FREQUENTLY ASKED QUESTIONS

THE TRIPS WAIVER –TRIPS AND THE WTO

As at
3 June 2021

1: WHAT IS THE WTO

The World Trade Organisation (WTO) is a body that was set up on 1 January 1995 to replace the General Agreement on Tariffs and Trade (GATT) which was established to govern the international trade in goods from 1 January 1948. South Africa has been a member state of GATT since 3 June 1948 and a member of WTO since 1 January 1995.

The WTO is a worldwide trade body and institution (164 countries belong to it out of 195 countries). The WTO is a multilateral forum that lays down trade rules, consisting of an agreement establishing the WTO.

WORLD TRADE ORGANIZATION

WTO AGREEMENTS

- Trade in Goods
- Trade in Services
- Intellectual Property
- Plurilateral Agreements
- Dispute Settlement

This FAQ deals with TRIPS - the agreement on Trade Related Aspects of Intellectual Property Rights.

As at 3 June 2021

2: WHAT IS THE TRIPS AGREEMENT

The Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement came into force in 1995. TRIPS prescribes the minimum standard of protection and enforcement of Intellectual Property Rights (IPR), including:

* Integrated Circuits

- Patents
- Protection of the Topography of IC*
- Trademarks
- Plant variety
- Copyrights
- Geographical indicators
- Trade secrets

The full TRIPS agreement is available here

TRIPS places an obligation on eligible member states to protect Intellectual Property (IP) in their own domestic legal system for all goods including medicines and medical products requiring member states to provide IP protection, which includes the grant of patent monopolies that block competitors.

Middle income countries (MICs), including South Africa, were required to incorporate TRIPS obligations into their domestic laws by 1 January 2000 (for 'pharmaceutical patents' the transitional period was until 2005).

Examples of Various Types of Intellectual Property Protected Medical Products in the context of COVID-19.

Medical products needed to deal with COVID-19	Type of IP protecting this technology
Test kits	Trade secrets or patents – e.g., on the chemicals and buffer used [1]
Masks	Patents [2]
Therapeutics to treat COVID-19 (e.g. remdesivir) [3]	Patents and regulatory data protection
Vaccines	Patent, trade secrets, regulatory data protection
Ventilators	Control mechanisms – patents [4]
	(replacement) valves – patents, industrial designs, copyright
	Software – copyright [5] [6]
	Machining templates and quality assurance protocols etc – trade secrets [7]
Artificial intelligence	Algorithms – copyright and trade secrets
	Patents
	Dataset and training process – copyright, database rights and trade secrets

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3: WHAT IS A WAIVER

A waiver is the suspension of the obligation that allows the implementation of certain or all provisions of any of the WTO agreement to be deferred, temporarily. This means that a patent holder will not be able to legally seek or legally enforce a patent or other IP rights during this time.

Example

Blood diamonds and the Kimberley Waiver

The waiver was used to resolve the conflict between provisions in GATT Article I(1) and GATT XI(1) - XIII(1), which paved the way for the adoption and implementation of the 'Kimberley Process Certification Scheme'. This related to curbing the trade in conflict diamonds while supporting legitimate diamond trade certification. This has been in place since 2003.

HOW WAIVERS HAVE BEEN USED BEFORE AT THE WTO

A waiver can only be issued under specific circumstances, and for a specific period of time.

Article IX (3) of the WTO provides for the temporary waiver of any provision contained in any applicable WTO agreement and this includes TRIPS.

A waiver requires adoption by three quarters of countries present at a relevant WTO meeting.

Under the GATT, waiver decisions were routinely taken by a vote, but this practice was abandoned with the establishment of the WTO in 1995.

Historically, the WTO has made waiver decisions by consensus, as a practice. This is not required by its governing framework, as a vote is the actual requirement for passing a waiver resolution.

Waivers have been sought and granted many times, in some cases even for periods of more than 10 years. In 2019, the WTO agreed to 6 new waivers and extended 18 previous waivers.

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4: HAVE WAIVERS BEEN USED FOR TRIPS OBLIGATIONS BEFORE

Yes.

Examples

A transition period to allow for waiver from all TRIPS provisions was first approved in 1995 for drug (medicine) patents for least developed countries (LDCs). The transitional arrangement has been extended to 2033.

The text of the transition arrangement can be accessed here

Since 2003, a waiver has been in place in respect of Section 31 of TRIPS (now called 31 bis) as part of an amendment referred to as the 'Doha Declaration'. This permitted developing countries to waive section 31(f) of TRIPS which had required developing countries to grant compulsory licences only for their domestic market. This is now no longer a requirement.

For more information see here

WTO member states agreed on 6 December 2005 to permanently incorporate the 2003 waiver (Doha Declaration) into the TRIPS Agreement. This amendment came into effect on 23 January 2017.

For more information see here

'DOHA DECLARATION' – Section 31bis of TRIPS (the TRIPS FLEXIBILITIES)

The flexibilities under the TRIPS agreement were agreed to at the Doha Ministerial Conference in 2001 to allow developing countries to interpret certain provisions in the TRIPS agreement to prevent frivolous patents and allow for easier access to medicines in a public health emergency.

Section 31bis has only been used once - initiated by Canada and Rwanda for the HIV-drug TriAvir in July 2007 - and the time it took to finalise it was so long that it has been heavily critiqued.

Compulsory licensing *is when a government allows someone else to produce a generic or biological version of a patented product (a drug, vaccine, for example) or process without the consent of the patent holder or plans to use the patent-protected invention itself. It is one of the flexibilities in the field of patent protection included in TRIPS. The patent holder still has rights over the patent, including a right to be paid compensation.*

The Doha Declaration confirms that countries are free to determine the grounds for granting compulsory licences, and to determine what constitutes a national emergency. Licenses must then limit the scope and duration of the licence to the purpose for which it was granted, it cannot be given exclusively to licensees and it must be subject to legal review.

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5: WHAT IS COVERED BY THE TRIPS WAIVER

The waiver proposal was submitted by South Africa and India on 20 October 2020. For many months it was blocked by a handful of wealthier countries, such as the US, UK, EU (especially Germany, Norway and France) and Switzerland, Australia, Canada, Brazil and Japan).

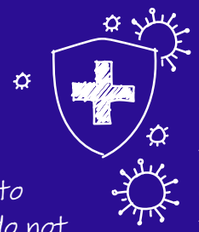
- On 5 May 2021, the United States Government (USG) announced partial support for the waiver proposal, and agreed to participate in negotiations. Since then, New Zealand, China and Ukraine have indicated support for the waiver proposal.
- A draft text was in turn submitted by 63 member states (co-sponsors) on 21 May 2021.

The proposal is for the waiver

1 To apply 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.

2 To be in force for at least 3 years from adoption. The WTO General Council must thereafter review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council must then determine the date of termination of the waiver.

The proposal is also drafted to ensure that member states do not challenge any measures taken by countries who use the waiver to expand access. This includes not taking member states through to a WTO dispute resolution mechanism.



The waiver proposal and text apply to patents, trade secret, copyrights and industrial design covering the technology and know-how on COVID19 medical products such as therapeutics, equipment as well as vaccines, all of which are essential to overcoming the COVID-19 pandemic.

HEALTH JUSTICE INITIATIVE

Médecins Sans Frontières (MSF) has set out 5 reasons why governments around the world should support the waiver and has explained the myths and realities behind the TRIPS Waiver proposal:

For more information see here

IT GOES WAY BEYOND PATENTS ON DRUGS/MEDICINES

IP also includes trade secrets, industrial designs and copyright protections. During the COVID-19 pandemic, treatment providers and governments have had to grapple with IP barriers to essential equipment such as masks, ventilator valves, crucial components of testing kits and other vital equipment that we have seen huge shortages of during peaks of the pandemic.

IT INCLUDES EVERYONE

The waiver stands until most of the world has reached immunity, and it includes developing and developed countries.

IT WILL SPEED UP THE COVID-19 RESPONSE

Overriding monopolies on COVID-19 drugs, vaccines, tools, and equipment will allow uninterrupted global collaboration to scale-up manufacturing and supply. Current IP barriers limit where these lifesaving medical tools can be sold and who can manufacture them, and most often keep prices sky high. The greater the diversity of manufacturers and suppliers, the sooner governments and treatment providers around the world will be able to access and utilise COVID-19 medicines and medical tools to save more lives.

IT WILL MAKE COVID-19 MEDICINES, VACCINES AND MEDICAL TOOLS MORE AFFORDABLE

Suspending monopolies on COVID-19 medicines, vaccines and medical tools in a pandemic will allow more affordable versions to come onto the market sooner through the diversification of production. Monopolies allow corporations to keep prices artificially high, to the exclusion of much of the world's population. Any medicine, vaccine or medical tools for COVID-19 should be affordable and available for anyone who needs it.

IT PUTS GOVERNMENTS BACK IN THE DRIVING SEAT

Relying on the voluntary actions of pharmaceutical corporations who hold exclusive rights is not an ideal solution in a global pandemic. Governments have a chance to back this proposal and put public health and people's lives over the business interests of pharmaceutical corporations.

healthjusticeinitiative.org.za

HEALTH JUSTICE INITIATIVE