The Role of Multilateral Actors in Promoting Equitable Access to Medicines, Vaccines and Therapeutics: A Global South Perspective

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Led by the World Health Organization, (WHO), multilateral actors such as the World Bank (Bank), United Nations (UN), World Intellectual Property Organization (WIPO) and World Trade Organization (WTO), have underscored the need to ensure equitable access to therapeutics and vaccines for the coronavirus disease (COVID-19) in the Global South. The 'Workshop on the Legal Dimensions of COVID-19' organized by the NYU Law School and the Bank's Global Forum for Law and Development, on 29 June 2020, will examine avenues to turn these multilateral actors' goals into reality by considering

intellectual property rights (IPRs), economic inequality and lack of infrastructure. This essay, which is an excerpt of the authors' forthcoming paper on a related topic, emphasizes the importance of recognizing, nurturing, and supporting indigenous and low-cost innovation systems for safe and efficacious therapeutics, vaccines, and medical devices particularly in the Global South.

This essay argues in favour of broadening innovation beyond the western-based intensive research and development corporate model backed by high-end manufacturing capacity. This widening of innovation options, we argue is an imperative triggered by the COVID-19 pandemic. The limited manufacturing capacity and infrastructure in countries in the Global South means that such western-based intensive research and development models backed by high-end manufacturing capacity cannot be a one-size fit all model for every context, especially those with limited health care capacity. It is particularly essential to remember that the WTO's goods barometer has not even bottomed out after precipitous fall in global trade following the COVID-19 pandemic. In addition, the International Monetary Fund's Global World Economic Outlook forecast for June 2020 shows that global growth is projected at (minus) –4.9 percent in 2020, 1.9 percentage points below the April 2020 World Economic Outlook (WEO) forecast. This higher-than-usual degree of uncertainty, the IMF notes, means that "the international community must vastly step up its support of national initiatives, including through financial assistance to countries with limited health care capacity and channeling of funding for vaccine production as trials advance, so that adequate, affordable doses are quickly available to all countries." This is together with the fact that the pandemic is not showing any signs of abating, means therapeutics, vaccines, and medical devices developed in the West or in the BRICS under conditions of extreme contraction of global trade will continue to have particular difficulties reaching the most vulnerable populations in the Global South and vulnerable populations elsewhere.

In addition, although the HIV/AIDS epidemic of the 1990s propelled a movement for the recognition and expansion of the compulsory licensing flexibilities in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), those solutions have been far from adequate. To clarify, the TRIPS Agreement, as orchestrated by businesses in

the pharmaceutical, software, music/entertainment, and agricultural/chemical industries, backed by the United States, the European Union, Japan and Canada, introduced global minimum standards for Intellectual Property Rights, (IPRs), with its entry into force on 1 January 1995. Global South countries, attracted by the promise to engage in the multilateral trading system in the Uruguay Round bargain, became signatories to TRIPS and implemented its standards for creativity and innovation. The most widely considered category of IPRs discussed in relation to therapeutics, vaccines, and medical devices is patents, set out in Section 5 (Articles 27 to 34) of the TRIPS Agreement.

Under Article 27 of the TRIPS Agreement, patents are available for inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Patent owners have the exclusive right to commercialize their inventions. However, Articles 7, 8, 30 and 31 of the TRIPS Agreement, provides for limitations to the exclusive rights conferred by patents in instances where it is necessary to protect the public interest and public health. In particular, Article 31 provides for compulsory licensing. This means that national governments are allowed to grant rights to produce, *export and import* patented inventions, without the authorization of the right holder, but subject to a host of conditions under Articles 31 and 31bis. To overcome some of these limitations, WTO members agreed on the amendment of the TRIPS Agreement to allow for the exportation and importation of patented products in December 2005. These provisions were formally incorporated in the TRIPS Agreement in January 2017. This amendment was possible following the adoption of the WTO Doha Declaration on TRIPS Agreement and Public Health (Doha Declaration) in 2001, and a General Council Decision on Paragraph 6 of the Doha Declaration in 2003. These revisions to the compulsory licensing provisions in TRIPS was possible because of very vibrant interventions of developing countries in alliance with activists and civil society organizations (CSOs) like James Love, Consumer Project on Technology, Health Action International, Médecins Sans Frontières and Oxfam. A case instituted by the South African Pharmaceutical Manufacturers Association in 1998 against the South African government for its use of the compulsory licensing flexibilities in the TRIPS Agreement fuelled the activists and CSOs interventions. Despite the formal revisions to the TRIPS Agreement, the compulsory licensing flexibilities have been undermined in

WTO Plus commitments in Free Trade Agreements and Bilateral Investment Treaties as well as by threats of Investor State Dispute Settlement (ISDS) cases, revealing the strong desire of Global North countries to protect their pharmaceutical sectors. Furthermore, due to the complexities in implementation, only a limited number of Global South countries, such as Brazil, India, South Africa, Thailand, and Rwanda, have issued the compulsory licences.

While the debates on expanding TRIPS flexibilities, inspired by the HIV/AIDS epidemic, were grounded on its benefits to the Global South, the COVID-19 pandemic has prompted a flurry of revisions to, or application of, compulsory license laws in both Global South and Global North governments. For example, Canada, Chile, Israel and Ecuador have revised their patent laws to make it more likely that compulsory licenses would be issued in response to the COVID19 pandemic. Indeed, in discussions about Global South countries' access to vaccines, therapeutics, and medical devices to tackle the COVID-19 pandemic, most multilateral actors have focused on promoting the use of compulsory licensing under the TRIPS Agreement. Other noteworthy initiatives include the UN-backed Medicines Patent Pool (MPP) and the WHO's Solidarity Call to Action. The MPP partners with CSOs, the pharmaceutical industry, governments, international organizations, patient groups, among other stakeholders, to provide non-exclusive licenses for IPRs to promote generic manufacturing and the development of new medicines. The WHO's Solidarity Call to Action seeks to ensure equitable global access to COVID-19 health technologies through the sharing of IPRs, knowledge and data. Thirty-seven countries, mostly from the Global South, have indicated an interest in joining the Call.

Our Proposal: Recognizing, Nurturing, and Supporting Indigenous and Low-cost Innovation Systems for Safe and Efficicous Therapeutics, Vaccines, and Medical Devices

One underexplored therapeutic is traditional medicines. The WHO recognizes indigenous innovations and traditional medicines as critical for addressing global health challenges. The WHO already recognizes that traditional medicines are either a mainstay of health care delivery or serve as a

complement to health care delivery, across the world and especially in the Global South. For example, the WHO's Traditional Medicines Strategy (2014-2023) lists the following two goals. First, harnessing the potential contribution of Traditional Medicines to health, wellness and peoplecentred health care. Second, promoting the safe and effective use of Traditional Medicines by regulating, researching and integrating Traditional Medicines products, practitioners and practice into health systems, where appropriate.

However, multilateral actors have paid only minimal attention to these innovations and medicines. While the WHO, WIPO and WTO's 'Promoting Access to Medical Technologies and Innovation' initiative recognizes the importance of traditional knowledge, it fails to address the IPRs debates on the subject. Yet, the WHO emphasizes the significance of traditional medicines in Africa and notes the long history of using traditional medicines and consulting traditional health practitioners. For the WHO therefore, these medicines contribute significantly to providing care to populations in many parts of the world.

In the context of the COVID19 pandemic, the WHO acknowledges that a medicinal plant, *Artemisia annua,* is a potential treatment. Resources are necessary to make sure that *Artemisia annua*, along with other proposed treatments in the traditional medicines sphere are tested for efficacy, safety, and side effects in scientifically verifiable trials. Similarly, Charlene Tsitsi Musiza's excellent recent essay on Afronomicslaw.org spotlights Covid Organics, a traditional medicine for COVID-19, developed in Madagascar. Other Global South countries, including China, Indonesia, Thailand, and Malaysia, have proposed a variety of traditional medicines to treat COVID-19. In a 2001 peer reviewed study, the authors "identified 122 compounds of defined structure, obtained from only 94 species of plants, [recognized and used in traditional medicine], that are used globally as drugs and demonstrate that 80% of these have had an ethnomedical use identical or related to the current use of the active elements of the plant."

Multilateral actors can support the legitimacy of traditional medicines and indigenous innovation systems through investment in activities such as research and development, suitable documentation, as well as clinical tests and trials, which would substantially promote the development and dissemination of

therapeutics and other innovations in the Global South. The multilateral actors' support can also contribute to normative changes to the IPRs systems for traditional knowledge at the international level. For example, CSOs successfully lobbied for normative changes to compulsory licensing under TRIPS during the HIV/AIDS epidemic with support from actors such as the Bank, WHO and UN.

The COVID-19 pandemic presents another pivotal opportunity to re-examine TRIPS and the international IPRs architecture. Here, we will recall that the before the firm bridge between trade, enforcement and IPRs following the introduction of the latter in the General Agreement on Tariffs and Trade (GATT)/WTO through the US's forum-shifting from WIPO to the WTO which has enforcement authority as the primary institution for IPRs. Since WTO-plus IPR protection are today embedded in bilateral and mega-regional trade and investment agreements, the role of these additional venues must be examined as well.

Also relevant to this discussion, are the UN's Convention for Biological Diversity (CBD), the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). These set of treaties create counter-norms to the strong protection fo IPRs embedded in TRIPS and TRIPS Plus IPR treaty provisions particularly on access and benefit sharing.

As a longer term goal for supporting recognizing, nurturing, and supporting indigenous and low-cost innovation systems, we also argue in favour of working within the existing fragmented and complex international IPRs architecture to achieve the following three goals.

- *Revisiting the Categories and Definitions of IPRs in TRIPS*. Inclusion of traditional knowledge as a distinct category of IPRs in the TRIPS Agreement. In addition, the inclusion of disclosure/source of origin for the use of genetic resources or traditional knowledge in patent applications as provided under Section 5 of the TRIPS Agreements. Other categories of IPRs in the TRIPS Agreement critical to the development of traditional

knowledge systems include trade marks, trade secrets and geographical indications. Debates about traditional knowledge are not new to the TRIPS Council. Paragraph 19 of the Ministerial Declaration Doha 2001 requires the TRIPS Council to examine *inter alia* the relationship between the TRIPS Agreement, the CBD and the protection of traditional knowledge. The enforcement provided under the WTO Dispute Settlement Body will strengthen traditional knowledge systems beyond the suggested initiatives in WIPO. We turn to this point below.

- *Expediting the text-based negotiations in WIPO.* We recommend expediting the text-based Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC). The WIPO-IGC offers a policy space to carefully craft an instrument that recognizes and rewards the innovation systems prevalent in the Global South. As Chidi Oguamanam, a leading negotiator for Nigeria at the WIPO-IGC rightly asserts, 'the IGC represents a crucial forum to negotiate how knowledge production at these complex intersections, [IPRs, genetic resources and traditional knowledge], can advance the needs, concerns and local conditions of stakeholders, especially developing countries, indigenous peoples and amorphous local communities.'
- *Investment in Research and Development*. We recommend that multilateral actors' invest in research and development of both the western therapeutics, vaccines, and medical devices produced by pharmaceutical companies and innovators in the Global North as well as the traditional medicines, traditional practices, vaccines, and low-cost medical devices produced by indigenous peoples/communities and traditional health practitioners in the Global South. To close the investment gap in science based research and development in many Global South countries, multilateral actors can fund laboratories and scientific equipment and training for the use of that equipment for research in traditional medicines and therapeutics. We note that this support would have utility beyond research in traditional medicines and therapeutics. Such support is critical to supporting a type of development that is poverty reducing and productivity increasing.

Our immediate goal calls upon multilateral actors to recognize, nurture, and support indigenous and low-cost innovation systems. In the longer term, we argue that the realization of this short term goal could be met more effectively through the implementation of the three action points noted above. To do so will require robust multidisciplinary studies and consultations with stakeholders such as the traditional health practitioners, indigenous peoples/communities, CSOs, pharmaceutical industry, academics with specializations in fields including IPRs, international relations, science and technology, government officials in agencies or bodies responsible for health, culture, agriculture, science, technology, regional/sub-regional intergovernmental organizations and multilateral actors. According to the WHO, there are 9, 825, 539 confirmed cases of COVID-19 and 495, 388 confirmed deaths across 216 countries, areas, or territories (last update: 28 June 2020, 01:00 BST). COVID-19 is an unprecedented pandemic. Only a few countries are left untouched, yet there is no specific treatment for COVID-19 at the moment. The WHO Director-General, Dr Tedros Adhanom Ghebreyesus, reminds us that although COVID-19 is a test to our economic, cultural, social and political infrastructure, and has taken so much from us, it is also giving us a rare opportunity to break with the past and build back better. With adequate investment in research and development directed towards indigenous and low-cost innovation systems, the Global South can contribute to the development of therapeutics, vaccines, and medical devices for COVID-19.

Ultimately, our point is that there is no reason to exclude traditional and indigenous medicines and therapeutics from the array of initiatives being supported to respond to the COVID19 pandemic. Traditional medicines have an equally important role as vaccines, therapeutics and medical devices protected through classical IPRs such as patents. For this reason, it is important to include traditional medicines within the scope of IPR protection, including within the WTO’s TRIPS Agreement. Doing so would go beyond the classical debate of protecting medicines, vaccines and therapeutics mainly through patents as currently understood within the TRIPS Agreement.

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