

Expanding the production of COVID-19 vaccines to reach developing countries

Lift the barriers to fight the pandemic in the Global South*

By Carlos M. Correa**

The United Nations (UN) Secretary-General and several head of States made at the beginning of the pandemic a call to consider COVID-19 products global public goods, so as to ensure an equitable distribution around the world. But it is widely known today that developing countries have only received a minor part of the available vaccines. Procurement of the various COVID-19 vaccines has been left to the supply and demand rules in the context of fierce competition among governments to be served first. Two-thirds or more of the available doses have been pre-purchased or otherwise secured by developed countries. While some of such countries have purchased vaccines that exceed several times their real needs, many developing countries have received none or a very limited number of doses. This has led to what has been rightly characterized as a catastrophic moral failure.¹

Despite the good intention of the World Health Organization (WHO) and of the COVID-19 Vaccines Global Access (COVAX) mechanism - a coalition set up by the WHO, the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi, the Vaccine Alliance - to ensure equitable access to COVID-19 vaccines of low-

and middle-income countries (LMICs), not even the population at risk in those countries has received the required number of doses. It is clear that the COVAX facility has not lived up to the expectations that it generated. The objective of an early vaccination of at least 20% of the population (including health workers and persons at risk) has manifestly been missed. A basic reason for this situation is the shortage in the supply of vaccines and the lack of a true spirit of solidarity to equally share whatever doses are available and the technologies to produce them. All this despite solemn declarations about international cooperation and solidarity.² UN declarations about COVID-19 vaccines have avoided any reference to the vaccines and other needed products as 'global public goods'. They rather refer to 'immunization' as such a public good, that is, the outcome expected from vaccination but not the tools that would allow to achieve it.

While some companies, notably Astra Zeneca, have entered into some manufacturing contracts,³ the number of subcontractors is limited, they are concentrated in developed countries (with some important exceptions such as the Serum Institute in India) and the contractual provisions impose a number of limitations on what the subcon-

Abstract

The unfolding of COVID-19 has shown that the international system has been unable to ensure equal access to the vaccines and other products necessary to fight the pandemic. While the need for a strong response remains obvious, proposals for scaling up the production of COVID-19 vaccines across the globe are still blocked in the World Trade Organization.

Le déroulement du COVID-19 a montré que le système international n'a pas été en mesure de garantir l'égalité d'accès aux vaccins et autres produits nécessaires pour lutter contre la pandémie. Alors que la nécessité d'une réponse forte reste évidente, les propositions visant à augmenter la production de vaccins COVID-19 dans le monde entier sont toujours bloquées à l'Organisation Mondiale du Commerce.

El desarrollo del COVID-19 ha demostrado que el sistema internacional ha sido incapaz de garantizar la igualdad de acceso a las vacunas y otros productos necesarios para luchar contra la pandemia. Aunque la necesidad de una respuesta contundente sigue siendo evidente, las propuestas para aumentar la producción de vacunas contra el COVID-19 en todo el mundo siguen bloqueadas en la Organización Mundial del Comercio.

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tractors can do. Notably, such contracts do not constitute conventional licensing agreements under which a licensee can decide how and when to manufacture and distribute the licensed products. The subcontractors rather undertake different steps of the manufacturing process for the technology owner who keeps control over the produced vaccines.

Upon an initiative of the President of Costa Rica, a COVID-19 Technology Access Pool (C-TAP) was established under the auspices of the WHO to compile, in one place, pledges of commitment made to voluntarily share technologies needed to address the pandemic. After one year of this initiative, the holders of vaccine technologies, however, have not responded to this call. WHO, the United Nations Development Programme (UNDP) and the United Nations Conference on Trade and Development (UNCTAD) also set up the 'Tech Access Partnership' (TAP) to support "developing countries to scale up local production of critical health technologies needed to combat COVID-19, including personal protective equipment, diagnostics and medical devices such as ventilators".⁴

In order to expand the capacity of LMICs to produce COVID-19 vaccines and scale up the manufacturing output, WHO will facilitate "the establishment of one (or more, as appropriate) technology transfer hub(s) that will use a hub and spoke model to transfer a comprehensive technology package and provide appropriate training to interested manufacturers in LMICs".⁵ This initiative has initially prioritized the mRNA-vaccine technology and has made a call for expressions of interest. To date, the lead mRNA vaccine manufacturers - i.e. BioNTech-Pfizer, Moderna - have not shown interest in joining the hub. Its establishment seems to signal the abandonment of the idea that a pool is feasible and rather represents a shift towards a bilateral model of collaboration facilitated by an intermediary. Will this model overcome the pharmaceutical companies' reluctance to transfer technology? There are no reasons to think that they would change their current strategy of keeping it under their control. Some companies - Incepta from Bangladesh, Biolyse from Canada, Getz Pharma from Pakistan, Teva from Israel - have reported that current vaccine producers have dismissed or not even responded to requests to obtain licenses for production. In this scenario, South-South Cooperation can play an important role in supporting the creation or strengthening of manufacturing capacity in developing countries as many countries in the South have manufacturing plants⁶ and the technical and scientific capacity required for vaccines' production (at least of those based on attenuated virus strains or inactivation of infectious virus).

The failure of the multilateral efforts to widen the dissemination of pandemic-related technologies was already evident at the end of 2020 given, in particular, the explicit rejection by pharmaceutical companies of contributing to C-TAP. In October 2020, South Africa

and India submitted to the Council for the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) 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 adoption of waivers is provided for in the Marrakesh Agreement Establishing the WTO (article IX). Waivers have been used to address a diversity of circumstances, including the production and exportation under compulsory licenses of pharmaceutical products to countries with no or insufficient manufacturing capacity.⁷ The proposed waiver would cover the sections of the TRIPS Agreement relating to copyright and related rights, industrial designs, patents and undisclosed information of Part II of the Agreement. If approved, the waiver would allow not to enforce such rights in relation not only to vaccines (in whose production patents and undisclosed information, for instance, are important) but other products such as diagnostics, equipment and medicines. The waiver will provide WTO Members the legal certainty to not be subject to complaints⁸ under the WTO rules by other Members (eventually leading to trade retaliations) if measures exist or are adopted at the national level that immunize manufacturers against infringement for the use of technologies that may be subject to intellectual property rights, or the importation of protected products (if parallel imports based on the principle of exhaustion of rights⁹ are not permitted). One example of such measures is the Public Readiness & Emergency Preparedness "PREP" Act which has been interpreted as providing immunity from liability under the United States federal and state law from intellectual property violations in the context of the COVID-19 emergency.¹⁰

The adoption of the waiver is sponsored by 59 and backed by more than 100 countries, more than 300 civil society organizations, the World Health Organization, Unitaid, South Centre and other international organizations,¹¹ lawmakers in various countries (including the USA), many academics and political leaders.¹² Despite this large support, it is objected to by a number of WTO Members on the basis of four main arguments: there is no evidence that intellectual property is relevant to COVID-19 products; other measures, such as compulsory licenses, are already available under the TRIPS Agreement and could be used; innovation will be discouraged if the waiver is adopted; allowing access to intellectual property will not be sufficient as the transfer of know-how, data, etc. will be needed to initiate production.

On the first argument, it is worth noting how intellectual property, particularly patents, relates to the production and commercialization of COVID-19 vaccines. A study by the World Intellectual Property Organization (WIPO) found - already in 2012 - 11,800 patent families for different components of vaccines to prevent some

infectious diseases.¹³ 113 patent families relating to the mRNA technology used by several COVID-19 vaccines producers were identified in 2020; many of these patents have been applied for through the Patent Cooperation Treaty with numerous States included, which means that these will enter to national phase processing in many developing countries.¹⁴ Moderna, Inc., the producer of one mRNA based vaccine for COVID-19, is reported to hold “over 270 issued or allowed U.S. and foreign patents protecting mRNA-based technology, with over 600 worldwide pending patent applications. The company has identified at least seven granted U.S. patents that it alleges protect its COVID-19 mRNA-1273 vaccine”.¹⁵ Although Moderna has pledged not to enforce its patents “while the pandemic continues”, it is unclear when it will consider that the pandemic is over.¹⁶ The company has been involved in litigation over three patents held by Arbutus Biopharma.¹⁷ Pfizer and its partner BioNTech have been sued by Allele Biotechnology and Pharmaceuticals, Inc. over the alleged infringement of a patent on a monomeric fluorescent protein used in assays of their COVID-19 vaccine.¹⁸ The US National Institute of Health has obtained a patent over a stabilized coronavirus spike protein that may impact the production and sale of at least 5 COVID-19 vaccines, including Moderna’s mRNA vaccine.¹⁹ The US patent office also granted a researcher at Tel Aviv University a patent for technology that could accelerate the development of a vaccine for COVID-19.²⁰

The second argument - the possible use of compulsory licenses, one of the important TRIPS flexibilities - ignores that issuing compulsory licenses takes time particularly if a previous negotiation with the patent holder is needed under the applicable law. In addition, it is often difficult to identify all the patents or other intellectual property rights covering a product or process, and patent applications are not published for 18 months after their filing. The waiver proposal provides a more functional and appropriate approach than individual and uncoordinated actions based on individual compulsory licenses. A waiver would allow “uninterrupted collaboration in the development and scale-up of production and supply of health products and technologies and collectively addresses the global challenge facing all countries”.²¹ In effect, compulsory licenses can only be granted case-by-case and product-by-product and the manufacture of a vaccine encompasses a large number of components. Importantly, a compulsory license applies only to already granted patents and not to pending applications and, unless article 31bis of the TRIPS Agreement (as incorporated in 2017) is applied with its cumbersome requirements,²² a compulsory license can only be issued to predominantly supply the domestic market.²³ Further, in some jurisdictions the decision to grant a compulsory license may be appealed and its implementation suspended until a final decision is made. Finally, given the territorial character of patents, there would be a need to sim-

ultaneously obtain compulsory licenses in several jurisdictions in order to put in place an efficient supply chain.

The third argument - negative impact on innovation - is particularly weak in the context of the COVID-19 emergency as there is no market failure that inhibits return from innovation, the basic economic justification for the grant of intellectual property rights. The demand is huge - as the vaccines need to reach at least all the world adult population - and governments as well as COVAX are competing against each other to secure the supply of vaccines. In addition, the Western companies now supplying vaccines have received massive subsidies from governments. Thus, Moderna received nearly 1 US\$ billion of taxpayers’ money to develop and produce the COVID-19 vaccine,²⁴ Pfizer/BioNTech received US\$ 445 million from the German government.²⁵ Overall, the COVID-19 producers may have received around £6.5bn from governments while not-for-profit organizations have provided nearly £1.5bn.²⁶ Public financing also reduced the risk of failure, as exemplified by the failed Merck/IAVI vaccine backed by the US Biomedical Advanced Research and Development Authority (BARDA).²⁷

The fourth argument alludes to the need to obtain know-how, data, etc. to initiate the production of vaccines. This is correct, but access to these inputs may be impeded or limited rather than facilitated by the enforcement of intellectual property rights. In addition, there are many manufacturers in developed and developing countries²⁸ that may produce COVID-19 vaccines, in some cases by repurposing plants used for the production of other biologicals. Access to know-how and data would allow them to move fast, but acquiring the needed skills would not be otherwise impossible if scientific and industrial support is available for the different phases of manufacturing (active ingredient, formulation, fill and finish).

Much is needed to be done to achieve a stage in which vaccines and other products to face a pandemic are truly treated as global public goods. This will require a reform of the current research and development (R&D) model essentially based now on the appropriation through intellectual property rights of the outcomes of innovation. From a long-term perspective, such a paradigmatic change will also ask for a reinterpretation or revision of the TRIPS Agreement in order to allow, for instance, for a broader exception to patent rights for the export of pharmaceutical products.

The adoption of the proposed TRIPS waiver alone will not achieve that objective but would represent a step forward to respond to the current health and economic crisis. Another option for WTO members is to invoke the national security exception provided for in the TRIPS Agreement (article 73).²⁹ In accordance with this exception, the obligations under the TRIPS Agreement can be suspended in case of an international emergency.³⁰ If the WTO is, however, unable to mitigate the impact of intellectual property rights in times of a pandemic, the demands for a more profound reform of the international intellectual property regime will be inevitable.

Endnotes:

¹ Lukas Oberndorfer and Oliver Prausmüller, “Am Rande eines ‘katastrophalen moralischen Versagens’”, *Makroskop*, No. 13/2021 (April 14, 2021). Available from <https://makroskop.eu/13-2021/am-rande-eines-katastrophalen-moralischen-versagens/>.

² See, e.g., Nirmalya Syam, “The UN General Assembly Resolutions on COVID-19: Solemn Assurances for Access to Health Technologies without an Action Plan”, Policy Brief, No. 81 (Geneva, South Centre, July 2020). Available from <https://www.southcentre.int/wp-content/uploads/2020/07/PB-81.pdf>.

³ See “COVID-19 Vaccine Purchasing & Manufacturing Arrangements”, last updated on April 16, 2021, available at <https://www.knowledgeportalia.org/covid19-vaccine-arrangements>.

⁴ See <https://techaccesspartnership.org/>.

⁵ WHO, “Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing”, April 16, 2021. Available from <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>.

⁶ In accordance with the Developing Countries Vaccine Manufacturers Network (<https://www.dcvmn.org/-/Vaccines->), there are 40 of such plants in 13 developing countries. This is not, however, an exhaustive mapping.

⁷ See, e.g., WTO, “TRIPS: Special Compulsory Licences for Export of Medicines, Guide to Notifications”, available at https://www.wto.org/english/tratop_e/trips_e/guidenotifications_e.pdf.

⁸ Gilead, for instance, challenged a compulsory license for Remdesivir before the Russian Supreme Court (see <https://makemedicinesaffordable.org/gilead-sues-russia-private-company-challenges-a-countrys-right-to-protect-public-health/>).

⁹ See article 6 of the TRIPS Agreement.

¹⁰ See Blankrome, “Special Exemptions from Product and Patent Liability for COVID-19 Countermeasures. Product Liability and Intellectual Property”, March 26, 2020 available at <https://www.blankrome.com/publications/special-exemptions-product-and-patent-liability-covid-19-countermeasures>.

¹¹ See, e.g., Amnesty International International Secretariat, “Briefing for WTO Member States on the TRIPS Waiver Proposal for the Prevention, Containment and Treatment of COVID-19”, November 2020, available at <https://www.amnesty.org/download/Documents/IOR4033652020ENGLISH.PDF>.

¹² See, e.g., People's Vaccine Alliance, “Open Letter: Former Heads of State and Nobel Laureates Call on President Biden To Waive Intellectual Property Rules for COVID Vaccines”, April 14, 2021, available at <https://peoplesvaccinealliance.medium.com/open-letter-former-heads-of-state-and-nobel-laureates-call-on-president-biden-to-waive-e0589edd5704>.

¹³ WIPO, *Patent Landscape Report on Vaccines for Selected Infectious Diseases* (2012). Available from <https://www.wipo.int/publications/en/details.jsp?id=264&plang=EN>.

¹⁴ See Cecilia Martin and Drew Lowery, “mRNA vaccines: intellectual property landscape”, *Nature Reviews Drug Discovery* 19, 578 (2020).

¹⁵ Daniel Shores, Dylan Haversack and Andrew J. Storaska, “The mRNA IP and Competitive Landscape Through One Year of the COVID-19 Pandemic – Part I”, IP Watchdog, April 11, 2021. Available from <https://www.ipwatchdog.com/2021/04/11/mrna-ip-competitive-landscape-one-year-covid-19-pandemic-part/id=132130/>.

¹⁶ See Raisa Santos and Elaine Ruth Fletcher, “Moderna Makes Milestone Pledge To ‘Not Enforce Our Patents’ On COVID-19 Vaccine Technologies During Pandemic & Issue Open Licenses Afterward”, Health Policy Watch, October 8, 2020, available at <https://healthpolicy-watch.news/77521-2/>.

¹⁷ Jan Wolfe, “Moderna loses challenge to Arbutus patent on vaccine technology”, Reuters, July 23, 2020. Available from <https://www.reuters.com/article/us-moderna-patent-idUSKCN24O2XY>.

¹⁸ Business Wire, “Allele Biotechnology and Pharmaceuticals Files Two Lawsuits for Patent Infringement for the Unauthorized Use of mNeonGreen in Development and Testing of COVID Vaccines and Therapeutics”, October 5, 2020. Available from <https://www.businesswire.com/news/home/20201005005984/en/Allele-Biotechnology-and-Pharmaceuticals-Files-Two-Lawsuits-for-Patent-Infringement-for-the-Unauthorized-Use-of-mNeonGreen-in-Development-and-Testing-of-COVID-Vaccines-and-Therapeutics>.

¹⁹ Christopher J. Morten, J.D., Laurel Boman, Joe Rabinovitsj and Celine Rohr, “U.S. 10,960,070: The U.S. Government Important New Coronavirus Vaccine Patent”, Technology Law & Policy Clinic, New York University School of Law, April 14, 2021; see also Selam Gebrekidan and Matt Apuzzo, “Rich Countries Signed Away a Chance to Vaccinate the World”, The New York Times, March 21, 2021. Available from <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html>.

²⁰ See Toi Staff, “US grants Israeli prof a patent for tech that could lead to virus vaccine”, The Times of Israel, April 20, 2020, available at <https://www.timesofisrael.com/us-grants-israeli-prof-patent-for-tech-that-could-see-virus-vaccine-in-months/>.

²¹ See WTO document, IP/C/W/672, “Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 - Responses to Questions, Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe”, available at https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=270209,270165,270173,270168,269875,269476,269346,269188,268935,268754&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=False&HasSpanishRecord=False.

²² See Carlos Correa, “Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?”, in *Routledge Handbook on the Politics of Global Health*, Richard Parker and Jonathan García, eds. (Routledge, 2019).

²³ Henrique Zeferino de Menezes, *The TRIPS waiver proposal: an urgent measure to expand access to the COVID-19 vaccines*, Research Paper, No. 129 (Geneva, South Centre, March 2021). Available from <https://www.southcentre.int/wp-content/uploads/2021/03/RP-129.pdf>.

²⁴ See Eric Sagonowsky, “After nearly \$1B in research funding, Moderna takes \$1.5B coronavirus vaccine order from U.S.”, August 12, 2020, available at <https://www.fiercepharma.com/pharma/after-nearly-1b-research-funding-moderna-takes-1-5b-coronavirus-vaccine-order-from-u-s>.

²⁵ See “BioNTech wins \$445 million German grant for COVID-19 vaccine”, Reuters, September 15, 2020, available at <https://www.reuters.com/article/health-coronavirus-germany-vaccine-idUSKBN2661KP>.

²⁶ See Lucy Hooker and Daniele Palumbo, “Covid vaccines: Will drug companies make bumper profits?”, BBC, December 18, 2020, available at <https://www.bbc.com/news/business-55170756>.

²⁷ U.S. Department of Health & Human Services, “BARDA partners with Merck and IAVI to accelerate development of a vaccine to prevent COVID-19”. Available from <https://www.medicalcountermeasures.gov/newsroom/2020/merck-iavi/>.

²⁸ See CEPI, “CEPI Survey Assesses Potential COVID-19 Vaccine Manufacturing Capacity”, August 5, 2020, available at https://cepi.net/news_cepi/cepi-survey-assesses-potential-covid-19-vaccine-manufacturing-capacity/.

²⁹ See South Centre, “COVID-19 Pandemic: Access to Prevention and Treatment is a Matter of National and International Security”, available at <https://www.southcentre.int/covid-19-open-letter/>.


³⁰ See Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, Research Paper, No. 116 (Geneva, South Centre, August 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/08/RP-116-reduced_1.pdf.



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