

In landmark move, India and South Africa propose no patents on COVID-19 medicines, tools during pandemic

Questions & Answers

What has been proposed?

On October 2, 2020, South Africa and India submitted a [joint communication](#) to the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) Council at the World Trade Organization (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 intellectual property (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.

Will WTO members make a final decision on this proposal at the TRIPS Council meeting in October? And how is a final decision reached?

No. 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 made 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.

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 a 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 to allow uninterrupted collaboration in development, scale up of production and supply, and to collectively address the global challenge facing all countries.

Countries should continue to use TRIPS flexibilities to safeguard public health, including issuing compulsory licenses and making limitations or 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.