Compulsory Licensing: The Key to Accessing the Future COVID-19 Vaccine?

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Following the outbreak of the novel coronavirus pandemic, the surge in global demand for essential COVID-19 products has resulted in a boom in trade in medical goods. With over 14 million infections and over 600,000 fatalities and counting across the globe, many governments have introduced restrictions and bans on the export of medical products. These measures have affected the supply chains of medical goods across the globe. This pandemic has been a vivid reminder of how intricately linked all our destinies are. There must be a coordinated global response – no one country can afford to adopt beggar-thy-neighbour policies. Thus, to contain this virus, every global citizen must be able to access relevant treatment and preventative medication.

United Nations Economic Commission for Africa (UNECA) estimates that around 300 000 people in Africa, out of a population of 1.3 billion, could die from this

respiratory disease. Thus far, African states' response to COVID-19 has been quick and strong, with comparatively low recorded numbers of infections in most countries. However, there are fears that if not contained, this virus could have a devastating impact on African countries. These deleterious consequences include debilitating Africa's public health systems, plunging its vulnerable citizens into further poverty, and slowing down the region's growth prospects for years to come.

An analysis of the recent studies by the WTO and the ITC indicates that the main providers of medical products and equipment to Africa have imposed restrictive measures on essential COVID-19 products. These restrictive measures disproportionately impact African states, which are net importers of medical products and equipment. According to UNECA, Africa imports around 94% of its pharmaceuticals from sources outside the continent. As a result, a global shortage of testing kits has left many African states struggling to increase their testing capacity,despite many of them having adopted trade-facilitating measures, such as suspending import tariffs on essential COVID-19 products.

Beyond trade restrictions on medical products, African states face other domestic challenges through medical staff shortages; limited or absence of ventilators; ill-equipped public health systems; and a high prevalence of HIV/AIDS, chronic respiratory, tuberculosis, malnutrition, and kidney diseases in certain countries that could compromise the populations' ability to cope with COVID-19 symptoms. These factors indicate that Africa may be particularly more vulnerable than other regions, although it is in the advantageous position of having 70% of its population below 30. To address domestic shortages, a few African states have developed cost-effective COVID-19 testing kits. Thus far, they have only catered to domestic needs and have not produced the quantities required to potentially meet the current continental demand. Consequently, Africa's ability to manage and contain COVID-19 depends heavily on the goodwill of its external trading partners. African governments must do all they can to ensure that the region is not left behind in accessing essential COVID-19 medical products.

Currently, one of the most important items on the global agenda is the successful, safe, yet quick development of a COVID-19 vaccine. On 21 July

2020, there were 24 vaccines at various stages of the clinical phase – thus far, no African institution or pharmaceutical company is leading the development of these vaccines. Due to the already identified lack of domestic pharmaceutical research and development (R&D) and manufacturing capacity in Africa, its access to the vaccine could be threatened by trade-restrictions.

The stark reality is that once the vaccine is developed, it will be subject to a patent for at least 20 years. This patented vaccine may not be easily affordable to everyone. At the same time, no country can afford to wait until a generic vaccine becomes available. Notwithstanding the looming threats posed by the prevailing protectionist trade measures, the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) might offer vulnerable countries a means of accessing the much-needed COVID-19 vaccine through the compulsory licensing mechanism in Article 31, as modified by Article 31*bis* and the TRIPS Annex.

Article 31 of the TRIPS Agreement contemplates the use of the subject matter of a patent by a WTO Member (Member) or a third party authorised by that Member through the use of a voluntary or compulsory licence. Article 31(b) stipulates that, as a first step under normal circumstances, a Member must try to obtain a voluntary licence from the patent holder to produce the patented product on reasonable commercial terms. However, this first step may be waived in situations of "national emergency" or "other circumstances of extreme urgency", such as, ostensibly, the COVID-19 pandemic. In these circumstances, a Member may authorise the use of a compulsory licence to enable a generic pharmaceutical producer to manufacture the necessary medical products, subject to certain conditions. The restrictions on the use of a compulsory licence include limits on the scope and duration of the use and the purpose of the authorization. Moreover, the use must be non-exclusive, non-assignable, and must cease as soon as the emergency ends and when it is unlikely to reoccur. There are two additional requirements that merit special mention: first, Article 31(f) requires that the use of a compulsory licence must be authorised predominantly for the supply of the domestic market and, second, Article 31(h) requires that the right holder must be paid "adequate remuneration".

Addressing the latter requirement first, the TRIPS Agreement does not define "adequate remuneration". The Member authorising the compulsory licence may decide on an amount, but the right holder has the right to review this decision. The former requirement under Article 31(f) does not enable countries that have little or no domestic production of the pharmaceutical products to issue compulsory licences.

This dilemma was highlighted by the African Group at the TRIPS Council's first session on TRIPS and Access to Medicines in June 2001. The African Members of the WTO and 16 other developing countries submitted a papersetting out the constraints that the TRIPS Agreement imposed on their countries' ability to address grave public health challenges. These countries sought to confirm that nothing in Article 31(f) of the TRIPS Agreement prevented Members that produce essential medicines from granting compulsory licences to supply offshore markets in need.

These interventions led to the 2001 Doha Declaration on the TRIPS Agreement and Public Health. Pursuant to paragraph 6, WTO Members recognised the difficulties that Members with insufficient pharmaceutical manufacturing capabilities faced in using the compulsory licensing mechanism under Article 31 of the TRIPS Agreement. The TRIPS Council was instructed to find an expeditious solution before the end of 2002. In August 2003, the General Council adopted the Decision on the Implementation of Paragraph 6 (Decision on Paragraph 6), which temporarily waived the obligations under Articles 31(f) and 31(h) and established procedures to facilitate the export of pharmaceutical products that are subject to a compulsory licence. In December 2005, the General Council agreed to amend the TRIPS Agreement to reflect the compulsory licencing provisions and modalities agreed upon in the Decision on Paragraph 6. This resulted in the Decision on Paragraph 6 being incorporated into what is now Article 31*bis* and the Annex to the TRIPS Agreement. These provisions were adopted through an amendment to the TRIPS Agreement that entered into force on 23 January 2017, after it was ratified by two-thirds of the WTO membership. It is the first amendment of a WTO agreement since the establishment of the WTO. Thus far, 28 of the 43 African WTO Members have ratified the TRIPS Amendment. However, the Decision on Paragraph 6 waiver remains in force for those Members that have not completed the ratification process – they have until 31 December 2021 to do so.

Compulsory licensing for export purposes has always been a sticking point at the WTO. Members with R&D capacities (mostly developed countries) have pushed for strong protection of intellectual property rights and those with little or no research or manufacturing capabilities (mostly developing countries) have argued for their right to protect public health through affordable access to essential medicines. Moreover, the pharmaceutical industry in the US has lobbied its government to renegotiate the terms of Paragraph 6. The International Federation of Pharmaceutical Manufacturers has warned against the dangers of compulsory licensing as a threat to good public health by denying global patients the benefits of R&D from which new therapies come. But, without compulsory licences, most developing countries simply cannot afford these vital medicines. For example, in 2015, the price for Hepatitis C drug Sofosbuvir was US$64,690 per treatment in the US. In contrast, the generic version of this drug in India cost just US$539. Thus, the mere threat of a compulsory licence can provide developing countries considerable negotiating leverage, which they can use to their advantage to access a future COVID-19 vaccine. In fact, many pharmaceutical companies opt to agree to a voluntary licence, donate the drugs, or even unilaterally provide deep discounts instead of just standing by while their patented products are subject to a compulsory licence.

While compulsory licences are often used, the WTO's Paragraph 6 solution has thus far, only been used once by a Canadian firm, Apotex, to export an anti-retroviral (Apo-TriAvir) to Rwanda. This case was initiated by Doctors Without Borders to test the Paragraph 6 mechanism and the suitability of the Canadian legislation, the Canadian Access to Medicines Regime, which was adopted in 2004. As the active ingredients of Apo-TriAvir were protected under a patent held by Canadian companies Boehringer Ingelheim (Canada) Ltd and GlaxoSmithKline Inc., Canada, Apotex had to first request a voluntary licence from these companies. Apotex initiated the process in December 2005 and the first batch of Apo-TriAvir was shipped to Rwanda in September 2008, almost three years after the process began. This experience left a bitter taste in Apotex's mouth. It is reported that the company lost USD$3-4 million by offering a lower price to win Rwanda's tender to compete with lower-cost products. The delay in the process was compounded by the cumbersome and rigid Paragraph 6 procedures.

Thus far, no importing WTO Member has made a notification under paragraph 1(b) of the amended TRIPS Annex to issue a compulsory licence for public health purposes. Another challenge the WTO's system poses is that few countries have amended their legislation to allow for compulsory licensing in this manner. Moreover, only China and India have the potential to provide pharmaceutical products at a low cost. Thus far, Israel has issued a compulsory license for the importation of lopinavir/ritonavir (brand name Kaletra), one of the drugs being tested for COVID-19, from a generic producer in India. Israel did not use the WTO's compulsory licensing mechanism. Other countries in the process of modifying their laws to allow for compulsory licensing for COVID-19 purposes include Germany, Ecuador, and Chile.

It is important to note that under paragraph 7 of the Doha Declaration on Public Health, Members originally agreed to extend the exemption for LDCs from protecting pharmaceutical patents until 1 January 2016. This carveout under Article 66.1 of the TRIPS Agreement was extended until 1 January 2033, provided these countries remained LDCs. This is of great significance to Africa because 26 of the 36 WTO Members that are LDCs are African countries. This waiver means that LDCs do not have to grant patents for medicines. Thus, an LDC government does not need to issue a compulsory licence to import pharmaceutical products. The only compulsory licence that is necessary would be the one issued in the supplying country if the medicine is patented in that country. This means that, for African LDCs, obtaining a future COVID-19 vaccine should be easier.

In sum, the cost associated with the R&D of a vaccine necessarily mean that African countries may have difficulties accessing a COVID-19 vaccine when one is finally available. However, the highly contagious nature of COVID-19 has highlighted that patent exclusivity of a future vaccine, at purely commercial rates, is not a feasible option for global public health. Although non-LDC African countries (like other developing countries) certainly have a compulsory licensing trump card in their hands, the mechanism of accessing a future COVID-19 vaccine through the WTO may prove to be a deterrent. African states might be better off negotiating directly with the manufacturers and countries involved either in sub-regional groups or at the continental level for better leverage to secure access to this essential vaccine.

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