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TRADE POLICY BRIEF

COVID-19 and Intellectual Property Rights: Battle Over the TRIPS Waiver at the WTO¹



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This Trade Policy Brief was prepared by Yusuf Daya (Director AU/AfCFTA Relations and Trade Policy) with support from Chidozie Ezeani (Associate AU/AFCFTA Relations and Trade Policy), Lillian Chakwe and Ayodeji Adimula (AfCFTA/AU Relations and Trade Policy Interns). For more information contact ARTP@afreximbank.com

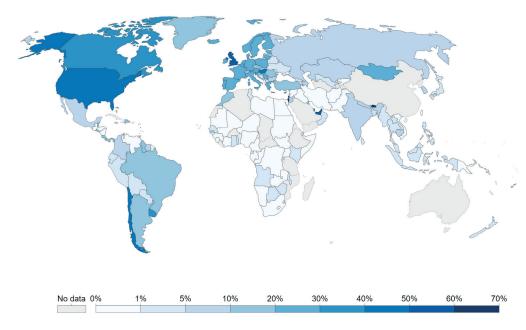


Introduction

With over 4.5 million infections and 121,000 deaths as at 29 April 2021, the fallout from the COVID-19 pandemic has been significant for African countries. The dual public health and economic shock threatens to slow Africa's growth prospects for years to come. Already, GDP in Africa contracted by 2.1 percent in 2020 – the continent's first recession in 25 years – and Africa's trade contracted by 12 percent, reversing the strong growth the continent achieved over the past two decades. The socio-economic impacts of the pandemic are also likely to be extremely severe and protracted for African economies unless the spread of the virus is contained. The best approach to effectively overcome the challenges created by the pandemic lies in the wide-spread production, distribution, and administration of affordable vaccines.

Share of people who received at least one dose of COVID-19 vaccine, Apr 29, 2021
Share of the total population that received at least one vaccine dose. This may not equal the share that are fully vaccinated if the vaccine requires two doses.





Source: Official data collated by Our World in Data

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However, in the global race to vaccinate against COVID-19, developing countries, most notably in Africa, are running dangerously behind. North America has now administered vaccine doses to about 30 percent of its population while Europe has reached about 20 percent. But in Africa less than 1 percent of the population have received a vaccine (Ritchie et al., 2021). The fallout from the COVID-19 pandemic and the race to ensure fair and equitable access to useful technologies and vaccines to protect people and save lives, has once again brought to the fore the tension between intellectual property rights (IPRs), global trade and the promotion of public health.

The TRIPS agreement and its importance in the context of COVID-19

In an effort to protect their firms and facilitate foreign direct investment in an era of expanding global trade and globalization, developed economies in the 1980's actively sought to ensure minimum levels of global IPRs protection to capture the rents generated by the intangible components of traded products and services. Efforts to conclude a global treaty on IPRs culminated in 1994, when the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was adopted as an outcome of the Uruguay Round of Trade Negotiations which established the World Trade Organization (WTO) framework. The TRIPS Agreement consequently established a common set of standards for all WTO members – for patents, trademarks, copyrights, trade secrets and other IPRs – which was enforceable through the WTO dispute settlement procedures and without differentiating on the basis of socio-economic and technological development.²

A recurring concern from developing countries since the conclusion of the TRIPS Agreement is that by establishing a common set of standards – which to a great extent mirrored the standards in force in industrialized countries at the time of negotiating the agreement – the TRIPS Agreement substantially limited the freedom and policy space available to countries to design and implement their own intellectual property systems in line with their development needs and ambitions. From a public health perspective, the TRIPS Agreement meant that developing countries had to adopt an IPR system, including a patent system, with minimum standards that would allow product and process patents for pharmaceuticals and vaccines with implications for widespread and affordable access to medicines. While the TRIPS Agreement provided for flexibilities, which developed nations argued were sufficient to address the concerns of developing countries, the veracity of these concerns manifested in the challenges some developing countries faced in securing affordable access to HIV/AIDS antiretroviral medication. This prompted developing countries to push for additional flexibilities to be incorporated into the TRIPS Agreement that would allow WTO members to address public health concerns.

These efforts ultimately resulted in the adoption of the Doha Declaration on TRIPS and Public Health at the 4th WTO Ministerial conference that held in 2001, which made it clear that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all" (WTO, 2001). The TRIPS Agreement was subsequently amended to provide the legal basis for WTO members to grant special compulsory licenses exclusively for the production and export of affordable generic medicines to other members that do not have domestic production capacity and need medicines in sufficient quantities to treat patients.

The COVID-19 pandemic has once again brought to the fore the public health implications of IPR protection and its potential to hinder the timely supply of affordable medical products. The scale and devastating impact of the COVID-19 pandemic has disrupted global supply chains, given rise to vaccine nationalism and vaccine hoarding, and witnessed the concentration of technological know-how and manufacturing capacity for COVID-19 vaccines, diagnostics and therapeutics in the hands of a few key firms. It has also seen the introduction of export bans and raised concerns that COVID-19 technologies are not being made available promptly, in sufficient quantities and at affordable prices necessary to meet global demand and stem the tide against the pandemic.

Citing the "exceptional circumstances" created by the pandemic and suggesting that current IPR protections are "hindering or potentially hindering timely provisioning of affordable medical products", South Africa and India tabled a joint proposal to WTO members in October 2020 that seeks to temporarily waive certain obligations under the TRIPS Agreement. The waiver looks to ensure that COVID-19 technologies, including vaccines, medical devices and protective and diagnostics kits, are more readily and easily accessible globally.

² The obligations that the agreement sets forth to protect inventions include: recognizing patents for pharmaceuticals without distinction between imported and locally produced products; granting patent protection for at least 20 years from the date of application; limiting the scope of exemptions from patent rights; and effectively enforcing patent rights through administrative and judicial mechanisms. In the area of copyright, the protection of computer programs became mandatory. The agreement also makes it mandatory to protect secret know-how, trademarks, geographical indications, industrial designs and integrated circuits (UNCTAD, 2010).

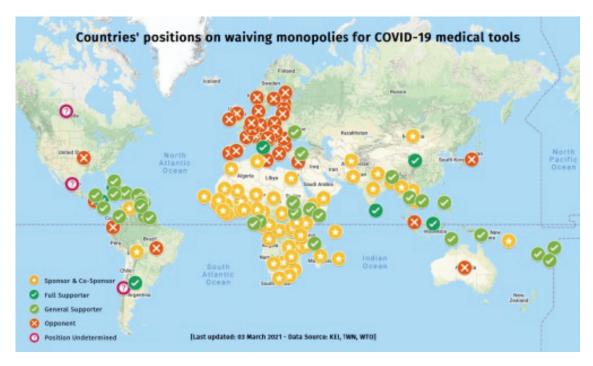
How the waiver can support COVID-19 response efforts

To effectively respond to the COVID-19 pandemic, a wide range of medical products and technologies have become critical, many of which are proprietary items protected through various types of IPRs. These IPRs potentially limit access to essential products, technology transfer, and opportunities to collaborate to scale up the production and supply of COVID-19 products (WTO, 2021). Under a TRIPS-compliant regime, WTO member states are required to guarantee product patents and processes and grant exclusive marketing rights to innovators. Similarly, protection of undisclosed information and trade secret laws would prevent utilization of clinical trial data for approving generic versions of medicines. IPR protection related to manufacturing, techniques, methods, compilations, processes etc. can therefore limit the widespread availability of COVID-19 technologies and restrict the sharing of vital research and information that could be utilized to develop new treatments and technologies (Tellez, 2020).

The proposal tabled by South Africa and India would allow WTO members to temporarily waive the implementation, application, and enforcement of four forms of IPRs (copyright and related rights, industrial design, patents, and protection of undisclosed information) on all medical products required for preventing the spread of COVID-19 – including vaccines, diagnostics, therapeutics, and medical equipment. Proponents of the waiver argue that the proposal 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" (WTO, 2021). If approved, the waiver would last for a specific number of years to be agreed by the WTO General Council, and at least until widespread vaccination is in place globally and most of the world's population is immune.

Status of discussions on the proposed waiver

Despite strong and growing support, the proposal is facing stiff opposition – especially from developed countries such as the United States, the European Union, Japan, Canada and the United Kingdom – that want to protect their pharmaceutical industries but who are also among the countries that have secured the largest number of vaccines and commenced large scale vaccination rollouts.



Source: Medecins Sans Frontieres (2021)

Countries opposing the proposal posit several arguments to suggest that the waiver is unnecessary. First, they argue that it is strong IPR protection that creates the environment and incentives for the private sector to invest in the type of research and development that led to the innovation and development of COVID-19 technologies, including vaccines. A waiver of IPRs would therefore undermine innovation as companies would not be able to recoup their research and development costs. However, advocates point out that proposed waiver does not intend to dismantle the innovation incentives created by IPRs but is rather a time bound waiver specifically restricted to COVID-19 related products and technologies given the exceptional circumstances occasioned by the COVID-19 pandemic. They also cite the significant public funding that has supported the research and development of available COVID-19 vaccines as a factor that mitigates the need for patent protection as a means for manufacturers to recoup investment costs in this particular instance.

A second objection put forward against the waiver is that the TRIPS agreement already provides sufficient flexibilities, particularly by making provision for compulsory licensing. Compulsory licensing allows the use of a patent without authorization from the patent holder in cases of emergency and for public non-commercial use. Those opposing the waiver argue that this flexibility is sufficient to allow governments to manufacture generic versions of medications and vaccines without the patent holder's consent. However, sponsors of the proposal highlight that whilst this flexibility is important, the territorial and procedural restrictions associated with compulsory licensing are complex and will need to be issued on a "case by case" or "product by product" basis, which is onerous and time consuming and could lead to unnecessary delays in a context where urgent access to COVID-19 technologies and vaccines is required. In addition, sponsors note that pressure from trading partners and fears over trade retaliation also limits the potential for utilizing compulsory licensing flexibilities (WTO, 2021).

The third reason advanced for not supporting the waiver relates to manufacturing capacity. Some opposing the waiver argue that, rather than intellectual property rights, it is the lack of advanced manufacturing capacity that is a major obstacle to the rapid scale-up of production of COVID-19 vaccines (Thrasher, 2021). However, advocates of the waiver point out this is not the case and suggest that potential production capacity in both developed and developing countries is being overlooked. For instance, Oxfam suggests that for the approved COVID-19 vaccines, only 43 percent of reported COVID-19 vaccine production capacity is currently being used globally (OXFAM, 2021).

Despite growing support for the proposal, with 58 WTO members joining the proposal as cosponsors and 100 members expressing their support for it, no consensus has been reached on the proposal which remains under discussion at the WTO. At the 34th Ordinary Assembly of the African Union held in February 2021, African leaders threw their weight behind the proposal and expressed their support for the waiver. More recently, 30 members of the U.S. Congress signed a letter calling on the Biden administration to support the waiver (Green, 2021). Two-hundred members of the European Parliament and of European National Parliaments also issued a joint appeal urging the EU and its Member States to support the TRIPS waiver noting that "it is in everyone's interest to work collaboratively to ensure that widespread vaccination is in place globally as quickly as possible and remove all obstacles" (European Parliament, 2021).

Conclusion

Given the unpreceded global fallout arising from the COVID-19 pandemic and the massive demand for COVID-19 technologies and vaccines, an equally massive global response is required. At a time when the global trading system faces immense challenges and calls for reform, the proposed TRIPS waiver – which will provide the space for an automatic, quick and open global mechanism that can facilitate collaboration and help scale up production and supply capacity – provides an opportunity for the multilateral trade system to show its relevance by contributing to saving lives and livelihoods and practically demonstrate its commitment to equitable development.

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Headquarters

72B El-Maahad El-Eshteraky Street, Roxy, Heliopolis, Cairo 11341, Egypt info@afreximbank.com T +(202) 2456 4100/1/2/3/4

Abuja Branch

No. 2 Gnassingbe
Eyadema Street
Off Yakubu Gowon Crescent
Asokoro, Abuja, Nigeria
PMB 601 Garki, Abuja, Nigeria
abuja@afreximbank.com
T +(234) 9 460 3160

Harare Branch

Eastgate Building, 3rd Floor (North Wing), Sam Nujoma Street Harare, Zimbabwe P.O. Box CY 1600 Causeway, Harare, Zimbabwe harare@afreximbank.com T +(263) 24 2 700 904/941

Abidjan Branch

3ème Etage, Immeuble CRRAE-UMOA, Angle Boulevard Botreau Roussel – Rue Privée CRRAE-UMOA Abidjan, Côte d'Ivoire abidjan@afreximbank.com T +(225) 2030 7300

Kampala Branch

Rwenzori Towers,
3rd Floor Wing A
Plot 6 Nakasero
P.O. Box 28412
Kampala, Uganda
kampala@afreximbank.com
T +(256) 417 892 700
+(256) 312 423 700

afreximbank.com