Original Paper

World trade organization’s export-oriented compulsory licensing mechanism: Foreseen policy concern for Africa to mitigate the COVID-19 pandemic

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Abstract
Africa has a history of grappling with outbreaks and high prevalence of disease. It currently confronts COVID-19 which is escalating because of local community transmission of the disease. Poorly resourced health systems in Africa are ill-prepared for the surging number of COVID-19 cases. This paper emphasizes that in the current battle against COVID-19, policymakers should not lose sight of future policy challenges. COVID-19 vaccine has become available, but patent exclusivities might play a major role in hindering access to it. With little or no indigenous pharmaceutical manufacturing capacity of its own, Africa will almost entirely rely on importing COVID-19 vaccines or treatment from third parties. The World Trade Organization’s (WTO’s) Paragraph 6 System, which relates to export-oriented compulsory licensing, is excessively formal and does not suit a pandemic situation which requires swift action. This paper draws policymakers’ attention of to a high priority policy concern for Africa.

Keywords
Africa, COVID-19 vaccine, , patent law,, TRIPS Agreement, Paragraph 6 System

Introduction
Africa is the second largest and second most populous continent. It accounts for 36% of the global disease burden but less than 2% of global health expenditure.1 In the past, the African region grappled with outbreaks and the high prevalence of diseases like HIV, cholera, tuberculosis, measles, diabetes, hypertension, dengue fever, yellow fever, and Ebola virus disease.2 Africa once again confronts a new pandemic. The first confirmed case of COVID-19 in the African region was reported in Egypt on the 14th of February 2020, over a month after the start of the outbreak in the Hubei province of China.3 Although COVID-19 started later in the African region than it did in other regions globally, the pandemic is escalating because of local community transmission of the disease.

The upsurge of the current pandemic has caused a global health panic and even the most sophisticated health systems are struggling to scale up a swift response to it. Poorly resourced and already vulnerable health systems in Africa are particularly ill-prepared for the surging number of COVID-19 cases. Africa’s capacity to provide critical and intensive care is already fragile. For instance, Uganda has only 55 ICU (intensive care unit) beds to serve its population of more than 42 million people. Most countries in sub-Saharan Africa have fewer than 20 ICU beds for their entire population.4 In addition to low testing efficiency, overcrowded health facilities, and poor medical conditions, there is a serious lack of medical supplies, personal protective equipment such as N95 masks, air-purifying respirators, respiratory isolation rooms, goggles, and experts to treat patients with complex respiratory needs.5 Furthermore, Africa’s
response to COVID-19 is adversely impacted by factors like family clustering, congested or overcrowded cities and slums, water and power deficits, presence of porous borders, poor health literacy, the double burden of infectious diseases, high out-of-pocket health expenditures, and high prevalence of malnutrition. These practical realities are a cause of concern because such conditions facilitate the spread of the epidemic.

National governments in Africa are taking preventive measure to control the outbreak to prevent excessive morbidity and mortality. For instance, Namibia and Ivory Coast have applied strong lockdown measures. The use of physical distancing as a strategy to slow the transmission of the virus has, however, serious implications for the informal economy in Africa. Prolonged economic disruption will lead to even more severe deprivation and hunger, which are longstanding problems in Africa. Many poor Africans may be forced to choose between complying with quarantine directives and engaging in communal activities for the day-to-day livelihood of their families.

Africa's sustained growth has been interrupted by the COVID-19 crisis. Affordable and universal access to a COVID-19 vaccine would be crucial for sustainable future of the African region. In this context, this article critically evaluates the effectiveness of the WTO's Paragraph 6 System, which relates to export-oriented compulsory licensing mechanism designed for poorer countries lacking drug manufacturing capacity of their own. This article questions efficiency of this safeguard mechanism and raises concerns about affordable universal access to COVID-19 vaccines or treatments in the African region.

Inefficiency of the export-oriented compulsory licensing mechanism

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), arguably WTO's most controversial multilateral agreement, provided mandatory patent protection to inventions in all fields of technology, including pharmaceuticals, for a period of twenty-years. The exclusive rights granted under patent law have direct implications for access to affordable medicines, especially for underprivileged patients in resource-constrained countries. It was anticipated at the time of drafting the TRIPS Agreement that drug patents may have serious practical implications for poorer countries. Public health safeguards were therefore included in the original draft. Compulsory licensing of drug patents is one of the most notable flexibilities or safeguards for public health. Actual use of this safeguard, which conflicts with the high-income countries’ IP protectionist agenda, is impeded by economic, political, legal and technical constraints. More importantly, the compulsory licensing safeguard, in its original form as initially provided under TRIPS, had no practical significance for least developed countries which lacked manufacturing capacity of their own because, under Article 31(f), the pharmaceutical products manufactured under compulsory license could only be used for domestic use. The 6th Paragraph of the ‘WTO Decision on TRIPS Agreement and Public Health 2001’, which is commonly referred to as the Doha Declaration, recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use compulsory licensing under the TRIPS Agreement and instructed ‘the Council for TRIPS to find an expeditious solution to this problem’. The subsequent Waiver Decision 2003 tried to address the problems of the least developed countries with little or no manufacturing capacity by allowing export of generics produced under compulsory licensing to these countries. Para 2 of the Decision waived the obligations of an exporting WTO Member under Art. 31(f) of the TRIPS Agreement ‘with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out’. Para 7 of the Decision recognized the ‘desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the [Doha] Declaration’. The Waiver Decision 2003 was transformed into a permanent amendment to the TRIPS Agreement on January 23, 2017. Vaccines were not specifically mentioned in the 2003 Waiver Decision. The Decision is applicable to ‘any patented product, or product manufactured through a patented process of the pharmaceutical sector needed to address the public health problems recognized in paragraph 1 of the [Doha] Declaration’. Paragraph 1 of the Doha Declaration reads as: ‘We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics’. It can be understood that vaccines are included in the scope of the 2003 Waiver Decision despite the fact that they are not explicitly mentioned. WTO Member States, especially low- and middle-income countries, need to press for a broader scope of the Decision because narrow interpretation of the
Decision fails to address a wide range of public health issues.

Efficiency of the Paragraph 6 System is crucial for the African region which lacks drug or vaccine manufacturing capacity of its own.\textsuperscript{12,3} COVID-19 vaccine has been approved, but patents might play a major role in hindering access. Having a weak technological base, Africa domestically manufactures less than 2\% of the medicines it consumes. Less than 1\% of vaccines used in Africa are made in Africa.\textsuperscript{12} A significant percentage of medicines and vaccines consumed in Africa are, therefore, imported.\textsuperscript{13} The African region chiefly imports pharmaceuticals from India and China.\textsuperscript{13}

The small molecule drug manufacturing involves the production of ‘active pharmaceutical ingredients’ (API) and drug formulation.\textsuperscript{14} It has been estimated that 126 developing countries lack API production capabilities and 42 among these countries lack competence in drug formulation as well.\textsuperscript{14} In the African region, only South Africa has limited API production capacity.\textsuperscript{15} The few local pharmaceutical manufacturing companies in the East African Community rely solely on the importation of active pharmaceutical ingredients (APIs) for production.\textsuperscript{13} Local manufacturers’ ability to manufacture APIs is constrained because of the substantial cost of producing APIs and a serious lack of high-level technical expertise and technology transfer.\textsuperscript{16,4} Many low-income countries having the technical capacity to replicate pharmaceutical drugs may lack the economic viability for the production of medicines even if they are able to import APIs.\textsuperscript{17} It is important to note that sterile vaccine manufacturing is even more difficult.

With little or no indigenous capacity to produce advanced pharmaceutical formulations and vaccines, Africa will almost entirely rely on importation of COVID-19 vaccines or treatments from third parties. To address such situations, the African region will hugely rely on the effectiveness of the Doha Declaration’s Paragraph 6 System which governs export-oriented compulsory licensing. A reliable and sustained universal supply of a critically needed COVID-19 vaccine or treatment can be foreseen as a policy challenge for Africa because this access enhancing safeguard mechanism is itself complex and cumbersome.

The Paragraph 6 System can be used by only least-developed countries (LDCs) or developing countries with insufficient or no drug manufacturing capacity. To be eligible, developing countries are required to demonstrate that they have insufficient or no manufacturing capacity for the product(s) in question. The use of this mechanism is subject to numerous other conditions like prior negotiation for a voluntary license; compulsory licensing applications in the importing and exporting countries; notification of authorization from the exporting country; and adoption of anti-diversion measures to prevent re-exportation.\textsuperscript{18} This safeguard mechanism has been available since the WTO General Council’s Waiver Decision in 2003. In the last 17 years, this mechanism has been used only once in the case of Rwanda importing antiretroviral drugs from Canada in 2007. This sole use was triggered by Médecins Sans Frontières (MSF), a humanitarian organization, which, need of fix-dose-combination of ARV for HIV/AIDS treatment, convinced the Canadian drug company Apotex Inc. to invoke the system.\textsuperscript{19} As observed by Horace Anderson, there are notable reasons for this underutilization:

Commentators have variously attributed this under-utilization to the scheme’s burdensomeness and lack of implementation flexibility, the scheme’s failure to recognize the need for economies of scale for exporting countries, political pressure and norm imposition by the West, failure of antitrust and competition policy, and inadequate existing market and private investment models of development and distribution of public goods.\textsuperscript{20} This excessively formal mechanism does not suit a pandemic situation where there is a requirement to act swiftly. The requirement of negotiating a voluntary license is an additional burden which tends to cause potential delays as these negotiations are normally complex, protracted and time-consuming. Two compulsory licenses – one in the exporting country and one in the importing country - are required to be granted, with all their procedural requirements, only for a pre-determined limited time-period. There is a restriction on the quantity of medicines that can be manufactured for export. This is an unreasonable requirement because it is almost impossible, both practically and economically, to have a clear estimate of the quantity of the needed drug in a pandemic situation.\textsuperscript{21} The entire cumbersome process of compulsory licensing needs to be repeated if the need exceeds the forecasted amount. This unnecessary procedure to renew the compulsory license for limited durations adds to the administrative burden of using this mechanism. Moreover, the exporting country is required to manufacture the drug with a distinguishable shape, colour, size, labelling or distinctive outer packaging of the drug in order to clearly identify the medicines produced under this system. These onerous anti-diversion measures not only add to the cost of production but can also be subject of litigation. Lisa Forman has summarized these strict conditions:
[B]oth importing and exporting countries must issue compulsory licenses; eligible importing members other than least-developed countries must establish insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question; such medicines are limited to the amount necessary to meet the needs of the importing country, and must be imported in their entirety to the member; the medicines must be clearly identified as produced under this system through labelling, distinguished by packaging and/or shaping and coloring; and importing countries must take reasonable measures to prevent re-exportation of products.\textsuperscript{22}

This non-functional system can be considered as ‘more of a political statement than a pragmatic licensing scheme’.\textsuperscript{23} This safeguard mechanism is ‘too complex in its administration for providing an expeditious solution as envisaged in paragraph 6 of the Doha Declaration’.\textsuperscript{17} The excessively strict and cumbersome conditions to prevent re-exportation of products are unnecessarily imposed as there is no empirical evidence to suggest that prior to TRIPS the western markets were flooded with generic medicines that had been exported to the developing world.

Because of its enormous procedural challenges and financial costs, the Paragraph 6 System is not considered worthwhile by generic manufacturers.\textsuperscript{14} Generic companies at least want to recover their investments even if they do not expect to earn handsome profits.\textsuperscript{17} Strict conditions on production and supply of predetermined quantities provide low economy of scale opportunities.\textsuperscript{17} There is no financial incentive of potential sales domestically or to another importing country. After the unpleasant experience of using this mechanism in Canada-Rawanda case, the generic manufacturer Apotex expressly announced that it will not use the Waiver scheme again because of costs and complexities involved in using the scheme.\textsuperscript{24} Apotex particularly referred to the ‘requirements of including the importing country into the application for the compulsory license and the duty to request a voluntary license from the patent holders and the limitations of the compulsory license with respect to quantities and duration’.\textsuperscript{17}

Reforming the Paragraph 6 System to address its shortcomings is important not only for low- and middle-income countries but also for high-income countries. A number of high-income countries – including the U.S., the EU, Canada, Australia, New Zealand, Switzerland, Norway, Iceland, Japan – handcuffed themselves by declaring to the WTO that they would not import patented medicines manufactured elsewhere under the Paragraph 6 System.\textsuperscript{25} As a result of this unnecessary self-imposed limitation, high-income countries cannot be eligible importing members in the use of Paragraph 6 System. This misstep of opting out of the WTO framework for export-oriented compulsory licensing can, however, be undone by simply notifying the WTO.\textsuperscript{24} High-income countries should consider the removal or revoking of this opt-out in order to overcome patent obstructions if a need arises to import COVID vaccines and/or treatments from other countries. National manufacturing capacity of high-income countries and supply chains can be adversely impacted by a public health crisis. Concerns of Western countries are highlighted by the current crisis in obtaining COVID-19 vaccines in Western Europe and in particular the recent EU restrictions on export of Astra Zeneca vaccines manufactured in Italy to Australia and the UK.

**Conclusion**

A substantial number of vulnerable people, especially children, in Africa die every day from diseases that could have been prevented or treated through improved access to effective medicines and vaccines.\textsuperscript{12} Africa has contained serious infectious diseases, some of which still prevail in some parts, with Ebola eradicated in Congo only very recently. Lacking a viable local pharmaceutical and vaccine manufacturing capacity, the African region relies on importation of innovative medicines and vaccines. The WTO’s Paragraph 6 mechanism for export-oriented compulsory licensing failed to provide a workable solution to problems faced by the African region in accessing newer and effective medicines and other innovative health technologies. This mechanism is too formal and too technically cumbersome to provide a workable solution in a pandemic situation where there is a requirement to act swiftly. The Paragraph 6 System, therefore, needs to be revisited and revised.

The global civil society and political leadership should use the impetus of COVID-19 to press for a proper solution to the long-standing issue of access to innovative health technologies in the African region. The global community needs to realize that Africa cannot be left out. Although COVID-19 is spreading more from wealthier countries to Africa, the virus may be reintroduced to wealthier countries if the pandemic continues to prevail in the poorer African region after availability of COVID-19 vaccine or treatment in economically advanced countries. It is also the time for political leadership in Africa to start looking beyond foreign aid, charitable donations or emergency solutions and use COVID-19 as an opportunity to negotiate a long-term workable solution to the extensively debated problem of access to medicines that has direct synergies with the socioeconomic growth and sustainable development in the region. The current global pandemic provides the best opportunity for African
countries to reshape the international IP debate in favour of sustainable access to essential medicines for improved health equity.

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Notes
a. A compulsory license is a statutorily created license that allows certain people to pay a royalty and use an invention without the patentee’s permission. It is a public health safeguard provided under Art. 31 of the WTO TRIPS Agreement 1995.
b. In 2003, the General Council decided to waive the provisions of Article 31 Paragraph (f) and (h) of the TRIPS Agreement for a special regime of export-oriented compulsory licensing. Full text of WTO’s General Council’s Waiver Decision of August 30, 2003.
c. Universal access to vaccines is critical not only to reduce mortality and disease burden but also to improve life expectancy and economic growth in Africa. Nevertheless, the global vaccine stakeholders have shown less preference in investment for vaccine production establishment in Africa. For local production of vaccines, the African region relies on technical and financial support of developed countries for construction of facilities, acquisition of technology and access to expertise.
d. East African Community argued that developed countries should be reminded of their commitments to materialize one of the key objectives of the World Trade Organization as stipulated under Article 7 of TRIPS which clearly states that the agreement ‘should contribute to the promotion of technological innovation and the transfer and dissemination of technology’. Article 67 of TRIPS imposes an express obligation on developed countries for the provision of technical and financial cooperation. Unfortunately, technology transfer to low- and middle-income countries has remained a pipe dream. The African region is yet to navigate its way to fix its technical, technological, and financial deficiencies.

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