

De Menezes, Henrique Zeferino

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The TRIPS waiver proposal: An urgent measure to expand access to the COVID-19 vaccines

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Henrique Zeferino de Menezes




**SOUTH
CENTRE**



RESEARCH PAPER

129

THE TRIPS WAIVER PROPOSAL: AN URGENT MEASURE TO EXPAND ACCESS TO THE COVID-19 VACCINES¹

Henrique Zeferino de Menezes²

SOUTH CENTRE

MARCH 2021

¹ The final version of this paper was submitted to the South Centre on 15 February 2021.

² Henrique Zeferino de Menezes is Senior Lecturer at the Department of International Relations at the Federal University of Paraiba, Brazil. He has a PhD in Political Science at the State University of Campinas, Brazil. His research focuses on international political economy, intellectual property rights, international cooperation, innovation and sustainable development. He has published peer-reviewed articles in academic journals, and recently published three books on the Sustainable Development Goals, United States international political economy, and intellectual property, health and development. E-mail: hzmenezes@ccsa.ufpb.br

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Any comments on this paper or the content of this paper will be highly appreciated. Please contact:

South Centre
International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

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ABSTRACT

Despite multilateral commitments and political statements of solidarity and cooperation to guarantee the availability and access to COVID-19 vaccines (and other relevant technologies for control and treatment), the scenario after the beginning of vaccination is marked by the deepening of vaccine nationalism, the concentration of inputs and vaccines production, and the uneven distribution of options of vaccine doses already approved for use. This pattern of production restrictions and unequal access will lead to an increase in international inequalities, leaving a large part of the world to have access to vaccines not until 2024. While advanced purchase agreements (APAs) among pharmaceutical companies and some developed countries are multiplying, the proposed mechanisms for voluntary licensing of technologies and the COVAX Facility do not achieve their goal of democratizing access to vaccines. In this sense, the current TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) waiver proposal seems to be the political and institutional response with the greatest potential to guarantee the scaling of the production of pharmaceutical inputs, allowing the adoption of a comprehensive strategy to ensure timely, sufficient, and affordable access to all technologies developed to fight COVID-19.

Malgré les engagements multilatéraux qui ont été pris et les déclarations politiques en faveur de mesures de solidarité et de coopération permettant de garantir la disponibilité et l'accès aux vaccins contre la COVID-19 (et aux autres technologies pertinentes de contrôle et de traitement), le lancement des premières vaccinations est marqué par un nationalisme vaccinal exacerbé, une concentration des intrants et de la production de vaccins, et une distribution inégale des doses de vaccins dont l'utilisation a été approuvée. Ces restrictions en matière de production et l'accès inégal aux vaccins sont un facteur d'augmentation des inégalités à l'échelle internationale et auront pour conséquence qu'une grande partie du monde n'aura accès à la vaccination qu'en 2024. Alors que les accords d'achat anticipé conclus entre les sociétés pharmaceutiques et certains pays développés se multiplient, les mécanismes proposés pour l'octroi de licences facultatives de technologies et le mécanisme COVAX n'ont pas permis d'atteindre les objectifs en matière de démocratisation de l'accès aux vaccins. Dans cette optique, la proposition actuelle de dérogation aux dispositions de l'ADPIC (Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce) semble être la réponse politique et institutionnelle la plus à même de garantir un accroissement de la production d'intrants pharmaceutiques et de favoriser l'adoption d'une stratégie globale pour assurer un accès rapide, suffisant et abordable à toutes les technologies développées pour lutter contre la COVID-19.

Pese a los compromisos multilaterales y las declaraciones políticas de solidaridad y cooperación para garantizar la disponibilidad y el acceso a vacunas de la COVID-19 (y otras tecnologías de control y tratamiento relevantes), la situación tras el comienzo de la vacunación está marcada por la intensificación del nacionalismo de vacunas, la concentración de la producción de insumos y vacunas, y la distribución desigual de las opciones de dosis de las vacunas cuyo uso ya se ha aprobado. Este modelo de restricciones a la producción y de acceso desigual dará lugar a un incremento en las desigualdades internacionales, y dejará a gran parte del mundo sin acceso a las vacunas hasta 2024. Mientras los acuerdos de adquisición anticipada entre las empresas farmacéuticas y algunos países desarrollados se multiplican, los mecanismos propuestos para la concesión voluntaria de licencias de tecnologías y el Mecanismo COVAX no alcanzan su objetivo de democratizar el acceso a las vacunas. En este sentido, la actual propuesta de exención prevista en el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC) parece ser la respuesta política

e institucional con más posibilidades de garantizar la ampliación de la producción de insumos farmacéuticos, que permita la adopción de una amplia estrategia cuyo objeto sea garantizar un acceso oportuno, suficiente y asequible a todas las tecnologías desarrolladas para combatir a la COVID-19.

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INTRODUCTION

The COVID-19 pandemic has already victimized more than two million people, overloaded national health systems causing more deaths and illnesses, and led to a severe economic crisis, threatening the lives of millions of women, children, and men by hunger, insufficient access to public services and violence. Politically, the coronavirus outbreak challenged multilateralism and its institutions and brought nationalism back to the global agenda spotlight. The World Health Organization (WHO) and its protocols have become the target of conservative political leadership and the spread of protectionist practices have hampered the export of medical and hospital supplies, food, and other essential goods, limiting the efforts to address the COVID-19 pandemic.

The urgency to respond to the ongoing pandemic made clear the need for broader collaboration and solidarity and an effective and responsive global health security system to face global pandemics. One of the most serious problems that emerge in situations like the COVID-19 outbreak is the unequal availability of pharmaceuticals and essential medical equipment. This highlights the importance of reforming the current global innovation system, aiming at boosting the production and dissemination of therapeutics, vaccines, and other medical products and technologies. The beginning of the COVID-19 vaccination brought encouragement and hope - as it confirmed that COVID-19 would not become a neglected disease. The high volume of resources allocated to the vaccine race and the demand for a global immunization agenda secured the development of some quality COVID-19 vaccines, preventing a vaccination failure like what had happened in other recent cases (RAVIGLIONE and MAHER, 2017; HOTEZ et al., 2020; RUTSCHMAN, 2020).

However, the COVID-19 has unequal effects and the benefits generated by scientific progress do not seem to benefit everyone at the same time – the pandemic impacts countries and populations in many different ways, imposing a brutal human and economic burden on the most impoverished and already vulnerable population. The first weeks of vaccination underlined the reproduction and accentuation of international inequalities, already visible in the way countries have planned and implemented their policies to tackle COVID-19. The COVID-19 pandemic accentuated the lack of coordination for the development, production, and diffusion of essential technologies to respond to the outbreak and can worsen global inequality due to the robust concentration of doses contracted and delivered for a few developed countries. The most pressing need at this moment is to guarantee widespread access to the recently approved vaccines, but access to affordable medical products - diagnostic kits, personal protective equipment, ventilators - and medicines for patients' treatment is still needed.

It is urgent that a comprehensive strategy to ensure massive vaccination and that people in the poorest regions have timely, sufficient, and affordable access to all technologies developed to fight COVID-19 – i.e. the rapid manufacture of billions of doses of high-quality vaccines, financial support for the purchase of vaccines, and the coordination of logistics for the adequate supply and equitable distribution. Data analysis carried out by the Coalition for Epidemic Preparedness Innovations (CEPI) estimates that only in 2024 will there be the production of the vaccines necessary to generate global immunization - that is, the production of approximately 11 billion doses at a rate of 2 to 4 billion per year (KIM, MARKS and CLEMENS, 2021).

However, expecting effective responses and correct productive and distributive stimuli through the market's normal functioning and the current global research and development (R&D) system does not seem reasonable. Thus, several international cooperation initiatives have been proposed - encouraging coordinated actions for technological development,

sharing, acquisition, and distribution. International cooperation is mandatory for new products and technologies to fulfill their social function and reach the most vulnerable, allowing for a real immunization agenda. At this point, South-South cooperation is essential for the building of strategies aiming at strengthening productive and technological capacity in the South, that guarantees the production of sufficient inputs and goods, securing access to a massive population contingent.

In this context, it is imperative to build political commitments that limit unilateralism, especially by the richest countries which have a greater capacity to obtain the vaccines. Only then it would be possible to ensure equitable distribution to properly respond to the COVID-19 outbreak. As stated by Tedros Adhanom Ghebreyesus, WHO Director-General, it is crucial to prevent *vaccine nationalism*, which has been underway since the beginning of the pandemic³. The multiplication of advance purchase agreements⁴ between pharmaceutical companies that are producing a few approved vaccines (and vaccines in phase III of clinical trials) and a few countries is the new and most threatening form of vaccine nationalism. On the other hand, the global community needs to expand the production and distribution of medical products, medicines, and especially vaccines.

A fundamental aspect to be considered at this point is the impact that intellectual property (IP) rights will have on production capacity and the availability of technologies to respond to the pandemic. The main technologies associated with the treatment of COVID-19, whether drugs or technological equipment, are already patented and many therapeutics will receive a secondary patent because they are repurposed therapeutics or will be registered for new uses. The same scenario happens with vaccines - they are or will be under a patent protection and will have their fundamental components and background technologies patented as well.

Historically, developing countries have cooperated in intellectual property negotiations by strengthening cooperation within key partners and cross-issue alliances for building shared understandings on the global IP regulations; building multisector coalitions for specific IP negotiations; and using different forums for the diffusion of policies that promote national IP systems best suited to their social and technological interests (MENEZES, 2018). Likewise, it is strategic for these countries to deepen productive integration⁵, share knowledge and technologies to expand the production and the distribution of pharmaceutical inputs, medicines, and vaccines.

On October 2, the Indian and South African governments presented a proposal for a waiver⁶ of several specific provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a legal-institutional response necessary to fight the COVID-19 emergency. The proposal shares the spirit of important resolutions approved by the WHO and the United Nations (UN) during 2020 and it is aligned with other initiatives to guarantee access to technologies for control, treatment, and immunization.

In May 2020, the World Health Assembly approved the “COVID-Response” Resolution (WHA 73.1). It is an ambitious document that proposes a global response to the COVID-19

³ See <https://news.un.org/en/story/2020/08/1070422>.

⁴ The advance purchase agreements are legally binding contracts whereby a government commits to purchasing from a vaccine manufacturer a specific number or percentage of doses of a potential vaccine at a negotiated price if it is developed, licensed, and manufactured. This kind of agreement often secures priority access to vaccine and manufacturing capacity. Governments of countries that do not adhere to this type of agreement are at risk of having access delays. (PHELAN et al., 2020, p. 800)

⁵ See <https://unctad.org/es/node/2420>.

⁶ Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of Covid-19, Communication from India and South Africa, 2 October 2020 (IP/C/W/669). Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W/669.pdf&Open=True>.

pandemic, demanding responsibility and action of all members of the international community. Its political objective is to affirm the need for "universal, timely, and equitable access to and fair distribution of health technologies and products to combat the virus". To be effective, the proposal requires the development, testing, and large-scale production of all types of technologies associated with the treatment and containment of the virus. The resolution also addresses the need to recognize the responses to COVID-19 as a global public good - to do so, any unjustified obstacles must be removed and TRIPS flexibilities should be strengthened (SYAM et al., 2020)⁷.

The United Nations General Assembly (UNGA) also passed two resolutions on the matter. They both emphasize the need to rapidly scale manufacturing and strengthen supply chains to ensure efficient, timely, fair, transparent, and equitable access to and distribution of diagnostics, drugs, and COVID-19 vaccines to all of those in need, particularly in developing and least developed countries⁸. These are critical documents, with ambitious proposals, emphasizing the need for an open approach that assures production and public access (SYAM, 2020b). However, there is no clear definition of what "equitable access to and fair distribution" means in practice and how to concretely implement this commitment. The challenge is to build political and institutional arrangements that concretely reach a proposal of this magnitude. For that, a broad sharing of intellectual property rights and know-how to facilitate deep technology transfer would be necessary.

However, the global legal and political landscape has shifted from a rhetoric of global public goods to a harder reality of vaccine nationalism. As David Fidler explains, *vaccine nationalism* is more evidence that efforts to elevate health cooperation have produced more rhetoric than political roots within countries and the international community. The dissemination of individualistic attitudes opens the gap between science – which affirms the need for the dissemination and expansion of vaccination - and politics - that insists on nationalist strategies that can bring catastrophic global results⁹.

According to the governments of India and South Africa, despite the language and the affirmations "on solidarity and global public goods" there are still no concrete actions and policies to guarantee the staggered production and sufficient distribution of the vaccines already approved¹⁰. It seems that international institutions are failing to stop vaccine nationalism and some more active and radical options must be put available for countries to build their plans to achieve massive vaccination.

⁷ It is interesting to notice that the United States, despite voting for the resolution, "drifted away" from some of its elements and decisions - especially the reference to TRIPS flexibilities (<https://geneva.usmission.gov/2020/05/19/explanation-of-position-covid-19-response-resolution/>).

⁸ UNGA Resolution 74/274 - *International cooperation to ensure global access to medicines, vaccines, and medical equipment to face COVID-19*; and UNGA Resolution 74/270 - *Global solidarity to fight the coronavirus disease 2019 (COVID-19)*.

⁹ See <https://science.sciencemag.org/content/369/6505/749.long>.

¹⁰ Nirmalya Syam, "WTO TRIPS Council discusses major proposals from developing and least developed countries for waiving certain TRIPS obligations and extension of the transition period for LDCs", *SouthNews* 347, 23 October 2020. Available from <https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=a9b27dc5a8>.

THE GLOBAL INITIATIVES TO ENSURE ACCESS: TRADE-OFFS AND CHALLENGES FOR THE FUTURE

As we learn about the COVID-19 vaccination, the most latent concern regards the timely availability in sufficient quantity and at affordable prices for the most vulnerable and marginalized populations in the world. In addition to the political commitment expressed with the resolutions adopted by the WHO and the UN, international organizations, governments of developed and developing countries, and other private and public actors implemented some initiatives to boost the development and production of vaccines and the definition of safe and effective treatments.

In the first months of the pandemic, the President of Costa Rica presented a proposal to create a pool for voluntary licensing on a non-exclusive basis of technologies that are useful for the diagnosis, prevention, control and treatment of the COVID-19 pandemic¹¹. In the proposal, the **COVID-19 Technology Access Pool (C-TAP)** should include “existing and future rights in patented inventions and designs, as well as rights in regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines”¹². Initially, the proposal was received with great enthusiasm and a rationale was even then developed - Unitaid and Medicines Patent Pool (MPP)¹³ announced that they would like to include COVID-19 medical products in its voluntary licensing pool (CHAUDHURI, 2020).

Over time, optimism has diminished due to the low commitment of developed countries and lack of interest from the large multinational companies. The industry has “repeatedly said that it doesn’t see itself as a player in C-TAP”¹⁴. Despite previous successful cases under MPP management, C-TAP does not seem to work. Any voluntary mechanism to be successful would depend on the participation and direct collaboration of the “Big Pharma” since they own the most relevant technologies to respond to the pandemic. However, until now there is no commitment from the private sector to broadly license their technologies to ensure dissemination and universal access.

It is important to note that voluntary licensing is significantly different from treating the COVID-19 related technologies as global public goods. In this case, in a more radical understanding, one should give up recognizing any intellectual property right associated with technologies for COVID-19 immunization and treatment. However, the global R&D system and the business model of pharmaceutical companies are based on the enforcement of their proprietary rights over drugs and other knowledge-based assets. The implications of the running current R&D model, as abundantly reported by the literature, is the low commitment to global social demands and the multiplication of private appropriation strategies disconnected from real innovation and the development of medicines and vaccines for some neglected diseases (CORREA, 2009).

In parallel to the patent pool proposal, the WHO launched the **Access to COVID-19 Tools (ACT) Accelerator** - a global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. The ACT-Accelerator is

¹¹ See https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9_36&download=true.

¹² See <https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf>.

¹³ See <https://unitaid.org/news-blog/medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-covid-19-treatments-and-technologies/#en>.

¹⁴ See <https://healthpolicy-watch.news/world-trade-organization-enters-covid-pandemic-fray-with-dispute-brewing-over-patent-rights/>.

structured on four pillars: diagnostics, treatment, vaccines, and health system strengthening. The vaccine procurement pool (COVAX) is the vaccines pillar - CEPI coordinates vaccine “development and manufacturing,” the WHO oversees “policy and allocation” issues, and Gavi, the Vaccine Alliance, is responsible for “procurement and delivery”. Essentially, COVAX is a pool for procurement and equitable distribution of vaccines. By aggregating the demands of different countries and supporting different suppliers, it could reduce the purchase prices and avoid the natural risks of developing and producing vaccines. In their initial stages, many vaccines do not achieve the necessary efficacy and safety requirements in clinical trials and need to be discarded. So, relying on bilateral agreements with one or a few companies can lead to risks of shortages, especially in the case of countries with restricting financial resources (RUTSCHMAN, 2020).

The commitment to obtain established quantities of doses ensures that companies will be safe while making investments for research, development, testing, and production of vaccines. Furthermore, it guarantees that the involved countries will have immediate access to a significant quantity of doses. The organization and operation of COVAX allows that the purchased vaccines will be distributed to countries that have made financial contributions and countries that would receive them as a donation. The financial support to the least developed countries would guarantee a more equitable distribution, as well as the balanced allocation of doses between countries - each country would receive a total of sufficient doses to vaccinate 20% of its population, following specific priority criteria.

To ensure that this arrangement is carried out properly, the WHO initiated fundraising campaigns to finance the donation to less developed countries. There are 92 countries in Africa, Asia, and Latin America - part of an Advance Market Commitment (AMC) - able to receive vaccines as donations or by contributing with significantly lower amounts. According to what was estimated by COVAX, more than 2 billion doses would be obtained by the end of 2021, half of which being destined to the poorest countries. For this production and distribution model to work, the COVAX Advanced Market Commitment is the critical element of the whole architecture, because it is only through this financial mechanism that the poorest countries will get access to COVID-19 vaccines.

Although COVAX initially faced a significant funding gap, it has captured much more interest recently. The European Union and the USA have both announced financial support for COVAX¹⁵.

Advance Purchase Agreements are not always legal tools for vaccine nationalism but can be used by global health organizations to secure vaccines for low-income and middle-income countries as part of an Advance Market Commitment. Global health organizations, most notably Gavi, The Vaccine Alliance, have used donor-funded AMCs to enter into APAs with vaccine manufacturers to supply a guaranteed number of vaccine doses to countries with limited profit-based markets; AMCs were used in this way for childhood pneumococcal vaccines and Ebola vaccines (PHELAN et al., 2020, p. 801).

However, the reality has turned out to be a little different, and the COVAX facility does not seem to work as well. The program faces intense problems, from a lack of funds to guaranteeing access to the vaccine for the poorest countries (US\$ 4.9 billion beyond the US\$ 2.1 billion already collected is needed) to supply risks and complex contractual arrangements, which could make it impossible to achieve its goals¹⁶. The reality seems so complicated that Tedros Adhanom Ghebreyesus stated that COVAX equitable distribution

¹⁵ See <https://www.devex.com/news/eu-finalizes-500m-boost-for-covax-98793>.

¹⁶ See <https://www.reuters.com/article/health-coronavirus-who-vaccines-exclusiv/exclusive-who-vaccine-scheme-risks-failure-leaving-poor-countries-no-covid-shots-until-2024-idUSKBN28Q1LF>.

system would be at "serious risk". According to recently published internal documents, vaccine supply contracts threaten the distribution and access to vaccines, putting COVAX itself at risk. The proliferation of Advance Purchase Agreements between private companies and developed countries has directed a large number of doses already produced, and to be produced, for a small group of countries. Poor dose distribution could give many countries and hundreds of millions of individuals access to vaccines only in late 2024¹⁷.

The Advance Purchase Agreements and the different types of licensing agreements for local production and marketing of vaccines have gathered the attention either because of their potential to meet specific demands, but also because of the risks associated with the proliferation of this kind of vaccination strategy. As Rutschman (2020) explains, some countries use these agreements to reserve a substantial amount of vaccine early on during a vaccine race. They place these orders before vaccines are fully developed, tested, and approved by the regulatory authorities. COVID-19 vaccines are still a scarce commodity, and countries with a greater purchase capacity will secure larger quantities in advance. In the sense that COVAX is not a binding agreement, it is impossible to enforce any kind of commitment to stop countries from purchasing most of the existing doses even in this constrained supply scenario¹⁸.

The vaccine nationalism and the COVAX crisis are widening the access gap, placing serious risks such as prolonging and worsening the pandemic, and severely deepening international inequalities. European Union countries with the United States, Canada, Australia, and Japan, have pre-ordered more than half of all the vaccines (including options to order extra doses). Only Canada has pre-ordered approximately eight doses per capita (MULLARD, 2020), and at least 30 countries purchased more COVID-19 vaccine per capita than the US¹⁹. In late January, the European Union put in place some procedures to control the export of vaccines outside of its territory, with the justification of giving greater transparency to the companies' business strategies and guaranteeing the necessary supply for the local populations²⁰.

Vaccine nationalism has the potential to create what the world sought to avoid through its multilateral resolutions and the creation of COVAX - a scenario of conflicts and economic disputes with profound social and human effects, which will mainly fall on the poorest and most vulnerable countries²¹. According to the data analyzed by The Economist Intelligence Unit (EIU), only 32 countries will be able to reach the level of vaccination needed to guarantee immunization by the end of 2021 – they are almost exclusively in Europe in addition to the USA, Canada, and Israel. Most countries will only have achieved immunization after 2023. According to the report, the only middle-income country that will keep up to the developed countries pattern will be Russia, because of the local production of the Sputnik V vaccine²². Most middle-income countries and all low-income countries will depend on COVAX to have any access to vaccines. However, it's been a struggle to distribute COVAX supplies, as delays in the production for and delivery to richer countries push back delivery dates for poorer nations.

¹⁷ See <https://www.reuters.com/article/health-coronavirus-who-vaccines-exclusiv/exclusive-who-vaccine-scheme-risks-failure-leaving-poor-countries-no-covid-shots-until-2024-idUSKBN28Q1LF>.

¹⁸ See <https://blogs.lse.ac.uk/globalhealth/2020/12/14/12-days-of-global-health-power-and-the-reproduction-of-global-inequalities>.

¹⁹ See <https://www.bloomberg.com/news/articles/2020-12-09/which-countries-have-reserved-the-most-covid-19-vaccines-u-s-is-32nd-on-list>.

²⁰ See https://ec.europa.eu/commission/presscorner/detail/en/ip_21_307.

²¹ One modeling study provides data that, if high-income countries exclusively acquire the first 2 billion doses without regard for vaccine equity, the number of COVID-19 deaths could double (KIM, MARKS, and CLEMENS, 2021).

²² See <https://www.economist.com/graphic-detail/2021/01/28/vaccine-nationalism-means-that-poor-countries-will-be-left-behind>.

In February, COVAX released a schedule for the first delivery of vaccines for its participants - until now there are only two vaccine options available, the Pfizer-BioNTech vaccine and the AstraZeneca/Oxford vaccine - and the numbers are not so exciting. For instance, Brazil is about to receive near 10 million of the two doses pack of AstraZeneca/Oxford vaccine, which means no more than 5% of its population²³. Even Brazil, which was a "privileged stage" for the testing of the main vaccines is facing severe restrictions on access to active pharmaceutical ingredients and doses of vaccines.

²³ See <https://www.gavi.org/sites/default/files/covid/covax/COVAX-Interim-Distribution-Forecast.pdf>.

INTELLECTUAL PROPERTY RIGHTS: A BARRIER TO CONTAIN THE PANDEMIC

Despite some moments of optimism during the COVID-19 outbreak, the scenario of the beginning of vaccination is one of apprehension. The intensification of vaccine nationalism threatens the functioning of the COVAX facility, creating a risk of deepening global inequalities and lengthening the pandemic. The concentration of the production of pharmaceutical inputs and vaccines in few countries, coupled with the fact that the developed pharmaceutical technologies are proprietary, lead to the conclusion that urgent measures need to be taken - among them, the overcoming of the obstacle to allow scaling up vaccine production and availability.

As mentioned, the R&D model for the development of pharmaceutical products is based essentially on the enforcement of intellectual property rights by large multinational companies. This market-based logic defines the allocation of resources for R&D and the definition of therapeutic priorities according to their profitability, creating barriers for the prioritization of socially relevant diseases. To illustrate, after 17 years of the SARS outbreak and 8 years after the MERS crisis, there is still no vaccine for both - there is a lack of private interest in the development and/or undertaking of clinical tests to guarantee its commercialization²⁴. The speedy and violent spread of the COVID-19 pandemic has ensured the success of vaccine development. However, nothing guarantees the fast diffusion of the solutions to this serious public health crisis.

As noted, on October 2, 2020, the governments of South Africa and India presented to the TRIPS Council²⁵ a proposal for a waiver *from the implementation, application, and enforcement* of the intellectual property rights of products and their underlying technologies for prevention, containment, or treatment of COVID-19, until *widespread vaccination is in place globally, and the majority of the world population has developed an immunity*. The waiver would encompass Sections 1 (copyright and related rights), 4 (industrial design), 5 (patents), and 7 (protection of undisclosed information) of Part II of the TRIPS Agreement. Accordingly, the waiver proposal would cover all medical products, including diagnostics, therapeutics, vaccines, and medical equipment required for preventing the spread of coronavirus, which are protected by several types of intellectual property.

The reality has shown that the option for voluntary licensing is not efficient or sufficient. The COVID-19 Technology Access Pool (C-TAP) failed because there was no support from countries and companies with technological capacity. Despite the initial success of COVAX in building an immunization access mechanism, it faces severe limitations and shortcomings. In addition to the financial crisis and supply barriers, a purchasing pool mechanism does not allow the development of stable production strategies, as there is no dissemination and transfer of technology that allow long-term technical collaboration and the construction of local productive capacities in developing economies.

Building local production capacity is the final and main objective of the Indian and South African proposal, as explained by its proponents - "we are not seeking a donation and we are not confident about the market-based instruments such as COVAX ... the developing countries want to create manufacturing and industrial capacities to ensure that we are in a

²⁴ The Ebola case is also emblematic. In 2009, there were at least seven Ebola vaccines with promising results when tested on monkeys. However, only one of these seven candidates was tested on humans but was also abandoned later and none of the vaccines reached the licensing and deployment stage before the recent epidemics in West Africa. Just one decade later, in 2019, an Ebola vaccine was approved (NAMBOODIRI, 2020).

²⁵ Using the provisions of Article IX of the Marrakesh Agreement.

position to fight the current COVID-19 as well as future pandemics²⁶. The case of Russia and China, which developed their vaccines and have already started a national immunization policy, explain the importance of strengthening the domestic capacity to produce inputs, medicines, and vaccines. The same is true for India.

As expected, the waiver proposal faced resistance from the United States, the European Union, and Japan - those who traditionally irreducibly defend the protection of their companies' intellectual property rights (Brazil also associated to this position). According to these countries, intellectual property would be fundamental for innovation and the development of technologies for the COVID-19 treatment; and not a barrier to production and access.

The World Trade Organization (WTO) Secretariat itself also argued that the current intellectual property system can be an enabling factor in facilitating access to existing technologies, as well as supporting the creation of new ones: "the way in which the intellectual property system is designed - and how effectively it is put to work - can be a significant factor in facilitating access to existing technologies and in supporting the creation, manufacturing, and dissemination of new Technologies"²⁷.

In general, developed countries and the WTO assume market mechanisms, voluntary collaboration and licensing arrangements – which are showing low efficacy and helping to widen global inequalities - as the most appropriate instruments when compared to any intellectual property rights flexibilities. Another argument against the waiver is that TRIPS would already have sufficient flexibility to guarantee access to technologies in the event of health emergencies. In general, it can be said that TRIPS allows some flexibilities for public health purposes, which would include the implementation of rigorous patentability requirements, the use of exceptions and limitations for research and security exceptions, not accepting secondary patents, and the grant of compulsory licenses or government use authorizations.

However, the issue of compulsory licenses faces different restrictions. The negotiation is complex, costly, and often inefficient because a) it needs a previous negotiation with the patent holder as pre-condition and for the establishment of adequate remuneration; b) they are case-by-case and product-by-product; c) a compulsory license applies only to technologies already patented and not those in the pipeline; d) the technical and institutional inability of many countries to deal with compulsory license, especially when it comes to forms of protection other than patents; e) they mainly serve to supply the domestic market and the case of issuing licenses to supply countries without productive capacity is even more complex and costly²⁸.

The issuance of compulsory licenses in the event of a health emergency such as the COVID-19 pandemic severely limits the possibility of technical coordination between companies aiming at increasing the supply of vaccines. In practice, the use of a compulsory license in this particular context would be ineffective – what makes the waiver proposal more appropriate than uncoordinated and individual actions²⁹. A broad waiver would allow "uninterrupted collaboration in the development and scale-up of production and supply of

²⁶ Third World Network, "Proposal for TRIPS waiver secures strong support from South", TWN Info Service on WTO and Trade Issues (Oct20/20). Published in SUNS #9214 dated 20 October 2020.

²⁷ See https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf.

²⁸ Article 31bis, which allows support to countries without domestic production capacity, was rarely used in times of normality due to the complexity of its operation. In a crisis like the COVID-19 pandemic, this option is even more difficult.

²⁹ Some countries have taken isolated actions to facilitate the issuance of compulsory licenses to have access to treatments, vaccines, and other existing and future technologies. However, the changes in the laws of Canada, Germany and France do not seem to have significant repercussions.

health products and technologies and collectively addresses the global challenge facing all countries". The scale-up of vaccines and other biologics require more than the use of patents alone. It involves the transfer of technology, data, know-how, and cell-lines.

THE ROLE OF SOUTH-SOUTH COOPERATION IN ENSURING ACCESS TO COVID-19 RELATED TECHNOLOGIES

Over the past few decades, developing countries have cooperated to advance their demands related to intellectual property as reflected in i) the 2001 Doha Declaration on TRIPS and Public Health and the subsequent amendment to the TRIPS³⁰; ii) the approval of the World Intellectual Property Organization (WIPO) Development Agenda³¹; iii) the adoption of some global IP rules that strengthen *IP flexibilities for development* proposes in areas such as food security and biodiversity, access to knowledge; iv) cooperation and diffusion of policy reforms and legislations aimed at making use of existing TRIPS flexibilities.

These types of initiatives were based on diverse strategies that include: a) strengthening cooperation with key partners and the use of permanent cross-issue alliances such as BRICS (Brazil, Russia, India, China and South Africa), IBSA (India, Brazil and South Africa) or the Group of 77 (G77)³² for building clear understandings on the global intellectual property regulation to support particular political propositions – and also to avoid the progress of positions contrary to their interests in multilateral forums; b) building multisector coalitions for specific intellectual property negotiations aimed at advancing specific demands and reforming international regulations. The approval of the Doha Declaration and Public Health in 2001 and the waiver of article 31 are certainly the most relevant case of coordinated action by developing countries and various civil society organizations to guarantee the access to medicines; c) the use of different forums to foster technical cooperation and the diffusion of policies and institutions that promote national intellectual property systems best suited to the national interests of those countries, and also that allows the transfer of knowledge and technologies to deal with sensitive economic and social issues.

Therefore, these kinds of initiatives can be understood as part of a broad agenda built for maintaining and deepening the remaining flexibilities in the intellectual property regime. Intellectual property flexibilities allow countries to adapt their national intellectual property systems to specific demands, and to implement key public policies for social and economic development. Maintaining the policy space needed to adapt national intellectual property laws to national interests requires a degree of autonomy, and the ability to use TRIPS flexibilities. Strengthening South-South collaboration is an important strategy for building an intellectual property system more closely aligned to developing countries' long-term developmental needs and interests, but also more responsive in emergencies such as the COVID-19 pandemic (MENEZES, 2018).

As mentioned, one of the main challenges to deal with the COVID-19 pandemic is to increase the supply of vaccine production to ensure their universalization. Therefore, it is necessary to expand the production capacity of pharmaceutical active ingredients and high-quality vaccines. The pace of production of only a few vaccine options and only in a few productive plants, together with the concentration of purchases by a small group of developed countries, will have profound social and human consequences due to the massive inequality in access. The increase in the production scale will require greater integration and productive diversification. Thus, flexibilization of the intellectual property of technologies needed for the production of COVID-19 vaccines is crucial. In this sense, the success of the proposal presented by South Africa and India will demand the support of a wide range of countries that are part of the TRIPS Council and political actors outside the institution, such as other international organizations and other critical international actors.

³⁰ See https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

³¹ See <https://www.wipo.int/ip-development/en/agenda/>.

³² See <https://undocs.org/en/A/74/803> and <https://www.g77.org/statement/getstatement.php?id=201215>.

Kenya and Eswatini immediately subscribed to the proposal, and later seven other countries signed on as co-sponsors. In the TRIPS Council Meeting held on October 16, 13 other Member States, including Indian neighbors Bangladesh, Nepal, Pakistan, and Sri Lanka, fully supported the proposal, while 14 others, including China and Nigeria, gave qualified support, and approximately 50 countries formally supported the proposal³³. In a document presented to the international community, 380 civil society organizations called on WTO to adopt the proposal, including critical international groups like Médecins Sans Frontières, Oxfam, Knowledge Ecology International, People's Health Movement, Friends of the Earth International; Health Action International, Institute for Agriculture and Trade Policy, International Trade Union Confederation, LDC Watch, Public Services International, Social Watch, Society for International Development, Transnational Institute and Third World Network, as well as dozens of regional and national groups from Europe, Latin America, and Africa.

However, developed countries intend to maintain 'business as usual', upholding the intellectual property rights of their industries for all COVID-19 technologies. This proprietary strategy prevents the diversification of production and especially the possibility of expanding the offer of vaccines. While thousands of people die daily and the cooperation mechanisms to provide access fail, the profitability of the pharmaceutical industry increases.

³³ Argentina, Bangladesh, Egypt, Honduras, Indonesia, Mali, Mauritius, Mozambique, Nepal, Nicaragua, Pakistan, Sri Lanka, Tunisia and Venezuela supported the proposal. Other countries such as Chad (Least Developed Countries Group), Chile, China, Colombia, Costa Rica, Ecuador, El Salvador, Jamaica (Africa, Caribbean and Pacific Countries Group), Nigeria, the Philippines, Senegal, Tanzania (African Group), Thailand, and Turkey welcomed the proposal.

FINAL REMARKS

At a meeting held on January 19, 2021, the representative of the Indian government warned that the country would not be able to ensure vaccine doses to the world in the necessary quantity and speed and that the main barrier would be the production limitations. While there are a large number of facilities capable of manufacturing safe and effective inputs and vaccines in different parts of the world, it becomes not feasible due to restrictive contractual terms and barriers created by intellectual property rights. Voluntary licensing agreements are insufficient to meet demand and are still limited by terms of secrecy and insufficient³⁴ production conditions. This, together with the nationalist approach and individualist behavior demonstrated by developed countries, which strive to anticipate the purchase of large volumes of doses, only widens the global inequalities in access to vaccines.

The outbreak of (re)emerging infectious diseases exposes national vulnerabilities (health care and surveillance systems; social and economic inequalities) and international vulnerabilities (constraints of multilateralism and global health security), highlighting the urgent need to rethink the global R&D system for the development of drugs and other health technologies - and to create ways for the dissemination of knowledge and socially relevant technologies. Therefore, there is a need to establish an R&D system that is responsive to health demands and priorities; reconstructing the elements that define the allocation of resources and the sustainability of financing, disseminating, and securing access for vulnerable countries and populations.

The effects of the COVID-19 pandemic on the world; on the international political economy - global patterns of production and consumption; on international cooperation and its institutions; and on mankind's relationship with nature, are still uncertain. However, some convictions are that public health systems must be strengthened and their centrality in any development trajectory must be emphasized; policies to stimulate local production of pharmaceutical products must be rethought and resumed, especially in developing countries; and that South-South cooperation must be strengthened. Boosting local production of medicines and vaccines for COVID-19 is also urgently required in developing countries (SYAM, 2020a) - South-South cooperation may also play an important role in increasing the contribution of developing countries to the global production of pharmaceuticals.

³⁴ See <https://noticias.uol.com.br/colunas/jamil-chade/2021/01/19/india-falta-de-vacina-e-culpa-de-impasse-criado-por-brasil-e-paises-ricos.htm>.

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International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
<http://www.southcentre.int>

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