

## The WTO TRIPS Waiver Should Help Build Vaccine Manufacturing Capacity in Africa

By Faizel Ismail\*

### Introduction

An invisible object—COVID-19—has exposed the underlying weaknesses, asymmetries and contradictions in our world, our economies and our societies. Africa has been particularly impacted by the virus that has created a triple crisis in its healthcare system, economy and environment. The virus has also led to a contestation of the analyses, narratives and policy options to national and global challenges. The COVID-19 pandemic is regarded by scientists as the most devastating health pandemic since the Spanish flu in 1918–19, and by economists as the worst economic crisis

since the Great Depression in the 1930s. The pandemic has also exacerbated a deepening climate change crisis observed in the floods, prolonged droughts and locusts outbreaks in several parts of the African continent (Lopes, 2021).

While most high-income countries such as Canada, the United Kingdom, Australia, New Zealand, the European Union and the United States have secured more than necessary vaccine doses of over 200 per cent population coverage, only 27 per cent of the population of low-and middle-income countries would be covered by the end of 2021 (Independent Panel,

### Abstract

The current global health crisis created by the COVID-19 pandemic has re-focused our attention on the inadequacy of the TRIPS agreement and the patent system to address global public health crises. This time, developing countries must ensure that the TRIPS waiver succeeds in creating the impetus for the building of manufacturing capacity in the poorest countries, especially in Africa, for vaccines, pharmaceuticals and other health technologies. This is the only effective way in which African countries can reduce their dependence on imports of essential medicines and build their health security, contributing to the achievement of the sustainable development goals, for the poorest countries.

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*La actual crisis sanitaria mundial creada por la pandemia de COVID-19 ha vuelto a centrar nuestra atención en la insuficiencia del Acuerdo sobre los ADPIC y del sistema de patentes para hacer frente a las crisis sanitarias mundiales. Esta vez, los países en desarrollo deben asegurarse de que la exención de los ADPIC consiga crear el impulso necesario para la creación de capacidad de fabricación en los países más pobres, especialmente en África, de vacunas, productos farmacéuticos y otras tecnologías sanitarias. Este es el único modo eficaz en que los países africanos pueden reducir su dependencia de las importaciones de medicamentos esenciales y reforzar su seguridad sanitaria, contribuyendo a la consecución de los objetivos de desarrollo sostenible para los países más pobres.*

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*La crise sanitaire mondiale actuelle créée par la pandémie de COVID-19 a recentré notre attention sur les lacunes de l'accord sur les ADPIC et du système des brevets pour faire face aux crises sanitaires mondiales. Cette fois, les pays en développement doivent s'assurer que la dérogation à l'accord sur les ADPIC parvienne à créer l'élan nécessaire à la mise en place de capacités de fabrication dans les pays les plus démunis, notamment en Afrique, pour les vaccins, les produits pharmaceutiques et autres technologies de santé. C'est le seul moyen efficace pour les pays africains de réduire leur dépendance à l'égard des importations de médicaments essentiels et de renforcer leur sécurité sanitaire, contribuant ainsi à la réalisation des objectifs de développement durable pour les pays les plus démunis.*

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2021). While over 50 per cent of the populations of the major developed countries had received at least one vaccine dose, the whole of the African continent had only administered 36 million doses by 1 July 2021 (Our World in Data, 2021). These trends in access to vaccines reflect the deep global structural inequalities that are exacerbated by the patent system and the WTO trade related intellectual property rights agreement (TRIPS) that all developed countries were required to sign onto at the end of the Uruguay Round of trade negotiations in 1993. Public protests at the inequity of these GATT/WTO rules arose during the AIDS pandemic in the late 1990s and created sufficient pressure to ensure that the need to review the patent system for public health diseases was placed on the agenda of the WTO Ministerial Conference in Doha, Qatar in December 2001. The Doha Declaration on TRIPS and Public Health, adopted at this conference called for a major reflection of the relationship between TRIPS and public health.

Both the current COVID-19 pandemic and the AIDS pandemic that shook the world more than 20 years ago illustrate the inequity and inadequacy of the TRIPS Agreement to address global systemic health crises. While the TRIPS flexibilities agreed by the WTO was ineffective, the struggle for these flexibilities did succeed in reducing the high prices for life-saving AIDS drugs and focused the attention of the international community on the inequity of the patent system for public health diseases. The current global health crisis created by the COVID-19 pandemic has re-focused our attention on the inadequacy of the TRIPS agreement and the patent system to address global public health crises. This time, developing countries must ensure that the TRIPS waiver succeeds in creating the impetus for the building of manufacturing capacity in the poorest countries, especially in Africa, for vaccines, pharmaceuticals and other health technologies. This is the only effective way in which African countries can reduce their dependence on imports of, essential medicines and build their health security, contributing to the achievement of the sustainable development goals, for the poorest countries.

This Policy Brief advances the above argument in the following manner: First, a brief overview of the history of the Doha Declaration and TRIPS and Public Health and subsequent negotiations is provided in section two. Then, a summary of the recommendations of several global commissions on the relationship between patents, innovation, and public health is provided in section three. The WTO proposal by South Africa/India for a TRIPS waiver for vaccines, pharmaceuticals and health technologies for COVID-19 is discussed in this context, in section

four. It is argued, in section five, that the COVID-19 pandemic provides African countries with the opportunity to develop their health security by building their manufacturing capacity in vaccines, pharmaceuticals and health technologies. Finally, the Policy Brief concludes by calling on the developed countries to support the COVID-19 IP Waiver proposed by South Africa/India and over 100 countries in the WTO and help to build the manufacturing capacities of the poorest countries in Africa—thereby reducing the current inequity in vaccine access and contributing to global health security and the sustainable development goals.

### **The Doha Declaration on TRIPS and Public Health**

Almost 20 years ago, in Doha, Qatar, at the World Trade Organization (WTO) Ministerial Meeting in 2001, the world agreed to provide flexibilities from the strict requirements of the Trade Related Intellectual Property Rights (TRIPS) agreement to poor countries that had insufficient or no manufacturing capacity to access affordable medicines to save lives from the HIV/AIDS pandemic and other public health diseases, such as TB and Malaria. It took another two years before the WTO members could agree on the implementation of this agreement on 30 August 2003 when a waiver from the TRIPS agreement (article 31bis) was supported by consensus at the WTO General Council. A subsequent amendment to the TRIPS Agreement was agreed by WTO members in December 2005 and finally ratified in 2017 (Abbot and Reichman, 2020).

In 1998, 39 big pharmaceutical companies took Nelson Mandela's Government to court because South Africa's Health Minister decided to import AIDS drugs at the cheapest price using parallel imports under the TRIPS agreement to address the AIDS pandemic (Deere, 2008). The TRIPS Agreement came into existence at the end of the Uruguay Round due to the insistence of the United States (US) and other developed countries although most developing countries, led by India and Brazil were opposed to the intellectual property rights (IPRs) being brought into the World Trade Organization. Patents were regarded with suspicion by developing countries during the Uruguay Round as most Pharma patents were owned by developed country MNCs (Ismail, 2008). These Big Pharma were being challenged by generic companies and pensioners and NGOs in the developed countries due to their exorbitant pricing that was challenged on competition grounds. This inequity within the developed countries was to become globalized after the Uruguay Round (1986 to 1993). A famous trade economist, Jagdish Bhagwati, referred to this process as "the legitimization of the GATT to extract royalty payments for MNCs - of about 40 billion dollars a year" (Deere, 2008).

COVID-19 brings back the issues that made the world call for the review of the TRIPS agreement in 2001 and the WTO Doha Ministerial Conference. The Doha Declaration on TRIPS and Public Health affirmed 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, 2017). However, when the delegations returned to Geneva the real challenge of translating this mandate in the text-based negotiations into a workable and effective flexibility that could be utilized by developing countries to obtain accessible and affordable AIDS drugs began. There was a debate about the TRIPS provisions, Art 30 or 31f and the best way to create flexibility. The developed countries demanded that the flexibility provided by compulsory licenses should include new and additional conditions and safeguards. The result was the annex to the TRIPS agreement in Art 31bis which in the view of many observers only succeeded in making the TRIPS flexibility more cumbersome, complex and unworkable. Most developing countries did not use this “flexibility” due to coercive power of the major economies and real possibility of being put on a watchlist by the US Section 301 or being withdrawn from the trade preferences that they enjoyed in the US market through the African Growth and Opportunity Act (AGOA) (Thambisetty et al, 2021; Nkomo, 2013). However, the protests by global NGOs and the negotiations that led to the TRIPS and Public Health Declaration did succeed in exposing the TRIPS agreement as being imbalanced in favor of big Pharma and an inadequate response to global public health. For example, Big Pharma companies such as Merck, Roche, Abbott Laboratories, and Gilead negotiated with the Brazilian government and reduced their prices for AIDS drugs significantly (Deere, 2008).

### **The global health pandemic is a global systemic challenge for all of humanity**

In the wake of this protest by Civil Society and Developing Countries – several global commissions were created (viz, Report of the Commission on Intellectual Property Rights, 2002; WHO-Commission on Intellectual Property Innovation and Public Health, 2006; UN Secretary General’s High-Level Panel on Access to Medicines, 2016). Each of these global commissions called for global health crises, such as pandemics, to be treated as systemic issues. They saw the linkages between public health, global economic growth and sustainable development and global security. Above all they argued for global health to be treated as a human right!

The commissions’ investigations revealed that investments by the major Pharma companies went

to profit making drugs and the diseases of rich countries, with little or no investment in the diseases of the poor - such as TB, malaria and AIDS. The commissioners argued that a major review of how governments fund R&D in public health diseases was called for. These commissions brought to the fore the inequity of the Patent System and the inadequacy of global funding for global public health. Reflecting on this system Siva Thambisetty argues that “the entire ecosystem of patents, manufacture, supply, restrictive technology transfer, and the difficulty of injury-specific solutions (like compulsory licenses) have all contributed to a techno-legal complex that is in itself both a source of wealth for some and deprivation for others” (Thambisetty, 2021).

During the text-based negotiations in Geneva in August 2003 the representative of the Vatican to the WTO stated that the patent system is a “social mortgage” which creates both rights and responsibilities. In other words, society confers certain privileges on patent holders (market exclusivity for a period of up to twenty years) and in return there are expectations that these “privileges” will not be abused and access to affordable drugs shall be provided (Ismail, 2003).

The history of patents in developed countries indicates that most countries have abolished patent rights for a period in order to develop their domestic industry while others deliberately weakened IP rights to enhance domestic technological capacities (Thambisetty et al, 2021). Thambisetty et al. remind us that pharmaceutical products became patentable in France only in 1960, in Ireland in 1964, in Germany in 1968, in Japan in 1976, in Switzerland in 1977, in Italy and Sweden in 1978 and Spain in 1992. Developing countries were opposed to the introduction of IPRs, especially patents on pharmaceuticals, in the GATT negotiations at the start of the Uruguay Round in 1986. However, the campaign by Big Pharma lobbies in the United States to introduce IPRs into the GATT Uruguay Round succeeded, with strong US negotiating pressure, thus globalizing an inequitable patent system that created global monopolies and high prices for drugs for public health diseases. This inequitable patent system and the WTO TRIPS Agreement came into sharp focus during both the AIDS pandemic in the late 1990s and again 20 years later during the current COVID-19 pandemic.

### **South Africa and India lead the fight for a TRIPS waiver in WTO**

The COVID-19 pandemic is the biggest and most devastating pandemic to spread across the entire world since the Spanish flu in 1918, causing both a public health and economic crisis globally – with its social and economic impact on poorer African countries being more devastating. The developed countries’ reflex response to the COVID-19 pandemic has been to restrict

the exports of pharmaceutical products and personal protective equipment (PPEs) such as face-masks and sanitizers thus depriving many developing countries of these essential drugs and medical equipment. Africa is reliant on its external trading partners for more than 94 percent of its pharmaceutical products and medical equipment. In addition, several developed countries, in a spirit of “vaccine nationalism” (my country comes first), called for the shortening of global supply chains reducing Africa’s access to these vital products even further. African countries and their continental institutions, such as the African Union and the African Centre for Disease Control moved with speed and were able to train thousands of healthcare workers in the techniques of testing for COVID-19 and to create an African Procurement Portal to facilitate access to vaccines and PPEs for the smaller African countries (African Union, 2021b).

Since the devastating spread of the COVID-19 pandemic across the world in 2020/21 a similar debate to the WTO TRIPS and public health debate of 1998/2001 is taking place at the WTO in Geneva and in many capitals of the world. The WTO representatives of South Africa and India submitted a joint-proposal for a waiver to be granted by the General Council of the WTO “from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19” on 2 October 2021. Subsequently, India and South Africa submitted a revised proposal together with a large number of other developing countries, including, the African Group and the LDC Group in Geneva (WTO 2021a and 2021b). This revised proposal extended the demand for the waiver from the TRIPS Agreement for all “health products and technologies” for the “prevention, treatment or containment of COVID-19” and was supported by over 60 WTO delegations in June 2021. In October 2020 over 370 academic institutions and NGOs, such as OXFAM and Médecins San Frontières (MSF), have supported the proposal for a waiver from the strictures of the WTO TRIPS agreement (MSF, 2020; Carvalho, et al, 2021). While over 100 WTO Members in the WTO, including the United States, have supported the need for a TRIPS Waiver to make Vaccines and other health products and technologies more accessible and affordable, there are a few major countries that are still opposed. These countries include the United Kingdom, Canada, Australia, Japan and the European Union (Erfani et al, 2021).

While the US supports the waiver in principle it has called for text based negotiations on a narrow scope. Ambassador Katherine Tai, the Biden Administration USTR, stated that “the Administration believes strongly in intellectual property protections,

but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines” (USTR, 2021). Thus, the willingness of the USTR to negotiate a text-based agreement on “vaccines only” will limit the scope and will unduly delay the process of achieving the waiver until the 12th WTO ministerial conference that starts on 30 November 2021, at the earliest (Hannah et al., 2021). The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) said “waiving patents of COVID-19 vaccines will not increase production nor provide practical solutions needed to battle this global health crisis” (Furlong, 2021).

The French President Macron and the EU Parliament have taken a stance in support of the waiver ahead of the G7 Summit while the EU Commission and Germany have opposed the waiver (Phillips, 2021; Green, 2021; Leicht, 2021). The EU Commission has instead proposed an alternative proposal based on compulsory licensing and promises to provide “donations” to developing countries via the WHO COVAX facility. The EU also promises to provide technology transfer for manufacturing of pharmaceuticals through voluntary arrangements between EU developers and manufacturers to “scale up vaccine manufacturing in Africa” and “stresses that patent protection is a key incentive for innovation and research across the globe” (EU Parliament, 2021; Knowledge Ecology International, 2021).

Several leading scholars on public health policy from Harvard and Georgetown universities in the US have argued in support of the waiver and have called on World Trade Organization members “to rapidly pass the IP waiver, implement technology transfers, repurpose global manufacturing capacity, and boost production of raw materials. All of these require considerable global collaboration, not to mention the financial and political commitment of high-income countries” (Erfani et al, May 2021).

There are number of reasons for the South Africa/India revised proposal on a TRIPS waiver to be supported by all WTO members. First, the waiver will allow companies to produce COVID-19 vaccines without fear of being sued by the entity that holds the IPR for the technology (Hannah et al., 2021). Second, the South Africa/India proposal goes beyond the issue of vaccines production and calls for “trade secrets” to be shared “by transferring technology and disclosing data” (Thambisetty et al., 2021). While many manufacturers in developing countries have the capacity to produce vaccines, they have not been able to do so as Big Pharma are not willing to share the recipes for them to manufacture the vaccines (Leicht, 2021). While WHO has created a COVID-19 Technology Access Pool (C-TAP) to facilitate technology transfers and data sharing, this pool has remained empty according to the Harvard and Georgetown university health scholars as

of May 2021 (Erfani et al., 2021). Erfani et al. also argue that whilst WHO has launched the mRNA technology transfer hub model in April 2021 “to provide manufacturers in low- and middle-income countries with the financial, training, and logistical support needed to scale up vaccine manufacturing capacity” this initiative requires the potential manufacturers to receive the IP necessary for mRNA technologies and this has not yet occurred.

Third, the potential use of the compulsory license flexibility provided for in Art 31 bis of the TRIPS Agreement is unlikely to be utilized by developing countries due to the onerous conditions it imposes as the only effective case when it was used was in Rwanda’s imports of generic HIV TriAvir medicines from the Canadian company Apotex (Nkomo, 2013; Thambisetty et al, 2021). Thus, the EU proposal to use the existing TRIPS flexibilities on compulsory licensing contained in Art 31 bis is not plausible as this mechanism has not been effective. Fourth, it has been argued that the contributions by EU countries to the COVAX facility is no substitute for supporting the waiver in the WTO (’t Hoen, 2021). Ellen ’t Hoen, an expert on global health argues that “the COVAX system continues to underdeliver vaccines, failing to meet stated targets, due both to vaccine nationalism in HICs and to the absolute lack of vaccines worldwide”. COVAX is a facility created by WHO, Gavi (the vaccines alliance) and UNICEF, comprising self-financing countries and 92 low income and middle-income countries with the aim of creating a global mechanism to purchase vaccines and create more equitable access to vaccines (WHO, 2021). Fifth, the South Africa/India waiver proposal that is supported by over 100 countries in WTO is a pragmatic solution that is directed at the COVID emergency and is time-bound for a 3-year period and can be reviewed (WTO, 2021b).

### **The AfCFTA can facilitate vaccine/ pharmaceuticals manufacturing and health security in Africa**

African countries are totally dependent on external suppliers for their essential health needs – with imports of 94 per cent of their pharmaceutical needs and about 99 per cent of vaccines. A recent study by *Nature* has found that only 10 countries in Africa have some manufacturing capacity – with most African countries engaged in “fill and finish” only, i.e., packaging and distributing for Big Pharma (Irwin, 2021; UK AID, 2021). Africa’s leaders pledged to move away from this dependence which they described as “colonial” and that undermines Africa’s health security. At a 2-day summit held on the 12–13 April 2021 hosted by the Africa CDC and the African Union that was attended by over 40 000 delegates

and several Heads of State, African countries stated that they need to build their own production capacity on pharmaceuticals and healthcare products and are working on this as a priority (African Union, 2021a).

By 1<sup>st</sup> July 2021 only 3.4 per cent of Africans were vaccinated and it was estimated that at this rate it will take up to 2023 for Africa to reach herd immunity, by which time there may be new variants. African leaders argued that the current scarcity of vaccines and unequal and uncertain supply lines require each country and region to take responsibility to build their own manufacturing capacity and not to rely on handouts and charity from the developed countries. The only sustainable solution for African countries is to build their own vaccine manufacturing capacity against COVID-19 and future pandemics (Independent Panel, 2021). Even where vaccines are becoming available the inequity of the pricing policies of Pharma persists. For example, it was reported that AstraZeneca (AZ) charged South Africa more than double (\$5.25USD) the price per dose that it charged EU countries (\$2.16USD) (Thambisetty, et al., 2021). African countries thus launched the Partnerships for African Vaccine Manufacturing (PAVM), “which aims to leverage pan-African and global partnerships to scale-up vaccine manufacturing in Africa”. At the AU and Africa CDC summit, African leaders pledged to work with the newly created African Continental Free Trade Area (AfCFTA) to facilitate the building of regulatory harmonization and facilitation of vaccine production in Africa (African Union, 2021a).

### **Conclusion**

COVID-19 has exposed the inequities and imbalances of the global system of Health. The TRIPS waiver proposed by South Africa/India and over 100 countries in the WTO is not a panacea but a vital ingredient for the scaling up of manufacturing and provision of basic health technologies to address the pandemic and global health emergency. Moreover, the waiver can catalyze a structural re-balancing of monopoly power by Big Pharma making vital essential health medicines and vaccines both affordable and accessible to millions of people in the poorest countries (Thambisetty et al., 2021). Developed countries should thus support the expeditious conclusion of the waiver negotiations and support the transfer of technology to developing countries across the world, especially in Africa to build their manufacturing capacity and health resilience and security. This process will also contribute to economy recovery in Africa and put African countries back on track to achieve their Sustainable Development Goals targets by 2030. While the US Biden Administration has moved away from the confrontational approach of the previous Trump Administration, the narrow scope and move to “text based” negotiations is likely to draw the US pharmaceutical industry into the negotiations

making the waiver mechanism cumbersome and unworkable just as the Doha Declaration on Public Health led to the unworkable TRIPS Amendment in art 31bis. The EU position on the waiver it is argued, is also not helpful.

COVID-19 has called for bold new approaches to global crises –based on the values of solidarity and cooperation. The pandemic has made clear and the WHO reminds us every day of the systemic nature of global health crisis, that “no one is safe unless everyone is safe”. Several global Commissions on patents, trade, innovation and public health have long pointed out that the current global system of governance of health, trade and patents is not fit for purpose. They have called for governments to regain responsibility and leadership for investment in R&D and innovation for public health diseases and not contract this responsibility out to the private sector. Global rules on trade and patent law must reflect this new insight that COVID-19 has brought to the fore. As President Ramaphosa stated, IPRs and TRIPS must be at the service of humanity and human rights first before the interests of vested interests.

The lesson that Africa learnt from this experience was the need for African countries to build their own capacity to produce essential drugs for public health diseases and reduce their dependence on their external trading partners. Thus, the building both healthcare resilience and healthcare security has become a growing strategic need and priority for Africa’s institutions. The President of South Africa, Cyril Ramaphosa, clearly expressed the sentiments of African leaders on the continent when he stated: “We want to manufacture vaccines locally against the pandemic. It is for this reason that South Africa and India proposed the TRIPS waiver at the World Trade Organization to enable the manufacturing of COVID-19 vaccines in developing countries” (SA Gov News, 6 May 2021).

Those who support the WTO COVID-19 waiver know it will not expand production overnight. However, they understand that it will ease complex rules, eliminate the risk of trade-based retaliation and litigation and pave the way for better collaboration to transfer technologies and scale up manufacturing of life-saving vaccines, pharmaceuticals and healthcare products, especially in the poorest countries in Africa. AfCFTA is an exciting process that is building regional integration and cooperation in Africa. It will also facilitate and stimulate manufacturing capabilities in Africa – and regional value chains – especially in pharmaceuticals, vaccines and healthcare products. Building manufacturing capabilities in vaccines, pharmaceuticals and healthcare, especially in Africa, is essential for Africa’s health

resilience and health security, saving millions of lives and contributing to meeting Africa’s sustainable development goals.

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