patent disputes and can hinder vaccine development. Research has [revealed](#) that a large portfolio of background IP, such as more than 100 patents on mRNA platform technologies that are used for COVID-19 vaccines, has already been granted on key technology platforms used for COVID-19 vaccine development. Several bilateral voluntary agreements have been signed between vaccine developers and producers since the start of the pandemic on possible vaccine candidates, but none of the agreements have been made publicly available to allow for an assessment of the scope and conditions. Restrictive license terms can have a [detrimental impact on access](#).

Governments must learn from these past experiences and take the appropriate steps to ensure that access to new vaccines in developing countries is not compromised or blocked due to IP and monopolies.

### Diagnostics

The lack of access to affordable, adapted and simplified diagnostic tests for infectious diseases such as tuberculosis (TB), HIV and hepatitis C (HCV) in resource-limited settings has been an ongoing struggle. Starting in 2017, MSF conducted a series of analyses on the [causes of market monopolies](#) in the field of diagnostics for infectious diseases, especially concerning TB, HIV and HCV, and examined the [patent landscape](#) of three point-of-care diagnostics that are important in MSF's medical programmes: Xpert MTB/RIF (produced by Cepheid), AlereQ HIV-1/2 Detect (produced by Abbott) and OraQuick HCV Rapid Antibody Test (produced by OraSure).

MSF's [analysis](#) shows that the overall business model for diagnostics results in multiple dominant closed diagnostics systems (since each major diagnostics company develops both the device and the consumable parts – for example the reagent kits or reagent-loaded integrated cartridges – specifically tailored to that device), making competition extremely difficult. The high cost and burden of switching between systems results in a “locked-in” effect for end users since they have no choice but to buy both the device and the assays from the same company. Although it's not possible to say that one or two access-blocking patents are the key barrier, the analysis shows that major diagnostics companies hold a considerable number of patents, often bundled into thickets for various instrumentation, assays, methods and software, related to different aspects of the technologies, methodologies and devices. This proliferation of patents may contribute to discouraging the development of open platforms for interoperable diagnostics.

## **CASE STUDIES EXAMINING IP BARRIERS IN THE CONTEXT OF COVID-19**

*The following three case studies are based on published news reports and were developed with the support of [Third World Network \(TWN\)](#).*

### Testing kit reagents

The majority of COVID-19 laboratories in the Netherlands work with equipment made by pharmaceutical corporation Roche and depend on the company for supplies of the testing reagents, the liquid buffer needed to run the tests. A shortage of this buffer is one of the reasons why the Netherlands was not able to carry out mass testing for COVID-19 during the early stages of the pandemic in late March.

Despite the shortage, Roche initially [refused](#) to provide the recipe for the buffer, blocking labs from quickly making their own solution and ramping up their testing capability. Following public pressure, and after the Dutch Health Minister suggested issuing a compulsory license on the buffer formula and the European Commission started to investigate Roche for possible abuse of its market position, Roche [agreed](#) to release the buffer recipe for others to make.

IP can pose a barrier to produce testing kit reagents, including tests for COVID-19, which can negatively impact a lab or country's ability to screen samples for COVID-19 – an essential part of controlling the pandemic. Companies must share the recipes for critical medical products, like test reagents, to ensure the scale-up of supply worldwide.

### Ventilator valves

As reported in March 2020, a northern Italian hospital started to run out of ventilator valves and their regular supplier was not able to produce more in the short term. Two engineers from a nearby start-up with a 3D printer offered to help manufacture more valves. After the manufacturer [denied access to the valve's blueprint](#) and threatened to [sue for patent infringement](#), the engineers proceeded to reverse engineer a 3D-printed version themselves. The 3D-printed replacement valves, which saved many lives, cost about [\\$2-3 each](#) to produce, compared to [\\$11,000 per valve](#) from the manufacturer, and can be manufactured in a fraction of the time. The engineers received hundreds of requests for their 3D-printed valves, but did not share their digital print file more widely due to [possible legal and medical issues](#).

Following the story, a law firm [warned that](#) “[m]anufacturers should be aware of the complex intellectual property issues concerned with this 3D printing technology. In scanning a component such as a valve, and manufacturing a part using 3D printing equipment, there is a risk that this action will infringe an existing patent, design or copyright which protects the component, leading to an injunction or claim from the rights holder for damages or other remedies (such as delivery up of infringing parts).”

There are complex legal implications when producing copies of lifesaving medical tools. Any person or company intending to manufacture parts using 3D printing would have to identify: the extent of IP protection (including patents or registered design); who are the IP holders; and whether the IP holders are willing to permit the parts to be manufactured (including the terms and conditions that the right holder will impose). This is a costly, time consuming, and complex process as there could be multiple IP holders and an IP holder may refuse to license its IP.

In March 2020, WHO noted a [shortage of ventilators around the world](#). Removing IP barriers, including those around 3D printing, can be critical to address life threatening shortages during this pandemic.

### N95 respirators

N95 respirators, a critical type of protective mask for healthcare workers, has been in short supply throughout the COVID-19 pandemic. The respirator is protected by [hundreds of patents](#) owned by the US government, the multinational company 3M, paper and healthcare companies, individuals and universities. In March 2020, the Governor of Kentucky in the United States [called on 3M to release its patent](#) for the N95 respirator so that more manufacturers could start producing it. The company has not released its patent to date.

IP barriers, including patents, have exacerbated the shortages of N95 respirators faced by hospitals around the world. Companies and others holding patents on important tools, including masks, should announce now that they will not enforce their patents so that healthcare workers on the front line of this pandemic can be protected.

## **ARTICLE IX WAIVERS**

Many Article IX waivers on various trade issues have been granted at the WTO benefiting different members including developed, developing and least-developed countries (see, for example, the list of waivers granted [1995-2015](#) and [2019](#)). Table 1 below presents a non-exhaustive list of Article IX waivers granted with respect to provisions under the TRIPS Agreement.

**Table 1. Examples of Article IX waivers granted with respect to provisions under the TRIPS Agreement**

*Table 1 was developed with the support of [Third World Network \(TWN\)](#).*

<b>Decision number</b>	<b>Provisions waived</b>	<b>Beneficiaries</b>	<b>Grounds of the waiver</b>	<b>Duration</b>
<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 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 the LDC status (about 17 years)