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Making International Intellectual Property and Trade Regimes Work to Address the Health Response to COVID-19[1]

THE BURDENS OF EXCLUSIVITY

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ABSTRACT

The world was unprepared for COVID-19 despite other recent coronavirus outbreaks and despite multiple warnings from the World Health Organization (WHO) and others. Although there was an initial sharing of research among scientists and an unleashing of significant public, charitable, and private funding to develop, test, and expand manufacturing capacity of new COVID-19-related medicines, vaccines, and diagnostics, the status quo of exclusive rights ownership and commercial control by the multinational biopharmaceutical industry continues unabated. Existing intellectual property rules that allow private entities to maintain monopoly rights over the development, clinical testing, regulatory approval, pricing, supply, and distribution of essential medical products have not been altered. And, the determination of rich countries to secure preferential and disproportionate access to proven and promising vaccines, medicines, diagnostics, and personal protective equipment remains unchanged. In place of open science and coordinated clinical trials, scientific

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rigor in regulatory assessment and broad regulatory approval, low-cost pricing and rational expansion of manufacturing capacity, and equitable global access to all needed COVID-19 health products, we have needlessly high prices, inadequate supplies, and nationalistic hoarding, especially, but not exclusively, by the Global North.

Fortunately, there are multiple initiatives and proposals to counteract exclusivities, commercial prerogatives, and rich countries' preferential access to existing and novel COVID-19 health technologies. These initiatives include more radical proposals to waive recognition and enforcement of COVID-19-related intellectual property rights (IPRs) at the global and national level during the pandemic and to extend the general least developed country transition period for enforcement of IPRs. Other proposals focus on both voluntary and compulsory mechanisms to override IPRs, openly license, and facilitate technology transfer of coronavirus vaccines, medicines, and diagnostics. Several global partners have established an accelerator to speed development and marketing of new COVID-19 tools and secure at least some supplies for low- and middle-income countries (LMICs). Finally, regional cooperation initiatives have been established.

Although there have been multiple initiatives and proposals to overcome industry's exclusive rights and commercial prerogatives, these efforts have not resulted in the needed paradigm shift in global health such that lifesaving and enhancing health products are viewed as global public goods rather than as ordinary consumer products. Similarly, rich countries' hegemonic hoarding of COVID-19 health products and inadequate global coordination mechanisms have left the imperative of equitable distribution of COVID-19 health products disarrayed, with the risk that twice as many people will die from COVID-19 than if vaccines were to be shared globally. We can hope that this dystopian stasis will be overcome, but it will take far more activism from governments, institutions, and civil society to dislodge the current lethargic response and intellectual-property/market fundamentalisms that leave our world fractured in responding to this modern day plague. This global pandemic needs a global response now and as a proving ground for future threats.

INTRODUCTION

In most respects the world was unprepared for the COVID-19 pandemic despite multiple warnings from scientists, normative institutions like the World Health Organization WHO, and even opinion leaders like Bill Gates (Fauci 2004; WHO 2007; Gates 2018). Not only was the world relatively underprepared for the pandemic risks of emerging infectious diseases, more specifically it was underprepared for a coronavirus pandemic despite earlier experiences with SARS-CoV-1 and MERS-CoV (Perlman 2020; McKay & Dvorak 2020). Although the world did have brief flurries of coronavirus research, those frankly minimal efforts dissipated as those earlier threats proved to be relatively short-lived or minor (Branswell & Thielking 2020). Research that did occur was funded mainly by the US National Institutes of Health (NIH), as the private sector was largely disengaged (Rizvi 2020). On the plus side, the WHO and others became increasingly aware of the need for heightened surveillance of emerging infectious disease threats, establishing the Global Outbreak

Alert and Response Network (GOARN) in 2000, strengthening International Health Regulations in 2005,[2] jump-starting a Pandemic Influenza Preparedness Framework in 2011, creating the Coalition for Epidemic Preparedness Innovation (CEPI) in 2017, and establishing the Global Preparedness Monitoring Board (GPMB) in 2018 (WHO 2020a; WHO 2005; WHO 2011; WHO n.d.(a); WHO & World Bank n.d.). Despite the GPMB's prescient warning in 2019 concerning the risks of a lethal respiratory pathogen, private and public sectors were caught flat-footed when the COVID-19 pandemic rapidly circled the globe.[3]

Since SARS-CoV-2 exploded into the world's consciousness in early 2020, there have been lofty promises of global solidarity and collaboration, especially with respect to access to existing, repurposed, and novel health technologies. The United Nations General Assembly has twice emphasized that equitable access to COVID-19 related health products is a global priority. The first General Assembly resolution requested the Secretary-General "to identify and recommend options, including approaches to rapidly scaling manufacturing and strengthening supply chains that promote and ensure fair, transparent, equitable, efficient and timely access to and distribution" of health technologies to make them available to all those in need and more particularly in developing nations. UN Member States and other stakeholders are also urged to quickly take steps to "prevent, within their respective legal frameworks, speculation and undue stockpiling that may hinder access to safe, effective and affordable essential medicines, vaccines, personal protective equipment and medical equipment as may be required to effectively address COVID-19" (UNGA 2020a). The second resolution, available in draft form and adopted on September 11, 2020, "*Urges* Member States to enable all countries to have unhindered, timely access to quality, safe, efficacious and affordable diagnosis, therapeutics, medicines and vaccines, and essential health technologies, and their components, as well as equipment, for the COVID-19 response" (UNGA 2020b). In between these two resolutions, the World Health Assembly adopted a similar resolution recognizing the need for "the universal, timely and equitable access to, and fair distribution of, all quality, safe, efficacious and affordable essential health technologies and products, including their components and precursors that are required in the response to the COVID-19 pandemic as a global priority." The resolution further called for "urgent removal of unjustified obstacles" to the universal, timely, and equitable access to and fair distribution of health technologies (World Health Assembly 2020). Speaking in support of the resolution, several global leaders, UN Secretary-General Antonio Guterres, President Xi Jinping of China, President Emmanuel Macron of France, and President Moon Jae-in of South Korea stated that COVID-19 health products should be treated as "global public goods" available to all in need (TWN 2020a). Others have critiqued the resolution for its lack of concrete action steps

[2] The purpose and scope of the IHR (2005) are "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade." The IHR (2005) contain a range of innovations, including: (a) a scope not limited to any specific disease or manner of transmission, but covering "illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans"; (b) State Party obligations to develop certain minimum core public health capacities; (c) obligations on States Parties to notify WHO of events that may constitute a public health emergency of international concern according to defined criteria; (d) provisions authorizing WHO to take into consideration unofficial reports of public health events and to obtain verification from States Parties concerning such events; (e) procedures for the determination by the Director-General of a "public health emergency of international concern" and issuance of corresponding temporary recommendations, after taking into account the views of an Emergency Committee; (f) protection of the human rights of persons and travelers; and (g) the establishment of National IHR Focal Points and WHO IHR Contact Points for urgent communications between States Parties and WHO (WHO 2020a).

[3] In its prescient first report in 2019, the GPMB predicted the world's gross unpreparedness for an infectious respiratory disease like SARS-CoV-2:

> A rapidly spreading pandemic due to a lethal respiratory pathogen *(whether naturally emergent or accidentally or deliberately released)* poses additional preparedness requirements. Donors and multilateral institutions must ensure adequate investment in developing innovative vaccines and therapeutics, surge manufacturing capacity, broad-spectrum antivirals and appropriate non-pharmaceutical interventions. All countries must develop a system for immediately sharing genome sequences of any new pathogen for public health purposes along with the means to share limited medical countermeasures across countries. (Global Preparedness Monitoring Board 2019).

and its failure to support full use of flexibilities available in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Syam, Alas & Ido 2020).

Sadly, solidarity in rhetoric has not translated into practice. Perhaps the most disappointing aspect of the COVID-19 response to date is the business-as-usual approach that has governments pouring money into biomedical research and product development with no strings attached, the biopharmaceutical industry solidifying its ownership rights with intellectual property (IP)/ data/information exclusivities and maintaining rigid control over both supply and price, and rich country governments nationalistically racing to the front of the queue to secure prioritized access to medicines, diagnostics, and promising vaccine candidates rather than acting equitably to ensure global access (Torreele 2020). This paper will start by delineating the impediments imposed on a more effective response to the pandemic by the perpetuation of IP and market fundamentalism across the entire life-cycle of medicines from benchtop to bedside.

Despite this false start, in Section II, the paper argues that the COVID-19 pandemic gives the world a unique opportunity to recalibrate its biopharmaceutical eco-system to encourage: (1) open science for research and product development, (2) coordinated, collaborative, and comparative clinical trials, (3) regulatory harmonization, speed, and rigor, (4) expedited clinical guidance, (5) suspension of intellectual property (IP), data, and information exclusivities, (6) deployment of voluntary and compulsory mechanisms to accelerate technology transfer to expand biomedical manufacturing capacity, (7) guarantees of low-cost production and low-profit sale of pharmaceuticals and diagnostics and subsidization at point of use, and (8) truly equitable distribution and access for all populations globally. Section III describes a number of initiatives designed to implement some of the alternative approaches detailed above, but many of them are struggling to find traction because of opposition from industry and rich country governments. Accordingly, it is incumbent upon civil society, countries at risk of being left behind, global health institutions, and progressive health policy makers to make common cause to disrupt the status quo and to pave a path to a more efficient, equitable, and urgent response to the COVID-19 pandemic and to set the stage for even better responses to future global pandemics.

THE BURDENS OF EXCLUSIVITY AND POLICY ALTERNATIVES

Closed Science with Siloes and Secrecy vs. Collaborative and Open Science

The initial phase of collaboration between scientists in sharing the SARS-CoV-2 genome and other early scientific knowledge became compartmentalized once knowledge showed commercial potential. Instead of massive public investments resulting in open science, free sharing of knowledge, findings and data, and coordination and collaboration between scientists and product developers to optimize innovation and discovery, the innovation ecology reverted to the status quo. Thus, the world experienced a return to siloed, secretive research, premature touting of preliminary findings, a wild-west race for first discovery, and enclosure of knowledge with patents, data exclusivities, trade secrets, and informational dark holes.

Chinese and Australian scientists shared the genetic code of COVID-19 within weeks of the Wuhan outbreak, which triggered an initial "scientific spring" of data sharing, open-source publishing, and early open science (Cohen 2020; Roujian et al. 2020; Guillou 2020; Barbour 2020; Arrizabalaga, et al. 2020). At the same time that early research findings were being shared, the fundamental aspirations of open biomedical science – collaboration to speed the discovery of the best prevention, treatment, and cure options – were repeatedly espoused (Wellcome Trust 2020; Chesbrough 2020; King 2020; Morten, et al. 2020). The resulting initial scientific sharing allowed translational researchers to quickly develop diagnostic tests, to identify therapeutic and vaccine targets, to map COVID-19

proteins, and to use advance computation methods to screen existing and new compounds for use against COVID-19. One promising example of such cooperation was the Coronavirus Immunotherapy Consortium established at the La Jolla Institute for Immunology (La Jolla Institute 2020).

On the other hand, the flurry of non-peer reviewed studies created a cacophony of confusing results that were often exaggerated by authors and over-hyped and misreported in the press (Besancon, et al. 2020; Homolak, Kodvani & Virag 2020). Moreover, as soon as early scientific sharing produced commercially valuable information, the imperative to share was fractured. Researchers embedded in academic institutes and spin-off companies turned to commercial alliances with major pharmaceutical companies, like Oxford with AstraZeneca (Garrison 2020a; Strasburg 2020). Those researchers and start-ups, and certainly Big Pharma players, pivoted to the status quo of secrecy, pursuit of commercial advantage, and locking up valuable research findings, data, chemical entities, recipes, biological resources, and know-how in an elaborate web of intellectual property protections, including patents and trade secrets (Pede & Konski 2020).[4] For example, 3M and others have hundreds of patents on N95 masks, and trade secret protections confound the effort to mass produce equivalent masks (Decker & Yasieko 2020; Contrera 2020). Gilead has dozens of patents on its COVID-19 antiviral, remdesivir, many of which fail to acknowledge the role of US federal funding of their research and development (R&D) efforts (Ardizzone 2020). Similarly Regeneron, relying on a long history of public support from NIH, has filed broad families of patents on its promising monoclonal antibody treatment as has Moderna on its mRNA vaccine candidate (Abinader 2020a; Rizvi Feb. 2020). Multiple other novel and repurposed medicines are now likely to be surrounded by patent thickets, though many such patent applications have not yet been published.

A puzzling piece of this rush to enclose the COVID-19 research commons is the *laissez faire* role played by major public and private investors that have invested billions of dollars in COVID-19 research, product development, clinical trials, and manufacturing, but have imposed no strings on money they committed to de-risk industry. With the power of the purse, public funders, especially the US, which has committed the most, but have squandered their leverage, imposing few, if any, restrictions on their grantees and licensees who remain free to exploit their IP monopolies (Rizvi June 2020; Rizvi Feb. 2020; Knowledge Ecology International 2020; Love 2020; Ardizzone & Love 2020; Abinader 2020). Other investors, like the Bill and Melinda Gates Foundation and the Coalition of Epidemic Preparedness Initiative (CEPI), have adopted some equitable access safeguards but appear reluctant to use them so as to challenge IP prerogatives (Malpanni, et al. 2020; Rizvi Nov. 2020a; CEPI 2020). Government and other funders could have demanded transparency, collaboration, and sharing; they could have demanded commitments to open licensing and deep technology transfer; they could have imposed obligations to ensure early market entry and equitable distribution to all populations instead of national favorites. Alas, these golden opportunities were wasted, leaving scientific discovery, prioritization, and commercialization to the vagaries of commercial advantage and avarice.

Solution: *There should be incentives for open-science research and collaboration, including by pooling and open source publication of research findings and data. There should be much greater funding of biopharmaceutical R&D by governments, with a greater focus on neglected and emerging diseases. Government funding should come with strings attached with respect to maximizing transparency, minimizing exclusive rights, prioritizing open licensing and technology transfer, and requiring a commitment to equitable access.*

[4] Access to trade secret protected information, know-how, and biologic resources is essential to the technology transfer needed to allow other manufacturers to make vaccines and biologic medicines, including monoclonal antibodies (Price II, Arti & Timo 2020; Garrison 2020b; Levine 2020).

Clinical Trial Chaos vs. Clinical Trial Coordination, Comparative Studies, and Inclusion of Key Populations

The demise of open science was followed by a helter-skelter of underpowered and uncoordinated clinical trials designed to burnish scientific reputations and to secure individual commercial advantage rather than to develop robust, reproducible evidence of clinical safety and efficacy and to compare candidate products and combination products against each other to discover best detection, prophylactic, and treatment outcomes (Da-Re & Malillo-Fernandez 2020). Although there have been some efforts at better planning and coordination of trials and proposals for data sharing, including the WHO Solidarity Trial, the U.K. Recovery trial, and the US ACTIV project, by and large there has been a huge wastage of research potential that confounds efforts to identify and prioritize the best biopharmaceutical and diagnostic interventions and to simplify product adaption and further improvements (WHO 2019; Recovery 2020; Collines & Stoffels 2020; Glasziou, Sanders & Hoffman 2020; Herper & Riglin 2020). This wastage is particularly egregious with respect to clinical trial research relating to COVID-19 vaccines where the lack of comparative standards for assessment and the lack of comparative trials undermines efforts to identify best vaccine candidates (Kahn 2020; Bach 2020). The same trend is apparent in the race for monoclonal antibody treatments (Cohen 2020). The chaos in uncoordinated and underpowered COVID-19 studies reinforces the need for research collaborations, pooling of research findings, and more direct comparisons between competing products so that the best clinical options can be identified (Krause, et al. 2020; North, et al 2020; Petkova et al. 2020).

Paradoxically, some of the populations most at risk of COVID-19 have been disproportionately under-represented in clinical trials. Historic concerns about under-representative of diverse populations in clinical trials have extended to COVID-19 where trials have under-enrolled participants-of-color, older people, and pregnant women, though some trials have succeeded in achieving more proportionate representation (Chastain, et al. 2020; Borno, Zhang & Gomez 2020; Milman 2020; Farrell, et al. 2020; Helfand et al. 2020). An equally vexed form of discrimination arises from the under-enrollment of LMIC populations in COVID-19 clinical trials to investigate clinical efficacy and safety in varied human populations with different disease burdens and differential health systems resources (COVID-19 Clinical Research Coalition 2020; Gupta, et al. 2020; Waruru 2020).

Solution: *Clinical trials should be better planned both to detect comparative safety and efficacy and to weigh plausible combination regimens and should be inclusive to require participation by historically excluded or under-represented groups including women, pregnant people, people with disabilities, racial minorities, and people from low- and middle-income countries.*

Reckless and Politicized Product Authorizations vs. Assurance of Product Safety, Efficacy, and Built-In Quality

Commercial motivations have and continue to prompt companies to lobby for over-accelerated regulatory pathways, particularly emergency use authorizations and listings, conditional approvals, and the like, some of which have also been advanced in response to political pressure from government leaders intent on seeming proactive and in charge, rather than being guided by science (Baden, et al. 2020; Saag 2020). Other more behind the scenes regulatory pressures seem to be pure examples of cronyism (Swan 2020). To counteract this trend on the global front, the WHO has undertaken separate analysis of diagnostic tests and vaccine before allowing emergency use listings or prequalification (WHO 2020a; WHO 2020b).

Over recent years, biopharmaceutical and diagnostics companies are putting increased pressure on regulators to expedite marketing approval and to relax rigorous assessment of safety and efficacy before granting market approval. Instead of awaiting longer-term safety and efficacy readouts, companies recommend greater reliance on post-marketing studies and clinical experience, thereby putting patients at increased risk for little proven benefit (Puthumana, et al. 2018; Hwang, et al. 2018; Kesselheim, et al. 2015). Similarly, in the COVID-19 era, we have seen lax and politicized emergency use authorizations for hydroxychloroquine and convalescent plasma even in the absence of reliable clinical evidence (Zhai, et al. 2020; Sharfstein 2020; Mahase 2020). Even more concerning, Russia and China are rolling out COVID-19 vaccines without any large-scale studies proving efficacy and safety, and former President Trump was reported to have pressured the FDA to expedite emergency use authorization of vaccines before the November 2020 election (Peterson, et al. 2020; Mahase 2020b; Dou & Khurshudyan 2020; Dyer 2020). Relaxed standards and inadequate assessment of longer term safety and efficacy results, violates regulatory responsibilities of countries and ethical duties of companies to only market medicines based on reliable scientific evidence.

Solution: *It is appropriate to have accelerated regulatory pathways, but there is a baseline need to balance the benefits of the medical product against known and anticipated risks. The guidance for emergency use needs to be strengthened for riskier interventions used by larger populations, such as vaccines. There also needs to be rigorous post-marketing surveillance requirements.*

Commercial Prerogatives in Seeking Marketing Approval vs. Duty to Register Quickly and Broadly in All Countries

Both originators and generic companies frequently postpone or neglect to register their medical products in poorer and smaller markets, leaving people in those countries without the medicines they need (Baker 2018; Hill & Johnson 2004). Part of the problem is capacity deficits, inefficiencies, corruption, pluralistic regulatory requirements, and other barriers to registration that countries must redress. But an equal part of the problem is that commercial entities have no imperative to seek marketing approval by any other metric than commercial advantage. Even where originators do register their products, in some countries they have monopoly control over use of their regulatory data via what is known as "data exclusivity." This exclusivity and its related regulatory exclusivity, patent-registration linkage, can prevent regulatory approval of generic and bio-similar medicines and vaccines that could otherwise rely upon or reference the originator's regulatory data or the fact of prior registration (Baker 2008).

Regrettably, States have no viable mechanism under existing law to force an originator or a generic licensee to enter their market (Baker 2021). Moreover, where a comparator originator product has not yet been registered, registration of a generic equivalent is significantly harder, meaning that the generic licensee might have to conduct costly, time-consuming, and potentially unethical repeat clinical trials to gain the data needed for marketing approval. The most immediate work-around would be for countries to adopt registration rules allowing them to rely on the fact of registration elsewhere to register a generic product domestically (WHO Aug. 2020; National Academies 2020). Comparable efforts could speed up WHO prequalification of COVID-19 medicines, vaccines, and diagnostics, and to make better and broader use of WHO Collaborative Registration procedures to accelerate national registration or emergency use authorization efforts (WHO n.d.(c); WHO n.d.(d)). Efforts to harmonize regulatory documents, procedures, and standards on a regional level will also help, like the effort at regulatory harmonization underway within the African Union, which has even greater urgency now in the context of the COVID-19 pandemic (Jerving 2020).

Solution: *The risk of needlessly delayed registration of COVID-19 health technologies is terrifying. Efforts to increase reliance on, recognition of, and reference to trustworthy regulatory decisions elsewhere and WHO prequalification and emergency use listings need to be intensified. Policy makers need to pursue contracting and other rules that require that both originator and generic companies to register their COVID-19 health products broadly to ensure supply in all countries.*

Trial and Error vs. Informed Clinical Guidance

Initial stages of treating COVID-19 required clinicians to trial disease management without the benefit of informed clinical guidance based largely on hype from commercial researchers and anecdotal evidence from fellow clinicians (Vijayan, Qadir & Wang 2020). But reliance on social media for rumors of effective treatment and on non-peer-reviewed studies must now be met with faster clinical guidance based on sound clinical assessment that still remains open to revision based on rapidly accumulating medical knowledge (Califf, Hernandez & Landray 2020).

Solution: *The WHO in particular needs to expedite its guidance while still maintaining scientific rigor, fully admitting where evidence is weak or contested, but nonetheless giving signals to the market and to patients and clinicians on detection, treatment, and prevention. A positive example of the WHO's potential to issue treatment guidelines more quickly was its release of guidance on the use of dexamethasone and other corticosteroids for critically ill COVID-19 patients (WHO 2020c). For the WHO's global guidance to be actionable, countries will also have to move with increased speed to adopt guidance at the national level.*

Exclusive Rights, High Prices, and Limited Supply vs. Open Licensing and Full Technology Transfer, Low Prices, and Expanded Supply

Patent thickets, data exclusivities, and trade secret protections enclose the COVID-19 innovation commons and lead to higher prices and false scarcity. As previously discussed, both major transnational biopharmaceutical companies and start-ups have raced to the patent office and locked up crucial know-how and biologic resources in trade-secret vaults. Having gained control of the "geese that lay the golden eggs", IP rightholders thereafter entered into lucrative acquisition-, partnership-, manufacturing-, and distribution-agreements that maintain tight control over manufacturing and artificially limit supply that could meet the needs of the entire global population (Taylor 2020; Walker 2020; Kansteiner 2020; O'Sullivan, Rutten & Shatz 2020; Dalton & Walker 2020; Balfour 2020; Jensen 2020; So & Woo 2020).[5] The race to the finish line by bigger players risks leaving many promising products short on capital and without paths to commercialization, meaning the COVID-19 response will be weaker than it should be. The companies with the biggest purses entered into agreements with other companies and contract manufacturing organizations, which will reduce manufacturing capacity options for competitor products or for true generic competition.

Historically, access to medicines campaigns have focused on affordability with efforts to reduce the number of patents on medicines and to promote generic competition (Baker 2020). This competition has reduced the price of antiretrovirals in most low- and many middle-income countries by 99+ percent, which has been key to the enormous expansion of treatment from the hundreds of thousands in 2000 to over 25 million in 2020 (UNAIDS 2020b). There are some indications of price moderation in the pricing of COVID-19 vaccines, including by Johnson & Johnson, which has

[5] "Inefficiencies of the current patent system, which enables pharmaceutical corporations to artificially restrict supplies and inflate prices of life-saving medicines and vaccines, are already in the limelight" (Abbas 2020). For a trenchant explanation of the need for expanded manufacturing capacity, see, Correa 2020.

offered a non-profit price of $10 for its single dose vaccine, and by Oxford/AstraZeneca, which have promised a $6 price for a two-dose regimen; unfortunately, other vaccine innovators are announcing significantly higher prices for a double-dose vaccination: Sinopharm $145, Moderna $74, Pfizer $39, and Novovax $32 (Cao 2020). Similarly, Gilead's remdesivir, a repurposed antiviral, which has shown only limited benefit shortening hospital stays and easing moderate infection, is priced between $2340 and $3120 for a five-day course of treatment (Herper 2020). Promising monoclonal antibody therapies from Regeneron, Eli Lilly and other biologic innovators have not been formally announced, but estimates for a course of Regeneron treatment negotiated by the US result in a price range from $1500-$6428 (Nathan-Kazis 2020). Given the billions of people who will need COVID-19 vaccines and the tens of millions who will require access to therapeutics, the implications of high-priced medicines are staggering.

The COVID-19 pandemic, however, is also teaching new and hard lessons about the negative impacts of exclusivities on the supply of vaccine, medicines, and diagnostics Not only do innovators' exclusivities lead to supra-competitive prices, they also lead to artificially restricted supplies (Thomas 2020; Lovett 2020). Although biopharmaceutical manufacturers are investing in expanded production capacity and negotiating with each other and with contract manufacturing organizations to meet rich country demand, they are studiously avoiding efforts to more broadly license their medicines with full technology transfer to all qualified generic and biosimilar producers (Jenson 2020; Walker 2020; Kansteiner 2020; O'Sullivan, et al. 2020).

In response to the risk of high prices, inadequate supplies, and inequitable access, access-to-medicines campaigners and human rights proponents have reacted vigorously to promote open licensing and technology transfer of COVID-related IPRs, data, and information rights and to ensure that sufficient supplies of affordable medicines and vaccine are equitably distributed (MSF 2020a; Rizvi Nov. 2020b; UN High Commissioner 2020; Human Rights Watch 2020; Amnesty International 2020; International Commission of Jurists 2020; Nuffield Council on Bioethics 2020). This call has a new urgency given new evidence that death rates will be two times higher if vaccines are hoarded rather than shared globally (Arnsten 2020). Some of these initiatives are discussed at length in Section III.

Solution: *Instead of privately-owned exclusive rights, there should be open-licensing and voluntary or mandatory technology transfer of all new approved COVID-19 medical technologies to allow and incentivize supply by diverse manufacturers globally and to allow for production at efficient economies of scale and sale at affordable prices. To the maximum extent possible, these medical products need to be free at point of use, most certainly for poor people and people living in low- and middle-income countries.*

Nationalistic Hoarding and Commercial Control Over Distribution vs. Fair and Equitable Access

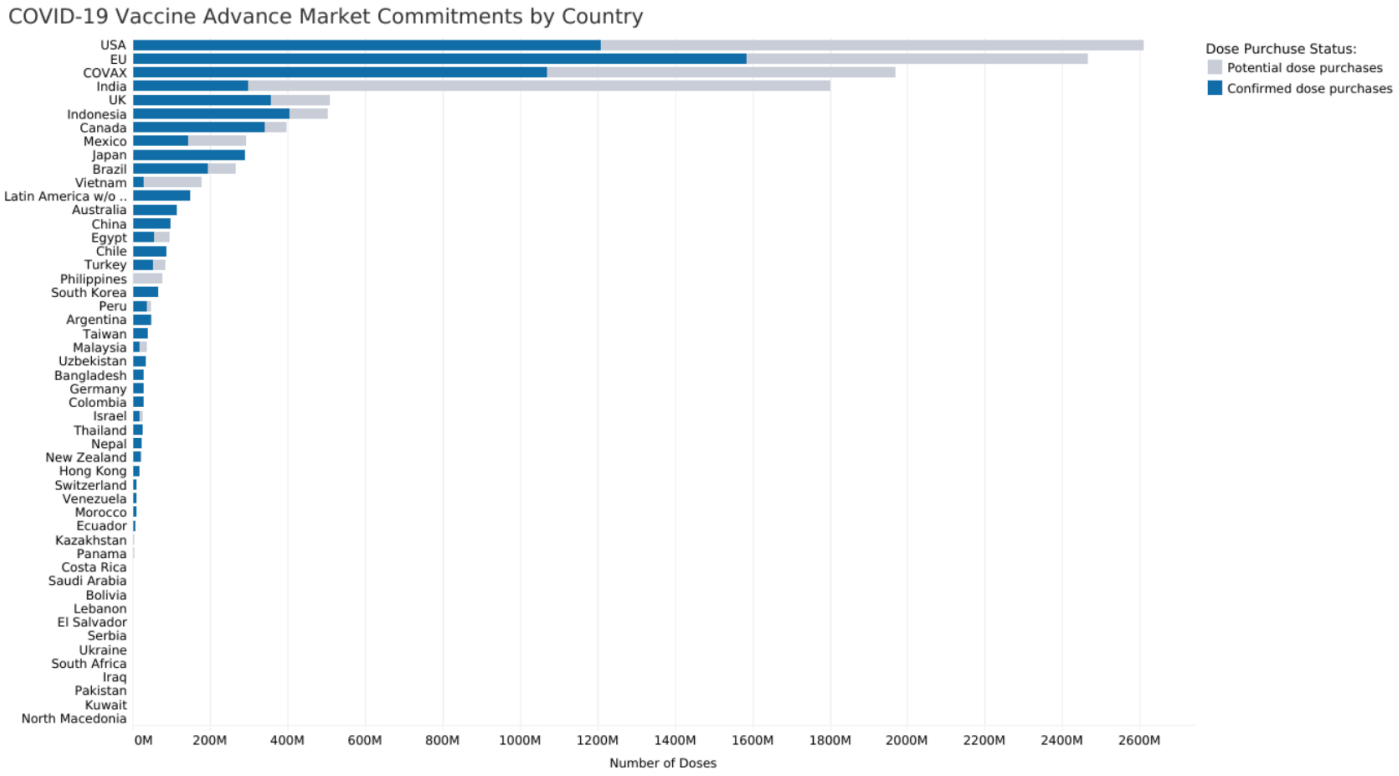
Biopharmaceutical and diagnostic companies typically sell their products at higher prices in rich countries, leaving them with less profit incentive to sell to LMICs. Not only does the current economic regime leave price and supply volumes in the hands of private, profit-maximizing companies, it gives them near total control over which customers to prioritize. Particularly in periods of scarcity, this can lead to bidding wars, which certainly occurred with respect to global supplies of personal protective equipment, and to export controls as well (Tully 2020; WTO 2020a).

In the wake of anticipated supply shortages, the world is experiencing an explosion of vaccine and therapeutics nationalism by the US, U.K., European Union (EU), Canada, Japan, and other countries that have entered into preferential advance purchase agreements, locking up the majority of initial vaccine supplies through the end of 2021 (Baker 2020b; Bollyy & Bown 2020; Phelan, et al. 2020;

Ren 2020; Kamal-Yanni 2020). Researchers at Duke University are updating information on vaccine nationalism, and as of January 11, reported that 12.5 billion doses of vaccines have been reserved (7 billion doses) or are under negotiation (5.5 billion doses) (See Figure 1, below): "High-income countries currently hold a confirmed 4.2 billion doses, upper middle-income countries hold 1.2 billion doses, and lower middle-income countries hold 495 million doses. We have not been able to find evidence of any direct deals made by low-income countries …" meaning they will be reliant on the purchases by the COVAX Facility (total now just over 1 billion doses) that will be shared with COVAX's other participants (Duke Global Health Innovation Center n.d.). As a consequence, mostly high income countries have hedged their bets and reserved supplies to vaccinate their population many times over, creating a risk that the majority of the population in LMICs may not be vaccinated until 2023 or 2024.

Similarly, the US sequestered initial supplies of Gilead's remdesivir, first securing 60 percent of Gilead's initial "donation" of 1.5 million doses and then 90+ percent of Gilead's initial commercial sales through July, August, and September of 2020 (Boodman 2020; HHS 2020). More recently, the US is undertaking to stockpile advance doses of Regneron's monoclonal antibody (Nathan-Kazis 2020). This sad state of affairs results from the perverse synergy of IP and market fundamentalism, whereby governments grant and protect exclusive rights, at the same time that they leave commercialization decisions entirely in the hands of IP right holders, who thereafter give preferential market access to rich countries that race to the front of the line and can afford premium prices. Once again, the risk is that the Global South will be left behind and the human right of every global citizen to equitable access to lifesaving and life-enhancing vaccines and medicines will be eviscerated.

Figure 1: COVID-19 Vaccine Advance Purchase Agreements and Options (as of January 8, 2021)



Source: Duke Global Health Innovation Center (n.d.) Launch and Scale Speedometer. Available at https://launchandscalefaster.org/COVID-19 Accessed January 8, 2021

Solution: *Governments, under the direction of a global framework, need to take control over the distribution of essential global public goods like COVID-19 health products. The market alone cannot be allowed to organize distribution on a profit-maximization basis. Truly global mechanisms must be established to ensure that COVID-19 health products are equitably distributed and ethically allocated to every country in the world and within each country. It is simply indefensible that "America First" or "UK First" or "Europe First" would result in everyone else being last. Rational pooled procurement mechanisms need to be established whereafter truly equitable distribution to all global populations must occur. Priorities may and should be established for early supplies according to disease vulnerability and essential job functions. COVID-19 health products are truly global public goods, essential to the realization of the right to health and to the benefits of scientific progress and its applications, and therefore must be equitably accessed.*

PROMISING INITIATIVES AND PROPOSALS

To mobilize a more effective and solidarity-based response to this unprecedented global pandemic, there have been a number of global initiatives and proposals to override the business-as-usual approach to COVID-19. Some of these responses are pending resolution and will demand advocacy and political will, whereas others are more nascent as they reside as mere proposals with uncertain prospects of being taken forward.

TRIPS Waiver Proposal

One of the most far-reaching proposals is a request from India and South Africa to the TRIPS Council to be forwarded to General Council of the World Trade Organization that it adopt a waiver to the enforcement of relevant IP obligations under the TRIPS Agreement on COVID-19-related health technologies until immunity is achieved (TRIPS 1994 art. 8(1); Waiver 2020; Usher 2020). The waiver proposal relies on Article IX of the Marrakesh Agreement Establishing the World Trade Organization, which allows waivers of obligations under the Agreement in exceptional circumstances for a set period of time (WTO 1994). A report on the waiver request to the General Council must be and was made within 90 days. Although decision by consensus is preferred, if the waiver request comes to vote, it could pass with a three-quarter majority.

In paragraph three, the waiver seeks to ensure that "patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19" (Waiver 2020). In paragraph twelve, the proponents "request that the Council for TRIPS recommends, as early as possible, to the General Council a waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19." In paragraph thirteen, they specify that "the waiver should continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity hence we propose an initial duration of [x] years from the date of the adoption of the waiver."

The waiver request received a mixed reaction from the TRIPS Council meeting in mid-October 2020.[6] South Africa and India spoke forcefully in favor of the waiver request (Balasubramaniam Oct. 2020a; India's Statement 2020; TWN 2020b). The vast majority of countries that supported the waiver request were least developed and developing countries, including Tanzania on behalf of the

[6] For a verbatim transcript of countries positions, see, WTO Waiver Minutes 2020.

African Group, Chad on behalf of the least developed countries (LDC) Members, and Bangladesh, Sri Lanka, Pakistan, Venezuela, Honduras, Nepal, Nicaragua, Egypt, Indonesia, Argentina, Tunisia, Mali, Mauritius, and Mozambique (TWN 2020 #9214). A number of other countries welcomed the proposal but requested clarifications and expressed a need to consult with their capitals, including Nigeria, Philippines, Turkey, Ecuador, China, Thailand, Senegal, Jamaica, Colombia, Costa Rica, Chile, and El Salvador.

It was predominantly rich countries that expressed their opposition to the request: the EU, US, Switzerland, Norway, Australia, Canada, Japan and the UK; they were also joined by Brazil (Balusabramaniam Oct. 2020b). The EU stated a commitment to work with all stakeholders on this global challenge, including researchers and the pharmaceutical industry, and to provide public funding for the development of future COVID-19 treatments and vaccines. The EU argued that a well-functioning IPRs system is crucial to ensure that industry's R&D efforts are adequately incentivized and rewarded. It also argued that there is no indication yet that IPR issues have been a genuine barrier in relation to COVID-19 related medicines and technologies. The EU noted that while maintaining continued supply of medicines is difficult, inefficient and underfunded health care, spiked demand, and lack of manufacturing capacity are what will negatively impact access. It concluded that a well-functioning IPR system includes wide ranging exceptions and flexibilities under the TRIPS Agreement and thus IP is part of the solution rather than an obstacle.

The US confirmed its goal of ensuring the swift delivery of potential COVID-19 therapeutics and vaccines around the globe, stating a belief that providing incentives for innovation, respecting IPRs, and supporting industry-led collaboration and voluntary knowledge sharing, would best achieve shared objectives (WTO Waiver minutes 2020). For the US, IP is important, but, ultimately, it is only one piece of addressing access to potential therapies. The US also noted that IP had not been an obstacle in addressing the pandemic, but rather had incentivized global efforts to find treatments and cures. It went on, saying that limits to manufacturing capacities and supply chain issues are of much greater concern, especially for vaccines, given the need to provide access to the entire global population.

Because of the range of positions at the October 2020 meeting, the Council chair said that the item would remain suspended as members continue to consider the proposal. An informal meeting to further discuss the waiver proposal was held on November 20, 2020, with mostly developed country proponents continuing to oppose the waiver and raising multiple questions, many of which had been previously rebutted and which South Africa again rebutted, quite persuasively (TWN 2020; Patnaik 2020a; MSF 2020b; Balasubramaniam Nov. 2020a). An additional TRIPS Council meeting was held on December 10 with some increased developing country support but little apparent change of developed country positions, which prompted a wide-range of critical commentary. The resulting factual report was delivered at a meeting of the WTO General Council on December 17, 2020; additional consultations will take place back at the TRIPS Council in early 2021, followed by additional discussions at the General Council as needed (Patnaik 2020b).

Given that the waiver could provide a dramatic opening in the battle against COVID-19, civil society and other advocates should push for a quick three-fourths vote at the WTO and eschew the illusory consensus option since it seems clear that the majority of rich countries are content with their own preferred access to COVID-19 vaccines, medicines, diagnostics and other health supplies and that they remain indifferent to the inferior and delayed access in developing countries. However, developing countries should also be reminded that they will need to take steps to implement any eventual TRIPS waiver into their national legal regime – the waiver will not be self-effectuating at the national level (Baker 2020d).

LDC Extended Transition Period

WTO LDC Members have requested a further extension of their general TRIPS transition period for each LDC Member until they no longer are an LDC, plus an additional twelve years (Extension Request Chad 2020). The LDC general transition period under Article 66.1 of the TRIPS Agreement has been previously extended on two occasions, first until in 2005 until 2013 and then in 2013 until to 2021. On each of those occasions, LDCs had sought an extension for LDC Members for as long as they were LDCs. Even though Article 66.1 states that requested extensions "shall" be granted upon well-motivated requests, LDCs were granted time-limits for relatively short periods of time only. This time, LDCs have more forcefully articulated their need to an extension as long as an LDC Member retains that status, but they also argued that they need a further transition period of twelve years before needing to enforce TRIPS IP protections. In paragraphs 4 and 5 of their request, LDCs draw special attention to the additional challenges they face from COVID-19. One thing they could have perhaps made more clear is that the general waiver will be needed for them to have IP-free access to COVID-19 health products other than "pharmaceutical" ones, which are already covered by their 2033 pharmaceutical product extended transition period under Article 66.1. Even though the LDC request was not acted upon at the October 2020 TRIPS Council meeting, it too requires urgent passage before July 1, 2021.

TRIPS Article 73 Security Waiver

South Centre has proposed that WTO Members use the national security provisions of Article 73 of the TRIPS Agreement to suspend recognition and enforcement of IP protections on COVID-19 health technologies for the duration of the pandemic (Correa 2020a; Abbott 2020). Article 73 of the TRIPS Agreement reads: "*Nothing in this Agreement shall be construed … to prevent a member from taking any action which it considers necessary for the protection of its essential security interests … taken in time of war or other emergency in international relations.*" It should be remembered as well that the Doha Declaration on the TRIPS Agreement and Public Health assures Member States that the TRIPS Agreement *"can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose"* (WTO 2001). Similarly, Articles 7 and 8 of the TRIPS Agreement provide further support for the argument that Member States can act to promote public health and to prevent abuse of IPRs, like that which occurs when biopharmaceutical companies refuse to voluntarily license their life-saving medicines, vaccines, and diagnostics (TRIPS 1994). Countries will have to effectuate the permission granted by Article 73 through proper means established in national law. For some countries, resort to executive action in the form of emergency declarations might suffice, but in other countries national legislative or parliamentary action might be needed on an expedited basis.

Compulsory Licenses

At the national level, multiple countries have explored or already expanded their policy space and willingness to use TRIPS public health flexibilities, including issuance of compulsory licenses. For example, Israel issued a compulsory license to import generic versions of lopinavir/ritonavir while legislatures in Germany, Canada, France, and Indonesia have adopted new easier-to-use compulsory licensing rules, while Chile, Ecuador, Brazil, and even the US are considering proposals for the issuance of compulsory licenses to address COVID-19 (WTO TRIPS Report 2020; People over Patents 2020 Public Citizen). On November 25, 2020, the European Commission issued an IP plan of action that includes EU-wide adoption of accelerated compulsory licensing rules to expedite access to COVID-19 products if the need arises (EC 2020; Balasubramaniam Nov. 2020b). Countries have

historically faced political and trade threats arising from resort to compulsory licenses even though such measures are fully legal under Articles 31, 31bis, and 44.2 of the TRIPS Agreement. Moreover, product-by-product, country-by-country licenses can be time-delayed and ineffective in creating a market incentive for generic entry. A recent proposal by Abbott and Reichman advocates for the establishment of global or regional platforms for coordinated issuance of compulsory licenses and for procurement of resulting generic products (Abbott & Reichman 2020). It does seem clear that countries will need to act more proactively on their own behalf, including by establishment of mandatory, automatic, or presumptive compulsory licenses for COVID-19 health products, if they want to overcome pricing and supply constraints

People's Vaccine Campaign

The People's Vaccine campaign was launched by 140 global luminaries and organizations May 2020 calling for vaccines to be freely and equitably distributed globally (UNAIDS 2020a). The Campaign has five principle goals: (1) governments and pharma companies must make vaccines free of patents and other monopolies, and companies should transfer their technology; (2) vaccines should be produced at low cost and distributed to all, with those most at risk receiving early preference; (3) politics should stay out of the process of assessing safety and efficacy of vaccines; (4) there should be transparency about the cost of production, (5) vaccines should be sold close to the cost of production, and they should be free of charge in the public in both rich and poor countries; and (6) the people's vaccine should be used to fight poverty and inequality, including that arising from the pandemic itself (Oxfam 2020). The Campaign had a day of action and sent a demand letter to the CEO of major COVID-19 vaccine manufacturers on December 14, 2020 (Global Justice Now 2020; CEO Letter 2020).

COVID-19 Technology Access Pool

Costa Rica sent a letter to the WHO dated March 23, 2020, advocating for the establishment of a voluntary IP pool for technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic (Quesada & Peraza 2020). Subsequently, thirty-seven countries and the WHO jointly issued The Solidarity Call to Action on May 29, 2020, which established the COVID-19 Technology Access Pool (C-TAP), a platform for sharing IP on COVID-19 treatments, vaccines and health technologies. C-TAP finally announced its implementation plan on October 27, 2020 (Solidarity Call 2020; WHO COVID TAP 2020; WHO 2020 "Operationalizing"). In addition to the Medicines Patent Pool expanding its mandate to address COVID-19, other initiatives to pool IPRs and to facilitate more open science, more supply, and lower prices, include the early Open COVID Pledge, the university-based COVID-19 Technology Access Framework, Japanese Open COVID-19 Declaration, and the COVID-19 Clinical Research Coalition (MPP 2020a; MPP 2020b; Open COVID Pledge n.d.; Contreras, et al. 2020; Stanford 2020; National Academies 2020; Suzuki 2020; COVID-19 Clinical Research Coalition 2020).

Civil society and academics quickly advocated for the establishment and utilization of C-TAP to enable faster and higher quality open-science research and product development. More significantly, open licensing of all rights needed to allow full technology transfer would greatly expand supply beyond the limitations of single-source suppliers. Allowing licensed manufacturers to expand production would help counteract the impulse to hoard and accelerate equitable distribution globally, while also assuring more affordable pricing (Baker 2020 "rationale"; 't Hoen 2020; Bassi & Hwenda 2020; Abbas 2020; Perehudoff & Sellin 2020). Although C-TAP is promising in theory, it is disappointing that no biopharmaceutical company has contributed to the pool. It is not surprising that the multinational drug industry banded together at the launch of the technology pool to condemn even

voluntary efforts geared towards global access ("Pharma leaders" 2020). Industry and rich countries may warm to the idea of voluntary efforts if countries become more resolute in seeking IP waivers and the use of compulsory licensing mechanisms.

ACT Accelerator

The initiative that has received the most fanfare to date is the establishment of the Access to COVID-19 Tools Accelerator (ACT Accelerator), which has committed to the repurposing or development of novel vaccines, therapeutics, and diagnostics and equitable global access to those tools, including in LMICs (WHO Sept. 2020a). The ACT Accelerator, relying on a partnership framework, has established three distinct pillars for diagnostics, therapeutics, and vaccines, as well as a health systems connector (WHO n.d.(g)). With respect to vaccines, the ACT Accelerator has pre-established goals of accelerating development of safe and efficacious new vaccines, establishing a broad portfolio of vaccines to mitigate risk, and securing access to 2 billion doses of vaccines by the end of 2020, to be split equally between low-income and lower- and upper-middle-income countries (Berkley 2020). Its ambitions for therapeutics is to identify more effective treatments and catalyze manufacturing, procurement and delivery of safe, effective, and quality assured therapeutics for 245 million courses of treatment by the end of 2021 (ACT Accelerator Therapeutics Partnership 2020). For diagnostics, its goals are to identify game-changing diagnostic tests and bring high quality, rapid diagnostic tests (RDTs) to scale, hoping to procure 125 million molecular tests and 375 million antigen RDTs for LMICs (WHO Sept. 2020c). At present, the health systems connector is principally focused on enabling effective deployment of COVID-19 tools and delivery of essential health services, including supplying personal protective equipment and oxygen to those in need. The WHO is specifically tasked with adopting a framework and guidelines for equitable access and fair allocation of COVID-19 tools.

The ACT Accelerator, conceptualized by the Bill and Melinda Gates Foundation, was launched with other partners on April 24, 2020 (White paper on COVID-19; WHO Commitment and Call 2020). It has adopted many of the Foundation's approaches and priorities especially in the Vaccine and Therapeutics Pillars. The Vaccine Pillar is led by Gavi, the Vaccine Alliance (Gavi) and the Coalition for Epidemic Preparedness Innovation (CEPI) both of which were founded by the Gates Foundation to focus on vaccine distribution and vaccine development respectively (Gates Foundation 2020; CEPI 2020). CEPI's work focuses on identifying and supporting promising vaccine candidates and reserving manufacturing capacity for proven vaccines (CEPI COVAX 2020). Gavi's COVAX Facility and its Advance Market Commitment for COVID-19 Vaccines (Gavi COVAX AMC) aims at incentivizing vaccine manufacturers to produce sufficient quantities of COVID-19 vaccines, and to ensure at least partial access for ninety-two developing countries via the Gavi COVAX AMC (Berkley 2020; GAVI 2020). Although Gavi COVAX AMC was initially slow in reserving needed doses and was projected to fail, it announced major new supply deals in December 18, 2020 (Guarascio 2020; Beaumont 2020; Cheng & Ghosal 2020; CEPI, GAVI & WHO 2020). One promising development is that some rich countries may be willing to donate or transfer excess vaccine doses to Gavi COVAX AMC, but are encouraged to do so in accordance with five criteria (COVAX 2020). In the Therapeutics Pillar, a second project was a proposed multimillion dollar capacity reservation by the Gates Foundation with Fuji Films to manufacture doses of a novel monoclonal antibody being developed by Eli Lilly (Eli Lilly 2020). Likewise, in the Diagnostics Pillar, the Gates Foundation executed a volume guarantee for 120 million rapid diagnostic antigen tests (WHO Sept. 2020b). Despite its ambition, the ACT-Accelerator is grossly under-resourced to achieve its goals. Out of an estimated budget need of $38 billion by the end of 2022, the ACT Accelerator had raised only $3 billion by September 21, 2020 (ACT Accelerator 2020a). A more recent analysis still shows a $28 billion funding shortfall after several months of intensive resource mobilization (ACT Accelerator 2020b, 2020c, 2020d).

Although the ACT-Accelerator represents an important effort to achieve access to safe and effective COVID-19 vaccines, therapeutics, and diagnostics for LMICs, its ambition is actually quite limited. For example, the ACT Accelerator was established to address the so-called acute phase of the pandemic and to prevent hospitals from being swamped with COVID-19 patients. Thus, for example, the Accelerator limits its ambition to facilitating supply sufficient to meet only 20 percent of projected vaccine need in LMICs and similar proportions of short-term needs for therapeutics and diagnostics. The ACT Accelerator specifically assumes that ordinary market forces will normalize equitable supply and affordable access to COVID-19 health products thereafter, but, as discussed previously, such supply and access cannot be assured by profit-driven companies that remain free to raise prices, limit manufacturing capacity, and serve preferred buyers first. The ACT Accelerator is also using a very small toolbox of market interventions to secure COVID-19 health products, mainly advance market commitment, volume guarantees, and capacity reservations – none of which disrupt the status quo. Similarly, the ACT Accelerator has not placed conditions on the companies it supports requiring them to greatly expand supply capacity by requiring or incentivizing open licensing and full technology transfer of proven vaccines, medicines, and diagnostics. Instead companies can go it alone – even though none have anywhere near sufficient capacity to meet global need – or they can enter into limited contract manufacturing agreements with a small subset of qualified producers. The foreseeable consequence of not focusing on the imperative of expanded supply is that global need cannot and will not be met. The net result of all these false steps is that even if the ACT Accelerator "succeeds" and gets all the resources it needs to fulfill its goals, only a fraction of medical supply needs in LMICs will be met.

Focusing more specifically on COVAX, there have been too many concessions to rich countries that get four bites at the vaccine apple: (1) they can secure up to 50 percent of their population need instead of the 20 percent maximum for the 92 countries covered by the Advance Market Commitment; (2) they can secure vaccines doses from COVAX without any accounting for the bilateral advance purchase agreements they already may have with multiple vaccine producers; (3) they can choose to exercise "options" whereby they can select their preferred, presumably more effective and safe vaccines from COVAX while rejecting other vaccines; and (4) they can trade or exchange unwanted or inferior vaccines, including those sourced bilaterally, within COVAX for preferred vaccines. Although not all of the Accelerator's narrow assumptions and false steps can be corrected, it could use the reality of insufficient funds to pivot from procuring COVID-19 health products to working more intensely on pricing, supply, and equitable distribution issues.

Regional Solidarity Efforts

In addition to these global efforts, regional mechanisms have also been established to promote collaboration and sharing. For example, ASEAN nations announced a Declaration on COVID-19 at their special summit on April 14, 2020, promising cooperation on health, trade, and supply of essential medical tools (including diagnostics, PPE, and medicines). Member States agreed to share scientific information, to cooperate in developing vaccines and antiviral medicines, to allow the free flow of essential medicines and medical supplies, to encourage adequate supplies and establish a regional emergency reserve, and to provide emergency assistance via a COVID-19 ASEAN Response Fund (ASEAN 2020). Similarly, within the WHO SEA region, the Health Ministers issued a Declaration on Collective Response to COVID-19 focusing on strengthening health systems and collaboration within the region and agreeing to engage in global discussions on equitable allocation of vaccines, medicines and diagnostics (WHO Southeast Asia 2020). Subsequently, in July, African Union ministers of health committed to pursue local manufacturing of COVID-19 vaccines using flexibilities in the TRIPs agreement (AU 2020). In addition, the African Union Centre for Disease Control has been quite proactive in organizing regional distribution of scarce supplies. It's most noticeable achievement to date was its ability to secure 270 doses of vaccines for the African region in early 2021

(South Africa 2021). Regrettably, the Latin America/Caribbean region has been less proactive in mounting a coherent regional response to COVID-19 because of intraregional disputes, though some progress has been made for pooled procurement and distribution of COVID-19 medical products (Political Settlements Research Program 2020).

CONCLUSION

Intellectual property rights, research findings, clinical trial data, trade secrets, and other exclusivities interfere with all phases of the global system for researching and accessing needed COVID-19 health products. Research silos, commercial ownership of research data, and delayed publication of research findings interfere with the collaborative and open-science approach needed to develop the best medical products at the fastest pace. Exclusive rights in some countries prevent reliance on or reference to earlier clinical trial data establishing the safety and efficacy of medicines and devices can delay or even block marketing approval of generic equivalents. Not only do exclusive rights give biopharmaceutical companies and testing and device manufacturers the power to set exorbitant, monopoly prices, they limit options for governments and competitors to expand manufacturing capacity to meet global need for billions of doses of medicines and vaccines, billions of diagnostic tests, and billions of pieces of personal protective equipment. Faced with inadequate supply and high prices, rich country governments have rushed to the front of the line and entered into advance purchase agreements with profit-maximizing companies to stockpile supplies, crowding out fair sharing and equitable access to people in need elsewhere. Instead of mobilizing, coordinating, and maximizing the global response to COVID-19, the monopoly-based system results in more research wastage and delay, fewer sources of supply, higher prices, and inequitable distribution.

Although there have been multiple initiatives and proposals to overcome industry's exclusive rights and commercial prerogatives, these efforts have not resulted in the needed paradigm shift in global health such that life-saving and enhancing health products are viewed as global public goods rather than as ordinary consumer products. Similarly, rich countries' hegemonic hoarding of COVID-19 health products and inadequate global coordination mechanisms have left the imperative of equitable distribution of COVID-19 health products disarrayed, with the risk that twice as many people will die from COVID-19 than if vaccines were to be shared globally. We can hope that this dystopian stasis will be overcome, but it will take far more activism from governments, institutions, and civil society to dislodge the current lethargic response and IP/ market fundamentalisms that leave our world fractured in responding to this modern day plague. This global pandemic needs a solidarity-based global response now and as a proving ground for responding to inevitable future health threats.

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