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COVID-19 Vaccines as Global Common Goods: An Integrated Approach of Ethical, Economic Policy and Intellectual Property Management

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Abstract: The article deals with the current debate about COVID-19 Vaccines as global public/common goods. After a brief introduction on the global epidemiological and economic implication of the pandemic, the problem of the correct characterization of either vaccine or immunization/herd immunity as global public/common good, according to the necessary characteristics outlined by the pertinent economic theories, is addressed. The conclusion is that the term "global public good"/global common goods" has been extensively used in the last two years by policy makers, political leaders, academics, economists, international organizations, NGOs and others health groups, in a sort of "loose way". Substantially, in order to underscore that equitable access to health products, including vaccines, health and biomedical technologies, medical services, medical devises, whose availability, accessibility, acceptability, affordability to the world is fundamental to tackling the pandemic. The current legal proprietary regime applied to vaccines, extensively covered by IPRs, has transformed an intrinsically non-excludable common/public good (the vaccines, due to their nature and characteristics) in something excludable and rival in consumption. Consequently, the article argues that what is needed is a swift in their legal governance. The current legal discipline of vaccines and health technologies must be changed to bring it into line with the non-excludable nature of these goods. The richest countries in the world, in pursuit of their "vaccine nationalisms", have already collectively preordered 8.8 billion doses of vaccine, far in excess of need, thus obliging billions of people in the Global South to wait years to be vaccinated. In this respect, the article investigates the EU vaccines strategy and analyzes the Advanced Purchase Agreements signed by the European Commission with the major vaccine producers, enlightening the untenable secrecy and opacity with which the European Union's executive has handled

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COVID-19 vaccine supply contracts, and how it has simply paid no more than lip-service to the concept of global common/public good by attributing a broad "private governance" to the pharmaceutical companies. Then, the various arguments, for and against, the Waiver Proposal to several sections of the WTO TRIPS agreement, introduced by India and South Africa on the TRIPS Council on October 2020, have been briefly summarized, accounting the current luck of needed consensus among the various members of the WTO. The article however describes an important number of new global and collaborative efforts already put in place by a myriad public and private actors to allow efficient development and production of vaccines in order to enhance a global access to vaccines. The article concludes by stressing the major developments in the U.S. patent's landscape and in the Biden Administration's attitude towards the current global health crisis, that leave hope for "extraordinary measures" to be agreed by the international community in near future. The auspice is that the time has finally arrived for the international community to develop reliable and long term solutions to tackle future global pandemic, preferably by the negotiation of a new WHO global health treaty, to secure universal fair access to essential technologies and vaccines and protecting them as global public/common goods.

Keywords: COVID-19, vaccines, health care products, global common goods, economic crisis and costs of the pandemic, inequalities, intellectual property rights, management of the commons, cooperation and solidarity

1 Introductory Remarks: Coronavirus is Here to Stay; Global Epidemiological and Economic Implications

Virus and diseases are given different names (like the HIV, the virus that causes AIDS). COVID-19 is the *official* name announced on 11 February 2020 by WHO, in the International Classification of Diseases (ICD), for a new coronavirus *disease* caused by a responsible *virus*, named by virologists within the International Committee on Taxonomy of Viruses (ICTV) as "the severe acute respiratory syndrome coronavirus 2" or SARS-CoV-2.[1] For simplicity, we will refer to it in this article as COVID-19. This is the highly infectious, and highly contagious in humans, *respiratory disease* caused by the newly discovered *successor* to

1 WHO. "Naming The Coronavirus Disease (COVID-19) And The Virus That Causes It". https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it.

SARS-CoV-1, the virus that caused 2002–2004 SARS outbreak, which heavily affected Asia specifically. The reason for this delineation is two-fold. First, COVID-19 is the name already colloquially known for the virus, and second, the term COVID-19 effectively distinguishes the new virus from the coronavirus responsible for the previous SARS epidemic which happily did not spread widely from the temperate climate places where it generated, and was thought to be highly pathogenic.

The first known infections from COVID-19 were discovered in Wuhan, China, in November 2019, although the original source of the viral transmission to humans remains unclear. Because many of those early infected were workers at the Huanan Seafood Market it has been suggested that the virus might have originated from the market, coming either from bats directly or indirectly through any number of intermediate hosts. It is also possible that visitors may have introduced the virus to the market, which then facilitated rapid expansion of the infection.[2] The virus, in fact, primarily spreads between people through close contact and via respiratory droplets produced from coughs or sneezes.

Those infected with the virus have a wide variety of symptoms as some people experience mild to moderate respiratory illness and recover without requiring special treatment, while others, especially those older, vulnerable and fragile (with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer) might develop much more serious illness or even die as a result.[3]

On 30 January 2020, following the recommendations of the Emergency Committee, the WHO Director General, Tedros Adhanom Ghebreyesus, declared that the outbreak constitutes a *Public Health Emergency of International Concern* (PHEIC).[4] This was due to the rapid increase in the number of cases outside China in the first weeks of 2021, that has since affected a growing number of countries. The virus spread from the People's Republic of China, first to 20 others countries, and then to the entire globe. Subsequently, the WHO declared the outbreak a

2 A WHO report on a joint WHO-China study stated that human spillover via an *intermediate animal host* was the most likely explanation, suggesting it emerged from a bat-borne virus. See "Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19)", 16–24 February 2020, https://www.who-china-joint-mission-on-COVID-19-final-report.pdf.

3 WHO. "Clinical Management Of COVID- 19, Interim Guidance", 27 May 2020, https://apps.who.int/iris/rest/bitstreams/1278777/retrieve.

4 WHO. "COVID 19 Public Health Emergency of International Concern (PHEIC) Global Research and Innovation Forum: Towards a Research Roadmap", 11–12 February 2020, https://www.who.int/publications/m/item/COVID-19-public-health-emergency-of-international-concern-(pheic)-global-research-and-innovation-forum.

"*pandemic*" on 11 March 2020.[5] The WHO then issued temporary recommendations relating to trade, travel, cargo and goods. The United Nations (UN) General Assembly (collectively UNGA) adopted a number of resolutions to combat the pandemic. First, on 2 April 2020, the UNGA adopted a resolution entitled "Global solidarity to fight the coronavirus disease 2019 COVID-19"[6]; following this, a second resolution was adopted on 20 April 2020, entitled "International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19".[7] Finally, a third resolution was adopted on September 2020, known as "United response against global health threats: combating COVID-19".[8] These resolutions were responsible for recognizing the unprecedented negative health, economic and social impacts on the international community, including the severe disruption to societies, economies, global trade and travel and the devastating impact on the livelihoods of people caused by COVID-19 pandemic which continues to spread globally. The UNGA acknowledged that the poorest and most vulnerable are the hardest hit by the pandemic and that the impact of the crisis will reverse hard-won development gains and hamper progress towards achieving the Sustainable Development Goals. The General Assembly also emphasized that this pandemic "is a powerful reminder of our interconnectedness and vulnerabilities, as the virus respects no borders, and that combating this pandemic call for an open, transparent, robust, coordinated, large-scale, science-based and inclusive global response in the spirit of solidarity". The same concerns and suggestions for cooperation and collaboration in the spirit of *unity* and *solidarity* were advanced in the World Health Assembly resolution WHA73.1 "COVID-19 response".[9]

At the time of this writing (early August 2021), the numbers of people that have fallen victim to this *pandemic* are impressive: between 31 December 2019 up to date, 198,778,175 cases of infection, and 4,235,559 deaths have been reported globally.[10] Even more staggering, these numbers continues to grow every hour and every day. We already passed fourth million deaths worldwide. Governments

5 WHO. "Director-General's Opening Remarks At The Media Briefing On COVID-19", 11 March 2020, https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-COVID-1911-march-2020.

6 A/RES/74/270.

7 A/RES/74/274.

8 A/RES/74/307.

9 See https://undocs.org/pdf?symbol=en/A/HRC/47/L.21; https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf.

10 WHO. "Corona Virus Disease (COVID-19) Pandemic", https://www.who.int/emergencies/diseases/novel-coronavirus-2019?gclid=CjwKCAjw9aiIBhA1EiwAJ_GTStvAhAcf5nP74yqu51UUuKUC-GT-2MbeHTiKJPKFq2V-ibz5i7XeZhoC4RsQAvD_BwE (visited on 3 August, 2021).

around the globe immediately implemented serious restrictions to economic and social activities in order to slow the spread of the virus, including through policies of confinement, physical distancing and restrictions on travel. These restrictions aimed at reducing pressure on health systems, allowing sufficient time to improve health infrastructures and develop diagnostics, vaccines and treatments to effectively respond to the virus. There are already several vaccines that are in use and that were recently introduced in many countries. Some of these vaccines are based on the traditional method of using an inactivated vaccine to expose the body's immune system to the virus without risking the serious disease responses. Other are based on an innovative formula (mRNA vaccines) that inject the coronavirus' genetic code into the body, with the goal of triggering the body to make viral proteins in order to train the immune system to attack the virus.

The first mass vaccination program started in early December 2020 and, according to WHO data as of 15 February 2021, at least seven different vaccines and 175.3 million vaccine doses had already administered by the WHO, and many other potential vaccines are still being developed.[11] In principle, the process for developing a vaccine is normally very long: each vaccine must be proven safe and effective in large (phase I, II, and III) clinical trials. Once vaccines are demonstrated to be safe and efficacious, they must be authorized by national regulators, manufactured to exacting standards. As a final step, all approved vaccines require distribution through a complex logistical process, which includes rigorous stock management and temperature control.[12] In the case of COVID-19, this process has, not surprisingly, been very fast. In order to tackle concerns with the pandemic as soon as possible, not all the COVID-19 vaccine candidates have completed their phase III trials, and in fact some have been distributed after only providing interim testing results. To this end, the European Union (EU) has proposed an *EU vaccine strategy for COVID-19* including several temporary (strictly COVID-19-related)

11 WHO issued an Emergency Use Listing (EULs) for the Pfizer/BioNTech COVID-19 vaccine on 31 December 2020. On 15 February 2021, the WHO issued EULs for two versions of the AstraZeneca/Oxford COVID-19 vaccine, manufactured by the Serum Institute of India and SKBio. On 12 March 2021, the WHO issued an EUL for the COVID-19 vaccine developed by Janssen (Johnson & Johnson). The WHO is on track to EUL other vaccine products through June. See also "Status Of COVID- 19 Vaccines Within WHO EUL/PQ Evaluation Process" (unfortunately updated only as to 16 February 2021).

12 On paper, some vaccines prove to have some substantial advantages: that they can be stored in a standard refrigerator at 2–8 °C. This is the case of the two Chinese vaccines (Sinovac and Sinopharm) and of the Oxford- AstraZeneca vaccine, which is made from a genetically engineered virus that causes the common cold in chimpanzees. Others, like Moderna's vaccine needs to be stored at –20 °C and Pfizer's vaccine at –70 °C. It means that both the Chinese and the Oxford-AstraZeneca vaccines are definitively more useful to developing countries which might not be able to store large amounts of the vaccine at such low temperatures.

derogations from certain rules for clinical trials, in order to facilitate the development, authorization and availability of COVID-19 vaccines and treatments.[13]

On the one hand, the unprecedented development of several COVID-19 vaccines in such a short time is an historic achievement in the field of global scientific research. On the other, increased concerns surrounding severe blood-clotting incidents have emerged with AstraZeneca COVID-19 vaccine, recently renamed *Vaxzevria*, as well as with the *Johnson & Johnson's* single-dose vaccine. The potential link of these unusual blood clots with these vaccines already led some countries (including the United States and the European States) to came to a sudden halt of immunization after their respective health agencies and regulators either called for a pause in inoculations, or limited it to certain population groups. Even if the adverse effects appear to be extremely rare, the nations' vaccination efforts are now certainly addressing the vast issue of *vaccine hesitancy*. The great risk is that if the public suspected their governments of concealing serious potential side effects, far more people might decide *against vaccination*, which would ultimately result in exposing the world population to increased risk of contracting COVID-19. There is, therefore, difficult work to do in order to facilitate equitable access *to safe and effective COVID-19 vaccines* for the billions of people who will need them. One of the major and unprecedented challenges posed by this pandemic is the need to manufacture the vaccines in large quantities, while continuing to produce all the other important life-saving vaccines already in use.

Besides that, obvious challenge, more than 90% of the 100 scientists (including immunologists and infectious-disease researchers), interviewed on January 2021 (by the leading journal *Nature*) and asked whether the virus that causes COVID-19 could be eradicated, responded that they think coronavirus could become *endemic*, meaning that it will continue to circulate within the global population for years to come.[14] There are many reasons for this conclusion. According to the *Nature*'s survey, even if it is possible to eliminate COVID-19 from some regions, it will continue to circulate in others. In zero-COVID regions there will be a continual risk of disease outbreaks, with an ever-present risk of reintroduction from places where vaccine coverage and public-health measures have not been good enough. Particularly, it is unclear thus far exactly how *effective vaccines* can be at reducing transmission of the disease, stopping a person from passing on

13 Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank. "EU Strategy for COVID-19 Vaccines", COM/2020/245 final, 17.6.2020.

14 "The Coronavirus Is Here To Stay – Here's What That Means", Nature, 16 February 2021, https://www.nature.com/articles/d41586-021-00396-2.

the virus, and thus contributing to the so-called *herd immunity*. Herd immunity is only relevant if the world succeeds in having a "transmission-blocking vaccine". Firstly, scientists have outlined that a vaccine which is 90% effective in blocking transmission will need to reach *at least* 55% of the population, in order to achieve *temporary herd immunity*. This number increases to 67% if fundamental preventive measures (like social distancing, face masks, remote working etc.) are lifted. Clearly, vaccinating 55% of the population would be a monumental task for many countries and, in any case, it would take longer to see how effectively vaccines can reduce transmission. Secondly, as of late 2020, several variants of COVID-19 have emerged and are spreading globally. It unclear, however, whether the current vaccines will continue to remain effective against *newer variants of the virus*.[15] Therefore, it is likely that COVID-19 vaccines will need to be updated, possibly every year.[16] Thirdly, the future nature of this virus will also depend on whether it establishes itself in the wild animal population. There is already evidences that the virus has infected many animals (not only minks but also cats), with the consequences that it might continue to be passed to people through those intermediate hosts. Periodic re-vaccinations may continue to be necessary (perhaps indefinitely and essentially everywhere) to contain the steady stream of new variants. Long-term prospects for the pandemic probably include COVID-19 becoming a permanent endemic global health disease, much like influenza.[17]

In sum, this new virus is here to stay for years to come. It will continue to be a significant burden on both families and societies and will especially affect those people who have lost their lives to the disease, those who are battling for their

15 Currently, the most currently prevalent variants, all of which share a mutation in the virus's spike protein which vaccines target, are: *B.1.1.7*, first detected in the UK, which has spread to over 70 countries; *P.1*, first detected in Brazil, which has spread to more than 4 countries; *B.1.351*, first detected in South Africa, which has spread to over 30 countries; *B.1.427*, first detected in California, which has spread to 14 countries; *B.1.429*, first detected in California, which has spread to 25 countries. See "Five Reasons Why COVID Herd Immunity Is Probably Impossible", Nature, 520–522, 18 March 2021, https://doi.org/10.1038/d41586-021-00728-2. For an overview of "SARS-CoV-2 Variants of Concern" (VOCs) named Alpha, Beta, Gamma and Delta, see https://www.who.int/publications/m/item/weekly-epidemiological-update-on-COVID-19—27-july-2021.

16 DE BOLLE M. "Novel Viral Variants: Why the World Should Prepare for Chronical Pandemics, in Economic Policy for a Pandemic Age. How the World Must Prepare", PIIE Briefing 21–22, April 2021.

17 A survey of the WTO on the global production capacity for seasonal and pandemic influenza vaccines in 2019, stated that the production capacity had changed marginally since 2015, rising from 1.47 billion doses to 1.48 billion, see Sparrow E. et al. "Global Production Capacity Of Seasonal And Pandemic Influenza Vaccines in 2019", Vaccine, 15 January 2021, 512–520.

survival and those whose lives and livelihoods have been affected by the crisis. This crisis overall has caused a horrendous loss of lives, loss of jobs, and an unprecedented *shock* to the global economy.[18] In this regard, it is noteworthy that the levels of extreme poverty were steadily declining for more than two decades prior to the pandemic. Now, for the first time in a generation, in the light of the confirmed cases and deaths worldwide and the distribution of economic losses largely allocated to countries where the infection was least controlled (with the poorest in each country suffering the most), UN Sustainable Development Goal 1 (*end poverty in all its forms everywhere*) of the UN Agenda 2030 has suffered its worst setback. The World Bank estimated that *global extreme poverty* (defined as living on less than $1.90 a day) is expected to rise in 2020/2021 for the first time in over 20 years. According to this estimate, the COVID-19 pandemic will push an additional *88* to *115 million people* into extreme poverty, with the total rising to as many as *150 million* by 2021, depending on the severity of the economic contraction. Extreme poverty already affects between 9.1 and 9.4% of the world's population as of 2020.[19] Before this pandemic, the poverty rate was expected to drop to 7.9% in 2020. Of the 124 million people living in extreme poverty in 2020, the World Bank calculates that 8 of 10 of these people were living in middle income countries.[20] Of the million people expected to be pushed into (extreme) poverty by the pandemic, two-third will be in South Asia.[21] According the World Trade Organization (WTO) Secretariat, Least Developed Countries' (LDC) economies have been hit hard by the COVID-19 crisis, with a 10.3% decline in exports of merchandise in 2020 compared to 2019 and a 10.5% decline in imports. Due to their dependence on travel exports, LDC exports of services are estimated to have dropped around 40%

18 *Supra,* note 14.

19 World Bank. "Poverty and Shared Prosperity Report 2020. Reversal of Fortune", https://www.worldbank.org/en/publication/poverty-and-shared-prosperity.

20 World Bank, "COVID-19 to Add as Many as 150 Million Extreme Poor by 2021", 7 October 2020, https://www.worldbank.org/en/news/press-release/2020/10/07/COVID-19-to-add-as-many-as-150-million-extreme-poor-by-2021.

21 Oxfam International. "Download Dignity Not Destitution: An Economic Rescue Package for All", 9 April 2020. The report presents analysis which suggests that between 6 and 8% of the global population could be forced into poverty as governments shut down entire economies to manage the spread of the virus. This could set back the fight against poverty by a decade, and as much as 30 years in some regions such as sub-Saharan Africa and the Middle East and North Africa. Over half the global population could be living in poverty in the aftermath of the pandemic. See the analysis, published by the United Nations University World Institute for Development Economics Research, conducted by researchers at King's College London and the Australian National University at https://www.oxfam.org/en/research/dignity-not-destitution.

in the first three quarters of 2020, double the decline experienced by the rest of the world (19%).[22]

In addition to the public health imperative, it is crystal clear that the quicker the vaccines are distributed globally, the sooner the world economy can start to recover. In October 2019, the International Monetary Fund (IMF) forecasted that the world economy would grow by 3.4% in 2020; however, in January 2021 the IMF estimated that world GDP, in fact, fell by 3.5%. The gap between the pre-pandemic growth path and the 2020 outcome has resulted in a loss of potential output of $6 trillion.[23] Only huge investments in development and manufacturing capacity, along with a robust global recovery and a "reset" of multilateral trade governance could reverse this trend.

2 Understanding the Concept of "Global Common/Public Good". Should Global Immunizations or COVID-19 Vaccines Be Considered a Global Common/Public Good?

During this pandemic the concept of "global public good"/global common goods", has been extensively used by policy makers, political leaders, academics, economists, international organizations, Non-Governmental Organizations (NGOs) and others health groups. In the light of the current discussions about the COVID-19 pandemic, the term *global* is easy to understand. The coronavirus disease

22 https://www.wto.org/, 19 April 2021; see also International Monetary Fund (IMF). "The IMF's Response to COVID-19", April 8, 2021, https://www.imf.org/en/About/FAQ/imf-response-to-COVID-19. The *Catastrophe Containment and Relief Trust* (CCRT) allows IMF to provide debt service relief for the poorest and most vulnerable countries hit by catastrophic natural disasters or public health disasters. In April 2020, the IMF expanded its provision of debt service relief under the CCRT to cover exceptional balance of payment needs arising from COVID-19, to help low-income countries create space for urgent spending needs to address the pandemic. See Collins G.C and Truman E.M. "IMF's Special Drawing Rights to the Rescue" in PIIE. "How the G20 Can Hasten Recovery from COVID-19", PIIE Briefing 20-1, April 2020, 56–60; Mazarei A. "Developing Countries Need Greater Financing And Debt Relief For COVID-19 And Future Pandemics", in PIIE. "Economic Policy for a Pandemic Age. How the World Must Prepare", PIIE Briefing 21-2, April 2021, 52–56.

23 Ahuja A. et al. "Preparing for a Pandemic: Accelerating Vaccine Availability, Stanford Institute for Economic Policy Research Working Paper 21-003, 2021", https://siepr.stanford.edu/sites/default/files/publications/21-003_0.pdf; on global trade growth's loosing moment and hard time for an already fragile framework of international trade, with COVID-19 as a stumbling block preventing global recovery for trade in services, see https://www.org/ 2 April 2019.

constitutes an extraordinary "global" peril and has already created a global public health crisis. COVID-19 pandemic could be easily characterized as the "global evil". By contrast, the term *global common good* or *global public good* is subject to diverse uses, depending upon one's educational and academic background.

In the legal discourses of public international law, the term "global commons" normally refers to resource domains or areas that lie outside the political reach of any nation State. According to the United Nations Environment Programme (UNEP), international law identifies "four global commons, namely: the High Seas, the Atmosphere, Antarctica and Outer Space".[24] In this context the term has a close relationship with many others corresponding concepts such as "public goods", "common interest", "common concerns", and "common heritage of the mankind", each of which are all living concepts that could accommodate over time to other concepts of commons at the international level, such as biodiversity, ecosystems, oceans, international sea-bed, climate change and others.[25] In respect of these concepts, two main legal regulatory discourses have been prominent over the years: the well-known theory of "the tragedy of the commons" and what principles, rules and standards (governance) are needed to regulate the commons. The concept of "the tragedy of the commons" was first articulated by biologist Garrett Hardin to the Pacific Division of the American Association for the Advancement of Science in June 1968, with a six-page article conceived as a critique of *laissez faire theory,* through the use of a metaphor describing the destruction of common pastures as herdsmen increased the cattle graze on them.[26] The public international law's discourses on global commons have generally focused on the idea that some resources belong to all of us, including future generations, and that they need strong, fair and efficient public regulation to allocate properly exploitations rights, costs and benefits properly.

Applying these concepts to the COVID-19 pandemic, it appears immediately clear that the term "global common good" has been invoked in a sort of loose way.

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24 UNEP. "IEG of the Global Commons", http://staging.unep.org/delc/GlobalCommons/tabid/54404/Default.aspx.

25 Nakicenovic N. et al. 2016. "Global Commons in the Anthropocene: World Development on a Stable and Resilient Planet", IIASA Working Paper; Zou K. 2018. "Global commons and the law of the sea", Leiden and Boston, Brill Nijhoff, XXIV+349. Chapter 1; Ranganathan S. 2016. "Global Commons", European Journal of International Law, 693–717; Mattei U. 2015, Il benicomunismo e i suoi nemici, Torino, Giulio Einaudi Editore.

26 Hardin G. 1968. The Tragedy of the Commons, Vol. 162, Issue 3859, 1243: "As a rational being, each herdsman seeks to maximize his gain Therein is the tragedy. Each man is locked into a system that compels him to increase his herd without limit – in a world that is limited. Ruin is the destination toward which all men rush, each pursuing his own best interest in a society that believes in the freedom of the commons. Freedom in a common brings ruin to all".

The term has been used substantially in order to underscore that equitable access to health products, including vaccines, health and biomedical technologies, medical services, and medical devices, are a global priority, and that availability, accessibility, acceptability, and affordability for all are fundamental to tackling the pandemic. The scientific consensus believes that the only way this pandemic will be possibly eradicated is through the vaccination of all the people worldwide. This goal requires equitable access to vaccines for all people, irrespective of age, gender, ethnicity, country, social and economic conditions, thus "rendering vaccines a global common good".[27] The South Centre statement to the World Health Assembly (WHA) 73 session, on the launch of the WHO's Access to COVID-19 Tools (ACT) Accelerator, called on the WHO and its Member States "to enable timely and adequate supply, to all and on an equal basis, of diagnostics, treatments and vaccines for COVID-19 as essential public goods"[28] (emphasis added), to prove that "beyond solemn declarations, the international community can work together to ensure that nobody is left behind". On the same line, Médecins Sans Frontières International (MSF) in its Access Campaign, appeal to all WTO members "to work together for a global solution that empowers all countries to protect all populations, and truly treat vaccines as a global public good. It is about saving lives at the end, not protecting systems" (emphasis added).[29]

The United Nations Educational, Scientific and Cultural organization's (UNESCO) *International Bioethics Committee* (IBC) and the *World Commission on the Ethics for Scientific Knowledge and Technology* (COMEST) have called for a change of course in current COVID-19 vaccination strategies, specifically urging that vaccines be treated as a *global public good* to ensure they are made equitably available in all countries, and not only to those who bid the highest for these vaccines. According to UNESCO, availability to vaccines to all, in all countries, is "an essential ethical issue" and that "for real equity in the global access to vaccines, a shared ethical recognition of health as a global common good, with no territorial limit, is needed".[30] On 11th March 2021, the Secretary-General of the United Nation, António Guterres, issued a statement for the launch of the "Only Together" campaign, saying that "COVID-19 vaccines must be considered a *global*

27 Yunus M. et al. 2020. "COVID-19 Vaccines A Global Common Good", The Lancet, https://www.thelancet.com.

28 South Centre Statement, Item 13, https://www.southcentre.int/wp-content/uploads/2020/11/South-Centre-statement-Item-13-WHA-73-resumed.pdf.

29 MSF'S intervention at a virtual event titled "COVID-19 and Vaccine Equity: What Can the WTO Contribute?" held on 14 April 2021.

30 UNESCO. 2021. "Calls For COVID-19 Vaccines To Be Considered A Global Public Good", https://en.unesco.org/news.

public good. No country can overcome this crisis in isolation".[31] In a statement given during the Africa Dialogue Series, the UN Secretary-General affirmed that "quick, equal, affordable access to COVID-19 Vaccine must be considered *global public good* (emphasis added).[32] The United Nations Programme on HIV/AIDS (UNAIDS) called for a "people's vaccine" against COVID-19, stating that: "governments and international partners must unite around a global guarantee which ensures that, when a safe and effective vaccine is developed, it is produced rapidly at scale and made available for all people, in all countries, free of charge. The same applies for all treatments, diagnostics, and other technologies for COVID-19… Now is not the time to allow the interests of the wealthiest corporations and governments to be placed before the universal need to save lives, or to leave this massive and moral task to market forces. Access to vaccines and treatments as *global public goods* are in the interests of all humanity. We cannot afford for monopolies, crude competition and near-sighted nationalism to stand in the way" (emphasis added).[33]

By contrast, during the negotiations of the WHA resolution on COVID-19, finally adopted on May 19, 2020, the EU submitted a proposal for a consolidated zero draft on a WHA73 "COVID-19 response", according to which the Seventy-third World Health Assembly, would have had to recognize "*population-wide immunization* against COVID-19 as a *global public good* for health and the crucial role of quality, safe, and efficacious vaccines therein" (emphasis added). The United States objected to this and instead proposed to change the term "global public good" substituting it with the term "global benefit", after a long discussion in the drafting process about the distinction to be drawn between "vaccination" and "vaccines".[34] In the end, Point 6 in the final adopted text recognizes "*the role of extensive immunization against COVID-19 as a global public good* for health in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available" (emphasis added).[35]

The distinction between *vaccination* and *vaccine* as global common/public good for legal discourses is important. Conceptually, global common/public goods are

31 United Nations. "COVID-19 Vaccines Must be Global Public Good", 11 March 2021, https://www.un.org.press/en/2021/sgsm20620.doc.htm.

32 SG/SM/20089, 20 May 2020.

33 UNAIDS. 2020. "Uniting Behind A People's Vaccine Against COVID-19" https://www.unaids.org/en/resources/presscentre/featurestories/2020/may/20200514_covid19-vaccine-open-letter.

34 Love J. 2020. "A Flawed Understanding of the Concept of "Public Good" Hampers the Fight for Equitable Access to the Upcoming COVID-19 Vaccine, Developing Economics, A Critical Perspective on Development Economics", https://developingeconomics.org/author/jamespackardlove/.

35 WHA73.1, 19 May 2020.

characterized by economists as any material or immaterial entity according to whether it is excludable (no one can be stopped from consuming it) or rivalrous (its consumption does not reduce its availability to others).[36] *Firstly*, a clarification is needed. Excludability and non-rivalry are characteristics inherent to the goods which serve to justify different legal regimes. Global warming is a good example because it is generally characterized as "a global public good", but nobody denies that it has disastrous negative effects for the entire world. Consequently, it would be more correct to describe it as a *global public evil* and as such global warming deserves strong commitments to defeat it, namely through international collaboration.[37] In conclusion, global public good could be used in nefarious ways depending on who make use of these things. The decisions of policy makers and politicians determine the uses these goods. It is always about choices related to *governance* and *political decisions*.[38] Even fresh air, a good that everybody consider non-excludable and non-rivalrous, could in a near future be put in bottles to be sold like mineral water, and thus transformed in a private good.[39] Therefore, what really matters is not the intrinsic nature of the good but the social and political decisions made by the governments to best balance the potential conflicting interests.[40]

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36 Depending on these two features, economists divide entities in four categories: private goods, club goods, common goods, and public goods; applied to the COVID-19 Pandemic we can say that pills and syringes are private goods; knowledge protected by patent a club good; universal healthcare and health are common goods; public information data-sharing and result-sharing public goods. "Pure public goods" are considered entities that are non-excludable and non-rivalrous. See. Smith RD. 2003. "Global Public Goods and Health", Bulletin of the World Health Organization, 475; Smith RD. et al. (Eds.). 2003. Global Public Goods for Health: Health Economic and Public Health Perspectives, Oxford, Oxford University Press; Moon et al. 2017. Global Public Goods for Health: Weaknesses and Opportunities in the Global Health System, Health Economics, Policy and Law, Cambridge, Cambridge University Press, 195–205; Thomas Y.F. et al., 2020, Reaffirming the Significance of Global Public Goods for Health. Global Solidarity in Response to COVID-19 and Future Shocks, G20 Insights, https://www.g20-insights.org/policy_briefs/reaffirming-the-significance-of-global-public-goods-for-health-global-solidarity-in-response-to-COVID-19-and-future-shocks/.

37 GAVI. 2020. "Are Vaccine A Global Public Good?", https://www.gavi.org/vaccineswork/are-vaccines-global-public-good?gclid=Cj0KCQjw6.

38 Ottone S., Sacconi L. 2015. Beni comuni, economia comportamentale e istituzioni, Sacconi L., Ottone S. eds. 2015. Beni comuni e cooperazione: una prospettica etica, economica e giuridica, Bologna, Il Mulino, 145 ff.; Sacconi L. "Beni comuni, contratto sociale e governance cooperativa dei servizi pubblici locali", *ibidem*, 175; Denozza F. 2016. "Parliamo di beni comuni. Dalla tragedia dei (falsi) commons al dramma del bail in", https://www.casadellacultura.it/.

39 Denozza F., *ult. op. cit.*

40 See the reasonings of Denozza F. applied to the field of antitrust. 2017. "The Future of Antitrust: Concern of the Real Interests at Stake, or Etiquette for Olipopolists", Orizzonti del diritto commerciale, nine ff.; Denozza F. 2015. "La Società cooperativa e il problema degli strumenti istituzionali per la gestione dei beni comuni", in Ottone S., Sacconi L. eds. 2015, 145 ff.

In this article, the term "global common good" or "global public good" is not going to be used in the strict sense used by the economists. Rather it will be used in the sense used by the broad global health community to address the social, economic, and political determinants of global public health and well-being of people everywhere. There is no doubt that the COVID-19 pandemic, and the virus that caused it, are both *non-excludable* (to be infected does not depend, or at least does not totally depends, on personal behavior, due to the heavy negative externalities of the contagious), and *non-rivalrous* (if I get sick, you too can contract the disease). Therefore, COVID-19 is a *global public/common evil*. The solution to the pandemic (the global public evil) is both *global vaccination and immunization*. In principle, *herd immunity* is also a global common good, even if (strictly speaking) it is not a "good" but only a very hypothetical condition. Herd immunity is a *status* acquired by a large number of people having developed (*via* vaccines or on their own) the antibodies to survive. In order to reach this status worldwide, everybody need the ability, the capacity, and the legal right to access vaccines, which means positive actions and regulations need to be put in place by the State. Most important is the need to have enough vaccines (the relevant resources) to guarantee global access. Vaccines need to be produced at scale, priced affordably, and allocated globally so that they are globally available where needed. As shown above, herd immunity could only be eventually reached through a massive vaccination drive of people around the world.

Immunization is the *benefit* that people obtain through vaccination. This is something more than vaccines in themselves, since vaccination/immunization implies also how to administer and spreading them. Immunization via vaccination is not only a global health issue. Over several centuries, immunization was seen as a very successful story, since inoculations have saved millions of lives and continue to do every year. Immunization is a key component of primary health care and also a fundamental human right. It is critical to the prevention and the control of infectious-disease outbreaks that can underpin global security. Yet, despite enormous progress in the realm of disease management and immunizations, far too many people around the world, including more than 20 million infants each year, have insufficient access to vaccines. In fact, global vaccination coverage has remained the same over the past years.[41] In order to function properly, and efficiently as requested by economists, vaccination must be *non-excludable*, due to its huge positive externalities. Any limits in the manufacturing, or shortage, of vaccines must be remedied by the *correct legal discipline*. In this respect, according to economists, it is first necessary to determine the *nature* and the various

41 See WHO. 2020. "Immunization Coverage", https://www.who.int/news-room/fact-sheet/details/immunization-coverage.

characteristics (physic, technic, biological, cultural, or moral) of goods, which determine whether or not their consumption should/must be excludable or non-excludable, and rivalrous or non-rivalrous. Only after this analysis is completed, should a proper *legal regime* be established. It could be a regime of private property, collective ownership, state/public property or any other type of legal regime. In other words, it is important to distinguish the characteristics of consumption of the good from its form of governance, which may or may not be *appropriate* to the nature of the goods. For neoliberal theorists, the "commons" should be treated as private property, in order to avoid the so called *tragedy of the commons*. Other theorists consider that the best legal regime for such goods should consist of new forms of *governance*, appropriate for the commons, and should not, be excluded on the basis of price or of a private right.

In our opinion, even if it is true that privatization of common goods (for example via strong patent rights on vaccines) maybe avoids the tragedy of the commons, nevertheless it inevitably determines another tragedy: the *famine* of the common goods. People, deprived of access to vaccines due to the private property legal regime applied to such vaccines, will die not of hunger but of complications from the pandemic. Public health experts estimate that between 3.2 billion and 4.2 billion persons will need to be vaccinated worldwide.[42] According to other estimates, the number is much higher, amounting to 7.8 billion people.[43] These totals could obviously rise further if new vaccines are needed to limit the threat to livelihoods from new variants of COVID-19. Every scientist and policy maker agrees on the benefits of a COVID-19 vaccination, since it protects not only the person vaccinated, but also the community. A widespread vaccination eliminates hosts for the virus, therefore contributing to the control of the pandemic, an immense *external benefit* for the global community. The eradication of the disease benefits everyone, whether or not they contributed to the eradication effort. Therefore, immunization against the pandemic must be legally treated as a *global public/common good*. However, the reasoning behind this classification has become garbled since eradication (immunization) inevitably comes with *vaccines*. Vaccines are health products, and goods, similar to drugs, diagnostics, ventilators and other medical devices, including personal protective equipment used in hospitals. The dramatic shortage of these goods and other supplies, as well as access challenges, eliminates all these products (together with hospital beds and services of

42 Wang W. et al. 2020. "Global, Regional, and National Estimates of Target Population Sizes for COVID-19 Vaccination: Descriptive Study", The British Medical Journal 371.

43 WTO. Council For Trade-Related Aspects of Intellectual Property Right, IP/C/W/672, 15 January 2021, 5.

health care workers) from the category of goods that are "non-rival in consumption". As already explained, a good is *non-rival* if the use by one individual does not reduce availability for other. The point is that the current legal proprietary regime applied to vaccines has transformed an intrinsically *non-excludable* common/public goods (the vaccines) in something that is clearly excludable and rival in consumption.

Vaccines are regulated as *private goods,* protected by intellectual property rights (IPRs), an ever-growing set of exclusive rights that are granted to inventions, expressions, designs, data, know-how, clinical evidences used for regulatory approvals, trade secrets and so on.[44] The fundamental mission of IPRs consists, precisely, in making these goods "excludable", even if the global IP system in principle requires disclosure and dissemination of patent and other IPRs information in order to ensure access to technical information which could support research and development (R&D) needs.[45] Even for *knowledge*, a common/public good par excellence, the *non-excludability* can be a very hard condition to meet under the current IP system, which protects clinical trial data, as well as patented documents for inventions related to the prevention, detection, and treatment of COVID-19. While it is commonly recognized that the evaluation of safety and efficacy of products shows that they have undoubtedly *non-excludable qualities*, especially in presence of COVID-19's health products developed by essential publicly founded or donor-funded researches, regulatory national policies have made them totally ownable and excludable in too many jurisdictions.

To conclude on the widespread public call for *vaccines*, we can surely agree with their characterization as *global common/public goods*, which is in line with the "nature" and "characteristic" of the good. Nonetheless, at the time of writing, we must recognize, on the one hand, that these common goods are legally regulated as *private market goods*. On the other hand, *vaccination/immunization* is for sure *non-excludable*, but definitively considered *rivalrous*. Neither vaccines nor vaccination could, therefore, be characterized or declared as pure public common goods. One might wonder about the usefulness of such a characterization. It lays undoubtedly on the most important aspect of the concept of so-called *global commons* and the principles and the rules needed for their regulation. In sum, what matters is not so much the conceptual (academic) characterizations, but rather the problem of the *proper governance* and *policies of the commons* that should facilitate at maximum

44 *Infra* para 4.

45 On the tension between IPRs and public health needs, see Boschiero N. 2017. Intellectual Property Rights and Public Health: An Impediment to Access to Medicines and Health Technology Innovation? in Pineschi L. ed. 2017. La tutela della salute nel diritto internazionale ed europeo tra interessi globali e interessi particolari, Napoli, Editoriale Scientifica, 259–294.

openness of science, technical knowhow and knowledge relative to the development of vaccines and therapeutics, sharing of data, cross-border scientific collaboration within and between the public and the private sector, global production and distribution (through committing to non-exclusive and royalty-free licensing), non-enforcement declarations of patent rights for vital equipment, and finally drugs and vaccines that are effective, universally and cheaply available.[46] In addition to representing an impressive challenge to *global bioethics*, the COVID-19 pandemic presents too many health, economic and social concerns that simply result in treating all the health technologies developed to combat as something that could be excludable and rivalrous. What is needed, consequently, is a *swift* in governance of these goods. The current legal discipline of vaccines and health technologies must be changed in order to bring it into line with the non-excludable "nature" of these goods.[47] By affirming, at the same time, that global immunization or that COVID-19 vaccines are "global public goods", when at the same time too many pharmaceutical companies, backed by western governments, continue to act according to the "business-as usual" paradigm by privatizing goods that are not "private", is a highly hypocritical, completely untenable, attitude.

3 The Race for Vaccines: "Us First" Approach or "Vaccine Nationalism" of High-Income Countries and the Policy Implications in the Area of Vaccine Distribution. The Case of Europe

Like many other vaccines, those developed to tackle COVID-19 are produced in a relatively small number of countries. The same is true for the ingredients of these vaccines and, to a large extent, the medical kits needed to distribute them. These countries have been called, for the sake of simplicity, the "COVID-19 Vaccine

46 *Infra*, para 5.

47 On the "Governance of the Commons", see the fundamental studies of Ostrom Elinor, Co-Winner of 2009 Nobel Memorial Prize in Economic Sciences, The Royal Swedish Academy of Sciences: OSTROM E. 1990. Governing the Commons, Cambridge, Cambridge University Press; Ostrom E. et al. 1994. Rule, Games and Common Pool Resources, Ann Arbor, The University of Michigan Press; Ostrom E. 2005. Understanding Institutional Diversity, Princeton, Princeton University Press; Ostrom E. 2015. "Elinor Ostrom and the Bloomington School of political economy vol. 2 (Collected Papers on Resource Governance)", Lexington Books, Rowman & Littlefield; Id. 2017. "Elinor Ostrom and the Bloomington School of Political Economy Vol. 3 (Collected Papers on Framework for Policy Analysis)", Lexington Books, Rowman & Littlefield.

Club".[48] This conclusion inevitably amplifies a strong tension between "national" answers and reactions to the pandemic and a virus that does not respect jurisdictional borders.

The risks of witnessing governments engaging in "vaccine nationalisms" has already materialized, taking the world to a zero-sum result that comes at the expenses of public health (a truly global common good) of the world population.[49] This kind of nationalism, where each country prioritizes its own needs over the legitimate needs of others, takes very different forms ranging from export bans or limits, to increasing the domestic availability of vaccines at the expense of foreign supply, delays in shipments or conditions delivery imposed on imports of vaccines from foreign locations. The outbreak of the pandemic in 2019, induced several countries to adopt *trade restrictions measures* aimed at protecting the supply of key items, particularly "personal protective equipment". According to the Global Trade Alert (an independent organism which monitors policies that affect world commerce), *1863 new trade barriers* were raised globally in 2020, representing the highest value since the policies were first monitored in 2009.[50] This trend should not be underestimated since the "race for vaccines" could seriously undermine free trade, bringing new forms of "disguised" protectionism and reducing the diversification of supply sources.[51]

The exceptional rapid development of COVID-19 vaccines has been achieved by massive *public funding* in the United States, United Kingdom and the European Union. The *Operation Warp Speed* (OWS) is the largest of the global efforts for development of COVID-19 vaccines. This public–private partnership was officially announced on May 15, 2020 and was initiated by the Trump Administration to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics, intended for US populations. It provided $18 billion in funding from the CARES Act (Coronavirus Aid, Relief, and Economic Security). The program promoted mass production of multiple vaccines, and different types of vaccine technologies, based on preliminary evidence, allowing for faster distribution if clinical trials confirm one of the vaccines is safe

48 Evenett S.J. et al. 2021. "The COVID-19 Vaccine Production Club: Will Value Chains Temper Nationalism?" World Bank Group, Policy Research Working Paper 9565.

49 Bollyky T. J and Bown C. P. 2020. "The Tragedy of Vaccine Nationalism: Only Cooperation Can End the Pandemic", Foreign Affairs; Freund C. and McDaniel C., "Three Steps to Facilitate Global Distribution of a COVID-19 Vaccine", in Evenett S.J. Baldwin R.E., (eds.). 2020. Revitalizing Multilateralism: Pragmatic Ideas For The New WTO Director- General, CEPR Press.

50 https://www.globaltradealert.org. See also WTO. 2020, "Trade in Medical Goods in the Context of Tackling COVID- 19: Development in the First Half of 2020".

51 WTO. 2020. "Standards, Regulations and COVID-19-What Actions Taken by the WTO Members?".

and effective.[52] This is typically a U.S. centric program because developing enough vaccines for the American population, as opposed to the global public health needs, was the logical consequence of the Trump Administration's *America first* policies. The U.S. could also invoke the *Defense Production Act* (DPA) against vaccine manufactures with "priority contracts" with the U.S. Government, at the expense of foreign buyers. Reportedly, the U.S. government has used the DPA to compel manufacturers to accept and prioritize government contracts ahead of private sector orders.[53]

Other major western powers also partnered with big pharmaceutical companies, pouring billions of dollars and euro to procure raw materials, finance clinical trials and retrofit factories, plus billions more to buy the finished products. In a *Question & Answer* sheet, the European Commission affirmed that it has committed € 2.7 billion in financial support to the development and production of COVID-19 vaccines.[54] The European Union has implemented a *EU vaccines strategy* which rests on two fundamental pillars: 1) to secure sufficient production of vaccines in the EU and thereby *sufficient supplies for its Member States* through *Advance Purchase Agreements* (APAs) with vaccine producers via the *Emergency Support Instrument*[55]; and, 2) to adapt the EU's regulatory framework to the current level of urgency and make use of existing regulatory flexibility to accelerate the development, authorization and availability of vaccines while maintaining the standards for vaccine quality, safety and efficacy.

On 12 June 2020 the EU Council of Ministers for Health agreed on the need for joint action to support the development and deployment of a safe and effective vaccine against COVID-19 by securing rapid, sufficient and equitable supplies for

52 *Operation Warp Speed* (OWS) is an interagency program that includes components of the Department of Health and Human Services, including the Centers for Disease Control and Prevention, Food and Drug Administration, the National Institutes of Health, and the Biomedical Advanced Research and Development Authority (BARDA); the Department of Defense; private firms; and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. For more details on *OWS*, see Bown C.P., Bollyky T.J. 2021. "Here's How Get Billions of COVID-19 Vaccines, PIIE series on Economic Policy for a Pandemic Age: How the World Must Prepare"; Lancet Commission on COVID-19 Vaccines and Therapeutics Task Force Members. 2021. "Operation Warp Speed: Implications For Global Vaccine Security", https://www.thelancet.com/action/showPdf?pii=S2214-109X%2821%2900140-6.

53 Bown C.P and Bollyky T.J., *supra* note 52, 62.

54 https://ec.europa.eu/commission/presscorner/detail/en/QANDA_21_308.

55 Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak., OJ L 117, 15.4.2020, 3; https://ec.europa.eu/echo/what/civil-protection/emergency-support-instrument_en.

Member States. Consequently, the Commission adopted a *Decision* approving the *Agreement* with Member States on procuring COVID-19 vaccines on behalf of the Member States and related procedures.[56] On the basis of this Agreement, which sets out the practical modalities of the procurement procedure that will be conducted by the Commission, as well as the reciprocal commitments of the parties, the Commission has been asked to run a *single central procurement procedure*, on behalf of all Member States, with the idea of signing *EU level Advance Purchase Agreements* ("APAs") with vaccine manufacturers. Those APAs include up-front EU financing to de-risk essential investments in order to increase the speed and scale of manufacturing successful vaccines. In return, the APAs would provide the right – or under specific circumstances the obligation – to Participating Member States to buy a specific number of vaccine doses within a given timeframe and at a given price. To date, 4 safe and effective vaccines against COVID-19 have been authorized for use in the EU: *BioNTech-Pfizer*,[57] *Moderna*,[58] *AstraZeneca*,[59] *Johnson & Johnson*.[60] Two other contracts have been concluded with vaccines still in development: *Sanofi-GSK* and *CureVac*. *CureVac* is a European company based in Germany, that signed a € 75 million loan agreement with the European Investment Bank on 6 July 2020 for the development and large-scale production of vaccines. Exploratory talks have also concluded with pharmaceutical companies including *Novavax* and *Valneva*.[61]

56 C(2020) 4192 final.

57 The APA with Pfizer/BioNTech provides for the initial purchase of *200 million doses* on behalf of all EU Member States, plus an option to purchase up to a further *100 million doses*. On 15 December 2020, the Commission decided to purchase these *100 million additional* doses. On 8 January 2021 the Commission proposed to Member States to purchase an additional 200 million Pfizer/BioNTech vaccine doses, with the option to acquire another *100 million doses*. On 10 March 2021, the European Commission reached an agreement with Pfizer/BioNTech for the supply of *4 million* more doses of COVID-19 vaccines for Member States that come on top of the schedule of deliveries currently agreed between Member States and Pfizer/BioNTech.

58 The APA with Moderna provides for the initial purchase of *80 million* doses on behalf of all EU Member States, *plus* an option to request up to another *80 million* doses. On 15 December 2020, the Commission decided to purchase *80 million* additional doses. On 17 February 2021, the European Commission approved a second contract with Moderna, which provides for an additional purchase of *300 million* doses (150 million in 2021 and an option to purchase an additional 150 million in 2022) on behalf of all EU Member States.

59 The APA with AstraZeneca provides for initial *300 million* doses, plus an option to order an addition 100 million doses.

60 The APA with Johnson & Johnson provides for *200 million* of their single doses COVID-19 vaccine to the EU starting in the second quarter of 2021. The contract, that was closed on 7 October 2020, allows Member States to purchase an additional *200 million* doses.

61 Further information on EU Vaccines Strategy | European Commission (europa.eu).

In sum, the richest countries in the world (Australia, Canada, European Union, Japan, South Korea, United Kingdom and the United States) have collectively preordered 8.8 billion doses of the vaccine already, far in excess of need (over three times their total population) including options to order extra doses and negotiations not yet finalized. With Canada, specfically, counting up all vaccines deals *per capita*, this excess becomes nearly nine doses per person.[62] Just the confirmed advance purchases of these governments alone jointly accounted for about 60% of all APAs as of the end February 2021.[63] The deals already disclosed speak of 7.4 billion doses already secured by the wealthiest part of the world. Inevitably, the fact that some countries have already pre-ordered billions of doses of COVID-19 vaccines, including most of the 2021 manufacturing capacity for the leading new vaccine candidates, through advance purchase agreements implies, *de facto*, a decrease in the ability to address the gap in access to COVID-19 vaccines by organizations like the *Coalition for Epidemic Preparedness Innovations* (CEPI), GAVI (the Vaccine Alliance) and WHO. These Organizations lead an international plan for global access (and affordable cost) to COVID-19 vaccines, known as the *COVID-19 Vaccine Global Access (COVAX) Facility*, an activity of the *Access to COVID-19 Tools Accelerator*, to negotiate costs for large bulk purchases of those promising vaccines from companies able to guarantee a fair allocation.[64] Clearly, the prospect of billions of people *waiting years* to be vaccinated is not only intrinsically unfair, but it is also a threat to global health. No region is safe until the virus is under control everywhere. As rightly recognized by the EU Commissioner for Health and Food Safety, no one is safe, until everyone is safe.[65]

In addition, severe production delays and lack of deliveries of the vaccine's doses secured by APAs has induced the European Union to introduce an *export authorization* regime for COVID-19 vaccines, explicitly conditioning export authorization on the capacity of manufactures to meet domestic needs, thus *de facto* requiring exclusive and priority supply to the procurer. This export control

62 "How COVID Vaccines are Being Divided Up Around the World", Nature Medicine, 30 November 2020, https://www.nature.com/articles/d41586-020-03370-6; see also the statistic reported by Airfinity, a science information and analytics company founded in 2015, https://www.airfinity.com.

63 *Supra* note 62; Duke Global Health Innovation Center. 2020. "Mapping COVID-19 Vaccines Prepurchases Across the Globe", https://launchandscalefaster.org/COVID-19.

64 *Infra*, para 6; WHO. 2020. "Fair Allocation Mechanism For COVID-19 Vaccines Through The COVAX Facility" https://www.who.int/publications/m/item/fair-allocation-mechanism-for-COVID-19-vaccines-through-the-covax-facility. CEPI and the Duke Global Health Innovation Center estimates that it could be 2023–2024 before enough vaccines for the world population can be manufactured.

65 European Commission, Press Release, 17 June 2020, Brussels.

regime, that only applies to exports from companies with which the EU has concluded Advance Purchase Agreements (APAs), allows for an export shipment to be prohibited if it poses a threat to the execution of Union [Advanced Purchase Agreement] APAs concluded with vaccines manufacturers. With Regulation 2021/442 of 11 March 2021, the European Commission introduced a *new export authorization regime* for COVID-19 vaccines applicable until 30 June 2021 replacing the one initially established (Regulation 2021/111 of 29 January 2021).[66] On 24 March 2021, the European Commission further intervened on the export authorization mechanism through the adoption of EU Implementing Regulation 2021/521, which introduced the principles of *reciprocity* and *proportionality* as new criteria for the granting of the authorization.[67] According to said principles, the EU authorized the Italian Government to block shipment of 250,000 Oxford/AstraZeneca COVID-19 vaccine doses destined for Australia in early March of 2021, clarifying that, in order to grant the authorization, the national competent authorities must assess whether the country of destination of the export restricts its own exports of vaccines and active substances to the EU, as well as the relevant conditions prevailing in the country of destination of the export, including the epidemiological situation, and the existing availability of such products.[68]

It is no surprise that some western governments have indicated that *excess* COVID-19 vaccine doses will be made available for the rest of the world, only once secured access to a safe and effective vaccines at the scale needed by their population is achieved.[69] The point here is that the prospect of this scenario ever

66 Commission Implementing Regulation (EU) 2021/442 of 11 March 2021 making the exportation of certain products subject to the production of an export authorization, *OJ L 85*, 12.3.2021, 190–197.

67 Commission Implementing Regulation (EU) 2021/521 of 24 March 2021 making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorization, C/2021/2081, OJ L 104, 25.3.2021, 52–54; Eliantonio M. 2021. "Vaccine Wars and Composite Procedure, Gibt Es Noch Richter in Berlin?", Quaderni di Sidiblog. It is worth noting that up to date the main beneficiary of EU exports (since the measure was introduced, shipments were authorized to more than 30 countries) was the United Kingdom with over 10 million vaccine doses, by the way without receiving a single dose in return.

68 The Italian government justified this restriction on the basis that Australia was not a "vulnerable country".

69 President Biden, under intense pressure to do more to address the surging pandemic abroad, including a dramatic humanitarian crisis in India, recently declared to make up to 60 million doses of the AstraZeneca vaccine available to other countries, so long as federal regulators deem the doses safe, The New York Times, 26 April 2021, https://www.nytimes.com/2021/04/26/us/politics/biden-vaccine-india.html.

materializing will inevitably depend on the individual State's ability to secure effective and speedy government procurement policies. The attempt to secure preferential access to vaccines, inevitably jeopardizes supplies of vaccines elsewhere and more generally the equitable distribution of these vaccine.[70] This risk has obviously grown, with strong ethical concerns, since the richest nations are considering (summer 2021) the possibility of a third shot of vaccine to be inoculated to their elderly and fragile population, while the world "top priority" should be to vaccinate people who have received no doses of the COVID-19 vaccine as soon as possible.

This scenario has unsurprisingly determined a shift from "vaccine nationalisms" to "vaccine diplomacy". Vaccine diplomacy can be defined as a "strategic" use of vaccines, vaccines ingredients, and the necessary knowhow to produce them, in order to achieve geopolitical objectives. Obviously, from a public health perspective, as global common good, this is not an optimal solution, since it is intrinsically driven by foreign policy considerations rather than by the fundamental goal of improving global efficiency in vaccine production. However, this strategy has already produced some interesting results in the fight against this new coronavirus. Two countries, particularly, China and Russia are already at the forefront of this race. China's President Xi Jinping publicly pledged to subsidize $2 billion for the African continent, and offered Latin American and Caribbean countries a $1 billion loan to buy vaccines.[71] Sinopharm Group Co, Ltd, a subsidiary of the state-owned China National Pharmaceutical Group (*Sinopharm*), and *Sinovac*, plus the CanSino Ad5 vaccine that has already received approval in China, have already produced 250 million doses of COVID-19 vaccines, which have been administered both in China and overseas. Among the 19 current vaccines that are going through the process, five are made by Chinese firms and the Chinese government has promised nearly *half a billion* vaccines through *bilateral deals*, signed even before the vaccines had secured an emergency use listing. China has already entered into deals with United Arab Emirate, Brazil and Indonesia. In the end, by building some sort of "health silk road" (in parallel to Belt and Road Initiative's infrastructure project), China may ascribe to itself the merit of having corrected the strong imbalance between wealthy and poor nations, with the additional benefit of

70 McMahon A. 2020. "Global Equitable Access To Vaccines, Medicines and Diagnostics For COVID-19: The Role of Patents As Private Governance", Journal of Medical Ethics; Gupta R. and Morain S. 2020. "Ethical Allocation of Future COVID-19 Vaccines", Journal of Medical Ethics.

71 "Covid: What Do We Know About China's Coronavirus Vaccines?" BBC News, 14 January 2021.

increase its influence and soft power in the world.[72] Unfortunately, the contents of these Chinese deals are secret. It not clear if Chinese vaccines will be donated or provided in return for payment to local manufactures; it is also unclear how much these vaccines will cost. A deal-by-deal approach could mean that some (poorer) countries will end up paying more for the vaccine than richer countries. Already, countries including South Africa, Mexico, Brazil, Turkey and Uganda pay different amount per dose for the AstraZeneca vaccine and, ultimately, more than governments in the European Union.[73]

With regard to Russia, the Gamaleya Institute in Moscow, that has developed the Russian's vaccine *Sputnik V* (with V standing for vaccine), a vector vaccine, already employed and authorized in Russia, but that has yet to be licensed by an international regulatory body, has production agreements with at least five different pharmaceutical companies in India, to supply around 500 million doses per year. Russia also secured agreements with South Korea and a number of other places and has accepted to share its licensing and knowhow and related technology.[74]

In the end, even if these vaccines will have a lower efficacy rate than the Western-made ones, the extensive supply of Chinese and Russian vaccines will make a real difference to the low and middle-income countries of the Global South, which would rather have these vaccines than nothing. The poorer countries and developing nations will subsequently look to China and Russia for assistance. At the moment, seemingly, the only alternative for the Global South to gain more

72 Zhaoyi P. 2020. "Chinese Vaccines Will Be Made Global Public Good, Says Xi", https://news.cgtn.com/news/2020-05-19/Chinese-vaccines-will-be-made-global-public-good-says-Xi-QCpFSGlL2g/index.html. According to a report published by Reuters on March 9, 2021, India has urged the other Quad members (United States, Japan and Australia) to invest in its vaccine production capacity in an attempt to counter China's widening vaccine diplomacy. The financing agreement to support an increase in manufacturing capacity for coronavirus vaccines in India, will focus particularly on companies and institutions in India manufacturing vaccines for American drugmakers Novavax Inc and Johnson & Johnson. See "Quad Nations Meeting To Announce Financing To Boost India Vaccine Output – U.S. Official", https://www.reuters.com/article/us-health-coronavirus-vaccines-quad-excl-idUSKBN2B12QM.

73 "Is Vaccine a Private Patent or a Global Public Good?", CSmonitor.com., March 1, 2021. The prices of vaccines vary and differ from deal to deal. AstraZeneca has said that it will provide its vaccine around $3–4 US dollar per dose, that is to say between five and 10 times cheaper that the estimated prices of other leading vaccines, such as Pfizer/BioNTech and Moderna. The current explanation for different prizes imposed to low and middle-income countries, compared to U.S. and EU, is that these governments have already heavily subsidized R&D of the main manufacturer companies.

74 https://www.democracynow.org/2021/3/11/rich_countries_block_vaccine_patent_waiver, 11 March 2021.

access to COVID-19 vaccines consists entirely in buying them from China and Russia.[75]

4 Global Public Goods Versus Intellectual Property Rights: The Fallibility of EU's IPRs Traditional Management

In early June 2020, the EU Commissioner for Health and Food Safety Stella Kyriakides said that: "[w]orking together will increase our chances of securing access to a safe and effective vaccine at the scale we need and as quickly as possible. It will ensure fair and equitable access for all across the EU and globally, thus offering the best opportunity of finding a permanent exit strategy from the COVID-19 crisis".[76] The *Annex* to the Commission Decision approving the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States and related procedures,[77] which contains *Initial Considerations* regarding the structure, purpose, process and governance of the EU's procurement scheme consisting in Advance Purchase Agreements with vaccine manufacturers, via the EU *Emergency Support Instrument*, lists this precise objective for negotiations with pharmaceutical companies. Specifically, the objective states that

> In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a COVID-19 vaccine as a global public good. This promotion will include access for low and middle income countries to these vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort (emphasis added).

In principle, the EU's characterization of COVID-19 vaccines as *global public goods* should logically imply that the Commission has offered to run the single "central procurement procedure" on behalf of all Member States in line with the related need to guarantee the access to the vaccines *also* to low and middle-income countries as well. This is a societal, moral and ethical imperative, given the impressive loss of life and the millions pushed into poverty around the world as a result of the pandemic. Therefore, one would have expected that the terms and the

75 "It's Time to Trust China's and Russia's Vaccines", The New York Times, February 5, 2021.
76 European Commission, Press release, 17 June 2020, Brussels.
77 C(2020)4192 final, Brussels, 16.6.2020.

conditions of the APAs negotiated by the Commission reflect this fundamental objective. After months of growing pressure, from Members of the European Parliament (MEPs) and civil society, and the action taken by the *Corporate Europe Observatory* that has filed two *Freedom of Information requests* to the European Commission to throw light on the excessively secretive negotiations about APAs for COVID-19 vaccines,[78] the *European Ombudsman* started investigating, early this year, the secrecy with which the European Union's executive is handling COVID-19 vaccine supply contracts.[79] Finally, after this extensive back and forth, the EU Commission has only recently posted on its website the texts of the supply contracts agreed upon.

The released documents merit close scrutiny since they clearly reveal the highly *hypocritical attitude* of Europe in respect to its commitment to provide universal, fair access to COVID-19 diagnostics, treatments and vaccines and how such documents have simply paid no more than *lip-service* to the concept of *global common/public good*. All of the EU APAs show the same characteristics: the pricing, delivery terms and other key clauses are still confidential. As to the price per dose agreed for each of the vaccines covered by APAs, the Commission has continuously said it cannot disclose those prices as a result of the APAs commercial confidentiality agreements, notwithstanding the calling for months by civil society groups, MEPs and health advocates to reveal them under the argument that deals involving taxpayer funds should have greater transparency. Finally, for a short time, the EU's vaccine prices were made public by a tweet screenshot published, by accident, by Belgium's Budget State Secretary Eva De Bleeker.[80]

There are no indication in the EU APAs' texts whether the method used to set the essential terms in a "purchase contract" is fair or if the texts reflects the huge public investment in the development of the final product. This, is despite the announcement in the Annex of the EU Commission decision that the conditions of each contract will reflect the *balance* between the prospect of the producer

78 Tansey R. et al. 2020. "Power and Profit During a Pandemic. Why the Pharmaceutical Industry Needs More Scrutiny Not Less", https://corporateeurope.org/en/2020/09/power-and-profit-during-pandemic.

79 See the Ombudsman's letter announcing the inquiry, https://corporateeurope.org/sites/default/files/2021-01/INFO_202100085_20210122_090103.pdf; and the text of the Ombudsman's letter to the Commission, https://www.ombudsman.europa.eu/en/correspondence/en/137152.

80 According to the screenshot, the EU has spent between €1.78 and $18 US dollar per coronavirus vaccine. The price per dose listed for each of the six vaccines are as follows: Oxford/AstraZeneca: €1.78; Johnson & Johnson, $8.50; Sanofi/GSK: €7.56; Pfizer/BioNTech €12; CureVac: €10; Moderna: $18. See Deutsch J. and Gijs C. 2020. "Belgian Secretary of State Accidentally Reveals EU Vaccine Prices", POLITICO, https://www.politico.eu/article/belgian-secretary-of-state-accidentally-reveals-eu-vaccine-prices/.

providing a safe and effective vaccine quickly and the investment needed to deploy the vaccine on the European market. On the other hand, many clauses are redacted in extensive ways, showing how these APAs are simply "pull" incentive mechanisms in which huge European financial support is made available for the clinical development and production of what is hoped to become a marketable product at a later stage. The aim of EU APAs essentially consists in order " to de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production chain which is required for a rapid deployment of sufficient doses of an eventual vaccine in the EU and globally" (emphasis added). The funding provided up front will be considered "as an advance payment for any eventual purchase by Member States, thus reducing the amount that Member States will have to pay when eventually purchasing that vaccine".

The trouble with such an approach is that the EU has undertaken huge commitments with upfront payments without the necessary guarantees that effective and safe vaccines will be developed. In addition, all these financial contributions (whether given or promised) will be not refunded if the final product, a COVID-19 vaccine, is either not approved by EMA, or if development of vaccine ends up in causing serious and rare side-effects. This is, definitively, a curious way to link public founding with public interest. For example, the German pharmaceutical company CureVac has already received 300 million Euro from the German Federal Government, 75 million Euro in a loan from the European Investment Bank, supported by Horizon 2020 programme, and 13.5 million US dollars from the Coalition for Epidemic Preparedness Innovations, for Phase I research, into developing another potential mRNA-based coronavirus vaccine.[81] According to its CEO, CureVac plans to release late-stage trial results in the coming weeks. The company is now predicting an output of one billion doses in 2022, that, in prospect, could compensate the losses caused by the contracts signed by the Commission with AstraZeneca and J&J.[82]

The text of CureVac's APA,[83] on the other hand, contains many detailed articles on the *Exploitation of the Results* of the APA and on *Indemnification*. With

81 't Hoen E. and Boulet P. 2021. "The European Commission Says COVID-19 Vaccines Should Be Global Public Goods, But Do Their Agreements With Pharma Reflect This?" Medicines Law & Policy.

82 The EU has opted against renewing these two vaccine contracts once they expire at the end of the year, https://www.fiercepharma.com/pharma/europe-s-vaccine-rollout-slagging-after-j-j-and-az-holdups-curevac-readies-doses-for.

83 https://ec.europa.eu/info/sites/info/files/curevac_-_redacted_advance_purchase_agreement_0.pdf.

regard to the issue of exploitation, which deals with IPRs, the text (specifically article 1.20) expressly provides that

> [the] Parties acknowledge and agree that the *contractor* shall be the *sole owner of all intellectual property rights* generated during the development, manufacture, and supply of the Product, including all know-how (collectively, the "Product IP Rights"). The contractor shall be entitled *to exclusively exploit any such Product IP Rights*. Except as expressly set forth in this APA, the contractor does not grant to the Commission and/or the participating Member States by implication, estoppel or otherwise, any right, title, license or interest in the Product IP Rights. All rights not expressly granted by the contractor hereunder are reserved by the contractor (emphasis added).

It is, therefore, the contractor (in this case CureVac), and not the EU, that retains all the rights generated as a result of the EU funding, including *clinical data*. This means that the EU is not in a very favorable position to negotiate the final price (not yet disclosed in the Agreement), either for the European patients or for the least developed countries in the world that are in most need of the product, which is contrary to the explicit negotiation objectives stated in the EU/Member State Agreement. Furthermore, the EU member States are entitled to re-sell, export and/or distribute the future vaccine to any other EU or European Economic Area (EEA) Member State and Switzerland, provided that these States expressly agrees in writing to fully assume the indemnity obligations codified in the APA. The contract also contains an astonishing provision (Article I.10.2) which states that:

> [the] participating Member States shall take the appropriate measures to ensure that the Products supplied to them pursuant to this APA will not be (i) re-sold or (ii) exported, distributed or donated for free to another country outside the EU and EEA and Switzerland, including for donation via NGOs or the World Health Organization, without prior consent of the contractor.

This means that the EU has shamefully guaranteed a *de facto veto right* to the private company *to provide universal, fair access of vaccines through the current channel of global solidarity*. None of the EU APAs have clauses that will ensure global non-exclusive licenses to third parties, which would be able to guarantee the accessibility/affordability of COVID-19 health technologies. The EU has voluntary given up all its significant potential leverage in such context. The second shocking provision included in all EU APAs, concerns the problem of *Indemnification for liability*. With the excuse that these APAs are concluded under "epidemic conditions" and, as such, require some special/exceptional treatment reflecting the exceptional circumstances of the COVID-19 pandemic and the need to develop new vaccines at an unprecedented speed in order to allow for very large scale immunization, the Commission has undertaken steps to ensure (Article 1.23) that

> each participating Member State *shall indemnify and hold harmless the contractor*, its Affiliates, sub-contractors and sub-licensees, including contract partners involved in the research, development (including pre-clinical and clinical testing), manufacturing and/or delivery; and officers, directors, employees and other agents, representatives and service providers of each (together, the "Indemnified Persons") *for liability incurred and normally borne by them relating to harm, damages and losses* (together, the "Losses") as further specified in Article I.23.5 arising from the use and deployment of the Products supplied to the participating Member State (or another entity appointed by that participating Member State) under this APA, irrespective of the time when the Losses occur (emphasis added).

Therefore, the administration of the final product (the vaccine) will be conducted *under the sole responsibility of the participating Member States*. Contrary to what normally happens in ordinary agreements, where the risks are carried by the company, the Commission and the Member States will take all the responsibility for indemnification for liability. This is openly in contrast with the EU framework depicted rhetorically as "an insurance policy, which transfers *some of the risk* from industry to the public authorities in return for assuring Member States equitable and affordable access to a vaccine, should one become available" (emphasis added).

From the point of view of Big-Pharmaceutical companies this is, for sure, the best profit-maximizing model, as it is responsible for pushing for *public money* with no-strings-attached, strong monopoly patent rules, and the possibility to restrict access to COVID-19 drugs and vaccines, thus prolonging the pandemic in the name of profit.[84] The only action taken by the EU to secure its interests has been to start legal action after a longstanding dispute with AstraZeneca over shortfalls and delays in delivery hundreds of millions of doses of the vaccine (only a third of the 300 million doses are expected to be delivered). The issue is whether AstraZeneca has done everything in its power to meet its delivery schedule. in the light of the language of the contract that requires the "best efforts" to deliver the purchase doses on time.[85]

To conclude, it is abundantly clear that Europe is in no way pursuing the announced negotiating objective of promoting COVID-19 vaccines as *global public good*. Released documents confirm how the European Federation of

84 "Farmaceutica: per i big anti COVID profitti raddoppiati: 971 miliardi", Il Sole24Ore, 14.03. 2021. All the EU EPAs contains the same provision on *applicable law and settlement of disputes*: the Parties shall first refer such disputes to informal dispute resolution discussions between their respective representatives; if this informal procedure (through good faith negotiations) would fail, the EU APAs shall be governed by the laws of Belgium and the courts corresponding to that applicable law will be exclusively competent to hear settle any dispute which may arise under or in connection with this APA or the legal relationships established by this APA (see Article 1.21. of CureVac APA).

85 "EUSues AstraZeneca over Missing Vaccine Doses", The New York Times, April 26, 2021.

Pharmaceutical Industries and Associations (EFPIA) lobbied against the original European tool, designed to facilitate equitable access and pricing for pandemic treatments in Europe and elsewhere, thus de-prioritizing the public interest. The pharmaceutical industry, when it comes to protecting its monopoly privileges, unsurprisingly came out with the pandemic narrative saying "Support us – or lose out", and characterizing the US Biomedical Advanced Research and Development Authority (BARDA) (that had given $30 million to Sanofi to go towards its research) as the *best model* for how public collaboration with industry should work. This model provides that public money is used to 'de-risk' a pharmaceutical company's investment, and "if it is successful, the company still gets to keep the IP, dictate prices, and reap in the profits".[86]

A question for written answer (E-004464/2020) submitted by the European Parliament to the Commission asking if it can confirm that it wants the COVID-19 vaccine to be a "universal common good" as declared by the President, if the Commission could clarify the *legal definition* it uses for "universal common good", and what *legal implications* does this definition entails as it pertains to intellectual property rights and licensing, has received an astonishing answer given by Commissioner Ms. Kyriakides. According to the Commissioner,

> [the] notion of universal common good highlights the importance for humanity of finding a vaccine that can be employed in prevention of COVID-19, an infection that knows no borders. *It is not a legal concept producing legal consequences, also in the context of intellectual property (IP) rights.* An effective IP system is crucial to ensure incentives for the development of innovative vaccines. As set out in the abovementioned EU Vaccines Strategy, *the Commission supports voluntary pooling and licensing of IP related to COVID-19 therapeutics and vaccines, to promote equitable global access as well as a fair return on investments* (emphasis added).[87]

It is clear that when the EU Commissioner says that the global common good is not a *legal concept producing legal consequences* she is totally unaware of the efforts made by some national parliaments to regulate this legal category, elaborating a discipline specifically designed for ensuring a reinforced system of protection of these kind of goods that are essential for the collectivity and for the common interest of citizens. Just to mention the case of Italy, in 2007 the Minister of Justice established a special *Commission on public goods*, chaired by Professor Stefano Rodotà, for the elaboration of the principles and guidelines of a draft law delegated to the Government to amend the rules of the Italian Civil Code on

86 Tansey et al., *supra* note 78.

87 Parliamentary questions, 28 October 2020, https://www.europarl.europa.eu/doceo/document/E-9-2020-004464-ASW_EN.html.

Public Property,[88] in light of the express reference made by the Italian Constitution of Public Property and the social functionalization of the same assets for the general interest needs (article 42).[89] As explained above, the concept of global public/common goods has much to do with the "*governance*" of the commons. Therefore, it *also* has much to do with intellectual property, which attributes a broad "*private governance*" on any kind of innovation, including medical technologies and medicines urgently needed in relation to COVID-19 pandemic.

5 Intellectual Property Rights and the Pandemic: The Waiver Debate within the TRIPS and Beyond. The Same Old Arguments

The COVID-19 pandemic has amplified the systemic and structural inequities, and particularly the health inequities, that disproportionately and negatively impact poor and under-represented groups across and within communities, countries, regions, and continents.[90] The challenge and ongoing discourse about the response to COVID-19 crisis, its prevention and treatment, the development and fair global allocation and distribution of COVID-19 vaccines, has inevitably reignited the debate, that has lasted for nearly three decades, over the current IPRs system. The point is whether the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Agreement, the most comprehensive multilateral agreement on IPRs, represents a significant and positive factor in facilitating access to existing technologies and in supporting the creation, manufacturing and dissemination of new technologies, including the extensive array of medical products, medicines, diagnostics as well as vaccines, required to fully respond to the COVID-19 crises. Or if the TRIPS is rather a *suboptimal* system,

88 See *Disegno di legge recante modifiche al codice civile in materia di beni comuni e di contenuti del diritto di proprietà*, Senato della Repubblica, XVIII legislatura, n.1436, https://www.giustizia.it/giustizia/it/mg_1_12_1.wp?facetNode_1=3_1&facetNode_3=0_10_21&facetNode_2=0_10&previsiousPage=mg_1_12&contentId=SPS47617.

89 For an excellent analysis of global common goods and their governance, see Mattei U. 2011. Beni comuni. Un manifesto, 7ed, Bari, Laterza; Capra F., Mattei U. 2017. Ecologia del diritto. Scienza, politica, beni comuni, Arezzo, Aboca Edizioni.

90 Thomas Y.F. et al. 2020. "Reaffirming The Significance Of Global Public Goods For Health: Global Solidarity In Response To COVID-19 And Future Shocks" https://www.g20-insights.org/policy_briefs/reaffirming-the-significance-of-global-public-goods-for-health-global-solidarity-in-response-to-COVID-19-and-future-shocks/.

that simply facilitate the monopoly granted to IPRs owners over the R&D, manufacturing and distribution of new diagnostics, treatments, and vaccines.[91]

Following the declaration (on 11 March 2020) by the World Health Organization (WHO) of the COVID-19 as a global pandemic, and the caution expressed by the World Trade Organization WTO that this "[p]andemic represents an unprecedented disruption to the global economy and world trade, as production and consumption are scaled back across the globe",[92] taking into account the break down in global supply chains (coupled with growing supply-demand gaps), the delegations of South Africa and India have called (in the TRIPS Council meeting held on 30 July 2020) for a *holistic approach* that takes account of TRIPS flexibilities in the area of patents, copyright, design rights and trade secrets.[93] This request advanced by the two WTO members has been translated later in a formal *Communication on Intellectual Property and the Public Interest: Beyond Access to Medicines and Medical Technologies Towards a More Holistic Approach to TRIPS Flexibilities*,[94] followed (on 2 October 2020) by a joint *Communication on Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*.[95] By that time, the pandemic was already widespread, and there were no vaccines or medicines to effectively prevent or treat COVID-19. India and South Africa expressed their deep concern, as new diagnostics, therapeutics and vaccines for COVID-19 start to be developed, on how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand, outlining several reports about intellectual property rights (not only patents but also other IPRs) hindering, or potentially hindering, the timely provisioning of affordable medical products to patients. In addition, these countries stressed that many developing countries have faced institutional and legal difficulties when using the flexibilities available in the TRIPS agreement, particularly countries with insufficient or no manufacturing capacity to take advantage of the Special Compulsory Licensing for Export, first introduced in 2003 by means of a *waiver decision* to TRIPS and as of 2017 permanently incorporated in Article 31 *bis* of the amended TRIPS Agreement. This is a system that in principle has been conceived expressly to facilitate access to affordable medicines for countries that

91 An excellent résumé of the various positions and arguments, for and against, the current multilateral IPRs system is provided by the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, September 2016, http://www.unsgaccessmeds.org/final-report.

92 https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm.

93 WTO official document no. IP/C/M/95/Add.1, (all the WTO official documents are published at https://docs.wto.org/).

94 WTO official document no. IP/C/W/666.

95 WTO official document no. IP/C/W/669.

rely on import of medicines to deal with a public health problem,[96] but judged by India and South Africa as an overly cumbersome and lengthy process for the import and export of pharmaceutical products.

The proposal submitted by South Africa and India calls for a Waiver for all WTO members of certain provisions of the TRIPS Agreement in relation to the "prevention, containment or treatment" of COVID-19. According to the Proponents, the objective of the proposal is to avoid barriers to the timely access of affordable medical products including vaccines and medicines, and the scaling-up of research, development, manufacturing and supply of essential medical products. The Waiver would cover obligations in *four sections* of the TRIPS Agreement. It is proposed to last for a specific number of years, to be agreed by the General Council, in any case *until widespread vaccination is in place globally* and the majority of the world's population is immunized, but reviewed annually by the WTO members until termination. If agreed and enacted, the waiver would prevent WTO members from challenging any measures taken in conformity with the provisions of the waiver under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism.[97]

The Waiver proposal has been the subject of intense and comprehensive discussions in all the TRIPS Council (formal and informal) meetings following its submission.[98] Despite the growing support for the proposal, that has been cosponsored by Kenya, Eswatini, Mozambique, Pakistan, Bolivia, Venezuela,

96 See WTO doc. W/T/L/540, 2003 and WT/L/540/Corr.1, 2005. The *Special Compulsory Licensing System* covers pharmaceutical products, including medicines, vaccines and diagnostics, needed to address public health problems as set out in the Doha Declaration on the TRIPS Agreement and Public Health, addressing a specific problem identified in the Doha Declaration, enabling the vulnerable countries to make "effective use" of compulsory licensing. See WTO. 2020. "The TRIPS Agreement and COVID-19. Information Note", 10.

97 The interested Sections of TRIPS are: Section 1 on copyright and related rights, Section 4 on industrial designs, Section 5 on patents and Section 7 on the protection of undisclosed information. See Annex, Draft Decision Text: Waiver From Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of COVID-19, IP/C/W/669, 3–4.

98 The proposal has also been the subject of some doctrinal comments: see Bacchus J. 2020. "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines. The Last Thing the WTO Needs Is Another Debate Over Perceived Trade Obstacles to Public Health", https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-COVID-19-vaccines; Mercurio B. 2021. "WTO Waiver From Intellectual Property Protection For COVID-19 Vaccines And Treatments: A Critical Review", https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820, forthcoming in Virginia Journal of International Law Online 2021; McMahon A., *supra* note 70; Desierto D. 2021 – "Equitable COVID Vaccine Distribution and Access: Enforcing International Legal Obligations under Economic, Social, and Cultural Rights and the Right to Development" EJIL: Talk!.

Mongolia, Zimbabwe, and Egypt,[99] endorsed through civil society (more than 400 organizations in the United States calling on President Biden to endorse the waiver),[100] 115 members of the European Parliament who issued a declaration urging the EU to drop its opposition to the TRIPS waiver proposal, as well as national parliaments[101] multiple intergovernmental and other international organizations,[102] several high-income countries opposed the waiver. These opposing countries diverged with the Proponents on what role IPRs play in achieving that goal, while at the same time reiterating their common goal of providing timely and

99 Sixty-two countries, including the ACP (Africa, Caribbean, and Pacific) group, Afghanistan, Argentina, Bangladesh, Cambodia, Sri Lanka, Honduras, Cuba, Nepal, Nicaragua, Nigeria, Indonesia, Tunisia, Mali, and Mauritius strongly supported the waiver proposal; the same is true for the African Group and the LDCs Group. The total of countries in favor of the Waiver is more than two/thirds (at least 119 among the 164 WTO members). Also, the Holy See, which has *observer status* at the WTO, has expressed itself in support of the Waiver, underscoring the need to put billions of humans lives before the profits and patents of Big Pharma. See Third World Network. 2021. **"**Two-Thirds Of WTO Members Issue Call For A TRIPS Waiver", TWN Info Service on WTO and Trade Issues.

100 "Rich versus Poor (Again) at WTO", 10 March 2021, https://foreingpolicy.com. See also the appeal addressed to Italian Government to support the waiver proposal by the "Comitato Nazionale per l'Iniziativa dei Cittadini Europei (ICE)/petizione europea "Right2cure – No profit on pandemic" "Diritto alla Cura, nessun profitto sulla pandemic", which brings together 67 Italian organizations.

101 According to the "Declaration from Members of the European Parliament to urge the Commission and Member States not to block the TRIPS waiver at the WTO and to support global access to COVID-19 vaccines", Brussels, 24 February 2021, https://haiweb.org/: "The WTO decision on a potential waiver offers a crucial and much-needed act of effective solidarity, as it is an important step towards increasing local production in partner countries and, ultimately, suppressing this pandemic on a global scale". Also the Chamber of Deputies of the Italian Parliament has approved a motion (with 384 votes in favor, 28 against and 22 abstentions) which commits the Italian government to pushing within the European Union for a temporary waiver to TRIPS rules, Il Fatto Quotidiano, 24 March 2021. More than 65.000 European citizens have signed a petition calling upon the EU "to make anti-pandemic vaccines and treatments a global public good, freely accessible to everyone"; the campaign has one year to collect one million signatures in EU member States in order to encourage the European Commission to propose legislation to implement this demand. See https://europa.eu/citizens-initiative/initiatives/details/2020/000005_en.

102 African Commission of Human and Peoples' Rights, Amnesty International, Drugs for Neglected Diseases initiative (DNDi), Human Rights Watch, MSF, People's Health Movement, South Centre, Third World Network, Joint United Nations Programme on HIV/AIDS (UNAIDS), UNITAID, Experts of the UN Office of the High Commissioner for Human Rights, and World Health Organization (WHO). According to a brief document updated 18 November 2020, more than 300 civil society organizations, globally, have called for governments to support the proposal. See, "India and South Africa Proposal for WTO Waiver From Intellectual Property Protections For COVID-19-Related Medical Technologies", https://msfaccess.org/sites/deault/files/202011/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf.

secure access to high-quality, safe, efficacious and affordable vaccines and medicines for all.

It would be impossible, due to the length constraint of the present analysis, to summarize all the arguments (including both pros and cons) advanced during several months of discussions inside the Council for Trade-Related Aspects of Intellectual Property Rights, recorded in several WTO official documents.[103] In extreme synthesis, the arguments advanced are the same now as the old ones raised by developing countries 20 years ago to overcome the pharmaceuticl companies' monopolies on the drugs for treating the HIV/AIDS epidemic, in order to foster generic production and competition to save millions of people who could not afford the extremely high prices that Big Pharma charged for these medicines.

According to the Proponents many developing countries face limitations in developing and scaling up manufacturing capacity due to IP barriers and the fact that existing vaccine manufacturing capacities in those developing countries remain unutilized exactly because of IP barriers. As a result, insufficient amounts of vaccines were being produced to end the COVID-19 pandemic. It is, therefore, necessary that all IP, knowledge, technology and data related to COVID-19 health technologies can be utilized by everyone to ensure uninterrupted production and supply by any competent country or manufacturer worldwide, thus eliminating all IP and technology barriers. The Proponents see their Waiver proposal as a powerful enabler of meaningful knowledge-sharing and technology transfer, that will represent an *open* and *expedited* global solution allowing uninterrupted collaboration in the production and supply of health products and technologies required for an effective COVID-19 response. Additionally, the Proponents argued that all of the COVID-19 medicines being developed with substantial public funding. Consequently, the pharmaceutical companies' argument that IPRs are needed to protect *their* investment is weak. Since the start of this pandemic, pharmaceutical corporations have continued with their 'business-as-usual' approaches by maintaining their exclusive rights and refusing to offer non-exclusive licenses with worldwide coverage to facilitate global access. Rather these companies are simply pursuing secretive and monopolistic deals with wealthy countries representing only 13% of the global population, that already have pre-purchased half of the doses of the five leading vaccines.

According to the countries opposing the Waiver proposal, which not surprisingly account for 60% of the globally administered COVID-19 vaccines, the waiver is a too sweeping measure. In order to ensure the proportionality of any measures

103 See WTO official documents IP/C/W/670, 23 November 2020; WT/GC/223, 24 November 2020; IP/C/671, 27 November 2020; IP/C/W/672, 15 January 2021; IP/C/W/673, 15 January 2021; IP/C/W/674, 15 January 2021.

taken in response to the COVID-19 global pandemic, it should first be demonstrated that the option of compulsory licensing and other flexibilities under TRIPS are inadequate to address public health concerns. Citing the role of IP as an incentive for innovation to fight the current and future pandemics, and as underpinning the licensing, manufacturing, procurement and distribution of COVID-19 diagnostics, therapeutics and vaccines, they urged an *evidence-based* discussion on examples where IP would pose a barrier to manufacturing and access to vaccines that could not be addressed by the multiple existing TRIPS flexibilities. Particularly impressive are the declaration and communication submitted by the EU to TRIPS Council. Those texts simply reiterate the "legal certainty" of TRIPS flexibilities. In this respect they do not either meaningfully contribute to the text-based negotiations of the India–South Africa waiver proposal, nor do they aim at promoting any new policy measure that would effectively accelerate the production and equitable global distribution of vaccines and medicines.[104] Proponents were, conversely, asked to cite specific examples of where IP challenges have impeded or prevented local production or manufacturing and the timely procurement of COVID-19 diagnostics, equipment, therapeutics or vaccines,

104 See Communication from The European Union to The Council for Trips: Urgent Trade Policy Responses to The Covid-19 Crisis: Intellectual Property, Brussels, 4 June 2021, https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf; Draft General Council Declaration on The Trips Agreement on Public Health in the Circumstances of a Pandemic; Communication from The European Union to The Council For Trips, 18 June 2021, IP/C/W/681. Actually, a range of policy options (confirmed under the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health, adopted on November 2001), if implemented in domestic law, remains available to WTO members as tools to deal with public health issues where needed. For example, Article 30 of the TRIPS Agreement states that members may provide limited exceptions to the exclusive rights conferred by a patent (provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties); among the possible limited exceptions to patent rights, two in particular might have great relevance in the context of the current COVID-19 crisis: the *research and experimental use exception* and the *regulatory review (or Bolar) exception*. Article 31 of TRIPS Agreement also allows *compulsory licensing* and *government use* of a patent without the authorization of its owner under a number of conditions aimed at protecting the legitimate interests of the patent holder. All WTO members may grant such licenses and government-use orders for health technologies, such as medicines, vaccines and diagnostics, as well as any other product or technology needed to address COVID-19. Article 31 bis of the amended TRIPS Agreement provides a *Special Compulsory Licensing System* specifically designed to enable export to countries that are especially dependent on imports for medicines. TRIPS also provides policy options and flexibilities (exceptions and limitations) in other areas of IPRS of particular importance when considering the question of access to medical technology and innovation to aid responses to the COVID-19 such as copyright (Article 13), Trademarks (Article 17), clinical trial data and undisclosed information (Article 39.3). See WTO. *'The Trips Agreement and COVID-19", supra* note 96, 8–11.

particularly to describe when and how they were not able to issue compulsory licenses under Article 31 of the TRIPS Agreement in relation to COVID-19.

All the examples of IP issues and barriers in COVID-19 pandemic on access to therapeutics, vaccines and diagnostics, offered by the Proponents, have been dismissed by High Income Countries (HICs). They rejected also the observation that the existing mechanisms for compulsory licenses under Article 31 and Article 31 *bis* of the TRIPS Agreement contain *territorial* and *procedural* restrictions that make the practice of issuing *product-by-product* compulsory licenses a prohibitively complex process that can offer neither an expedited nor global solution, or the unduly political and trade pressure put by high-income countries on developing countries when they make use of compulsory licenses, as well as the geographical restrictions contained in all the voluntary licensing mechanisms, even the threat of legal dispute for patent infringement against two Italian engineers that in March 2020 reverse-engineered and 3D-printed replacements valves at a cost of about USD 1 in the Lombardy region in Northern Italy, thus stopping them from distributing the digital design file.[105] The opponents insist that equitable access can be achieved through the existing flexibilities provided by the TRIPS Agreement, particularly compulsory licenses, and donor-funded and voluntary collaboration mechanisms already in place, such as *COVID-19 Technology Access Pool* (CTAP), the *ACT- Accelerator* and *COVAX Facility*, arguing that suspending large parts of the TRIPS Agreement would be counterproductive, as it would undermine currently ongoing efforts to scale up manufacturing novel and highly complex COVID-19 vaccines in such a short time, to achieve global access, that has been only possible due to protection provided to intellectual property rights.

The result is that, as of July 2021, consensus on the Waiver proposal has not been reached within the deadline of 90 days set out in Article IX:3 of the Agreement Establishing the WTO, with the consequence that WTO members are still engaged in a stall dialogue within the TRIPS Council, without any outcome and no progress towards text-based negotiations.[106] The discussion around alternative routes to achieving equivalent results continues, with the WTO Director-General Dr. Ngozi Okonjo-Iweala proposing a "third way" to facilitate equitable access to COVID-19 medicinal products, namely a technology transfer within the framework of multilateral rules. In Addition, a concurrent proposal from the Ottawa Group at

105 IP/C/W/673, paras 36–43, 56; see also https://www.techtimes.com/articles/248121/20200317/maker-ventilator-valves-threatens-sue-volunteers-using-3d-printed-coronavirus.htm.

106 The WTO rules allow for Members to vote on the proposal; for the Waiver to be adopted a three-fourths majority of the WTO members is needed; nevertheless, the WTO members have never abandoned the "consensus decision-making" in favor of a vote. It is therefore unlikely that they decide so in respect of this Proposal.

WTO,[107] which calls for the easing of export restrictions and tariffs that might be restricting the flow of COVID-19 medicinal products, is in discussion.[108] But things on this matter go quickly, showing that Governments might reconsider their position in the view of the worsening of the pandemic, as we will see in our concluding remarks.[109]

We will investigate in the following section whether the many examples of voluntary collaborative efforts to facilitate cooperation for research and development of COVID-19 related health technologies put in place by some governments, private sector actors, and international bodies, can really deliver what is required in both developing and least developed countries to address the current pandemic. As to the model of donation and philanthropic responses suggested by HICs, it simply relies on the "business-as usual" monopolistic model. As such, in the end, it would undermine the very fundamental right of developing and least developed countries to produce the needed medical technologies for themselves.

6 The Inadequacy of Collaborative Global Efforts to Support Ethical, Qualify, Safety and Efficacy Global Access to COVID-19 Vaccines

It is certainly true that under Article 31 of the TRIPS Agreement, all WTO members may grant compulsory licenses for health technologies, such as medicines, vaccines and diagnostics, as well as any other product or technology needed to combat COVID-19. However, by insisting on such policy options, the HICs seem to voluntarily underestimate the multiple obstacles that exist to the effective use of compulsory licensing agreements for addressing the COVID-19 pandemic. First of all, compulsory licenses are granted only at the national level of the State, since patent rights are territorial in nature, and the legal avenues to obtain a compulsory

107 Australia, Brazil, Canada, Chile, the European Union, Japan, Kenya, Republic of Korea, Mexico, New Zealand, Norway, Singapore and Switzerland.

108 See Annex: Draft Elements of a "Trade and Health" Initiative to WTO doc. WT/GC/223.

109 *Infra*, para 8. After the Biden Administration declared its support for negotiating the TRIPS waiver, the co-sponsoring countries submitted a revised waiver language to the WTO TRIPS Council. See, Council For Trade-Related Aspects of Intellectual Property Rights: English Waiver From Certain Provisions of The Trips Agreement For The Prevention, Containment and Treatment of Covid-19: Revised Decision Text. Communication from The African Group, The Plurinational State Of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, The LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, The Bolivarian Republic Of Venezuela And Zimbabwe, 25 May 2021, IP/C/W/669/Rev.1.

license under national laws may be really heavy or unclear. Second, compulsory licensing needs to be considered for each and every single new drug/vaccine/health technology on a *case-by-case* basis. A preliminary patent landscape study has revealed a very high level of primary and secondary patents on anti-viral therapies filed and granted in nearly 50 out of 60 jurisdictions expiring between 2036 and 2038; more than 100 patents on mRNA platform technology used for COVID-19 vaccine development are exclusively owned by different companies,[110] and several patent disputes have already arisen between different mRNA vaccine developers.[111] Third, stricter legal protection for patent holders normally applies under investment treaty law or bilateral and regional trade agreements that limit the use of this policy option placing additional restrictions on its use. Fourth, many HICs (including the E.U.) provide severe regulatory obstacles to the effective use of compulsory licenses, like marketing and data exclusivity periods, thus preventing generic producers from obtaining approval for generic medicines during this time. Fifth, a powerful obstacle for effective utilization of compulsory licenses is the unwillingness of HICs to use this option. Many lower income countries that have resorted in the past to compulsory licenses for the procurement of medicines have faced litigation and trade sanctions.

However, the COVID-19 pandemic has brought about an important change, since some high-income countries have recently eased procedures to grant compulsory or government use licenses (Canada, Germany and Hungary) and, in March 2020, one State (Israel) allowed a compulsory license for the import of lopinavir/ritonavir (a generic version of AbbVie's patent drug Kaletra) from India for the purpose of exploring the possibility of treating COVID-19 patients.[112] This move had a powerful effect on the manufacturing company which subsequently announced it would not enforce its patents on Kaletra anywhere in the world, thus allowing the possibility of producing generic versions of Kaletra globally without fear of patent infringement challenges.[113] In addition, Moderna, a company that has developed a messenger RNA (mRNA) vaccine against COVID-19 and that holds a number of patents relevant to the vaccine, announced that it will not enforce

110 See IP/C/W/670; IP/C/W/673.

111 Hammond E. 2020, "Lawsuit Reveals Intellectual Property Is Holding Back Production Of CEPI-And Gates Foundation-Founded COVID-19 Vaccine Candidates," TWN Series on Intellectual Property and COVID-19 Vaccines, https://www.twn.my; "Moderna loses Key Patent Challenge", Nature Biotechnology (2020) 1009;; "Pfizer-BioNTech, Regeneron Sued For Patent Infringement With COVID-19 Products", October 6 2020, https://www.fiercepharma.com/pharma/pfizer-biontech-regeneron-sued-for-infringement-allele-s-patent-their-COVID-19-products; IP/C/W/672, para 53.

112 WTO. "The Trips Agreement and COVID-19", *supra* note 96, p. 9.

113 McMahon A., *supra* note 70,145.

those patents during the pandemic to allow other COVID-19 vaccines in development to use the technology. It also stated its willingness to license the company's intellectual property for COVID-19 vaccines to competitors upon request for the period after the pandemic.[114] Nevertheless, this decision has come after Moderna has lost patent disputes, over ownership of some of the intellectual property surrounding the delivery technology it uses, to Arbutus Biopharma and U.S. federal scientists.[115]

These example shows clearly that when the greater number of States show their willingness to use the deterrent of compulsory licenses for COVID-19, the more public intervention can be a powerful instrument against potential uses of patents for profiteering off of the Pandemic. Normally, the mere threat to use a compulsory license is enough to encourage patent holders to voluntary license their products on more reasonable and favorable terms. That said, the impossibility of obtaining a compulsory license in more than one State highlights in itself that such a measure, alone, could never be a blanket solution for access to COVID-19 vaccines and technologies, regionally or globally. Moreover, the recourse to this flexibility in the context of COVID-19 pandemic does not represent an expedited solution.[116] Compulsory licenses are simply part of a broader kit that permits the rebalancing of patent holders' power in favor of public health needs. Voluntary licensing agreements (VL) have multiple advantages over compulsory licenses.[117] First, they are premised on the patent holders' consent, with the consequence that, normally, they would not be challenged in courts or otherwise disputed. Second, VLs can be set up at a regional or an international level, and in contrast to compulsory licenses that are limited to the use of the patent rights, they can be, and normally are, designed to provide broad *transfer of technology and data sharing* to effectively help to expedite the development, manufacturing and marketing of tests, treatments and vaccines.[118] Scaling out global vaccine manufacturing requires the cooperation of multiple countries due to the complexity of upstream raw material and other components value chains. According to a WTO study, a typical vaccine manufacturing plant will use in the realm of 9000 different materials sourced from some 300 suppliers across

114 https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-COVID-19.

115 https://www.biopharmadive.com/news/moderna-coronavirus-vaccine-patents/586678/, 8 October 2020.

116 IP/C/W/672, para 76.

117 For the proposal to establish global, regional, or national licensing facilities for essential medicines, see Abbot F.M. and Reichman J. H. 2020. "Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic", Journal of International Economic Law, 535–561.

118 McMahon A, *supra* note 70, 146 ff.

approximately 30 different countries.[119] The components, raw materials and technology required to produce vaccines are normally subject to IPRs. Under conventional IP practice, patents could be applied for on nearly every single step and aspect of vaccine development, production and use, ranging from starting materials, composition process, and the final products to methods of filling and packaging, methods of vaccination and vaccine schedules.[120]

Simply relying on voluntary licensing agreements that entirely depend on the patent holders' willingness to ensure that patented inventions are licensed for the global pandemic is not enough. As UNESCO has clearly stated "new global approaches and mechanisms should be urgently put in place to allow efficient development and production of vaccines".[121] Happily, while the WTO members could not agree if an IPRs Waiver is the best way to achieve a full response to the COVID- 19 pandemic, since the outbreak of the global health crisis a myriad of public and private actors have launched *collaborative global efforts* to develop treatments, vaccines and diagnostics with the aim of guaranteeing equitable access to those technologies, including substantial investments in product development partnerships (PDPs), and large multi-stakeholder R&D initiatives, to support non-commercial development of a COVID-19 vaccine.[122] These kinds of collaborative arrangements represent an entirely different form of governance[123]

119 WTO. 2020. "Developing and Delivering COVID-19 Vaccines Around The World", https://www.wto.org/english/tratop_e/covid19_e/vaccine_report_e.pdf, p. 17-8; see also Bown C.P, Bollyky T.J., *supra* note 52, 64-5.

120 IP/C/W/673, para 24, https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf.

121 UNESCO's Ethics Commissions' Call For Global Vaccines Equity and Solidarity, SHS/BIO/IBC-COMEST/COVID- 19 Vaccines, 24 February 2021, 5, http://www.sbbioetica.org.br/uploads/repositorio/2021_02_24/Unesco2021GlobalVaccineEquityESolidarityStatement-fev2021.pdf.

122 See the standalone section "An Integrated Health, Trade and IP Approach to Respond to The COVID-19 Pandemic" in the 2020 study jointly published by the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the WTO. 2020. "Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property And Trade" (second edition), https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm, 7–13, 11 ff.

123 This is in line with Articles 7 and Article 8 of the TRIPS relating to its objectives and principles. Article 7 of the TRIPS Agreement describes the objectives of the global IP system in terms of a balance of rights and obligations. The objectives of TRIPS are the protection and enforcement of IPRs in a manner which contributes to "the promotion of technological innovation", "the transfer and dissemination of technology" to the mutual advantage of both "producers and users of technological knowledge", and also "social and economic welfare". Article 8 states that members may adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development that are consistent with the provisions of the TRIPS Agreement.

compared to the patent holders' private governance over discovery, development and delivery of new medical technologies that could restrain or adversely affect the international transfer of the knowledge necessary for research and development of COVID-19 related health technologies. In particular, this new form of collaborative governance can effectively help expedite the development, manufacturing and marketing tests, health treatments and vaccines (global public/common goods).[124]

In line with the call made by the UN General Assembly in its resolution A/RES/74/274, and the World Health Assembly resolution WHA73.1, on "international organizations and other stakeholders […] to work collaboratively at all levels to develop, test, and scale-up production of safe, effective, quality, affordable diagnostics, therapeutics, medicines and vaccines for the COVID-19 response, including, existing mechanisms for voluntary pooling and licensing of patents in order to facilitate timely, equitable and affordable access to them".[125]

The WHO launched in 2019 its *COVID-19 Strategic Preparedness and Response Plan* (SPRP) that includes actions to coordinate international R&D efforts and the use of a *R&D Blueprint Global Coordination Mechanism*.[126] This plan highlights the importance that "virus materials, clinical samples and associated data should be rapidly shared for immediate public health purposes and that fair and equitable access to any medical products or innovations that are developed using the materials must be part of such sharing".[127] The SPRP was updated in February 2021 and built upon what WHO has learned about the virus and collective response over the course of 2020.[128]

On 23 March 2020 the President of Costa Rica asked the Director-General of the World Health Organization to "undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic".[129] On 29 May 2020, the Pool was formally launched by President Carlos Alvarado Quesada and the Director-General of WHO with the *Solidarity Call to*

124 WHO. 2020. "Making the Response to COVID-19 A Public Common Good", https://www.who.int/docs/default-source/coronaviruse/solidarity-call-to-action/solidarity-call-to-action-01-june-2020.pdf?sfvrsn=a6c4b03d_4.

125 On the role of International Organization during the pandemic, see Acconci P. 2020. "Responses of International Organizations to the Health Emergency Due to the COVID-19. A First Impression", Rivista di Diritto Internazionale, 415–452; von Bogdandy A., Villarreal P. 2020. " International Law on Pandemic Response: A First Stocktaking In Light Of The Coronavirus Crisis" MPIL Research Paper Series, 1–29.

126 https://www.who.int/publications/i/item/strategic-preparedness-and-response-plan-for-the-new-coronavirus; https://www.who.int/teams/blueprint/COVID-19.

127 https://www.who.int/teams/blueprint/COVID-19.

128 https://www.who.int/publications/i/item/WHO-WHE-2021.02.

129 Letter to Dr. Tedros Adhanom Ghebreyesus, 23 March 2020, https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf.

Action.[130] The *Solidarity Call to Action* contains key elements addressed everyone from governments and other research and development funders, to the holders of knowledge, IPR, and data related to new therapeutics, diagnostics and vaccines, and to the researchers and stakeholders. On the premise that the COVID-19 pandemic has revealed the fallibility of traditional ways to deal with equitable access to essential health technologies, this alternative initiative aims to promote the global public health goods on the basis of equity, science, open collaboration and global solidarity. The document calls on the global community: to provide public disclosure of gene sequences and trial data through accessible data bases; the governments and R&D founders to include clauses in funding agreements with pharmaceutical companies and other innovators concerning equitable distribution, affordability and transparency; to voluntarily license IPRs on a non-exclusive and global basis to the Medicines Patent Pool and/or through other public health research and development mechanisms, consortia or initiatives that facilitate global and transparent access; the voluntary non-enforcement of intellectual property rights to facilitate the widescale production, distribution, sale and use of such health technologies throughout the world; the publishing under open licenses of all the research outcomes; and to share voluntarily the relevant knowledge, IP and data to enable worldwide production, distribution and use of all the needed technologies and raw materials through mechanisms such as *Technology Access Partnerships* (TAP) hosted by the UN Technology Bank or through the *Open CODIV Pledge Initiative*. To date, these initiatives have been endorsed by only 40 WHO members (not yet by E.U., U.S., China or India) and a number of intergovernmental and non-governmental organizations.[131]

To operationalize this call, the WHO has created voluntary licensing initiatives for COVID- 19 including pledges and pools. In May 2020, the WHO launched the *COVID-19 Technology Access Pool* (*C-TAP*) with the task of compiling, in one place, pledges of commitment made under the *Solidarity Call to Action* to voluntarily share COVID-19 health technology related knowledge, intellectual property and data. *C-TAP* means to accelerate the development of products needed to fight COVID- 19 as well as to accelerate the scale-up of manufacturing and the removal of barriers to access in order to make products available globally.[132] *C-TAP* works through its implementing partners: the *Medicines Patent Pool*, *Open COVID Pledge*,

130 WHO, "Making The Response To COVID-19 A Public Common Good, Solidarity Call To Action", https://www.who.int/initiatives/COVID-19-technology-access-pool/solidarity-call-to-action.

131 https://www.who.int/initiatives/COVID-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action.

132 WHO. 2020. "Operationalizing The COVID-19 Technology Access Pool (C-Tap). A Concept Paper", https://www.who.int/publications/m/item/c-tap-a-concept-paper.

and the *Technology Access Partnership* launched by the UN Technology Bank with UNDP and UNCTAD.[133] The *Open COVID Pledge* (OCP) was launched in April 2020 and operates as a *repository* mainly for soft and hard technologies relevant to COVID-19 but is also open to offers from vaccine or therapeutic manufacturers. The OCP has been conceived as a mechanism where companies make available a non-exclusive, royalty-free, world-wide license for a time-limited period, in this case until one year after WHO declares the COVID-19 pandemic over. So-far, about 30 companies have made pledges, including large technology companies such as Microsoft and IBM.[134] The *Open COVID-19 Declaration*, published on June 2020, for now is supported by 90 companies. By signing the declaration, the declarer undertakes a pledge to

> not assert any patent, utility model, design or copyright (against any individual or other entity during the period starting with the date of this Declaration and ending on the date on which the World Health Organization (WHO) declares that the COVID-19 outbreak no longer constitutes a Public Health Emergency of International Concern, with respect to the activities whose sole purpose is stopping the spread of COVID-19, such as diagnosis, prevention, containment and treatment of COVID-19.[135]

On 24 April 2020, as a complementary initiative to *C-TAP*, the WHO together with a group of other global health actors, private sector partners and other stakeholders,[136] also launched the *Access to COVID-19 Tools Accelerator* (ACT-A).[137] The mission of this global collaboration is the accelerated development, equitable allocation and scaled-up delivery of vaccines, therapeutics and diagnostics, principally through funding for the development of the new tools necessary to fight COVID-19 with associated activities seeking to promote equitable access to these new tools.

COVAX, is one of the three pillars of Access to COVID-19 Tools (ACT) Accelerator. Specifically, COVAX is the "vaccines pillar" of the ACT-A.[138] It is coordinated by GAVI, and co-led by the *Coalition for Epidemic Preparedness Innovations* (CEPI), and the WHO, alongside key delivery partner UNICEF. Its aim is to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and

133 https://www.who.int/initiatives/COVID-19-technology-access-pool/what-is-c-tap.
134 Open COVID Pledge, https://opencovidpledge.org/.
135 Open COVID-19 Declaration, https://www.gckyoto.com/s/COVID.docx.
136 Including the Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI), GAVI, the Vaccine Alliance, the Global Fund, UNITAID and Welcome Trust.
137 https://www.who.int/publications/m/item/access-to-COVID-19-tools-(act)-accelerator; WHO.2021. "One-year anniversary of the Access to COVID-19 Tools Accelerator", https://www.who.int/news-room/events/detail/2021/04/23/default-calendar/one-year-anniversary-of-the-access-to-COVID-19-tools-accelerator.
138 https://www.gavi.org/covax-facility.

equitable access for every country in the world. It is acting as a *platform* that will support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, and negotiate their pricing, in order to maximize the chances of successfully developing COVID-19 vaccines and manufacture them in the quantities needed to end this crisis. All participating countries, regardless of income levels, will have equal access to these vaccines once they are developed. The initial aim is to have *2 billion* doses available by the end of 2020. GAVI has also created the *COVAX Facility* through which self-financing economies and funded economies can participate and an entirely own funding mechanism. Self-financing countries and economies participating in the *Facility* can request vaccine doses sufficient to vaccinate between 10 and 50% of their populations. In addition, GAVI has established the *COVAX Advance Market Commitment* (AMC), which will support access to COVID-19 vaccines for lower-income economies.[139] So far, the AMC has raised about $700 million of the initial seed capital target of $2 billion US dollars needed by the end of 2020. As of the writing of this article, COVAX has delivered over 49 million COVID-19 vaccines (supplied by three manufacturers, AstraZeneca, Pfizer-BioNTech and the Serum Institute of India [SII]) to 121 participants across six continents, following the first deliver which covered 300,000 people in Ghana on 24 February 2021. Of the over 100 economies reached, 61 are among the 92 lower-income economies receiving vaccines funded through the Gavi COVAX Advance Market Commitment (AMC).[140] Alongside the above mentioned examples of technology polls, other notable examples of voluntary collaborative efforts include permissive licenses to allow open access to design files and software for ventilators and transfer of know-how; free global licenses to use IP; sharing of IP to develop vaccines; initiatives to transfer technology and know-how to make, adapt or use COVID-19-related technologies; free access to COVID-19 publications protected by copyright; open-source software for contact-tracing technology; open access to research results, and information-sharing initiatives.[141]

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139 https://www.gavi.org/vaccineswork/covax-explained. Other initiatives aimed to address local supply constraints in pharmaceutical production include the African Union's Pharmaceutical Manufacturing Plan which, through the Africa Medical Supplies Platform, seeks to ensure equitable and efficient access to critical supplies for African governments and expand COVID-19-related medical supplies from local manufacturers. The platform's pooled procurement uses an approach pioneered by the Pan-American Health Organization (PAHO) Revolving Fund (RF) in vaccination procurement. The PAHO RF is one of the procurement channels for the COVAX Facility.

140 https://www.who.int/news/item/08-04-2021-covax-reaches-over-100-economies-42-days-after-first-international-delivery.

141 Se for more information on these WTO. "The TRIPS Agreement and COVID-19" *supra* note 96, 3–5, 12–13.

All these initiatives are impressive because they show an unprecedented proactive level of partnership and coordinating efforts; therefore, they are very welcome. Unfortunately, they are not enough to ensure that all countries, regardless of their income levels, will have equal access to the developed vaccines. These initiatives are certainly helpful, but overall insufficient. Initiatives such as *COVAX, ACT-A*, *COVAX Advanced Market Commitment* aim to provide 2 billion vaccine doses (for one billion people if we consider the necessity of any two dose of vaccines) to the world, by the end 2020. This simply means that they have been designed to address only the initial, acute phase of the pandemic and to deliver to only 20% of the least or low developed countries in the world. This is largely inadequate to meet the medium- and long-term needs of the 7.8 billion people of the world.[142] The funding raised, though commendable, is only a low percent of the actual need.[143] Besides, the pharmaceutical industry collectively rejected participation in any initiative devoted to encourage voluntary contribution of IP, technology and data sharing to scale-up of manufacturing and supply of COVID-19 medical and pharmaceutical products,[144] citing concerns that these initiatives would undermine IPRs and disincentivize innovation and that manufacturing the vaccine is a very complex process that needs specific expertise and know-how. According to the western pharmaceutical companies, the manufactures in lower-income countries do not have either the equipment nor the capacity to effectively utilize this knowledge on their own.[145] The WTO estimated that more than one-third of vaccines manufactured at the moment have fewer than four suppliers, which is clearly a limited number to cater to the needs of the global population. It is noteworthy that CEPI's June 2020 survey of COVID-19 vaccine manufacturing capacity identified capacity in 41 countries,[146] parties of an already existing network, *Developing Countries Vaccine Manufactures Network*, a public health driven, international alliance of manufacturers, established in the year 2000, that supplied some 3.5 billion vaccines to the globe annually.[147]

142 IP/C/W/672, para 24.

143 The European Union has been among the largest global supporters of the COVAX initiative. Its *Global Coronavirus Response* pledging campaign (launched by European Commission President Ursula von der Leyen) and the *Global Goal: Unite for our Future* pledging summit co-organized with Global Citizen, raised out of €15.9 billion, by the Member States, the Commission and the European Investment Bank. See https://global-response.europa.eu/index_it.

144 Including the three U.S. base drug manufactures with approved vaccines (Pfizer, Moderna, Johnson & Johnson).

145 IP/C/W/672, paras 81, 108, 169.

146 WTO. "Developing and Delivering COVID-19 Vaccines Around the World", *supra* note 119, 16.

147 https://www.devex.com/organizations/developing-countries-vaccine-manufactures-network-dcvmn-international-68701#:~:text=About%20DCVMN%20The%20Developing%20Countries,of%20vaccines%20affordable%20to%20all.

7 Coup de Théâtre: The U.S. Government has Filed Multiple Patents Covering New Way to Stabilize Coronavirus Spike Proteins, Relevant to COVID-19 Vaccines

On November 18, 2020, Public Citizen, a nonprofit consumer advocacy organization that champions the public interest, published an article entitled *Leading COVID-19 Vaccine Candidates Depend on NIH Technology*.[148] It was about *coronavirus spike proteins*, under which coronaviruses are given their name (because of their crown-like appearance). These proteins play a critical role in viral infection, helping the virus fuse with human cells by attaching to cellular receptors. The article asserted that developing antibodies to the *prefusion spike protein* is critical for vaccines. Natural spike proteins – in isolation-are inherently unstable, and thus are unable to retain the prefusion shape. As a result, they represent a significant challenge for development of a coronavirus vaccine. The article went on to explain that in 2016, long before this pandemic, NIH (the U.S. National Institute of Health) scientists, working with academic researchers from the University of Texas, came up with a solution and obtained the prefusion spike protein for an earlier coronavirus known as Middle East respiratory syndrome coronavirus (MERS-CoV). The scientists filed one patent application covering this approach.[149] When COVID-19 emerged, the U.S. scientists realized that the same approach could work for the new virus and filed another patent application.[150] Then, they filed one patent that should have been issued on March 30, 2021, according to NHI.[151] The article concluded that "most of the leading first-generation COVID-19 vaccine candidates —including those by Pfizer/BioNTech, J&J, Novavax, CureVac and Moderna—are using the publicly developed 2P approach. Years of public investment have fueled the rapid advancement of COVID-19 vaccine candidates".[152]

148 Public Citizen. 2020. "Leading COVID-19 Vaccine Candidates Depend on NIH Technology", https://mkus3lurbh3lbztg254fzode-wpengine.netdna-ssl.com/wp-content/uploads/USG-Spike-Protein.pdf; Zain Zirvi, "The NIH Vaccine", 25 June, 2020, https://www.citizen.org/article/the-nih-vaccine/.

149 U.S. Application No. 16/344,774, https://www.ott.nih.gov/technology/e-234-2016.

150 U.S. Application No. 62/972,886; see also "A Coronavirus Vaccine Rooted in a Government Partnership Is Fueling Financial Rewards For Company Executives", The Washington Post, July 2, 2020, https://tinyurl.com/y5ex9z6s.

151 U.S. Patent No. 10,960,070.

152 See also Public Citizen, "Blind Spot: How the COVID-19 Outbreak Shows the Limits of Pharma's Monopoly Model", https://www.citizen.org/article/blind-spot/, which highlights the critical importance of government-funded research. Since the SARS outbreak, the National Institutes of

On March 25, 2021 the New York Times published an article, entitled *Prefusion Coronavirus Spike Proteins and Their Use*, on vaccine access and how the technology, invented and owned by the U.S. NIH worked, thus reaffirming that the invention would be needed to manufacture several COVID-19 vaccines.[153] The invention (developed under Dr. Berny Graham's direction) has been licensed to several companies, including BioNTech for the Pfizer-BioNTech vaccine and Moderna. According to a study on U.S. government-owned inventions related to COVID-19 vaccines,[154] all licenses must contain a clause stating that the government may terminate the license if the licensee fails to achieve practical application of the licensed invention (35 U.S.C. § 209(d)(3)(A)). U.S. law establishes an obligation to achieve practical application of technologies licensed from the federal government. Practical application is defined as manufacturing, operating, or practicing an invention in such a manner as "to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms" (35 U.S.C. § 201(f)). The "reasonable terms" on which an invention must be available to the public include reasonable price in addition to the timing of delivery and distribution. According to all the commentators, these specific regulations, to the extent that a vaccine relies upon the U.S. NIH's patented claims, give the U.S. government some leverage that could be used to expand access to the invention and the cell-lines, data and knowledge necessary to make the vaccine. If the company manufacturing the COVID-19 vaccine does not have a license, or if the license is terminated, the NIH could pursue remedies in the form of compensation for infringement.[155] The Biden Administration could also resort to use the *Defense Production Act* or other measures to force technology transfer and require corporations to share technology and the know-how to scale up supply around the world.[156] This is especially true for Moderna, which received over $1 billion dollars for research and development from the U.S. government. This amount represented 100% of Moderna's R&D costs.

Health (NIH) alone has spent nearly $700 million on coronavirus R&D; Wilbur T. 2019. "IP Explained: Myth versus Fact About Strong Patent Protections in the Biopharmaceutical Industry", PhRMA, https://tinyurl.com/rv5yntq.

153 Gebrekidan S. and Apuzzo M. 2021. "Rich Countries Signed Away a Chance to Vaccinate the World", The New York Times.

154 Ardizzone K. 2021. "License to NIH Spike Protein Technology Needed in COVID-19 Vaccines Demonstrates "Available to the Public on Reasonable Terms" Requirement", https://www.keionline.org/35746.

155 35 U.S.C. § 284.

156 See "The Biden-Harris Plan to Beat COVID-19", https://buildbackbetter.com/priorities/COVID-19/.

8 Concluding Remarks

Along with the European Union and other western HICs, the Trump administration blocked for long the proposal advanced by South Africa and India to waive IPRs for COVID-19 vaccines and treatments. Now, the new Democratic administration has recently decided to reverse course, considering the proposal positively, thus demonstrating that the U.S. is ready to prioritize human lives over U.S. corporate profit. As reported by the press, the White House in March 2021 was weighing whether to support South Africa's and India's formal request to the WTO to waive the patent protection until the pandemic is over.[157] This occurred in response to pressure from developing nations and subsequent support from progressive lawmakers in a letter sent in late March by House Speaker Nancy Pelosi, according to whom, by supporting the Waiver on a temporary basis, the Biden Administration could "help restore America's moral and public health leadership in the world by siding with the majority to prioritize saving lives over protecting pharmaceutical corporation monopolies and profits".[158] One month later, in May 2021, President Biden has publicly declared American administration's support for the Waiver Proposal. The U.S. Trade Representative, Ambassador Katherine Tai, released on May 5, 2021, a statement on COVID-19 TRIPS Waiver stating that

> [this] is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines. We will actively participate in text-based negotiations at the World Trade Organization (WTO) needed to make that happen. Those negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved. The Administration's aim is to get as many safe and effective vaccines to as many people as fast as possible. As our vaccine supply for the American people is secured, the Administration will continue to ramp up its efforts – working with the private sector and all possible partners – to expand vaccine manufacturing and distribution. It will also work to increase the raw materials needed to produce those vaccines.[159]

157 "The White House Weighs Temporarily Lifting Intellectual Property Shield On COVID-19 Vaccines", March 26 2021, https://www.cnbc.com/2021/03/26/covid-vaccine-updates-white-house-mulls-lifting-intellectual-propertyshield.html?source=sharebar|twitter&par=sharebar.

158 "To Help End the Pandemic as Quickly as Possible and Restore U.S. International Cooperation, Please End Trump's Blockade of the COVID-19 Emergency Waiver of WTO Rules So More Vaccines and Treatment Can Be Produced" February 26, 2021, Attachement-A-COVID-vaccine-patent-waver-letter.pdf (seattle.gov). https://www.amnestyusa.org/our-work/government-relations/advocacy/amnestyinternationalusa-and-400-ngos-call-on-biden-to-support-covid19-wto-trips-waiver/.

159 Available on https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-COVID-19-trips-waiver.

Immediately after this statement was released, the WTO Director-General, twitted that this move is "a *monumental moment* in the fight against COVID-19" (emphasis added). Clearly, the U.S. support is critical for reaching the needed consensus within the TRIPS Council, as demonstrated by the fact that the day after support was given, the President of the European Commission, Ursula von der Leyen, in a speech to the European University Institute in Florence, *finally* and for the first time abandoning the EU's hostility against any attempt to undermine TRIPS rules and the ongoing collaborative efforts, said that the European Union's priority is "to ramp up production to achieve global vaccination. At the same time, we are open to discuss any other effective and pragmatic solution. In this context we are ready to assess how the U.S. proposal could help achieve that objective".[160] Actually, as stated above, this proposal did not originate with the U.S., but was put forward by India and South Africa in early October 2020. Clearly the President of the European Commission refers herself to a new text that those original Proponents agreed to submit to the TRIPS Council in a bid to reconcile positions among the WTO members, that has to be discussed before the formal TRIPS Council meeting, scheduled for early June.[161]

In addition to supporting the temporary Waiver, the U.S. government also committed promote multilateral efforts to scale up the production of COVID-19 health products. In an important reversal of his predecessor's U.S.-centric approach to tackling the coronavirus pandemic, President Biden has not only rejoined the WHO, but has also indicated, during the last G7 virtual summit, that the U.S. would contribute up to $4 billion to COVAX (2 billion to COVAX up front, and then another $2 billion over the coming two years, provided other nations fulfill their own commitments to the program).[162] Apart from the Waiver's proposal, the fact that all the mRNA vaccines currently developed rely upon the NIH's patent, provides important leverage for the new U.S. government to force companies to adhere to the WHO's Technology Access Pool (C-TAP), the voluntary collaboration platform aimed at encouraging companies to share their IPRs on COVID-19 products and medicines to increase global supply. This clearly highlights the power that Governments have in pushing the so-called "third way", suggested by the Director-General of the WTO to encourage voluntary licensing schemes for COVID-19 that offer useful global/regional mechanisms to access COVID-19 health technologies. Without a strong public intervention in the

160 https://english.lokmat.com/international/eu-chief-says-ready-to-discuss-covid-vaccine-patent-waiver/.

161 WTO, General Council May 5, 2021, New Items; *supra* note 109.

162 "Biden Pledges Up To $4 Billion To Help Get Poorer Countries Vaccinated Against COVID-19", February 19, 2021, CBS News.

countries that at this point have administered 75% of all COVID-19 vaccines, drug companies will always try to maximize their profits at the expenses of global common/public good (in this case the public health).

Governments should learn from past experiences. For example, Gilead's monopoly pricing over a drug for HIV prevention therapy (called Truvada for PrEP), that made the company billions of dollars by marketing the medicine, induced the Trump administration, committed to eradicate new cases of HIV and AIDS by 2030, to file a lawsuit in 2019 to protect the public's investment in HIV prevention. The high price of the drug, in fact, prevented hundreds of thousands of Americans from accessing this technology, despite it being a taxpayer funded invention,[163] and a drug which was patented early in 2015 by the U.S. Centers for Disease Control and Prevention. Gilead is also the patent owner of the drug *remdesivir*, that proved to be effective against coronaviruses. In the United States, public investment supported and continues to support every stage of remdesivir's development through early federal grants ($70.5 million) and ongoing clinical trials around the world today. Gilead's Veklury® (remdesivir) has been approved for temporary use as a COVID-19 treatment in approximately 50 countries worldwide. Following significant pressure from civil society,[164] on top of the important precedent of the legal suit brought by the previous U.S. Administration, Gilead has finally published on its web-site that it has signed *non-exclusive voluntary licensing agreements* with generic pharmaceutical manufacturers based in Egypt, India and Pakistan to further expand supply of Veklury® (remdesivir). These agreements, according to the drug company, will allow nine companies to manufacture remdesivir for distribution in 127 countries (nearly all low-income and lower-middle income countries, as well as several upper-middle- and high-income countries that face significant obstacles to healthcare access). Under the licensing agreements, the companies have a right to receive a *technology transfer* of the Gilead manufacturing process for remdesivir to enable them to scale up production more quickly. In addition, the licenses are *royalty-free*, but only "until the World Health Organization declares the end of the Public Health Emergency of International Concern regarding COVID-19, or until a pharmaceutical product other than remdesivir or a

163 Pharma giant profits from HIV treatment funded by taxpayers and patented by the government, 06/12/2019, https://www.washingtonpost.com/business/economy/trump-administration; The Washington Post, November 7, 2019, https://www.washingtonpost.com/business/economy/trump-administration-sues-drugmaker-gilead-sciences-over-patent-on-truvada-for-hiv-prevention/2019/11/06/68b1cc52-010c-11ea-8501-2a7123a38c58_story.html1.

164 Public Citizen. 2020. "Remdesivir Should Be in the Public Domain; Gilead's Licensing Deal Picks Winners and Losers", https://www.citizen.org/news/remdesivir-should-be-in-the-public-domain-gileads-licensing-deal-picks-winners-and-losers/.

vaccine is approved to treat or prevent COVID-19, whichever is earlier".[165] Since many other vaccines have since already approved to treat COVID-19, clearly the royal-free licensing commitment has long ceased!

Another example is provided by the AstraZeneca's vaccine developed with the University of Oxford. This vaccine is already a part of the COVAX initiative. The agreement signed by AstraZeneca with COVAX and the Coalition for Epidemic Preparedness Innovations (CEPI), which helped fund AstraZeneca's vaccine manufacturing programme ($750 million to support the manufacturing, procurement and distribution of 300 million doses of the vaccine), was to sell vaccines at cost, with a ceiling price of $3 US dollar per dose. The company entered into a licensing agreement with the Serum Institute of India (SSI) that sought to produce one billion doses under license from AstraZeneca for India and low-income countries. In addition, the Serum Institute has received funding from GAVI and the Bill & Melinda Gates Foundation to produce COVID-19 vaccines both for India and the global South. Despite the agreements to sell vaccines at cost, recently it has come to light that Serum has begun selling vaccines to other low-income countries at much higher prices.[166] The intent of the Indian company to profiteer on public subsidized vaccines during the pandemic is in *blatant contrast* with the attempts of the India and South Africa's governments to seek the Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19. These examples clearly show how drug companies are always ready to embrace their "business as usual" practices, in addition to the intrinsic limits of mechanism such as voluntary licensing, as explained above.[167] Governments should be strong enough to impose to companies a *global health and bioethics perspective*. The public interest must prevail over pharmaceutical companies' profits.[168]

Apart from the final fate of the TRIPS' Waiver proposal, there is always the possibility of realizing the so-called *third way* (envisaged by the Director-General of the WTO) through *binding* commitments. The solution could consist of multilateral action in international institutions *outside the WTO*.[169] This can take either the form of a *COVID-19 Vaccine Investment and Trade Agreement*, whose purpose

165 See www.gilead.com/purpose/advancing-global-health/COVID-19/voluntary-licensing-.

166 "Reneging on the 'no-profit pledge' to supply Oxford vaccine", January 30 2021, https://www.thehindu.com/sci-tech/science/reneging-on-the-no-profit-pledge-to-supply-oxford-vaccine/article33705151.ece.

167 *Supra* para 6.

168 Recently, President Biden pressured the pharmaceutical giant Merck to help make vaccines for its competitor Johnson& Johnson; "Merck To Help Make Johnson & Johnson Coronavirus Vaccine", 3 March 2021, https://www.washingtonpost.com/.

169 Bacchus, *supra* note 98.

would be to create the incentives necessary to ensure the timely and sizable scaling up of output, as well as the input of investments to respond to the pandemic and future pandemic threats,[170] or a *new international treaty* negotiated at the highest political level and rooted in the WHO Constitution, to foster a comprehensive approach to strengthen national, regional and global capacities and resilience to future pandemics. This, in itself, would be a very important initiative to be pursued, due to the *temporary* nature of the Waiver proposal. Reliable and long-term solutions are needed to tackle any future global pandemic. In a letter published on 30 March 2021, on leading new platform and published by the world media, a number of Prime Ministers and Presidents of various WHO member States, along with the European Union, called for a collective commitment to ensuring universal and equitable access to safe, efficacious and affordable vaccines, medicines and diagnostics for this and future pandemics, restating that "immunization is a global public good". This proposal should be translated into a WHO global health treaty (which would be added to the extremely successful precedent of the WHO Framework Convention on Tobacco Control), whose main goal should be to foster an all-of-government and all-of-society approach, strengthening national, regional and global capacities and resilience to future pandemics. According to the letter calling for such initiative, this new treaty should include "greatly enhancing international cooperation to improve, for example, alert systems, data-sharing, research, and local, regional and global production and distribution of medical and public health counter measures, such as vaccines, medicines, diagnostics and personal protective equipment".[171]

The COVID-19 pandemic has already tested the commitment of wealthier nations to Agenda 2030 (leaving no one behind) and has dramatically revealed institutional rigidity, very weak accountability systems and inadequate police space to protect heath-governance systems.[172] The current crisis is an excellent opportunity to shape an entirely different *global legal framework*, tailored on different *global governance mechanisms* needed to secure universal fair access to essential technologies and vaccines and protect *global public/common goods*. The existing voluntary alliances and mechanisms such as COVAX, as well as other

170 For such a proposal see Bown C.P and Bollyky T.J, *supra* note 52.

171 See WHO. 2021. "COVID-19 Shows Why United Action Is Needed for More Robust International Health Architecture", United Nation. 2021. "World Leaders Call for New International Treaty To Improve Pandemic Response", https://news.un.org/en/story/2021/03/1088652.

172 Ekström A.M. et al. 2021. "The Battle for COVID-19 Vaccines Highlights the Need for a New Global Governance Mechanism", Nature Medicine, https://www.nature.com/articles/s4191-021-01288-8.

collaborative voluntary licensing arrangements and initiatives have proved to be insufficient for funding vaccines, their development and their allocation. What is needed is a strong international collaboration across all sectors based on political and legal solutions committed to justice and shared global responsibility.[173]

173 "Editorial, It's Time to Consider a Patent Reprieve for COVID Vaccines", 30 March 2021, Nature Medicine, https://www.nature.com/articles/d41586-021-00863-w; Thomas Y.F. et Al, *supra* note 36; Yunus et al., *supra* note 27. The proposal to the Italian Government to sponsor a new Treaty on Global Public Goods for Health has been also advanced a while back by the *Forum on Inequalities and Diversity*, coordinated by professor Fabrizio Barca, a renowned Italian statistician and economist.