HAMSTRINGING THE HEALTH TECHNOLOGY RESPONSE TO COVID-19: THE BURDENS OF EXCLUSIVITY AND POLICY SOLUTIONS

*By Brook K. Baker**

* Professor, Northeastern University School of Law; Honorary Research Fellow, University of KwaZulu Natal (South Africa); Senior Policy Analyst Health GAP (Global Access Project). This paper is based in substantial part on a paper commissioned for the 2020 Prince Mahidol Award Conference Webinar 2022.

Table of Contents

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 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 the development and marketing of new COVID-19 tools and secure at least some supplies for low- and middle-income countries. 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 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 intellectual property and 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,[1] normative institutions like the World Health Organization (WHO),[2] and even opinion leaders like Bill Gates.[3] Not only was the world relatively underprepared for the pandemic risks of emerging infectious diseases generally, but more specifically, it was underprepared for a coronavirus pandemic despite earlier experiences with SARS-CoV and MERS-CoV.[4] Although the world did have brief flurries of coronavirus research, those minimal efforts dissipated as earlier threats proved to be relatively short-lived or minor.[5] Research that did occur was funded mainly by the U.S. National Institutes of Health (NIH), as the private sector was largely disengaged.[6] 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,[7] strengthening International Health Regulations (IHR) in 2005,[8] jump-starting a Pandemic

1 *See*, *e.g.*, Betsy McKay & Phred Dvorak, *A Deadly Coronavirus Was Inevitable. Why Was No One Ready?*, WALL ST. J. (Aug. 13, 2020), https://www.wsj.com/articles/a-deadly-coronavirus-was-inevitable-why-was-no-one-ready-for-covid-11597325213.

2 WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2007 - A SAFER FUTURE: GLOBAL PUBLIC HEALTH SECURITY IN THE 21ST CENTURY 12–14 (2007).

3 Bill Gates, *The Next Epidemic Is Coming. Here's How We Can Make Sure We're Ready.*, GATESNOTES (Apr. 27, 2018), https://www.gatesnotes.com/health/shattuck-lecture.

4 Stanley Perlman, *Another Decade, Another Coronavirus*, 382 NEW ENG. J. MED. 760, 761 (2020); McKay & Dvorak, *supra* note 1.

5 Helen Branswell & Megan Thielking, *Funding and Flagging Interest Hurt Coronavirus Research, Leaving Crucial Knowledge Gaps*, STAT (Feb. 10, 2020), https://www.statnews.com/2020/02/10/fluctuating-funding-and-flagging-interest-hurt-coronavirus-research/.

6 Zain Rizvi, *Blind Spot – How the COVID-19 Outbreak Shows the Limits of Pharma's Monopoly Model*, PUB. CITIZEN (Feb. 19, 2020), https://www.citizen.org/article/blind-spot/.

7 WORLD HEALTH ORG., WHAT IS GOARN? (2020), https://extranet.who.int/goarn/sites/default/files/GOARN_one_pager_20200424.pdf.

8 WORLD HEALTH ORG., INTERNATIONAL HEALTH REGULATIONS 1–2 (2d ed. 2005), https://apps.who.int/iris/bitstream/handle/10665/43883/9789241580410_eng.pdf;jsessionid=1EA9C1883850DC3F9119D785B4FF1F94?sequence=1.

> 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) contains 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

Influenza Preparedness Framework in 2011,[9] creating the Coalition for Epidemic Preparedness Innovation (CEPI) in 2017,[10] and establishing the Global Preparedness Monitoring Board (GPMB) in 2018.[11] 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.[12]

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

> 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 travellers; and (g) the establishment of National IHR Focal Points and WHO IHR Contact Points for urgent communications between States Parties and WHO.

Id.

9 World Health Org., Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits 1 (2011), https://apps.who.int/iris/bitstream/handle/10665/44796/9789241503082_eng.pdf?sequence=1.

10 *Creating a World in Which Epidemics Are No Longer a Threat to Humanity*, CEPI, https://cepi.net/about/whyweexist/ (last visited Oct. 17, 2020).

11 Global Preparedness Monitoring Bd., A World at Risk: Annual Report on Global Preparedness for Health Emergencies 4 (2019), https://apps.who.int/gpmb/assets/annual_report/GPMB_annualreport_2019.pdf.

12 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 development of 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.

Id. at 30; *see Editorial: We Were Caught Flat-Footed by COVID-19. How Can We Do Better?*, L.A. Times (Apr. 12, 2020), https://www.latimes.com/opinion/story/2020-04-12/covid-19-planning-for-the-future.

technologies. The United Nations (UN) 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.[13] UN member states and other stakeholders were 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."[14] The second resolution, adopted on September 11, 2020, "*[u]rges* 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."[15]

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."[16] The resolution further called for "urgent removal of unjustified obstacles" to the universal, timely, and equitable access to and fair distribution of health technologies.[17] Speaking in support of the resolution, several global leaders, UN Secretary-General António 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.[18] Others have critiqued the resolution for its lack of concrete action steps and its failure to support full use of flexibilities permitted under the World Trade Organization (WTO) Agreement on

13 G.A. Res. 74/274, ¶ 2 (Apr. 21, 2020), https://undocs.org/en/A/RES/74/274.

14 *Id.*

15 G.A. Res. 74/306, ¶ 12 (Sept. 11, 2020), https://undocs.org/en/A/RES/74/306.

16 World Health Assembly [WHA], *COVID-19 Response,* WHA Res. 73.1, ¶ 4 (May 19, 2020), https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf.

17 *Id.*

18 *WHO: Leaders Call COVID-19 Vaccines a "Global Public Good,"* THIRD WORLD NETWORK (May 20, 2020), https://twn.my/title2/health.info/2020/hi200511.htm.

Trade-Related Aspects of Intellectual Property Rights (TRIPS).[19]

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) and data/information exclusivities while 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.[20] 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 Part I, this 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 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. Part II 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 policymakers 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.

19 Nimalya Syam et al., *The 73rd World Health Assembly and Resolution on COVID-19: Quest of Global Solidarity for Equitable Access to Health Products*, South Centre, May 2020, at 9, https://www.southcentre.int/wp-content/uploads/2020/05/PB-78.pdf.

20 Els Torreele, *Business-as-Usual Will Not Deliver the COVID-19 Vaccines We Need*, 63 Development 191 (2020).

I. THE BURDENS OF EXCLUSIVITY AND POLICY ALTERNATIVES

A. *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.[21] 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.[22]

Chinese and Australian scientists shared the genetic code of COVID-19 within weeks of the Wuhan outbreak,[23] which triggered an initial scientific spring of data sharing,[24] open-source publishing,[25] and early open science. 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

21 *Id.* at 7–8. For a different critique focusing on inefficient data sharing, see generally J. Homolak et al., *Preliminary Analysis of COVID-19 Academic Information Patterns: A Call for Open Science in the Times of Closed Borders*, 124 SCIENTOMETRICS 2687 (2020).

22 *See* Torreele, *supra* note 20, at 2, 4; *see infra* notes 29, 31–32 and accompanying text.

23 Jon Cohen, *Chinese Researchers Reveal Draft Genome of Virus Implicated in Wuhan Pneumonia Outbreak*, SCIENCE (Jan. 11, 2020), https://www.sciencemag.org/news/2020/01/chinese-researchers-reveal-draft-genome-virus-implicated-wuhan-pneumonia-outbreak; Roujian Lu et al., *Genomic Characterisation and Epidemiology of 2019 Novel Coronavirus: Implications for Virus Origins and Receptor Binding*, 395 LANCET 565, 565 (2020).

24 Ian Le Guillou, *Covid-19: How Unprecedented Data Sharing Has Led to Faster-than-Ever Outbreak Research*, HORIZON (Mar. 23, 2020), https://horizon-magazine.eu/article/covid-19-how-unprecedented-data-sharing-has-led-faster-ever-outbreak-research.html.

25 *See* Cohen, *supra* note 23; Matt Apuzzo & David D. Kirkpatrick, *Covid-19 Changed How the World Does Science, Together*, N.Y. TIMES (Apr. 14, 2020), https://www.nytimes.com/2020/04/01/world/europe/coronavirus-science-research-cooperation.html. For the United States's response to open-source publishing, see Virginia Barbour, *Scientific Publishing Has Opened Up During the Coronavirus Pandemic. It Won't Be Easy to Keep It That Way*, CONVERSATION (July 27, 2020), https://theconversation.com/science-publishing-has-opened-up-during-the-coronavirus-pandemic-it-wont-be-easy-to-keep-it-that-way-142984; Olatz Arrizabalaga et al., *Open Access of COVID-19-Related Publications in the First Quarter of 2020: A Preliminary Study Based in PubMed*, F1000RESEARCH (Aug. 12, 2020), https://f1000researchdata.s3.amazonaws.com/manuscripts/28399/2bdb944d-aaba-4ae9-aa04-1f1c067c25de_24136_-_olatz_arrizabalaga_v2.pdf.

cure options—were repeatedly espoused.[26] The resulting initial scientific sharing allowed translational researchers to quickly develop diagnostic tests, identify therapeutic and vaccine targets, map COVID-19 proteins, and use advanced computation methods to screen existing and new compounds for use against COVID-19.[27] One promising example of such cooperation was the Coronavirus Immunotherapy Consortium established at La Jolla Institute for Immunology.[28]

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.[29] 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.[30] Those researchers and start-

26 Henry Chesbrough, *To Recover Faster From Covid-19, Open Up: Managerial Implications from an Open Innovation Perspective*, 88 Indust. Mktg. Mgmt. 410, 412–13 (2020); Press Release, Wellcome, Sharing Research Data and Findings Relevant to Novel Coronavirus (COVID-19) Outbreak (Jan. 31, 2020), https://wellcome.org/coronavirus-covid-19/open-data; Jonathan Alan King, *Protecting Public Health Requires COVID-19 Treatments to Be Patent-Free*, Truthout (May 19, 2020), https://truthout.org/articles/protecting-public-health-requires-covid-19-treatments-to-be-patent-free/; Christopher J. Morten et al., *To Help Develop the Safest, Most Effective Coronavirus Tests, Treatments, and Vaccines, Ensure Public Access to Clinical Research Data*, Health Affs. Blog (Mar. 26, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200326.869114/.

27 *See* Edwin G. Tse et al., *Open Science Approaches to COVID-19*, F1000Research (Aug. 25, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7590891.1/pdf/f1000research-9-28785.pdf; Mark Zastrow, *Open Science Takes On the Coronavirus Pandemic*, 581 Nature 109 (2020); Org. for Econ. Co-operation & Dev., Why Open Science Is Critical to Combatting COVID-19 (May 12, 2020), https://read.oecd-ilibrary.org/view/?ref=129_129916-31pgjnl6cb&title=Why-open-science-is-critical-to-combatting-COVID-19 (documenting progress to date and future steps needed); *Why Share Scientific Data During a Pandemic?*, UK Rsch. & Innovation (May 15, 2020), https://coronavirusexplained.ukri.org/en/article/vdt0011/.

28 *La Jolla Institute for Immunology to Host Coronavirus Immunotherapy Clearinghouse*, La Jolla Inst. for Immunology, https://www.lji.org/news-events/news/post/la-jolla-institute-for-immunology-to-host-coronavirus-immunotherapy-clearinghouse/ (last visited Mar. 21, 2021).

29 Lonni Besançon et al., Open Science Saves Lives: Lessons from the COVID-19 Pandemic 11 (Oct. 30, 2020) (unpublished preprint), https://www.biorxiv.org/content/10.1101/2020.08.13.249847v2.full.pdf; Homolak, *supra* note 21, at 2677–701.

30 Christopher Garrison, Meds. L. & Pol'y, How the "Oxford" Covid-19 Vaccine Became the "AstraZeneca" Covid-19 Vaccine 7–8 (2020), https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf; Jenny Strasburg & Stu Woo, *Oxford Discovered Covid Vaccine, Then Scholars Clashed Over Money*, Wall St. J. (Oct. 21, 2020), https://www.wsj.com/articles/oxford-developed-covid-vaccine-then-

ups, and certainly Big Pharma players, pivoted to the status quo of secrecy,[31] the pursuit of commercial advantage,[32] and the locking up of valuable research findings, data, chemical entities, recipes, biological resources, and know-how in an elaborate web of IP protections, including patents[33] and trade secrets.[34] For example, 3M and others have hundreds of patents on N95 masks,[35] and trade secret protections confound the effort to mass-produce equivalent masks.[36] Gilead reportedly has dozens of patents on its COVID-19 antiviral, remdesivir, many of which fail to acknowledge the role of U.S. federal funding of their research and development (R&D) efforts.[37] Similarly, Regeneron, relying on funding support from the Biometrical Advanced Research and Development Authority, has filed a patent on its

scholars-clashed-over-money-11603300412.

31 *See* Rob Copeland, *The Secret Group of Scientists and Billionaires Pushing a Manhattan Project for Covid-19*, WALL ST. J. (Apr. 27, 2020), https://www.wsj.com/articles/the-secret-group-of-scientists-and-billionaires-pushing-trump-on-a-covid-19-plan-11587998993.

32 *See* Kamran Abbasi, *Covid-19: Suppression of Science*, 371 BRIT. MED. J. 307 (2020).

33 Aude S. Peden & Antoinette F. Konski, *Coronavirus Innovation Guideposts on the Eve of the COVID-19 Pandemic*, NAT'L L. REV. (July 30, 2020), https://www.natlawreview.com/article/coronavirus-innovation-guideposts-eve-covid-19-pandemic.

34 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. W. Nicholson Price II et al., *Knowledge Transfer for Largescale Vaccine Manufacturing*, 369 SCIENCE 912, 912 (2020) (arguing that "massive, rapid production" of adequate quantities of COVID-19 vaccines "will require firms to share know-how not just about what to make but how to make it"); CHRISTOPHER GARRISON, MEDS. LAW & POL'Y, WHAT IS THE 'KNOW-HOW GAP' PROBLEM AND HOW MIGHT IT IMPACT SCALING UP PRODUCTION OF COVID-19 RELATED DIAGNOSTICS, THERAPIES AND VACCINES? 8 (2020), https://medicineslawandpolicy.org/wp-content/uploads/2020/12/The-Know-how-gap-problem-Medicines-Law-Policy.pdf; David S. Levine, *COVID-19 Trade Secrets and Information Access: An Overview*, INFOJUSTICE (July 10, 2020), http://infojustice.org/archives/42493; Yanif Heled, *The Case for Disclosure of Biologics Manufacturing Information*, 47 J.L. MED. & ETHICS 54 (2019).

35 Susan Decker & Christopher Yasieko, *World War II-Style Mobilization Order May Carry Risks*, BLOOMBERG (Mar. 23, 2020), https://www.bloomberg.com/news/articles/2020-03-20/world-war-ii-style-production-may-carry-legal-risks-for-patriots (reporting that "[t]here are hundreds of patents on things related to N95 respirators . . . [owned by] the U.S. government, 3M Co., paper and health-care companies," and others).

36 *See* Jessica Contrera, *The N95 Shortage America Can't Seem to Fix*, WASH. POST (Sept. 21, 2020), https://www.washingtonpost.com/graphics/2020/local/news/n-95-shortage-covid/?utm_campaign=wp_post_most&utm_medium=email&utm_source=newsletter&wpisrc=nl_most.

37 KATHRYN ARDIZZONE, ROLE OF THE FEDERAL GOVERNMENT IN THE DEVELOPMENT OF REMDESIVIR 6–8 (2020), https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2020_1GS-5734-Remdesivir.pdf.

promising monoclonal antibody treatment,[38] as has Moderna, jointly with the NIH, on its mRNA vaccine candidate.[39] 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 almost no strings on the money they committed to de-risk industry's parallel efforts. With the power of the purse, public funders, especially the U.S., have squandered their leverage, imposing few, if any, restrictions on their grantees and licensees who remain free to exploit their IP monopolies.[40] 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.[41] Government

38 Luis Gil Abinader, Regeneron Failed to Disclose BARDA Funding in Their REGN-COV2 Patent 1 (2020), https://www.keionline.org/wp-content/uploads/rn-2020-4.pdf.

39 Zain Rizvi, Public Citizen, The NIH Vaccine 4 (2020), https://mkus3lurbh3lbztg254fzode-wpengine.netdna-ssl.com/wp-content/uploads/NIH-vaccine-final.pdf; Selam Gebrekidan & Matt Apuzzo, *Rich Countries Signed Away a Chance to Vaccinate the World*, N.Y. Times (Mar. 25, 2021), https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html.

40 Rizvi, *supra* note 39 at 4; Rizvi, *supra* note 6, at 13; Gebrekidan & Apuzzo, *supra* note 39; James Love, *Three Areas in Section 202 of the Bayh-Dole Act that Require Action to Ensure Sufficient Rights in Patents on Coronavirus Relevant Inventions*, Knowledge Ecology Int'l (Mar. 14, 2020), https://www.keionline.org/32364; Kathryn Ardizzone & James Love, Other Transaction Agreements: Government Contracts that May Eliminate Protections for the Public on Pricing, Access and Competition, Including in Connection with COVID-19 *passim* (2020), https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf; *see* Luis Gil Abinader, *Foundational mRNA Patents Are Subject to the Bayh-Dole Act Provisions*, Knowledge Ecology Int'l (Nov. 30, 2020), https://www.keionline.org/34733.

41 Rohit Malpani et al., *Corporate Charity – Is the Gates Foundation Addressing or Reinforcing Systemic Issues Raised by COVID-19?*, Health Pol'y Watch (Oct. 31, 2020), https://healthpolicy-watch.news/gates-foundation-address-systemic-covid-19/ (analyzing the Gates Foundation's pro-IP policies); Zain Rizvi, Public Citizen, COVAX's Choices 8–24 (Nov. 16, 2020), https://www.citizen.org/wp-content/uploads/Covax-choices-embargoed-Nov-16.pdf?eType=EmailBlastContent&eId=fb342c47-08be-4f8c-9bc6-9812e6767fb1 (analyzing several CEPI contracts with vaccine manufacturers with respect to their equitable access provisions governing transparency about production supply, pricing, sales, and cost; early and equal availability in low- and middle-income countries; reasonable pricing; contract manufacturing, and equitable licensing in certain circumstances); Coalition for Epidemic Preparedness Innovations, Enabling Equitable Access to COVID-19 Vaccines: Summary of Equitable Access Provisions in CEPI's COVID-19 Vaccine Development Agreements *passim* (2021), https://

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.

B. *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[42] 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 the best detection, prophylactic, and treatment outcomes.[43] Although there have been some efforts toward better planning and coordination of trials and proposals for data sharing, including the WHO Solidarity Trial,[44] the U.K. Recovery trial,[45] and the U.S. ACTIV project,[46] by and large, there has been a huge wastage of research potential

cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines-v4-18Mar2021.pdf (detailing CEPI's assessment of its contractual equitable access provisions).

42 *See generally* Rafael Da-Re & Ignacio Malillo-Fernandez, *Waste in COVID-19 Clinical Trials in Western Europe*, 81 EUR. J. INTERNAL MED. 91 (July 7, 2020).

43 Huseyin Naci et al., *Producing and Using Timely Comparative Evidence on Drugs: Lessons from Clinical Trials for COVID-19*, 371 BRIT. MED. J. 279, 279–81 (2020).

44 *"Solidarity" Clinical Trial for COVID-19 Treatments*, WORLD HEALTH ORG., https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments (last visited Oct. 23, 2020).

45 *This National Clinical Trial Aims to Identify Treatments that May Be Beneficial for People Hospitalised with Suspected or Confirmed COVID-19*, RECOVERY, https://www.recoverytrial.net (last visited Oct. 23, 2020).

46 Lawrence Corey et al., *A Strategic Approach to COVID-19 Vaccine R&D*, 368 SCIENCE 948 (2020); Francis S. Collines & Paul Stoffels, *Accelerating COVID-19 Therapeutic Interventions*

that confounds efforts to identify and prioritize the best biopharmaceutical and diagnostic interventions[47] and to simplify product adaption and further improvements. This wastage is particularly egregious with respect to clinical trial research relating to COVID-19 vaccines, where the lack of comparative standards for assessment[48] and the lack of comparative trials undermines efforts to identify the best vaccine candidates.[49] The lack-of-coordination trend is apparent in the race for monoclonal antibody treatments.[50] 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.[51]

Paradoxically, some of the populations most at risk of COVID-19 have been disproportionately under-represented in clinical trials. Historic concerns about under-representation of diverse populations in clinical trials have extended to COVID-19, where trials have under-enrolled participants of color, older people, and pregnant women,[52] though some trials, for example,

and Vaccines, 323 JAMA 2455, 2455 (2020).

47 Krishna Pundi et al., *Characteristics and Strength of Evidence of COVID-19 Studies Registered on ClinicalTrials.gov*, 180 JAMA Internal Med. 1398 (2020); Paul P. Glasziou et al., *Waste and Harm in Covid-19 Research*, 369 Brit. Med. J. 312, 312 (2020); Matthew Herper & Erin Riglin, *Data Show Panic and Disorganization Dominate the Study of Covid-19 Drugs*, STAT (July 6, 2020), https://www.statnews.com/2020/07/06/data-show-panic-and-disorganization-dominate-the-study-of-covid-19-drugs/; *see generally* Philip Krause et al., *For the World Health Organization Solidarity Vaccines Trial Expert Group, COVID-19 Vaccine Trials Should Seek Worthwhile Efficacy*, 396 Lancet 741 (2020).

48 Jeremy Kahn, *Scientist to Wall Street: You Don't Really Understand How COVID Vaccine Tests Work*, Fortune (Aug. 24, 2020), https://fortune.com/2020/08/24/scientists-question-wall-street-vaccines-antibodies/.

49 Peter B. Bach, *We Can't Tackle the Pandemic Without Figuring Out Which Covid-19 Vaccines Work the Best*, STAT (Sept. 24, 2020), https://www.statnews.com/2020/09/24/big-trial-needed-determine-which-covid-19-vaccines-work-best/.

50 *See* Jon Cohen, *The Race Is On for Antibodies that Stop the New Coronavirus*, 368 Science 564, 564–66 (2020).

51 *See* Krause et al., *supra* note 47, at 741–43; Crystal M. North et al., *Improving Clinical Trial Enrollment — In the Covid-19 Era and Beyond*, 383 New Eng. J. Med. 1406 (2020); Eva Petkova et al., *Pooling Data from Individual Clinical Trials in the COVID-19 Era*, 324 JAMA 543 (2020).

52 Daniela B. Chastain et al., *Racial Disproportionality in COVID Clinical Trials*, 383 New Eng. J. Med. e59(1) (Aug. 27, 2020), https://www.nejm.org/doi/full/10.1056/NEJMp2021971; Hala T. Borno et. al., *COVID-19 Disparities: An Urgent Call for Race Reporting and Representation in Clinical Research*, 19 Contemp. Clinical Trials Commc'ns 10,0630 (Sept. 2020), https://www.sciencedirect.com/science/article/pii/S2451865420301149; Oliver Milman, *COVID-19: Lack of Diversity Threatens to Undermine Vaccine Trials, Experts Warn*, Guardian (Aug. 7, 2020), https://www.theguardian.com/world/2020/aug/07/coronavirus-diversity-vaccine-trial-moderna; Melanie M. Taylor

Moderna, recognized the importance of more proportionate representation and took steps to address it.[53] An equally vexed form of discrimination arises from the under-enrollment of low- and middle-income country 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.[54]

Solution: Clinical trials should be better planned and coordinated 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 (LMICs).

C. *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.[55] Some of these efforts 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.[56] Other, more behind-the-scenes regulatory

---

et al., *Inclusion of Pregnant Women in COVID-19 Treatment Trials: A Review and Global Call to Action*, 9 LANCET GLOB. HEALTH e366, e366, e368 (2020); Ruth Farrell et al., *Pregnant Women in Trials of Covid-19: A Critical Time to Consider Ethical Frameworks of Inclusion in Clinical Trials*, 42 ETHICS & HUM. RSCH., July–Aug. 2020, at 17–19; Benjamin K.I. Helfand et al., *The Exclusion of Older Persons from Vaccine and Treatment Trials for Coronavirus Disease 2019—Missing the Target*, 180 JAMA INTERNAL MED. 1546–47 (2020).

53 Meg Tirrell & Leanne Miller, *Moderna Slows Coronavirus Vaccine Trial Enrollment to Ensure Minority Representation, CEO Says*, CNBC (Sept. 4, 2020), https://www.cnbc.com/2020/09/04/moderna-slows-coronavirus-vaccine-trial-t-to-ensure-minority-representation-ceo-says.html.

54 COVID-19 Clinical Research Coalition, *Global Coalition to Accelerate COVID-19 Clinical Research in Resource-Limited Settings*, 395 LANCET 1322, 1322–23 (2020); Maina Waruru, *Africa Lagging in COVID-19 Clinical Trials as Global Studies Cross 1000 Mark*, HEALTH POL'Y WATCH (Sept. 18, 2020), https://healthpolicy-watch.news/africa-lagging-in-covid-19-clinical-trials-as-global-studies-cross-1000-mark/.

55 *See* Caroline Chen, *FDA Repays Industry by Rushing Risky Drugs to Market*, PROPUBLICA (June 26, 2018), https://www.propublica.org/article/fda-repays-industry-by-rushing-risky-drugs-to-market; Priti Patnaik, *Regulatory Discoherence: The Case of Remdesivir*, GENEVA HEALTH FILES (Dec. 3, 2020), https://genevahealthfiles.wordpress.com/2020/12/03/regulatory-discoherence-the-case-of-remdesivir/.

56 *See, e.g.*, Lindsey R. Baden et al., *Editorial: The FDA and the Importance of Trust*, 383 NEW ENG. J. MED. e148(1) (Sept. 30, 2020); Michael S. Saag, *Misguided Use of Hydroxychloroquine for COVID-19: The Infusion of Politics Into Science*, 324 JAMA 2161 (2020).

pressures seem to be pure examples of cronyism.[57] To counteract this trend on the global front, the WHO has undertaken separate analyses of diagnostic tests and vaccines before allowing emergency use listings or prequalification.[58]

Over recent years, biopharmaceutical and diagnostics companies have put increasing 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.[59] 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.[60] Even more concerning, Russia and China are rolling out COVID-19 vaccines without any large-scale studies proving efficacy and safety,[61] and former President

57 *See, e.g.*, Jonathan Swan, *Trump Eyes New Unproven Coronavirus "Cure*," Axios (Aug. 16, 2020), https://www.axios.com/trump-covid-oleandrin-9896f570-6cd8-4919-af3a-65ebad113d41.html.

58 *See Regulation and Prequalification: Emergency Use Listing*, World Health Org., https://www.who.int/diagnostics_laboratory/EUL/en/ (last visited Oct. 23, 2020); *First Invitation to Manufacturers of Vaccines Against Covid-19 to Submit an Expression of Interest (EOI) for Evaluation by the WHO (Prequalification and/or EUL)*, World Health Org. (Oct. 1, 2020), https://www.who.int/news-room/articles-detail/1-EOI-Covid-19-Vaccines.

59 Jeremy Puthumana et al., *Clinical Trial Evidence Supporting FDA Approval of Drugs Granted Breakthrough Therapy Designation*, 320 JAMA 301, 302 (2018); Thomas Hwang et al., *Efficacy, Safety, and Regulatory Approval of Food and Drug Administration-Designated Breakthrough and Nonbreakthrough Cancer Medicines*, 36 J. Clinical Oncology 1805, 1809–11 (2018); Aaron S. Kesselheim et al., *Trends in Utilization of FDA Expedited Drug Development and Approval Programs, 1987-2014: Cohort Study*, 351 Brit. Med. J. 11, *passim* (2015) Peter Loftus, *Fast-Track Drug Approval, Designed for Emergencies, Is Now Routine*, Wall St. J. (July 5, 2019), https://www.wsj.com/articles/fast-track-drug-approval-designed-for-emergencies-is-now-routine-11562337924.

60 Joshua Sharfstein, *How the FDA Should Protect Its Integrity from Politics*, 585 Nature 161, 161 (2020); Elisabeth Mahase, *Covid-19: US Approves Emergency Use of Convalescent Plasma Despite Warnings over Lack of Evidence*, 370 Brit. Med. J. m3327 (2020); *see* Mike Z. Zhai et al., *Need for Transparency and Reliable Evidence in Emergency Use Authorizations for Coronavirus Disease 2019 (COVID-19) Therapies*, 180 JAMA Internal Med. 1145, 1145–46 (2020).

61 Eskild Petersen et al., *Advancing COVID-19 Vaccines – Avoiding Different Regulatory Standards for Different Vaccines and Need for Open and Transparent Data Sharing*, 98 Int'l. J. Infectious Diseases 501–02 (2020); Elisabeth Mahase, *Russia Approves Vaccine Before Large Scale Testing*, 370 Brit. Med. J. 216, 216 (2020); Eva Dou & Isabelle Khurshudyan, *China and Russia Are Ahead in the Global Coronavirus Vaccine Race, Bending Long-Standing Rules as They Go*, Wash. Post (Sept. 18, 2020), https://www.washingtonpost.com/world/asia_pacific/china-and-russia-are-ahead-in-the-global-coronavirus-vaccine-race-bending-long-standing-rules-as-they-go/2020/09/18/9bfd4438-e2d4-11ea-82d8-5e55d47e90ca_story.html.

Trump was reported to have pressured the FDA to expedite emergency use authorization of vaccines before the November 2020 election.[62] Relaxed standards and inadequate assessment of longer-term safety and efficacy violate 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.

D. *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.[63] Part of the problem is capacity deficits, inefficiencies, corruption, pluralistic regulatory requirements, and other barriers to registration that countries must redress.[64] But an equal part of the problem is that commercial entities have no imperative to seek marketing approval by any other metric than a commercial advantage.[65] Even where originators do register their products, in some countries, they have monopoly control over the use of their regulatory data via what is known as "data exclusivity."[66] 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.[67]

"Regrettably, states have no viable mechanism [under existing

62 *See* Owen Dyer, *Covid-19: Pharma Companies Promise Not to Bow to Political Pressure to Rush Vaccine Production*, 370 BRIT. MED. J. m3512 (2020).

63 SUZANNE HILL & KENT JOHNSON, EMERGING CHALLENGES AND OPPORTUNITIES IN DRUG REGISTRATION AND REGULATION IN DEVELOPING COUNTRIES 9, 42 (2004); Brook K. Baker, Registration Related Issues in Voluntary Licenses 6 (May 29, 2018) (unpublished manuscript) (on file with the author) [hereinafter Baker, Registration Related Issues].

64 Baker, Registration Related Issues, *supra* note 63, at 6, 9–11.

65 *Id.* at 6–7.

66 *See* Srividhya Ragavan, *Data Exclusivity: A Tool to Maintain Market Monopoly*, 8 JINDAL GLOB. L. REV. 241, 241 (2017).

67 Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 306–07 (2008) [hereinafter Baker, *Ending Drug Registration Apartheid*].

law] to force" an originator or a generic licensee to enter their market.[68] Moreover, where a comparator originator product has not yet been registered, registration of a generic equivalent is significantly harder,[69] 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.[70] Comparable efforts could speed up WHO prequalification[71] of COVID-19 medicines, vaccines, and diagnostics and make better and broader use of WHO Collaborative Registration procedures to accelerate national registration or emergency use authorization efforts.[72] Efforts to harmonize regulatory submissions, 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.[73]

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 in other countries and WHO prequalification and emergency use listings need to be intensified. Policymakers need to pursue contracting and other rules that require both originator and generic companies to register their COVID-19 health products broadly to ensure supply in all countries.

68 Brook K. Baker, *Campaigning for Both Innovation and Equitable Access to COVID-19 Medicines*, *in* COVID-19, Human Rights, and What's Next (Morten Kjaerum et al. eds., forthcoming 2021) (manuscript at 18–19) (on file with author).

69 *See* Catherine Tomlinson, *Breakthrough Hepatitis C Medicines Remain in Regulatory Limbo*, Spotlight (Aug. 4, 2020), https://www.spotlightnsp.co.za/2020/08/04/breakthrough-hepatitis-c-medicines-remain-in-regulatory-limbo/.

70 Nat'l Academies of Sciences, Engineering, & Medicine, Regulating Medicines in a Globalized World: The Need for Increased Reliance Among Regulators 2, 11 (2020); World Health Org. [WHO], *Good Reliance Practices in Regulatory Decision-Making for Medical Products: High-Level Principles and Considerations* 9–10, 30, (World Health Org., Working Doc. No. QAS/20.851, 2020), https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS20_851_Rev_1_Good_Reliance_Practices.pdf?ua=1.

71 *See Prequalification*, World Health Org., https://www.who.int/medicines/regulation/prequalification/en/ (last visited Oct. 23, 2020).

72 *See Collaborative Procedure for Accelerated Registration*, World Health Org., https://extranet.who.int/prequal/content/collaborative-procedure-accelerated-registration (last visited Oct. 23, 2020).

73 Sara Jerving, *African Union Needs More Country Support to Launch the African Medicines Agency*, Devex (July 7, 2020), https://www.devex.com/news/african-union-needs-more-country-support-to-launch-the-african-medicines-agency-97624.

E. *Trial and Error vs. Informed Clinical Guidance*

The initial stages of treating COVID-19 required clinicians to conduct trial disease management based largely on hype from commercial researchers and anecdotal evidence from fellow clinicians and without the benefit of informed clinical guidance.[74] Reliance on non-peer-reviewed studies and social media for rumors of effective treatment must now be met with faster clinical guidance based on sound clinical assessment that remains open to revision based on rapidly accumulating medical knowledge.[75]

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 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.[76] For WHO's global guidance to be actionable, countries will also have to move with increased speed to adopt guidance at the national level.

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

Patent tickets, 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 rightsholders thereafter entered into lucrative acquisition,[77] partnership,[78]

74 *See* Tara Vijayan et al., *Trusting Evidence over Anecdote: Clinical Decision Making in the Era of Covid-19*, BMJ OP. (July 23, 2020), https://blogs.bmj.com/bmj/2020/07/23/trusting-evidence-over-anecdote-clinical-decision-making-in-the-era-of-covid-19/.

75 *See* Robert M. Califf et al., *Weighing the Benefits of Proliferating Observational Assessments: Observational Cacophony, Randomize Harmony*, 324 JAMA 625, 625–26 (2020).

76 *See generally* WORLD HEALTH ORG., CORTICOSTEROIDS FOR COVID-19 (2020).

77 *See, e.g.*, Nick Paul Taylor, *Merck Inks $425M OncoImmune Buyout to Bag COVID-19 Drug*, FIERCE BIOTECH (Nov. 23, 2020), https://www.fiercebiotech.com/biotech/merck-inks-425m-oncoimmune-buyout-to-bag-covid-19-drug.

78 *See, e.g.*, Joseph Walker, *Regeneron Enlists Swiss Rival Roche to Help Make Covid-19 Drug*, WALL ST. J. (Aug. 19, 2020), https://www.wsj.com/articles/regeneron-enlists-swiss-rival-roche-to-help-make-covid-19-drug-11597813202; Fraiser Kansteiner, *AstraZeneca, Lilly, GSK and More Will Share COVID Antibody Secrets to Speed Manufacturing Scale-Up*, FIERCE PHARMA (July 24, 2020), https://www.fiercepharma.com/manufacturing/az-lilly-amgen-and-more-score-justice-department-nod-for-monoclonal-antibody-scale-

manufacturing,[79] and distribution agreements[80] that maintain tight control over manufacturing and artificially limit supply that could meet the needs of the entire global population.[81] 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.[82] This competition has reduced the

up.

79 *See, e.g.*, Cormac O'Sullivan et al., McKinsey & Co., Why Tech Transfer May Be Critical to Beating COVID-19, at 2 (2020), https://www.mckinsey.com/~/media/McKinsey/Industries/Pharmaceuticals%20and%20Medical%20Products/Our%20Insights/Why%20tech%20transfer%20may%20be%20critical%20to%20beating%20COVID%2019/Why-tech-transfer-may-be-critical-to-beating-COVID-19-vF.pdf; Matthew Dalton & Joseph Walker, *Covid-19 Vaccine Makers Tap Contractors to Produce Billions of Doses*, Wall St. J. (Dec. 19, 2020), https://www.wsj.com/articles/covid-19-vaccine-makers-tap-contractors-to-produce-billions-of-doses-11608373800; Hannah Balfour, *COVID-19 Is Benefiting Contract Manufacturing Services, Suggests Reports*, Eur. Pharm. Rev. (Nov. 18, 2020), https://www.europeanpharmaceuticalreview.com/news/133825/covid-19-is-benefiting-contract-manufacturing-services-suggest-reports/ ("[P]harma companies [had] publicly disclosed 42 contract manufacturing service agreements for 26 unique pipeline COVID-19 vaccines."); Kristin Jensen, *AstraZeneca Broadens Coronavirus Vaccine Manufacturing Deal with Catalent*, BioPharmaDive (Aug. 26, 2020), https://www.biopharmadive.com/news/astrazeneca-broadens-coronavirus-vaccine-manufacturing-deal-with-catalent/584186/.

80 Anthony D. So & Joshua Woo, *Reserving Coronavirus Disease 2019 Vaccines for Global Access: Cross Sectional Analysis*, 371 Brit. Med. J. m4750 (2020), https://doi.org/10.1136/bmj.m4750 (providing an overview of how high income countries have secured highly disproportionate future supplies of COVID-19 vaccines while access for the rest of the world remains uncertain).

81 "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." Muhammad Zaheer Abbas, Practical Implications of 'Vaccine Nationalism': A Short-Sighted and Risky Approach in Response to COVID-19, at 13 (2020), https://www.southcentre.int/wp-content/uploads/2020/11/RP-124.pdf; *see* Carlos Correa, *Lessons from COVID-19: Pharmaceutical Production as a Strategic Goal*, S. Ctr.: SouthViews (July 17, 2020), https://www.southcentre.int/wp-content/uploads/2020/07/SouthViews-Correa.pdf (providing a trenchant explanation of the need for expanded manufacturing capacity).

82 Brook K. Baker, *Access to Medicines Activism: Collaboration, Conflicts, and Complementarities*, *in* Intellectual Property Law and the Right to Health: A History of TRIPs and Access to Medicine (Srividhya Ragavan & Amaka Vanni eds., 2020) (forthcoming

price of antiretrovirals in most low- and many middle-income countries by 99+%, which has been key to the enormous expansion of treatment from the hundreds of thousands in 2000 to over 25 million in 2020.[83] There are some indications of price moderation in the pricing of COVID-19 vaccines, including by Johnson & Johnson, which has offered a non-profit price of $10 for its single-dose vaccine; unfortunately, other vaccine innovators are announcing significantly higher prices for a double-dose vaccination: Sinopharm, $145; NIH/Moderna, $74; BioNTech/Pfizer, $39; Novovax, $32; and Oxford/AstraZeneca, $74.[84] Similarly, Gilead's remdesivir, a repurposed antiviral, which has shown only limited benefit shortening hospital stays and easing moderate infection, is priced between $2,340 and $3,120 for a five-day course of treatment.[85] Promising monoclonal antibody therapies from Regeneron and Eli Lilly have recently been announced, but estimates for a course of Regeneron treatment negotiated by the U.S. result in a price range from $1,500 to $6,428.[86] 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 vaccines, medicines, and diagnostics. Not only do innovators' exclusivities lead to

2021) (manuscript at 1–3) (on file with author).

83 *Id.* at 10; John Elflein, *Access to Antiretroviral Therapy (ART) Among HIV-Infected People Worldwide from 2000 to 2019*, STATISTA (Aug. 4, 2020), https://www.statista.com/statistics/265921/access-to-art-for-hiv-treatment-in-low-and-middle-income-countries/ (reporting that the number of people receiving antiretroviral therapy in 2000 was approximately 570,000); *Global HIV & AIDS Statistics — 2020 Fact Sheet*, UNAIDS, https://www.unaids.org/en/resources/fact-sheet (last visited Feb. 24, 2021) (reporting that roughly 26 million people were receiving antiretroviral therapy as of June 2020).

84 Mark Terry, *Updated: Comparing COVID-19 Vaccines: Timelines, Types and Prices*, BIOSPACE (Feb. 8, 2021), https://www.biospace.com/article/comparing-covid-19-vaccines-pfizer-biontech-moderna-astrazeneca-oxford-j-and-j-russia-s-sputnik-v/; Angus Liu, *Sinopharm Chief Says COVID-19 Vaccine Will Cost Less Than $145 for 2-Dose Regimen*, FIERCE PHARMA (Aug. 18, 2020), https://www.fiercepharma.com/vaccines/china-sinopharm-chief-narrows-down-covid-19-vaccine-price-to-within-145-for-2-dose-regimen.

85 Matthew Herper, *Gilead Announces Long-Awaited Price for Covid-19 Drug Remdesivir*, STAT (June 29, 2020), https://www.statnews.com/2020/06/29/gilead-announces-remdesivir-price-covid-19/; Patnaik, *supra* note 55.

86 Josh Nathan-Kazis, *The U.S. Is Buying $450M of Regeneron's Experimental Covid-19 Antibody. Its Stock Is Jumping*, BARRON'S (July 7, 2020), https://www.barrons.com/articles/us-buys-450m-regeneron-experimental-covid-19-antibody-51594130963; Matthew Herper, *Eli Lilly Says Its Monoclonal Antibody Prevented Covid-19 Infections in Clinical Trial*, STAT (Jan. 21, 2021), https://www.statnews.com/2021/01/21/eli-lilly-says-its-monoclonal-antibody-prevented-covid-19-in-clinical-trial/.

supra-competitive prices, but they also lead to artificially restricted supplies.[87] Although biopharmaceutical manufacturers are investing in expanded production capacity and negotiating with each other[88] and with contract manufacturing organizations[89] to meet demand in rich countries, they are studiously avoiding efforts to more broadly license their medicines with full technology transfer to all qualified generic and biosimilar producers.

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 vaccines are equitably distributed.[90] Even mainstream media is echoing this call in their op-eds,[91]

87 *See* Samuel Lovett, *Pfizer Vaccine: Over 80% of Doses Already Sold to World's Richest Countries*, Independent (Nov. 13, 2020), https://www.independent.co.uk/news/health/covid-pfizer-vaccine-doses-latest-uk-supplies-b1721162.html (quoting Heidi Chow, "We need to break the monopoly over this vaccine so that more manufacturers can make it, . . . [o]therwise, we are heading towards an artificially created scarcity which is completely unacceptable during a global pandemic and will cost even more lives.").

88 Katie Thomas, *The Vaccines Will Probably Work. Making Them Fast Will Be the Hard Part.*, N.Y. Times (Dec. 7, 2020), https://www.nytimes.com/2020/11/17/health/coronavirus-vaccine-operation-warp-speed.html; Lovett, *supra* note 87.

89 *Supra* note 79 and sources cited.

90 *See, e.g.*, *WTO COVID-19 TRIPS Waiver Proposal: Myths, Realities and an Opportunity for Governments to Protect Access to Lifesaving Medical Tools in a Pandemic*, Medicins Sans Frontieres Access Campaign (Dec. 3, 2020), https://msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access; Zain Rizvi, *Leading COVID-19 Vaccine Candidates Depend on NIH Technology*, Pub. Citizen (Nov. 10, 2020), https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/; U.N. Office of the High Commissioner for Human Rights, Statement by UN Human Rights Experts Universal Access to Vaccines Is Essential for Prevention and Containment of COVID-19 Around the World (Nov. 9, 2020), https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E; Hum. Rts. Watch, "Whoever Finds the Vaccine First Must Share It": Strengthening Human Rights and Transparency Around Covid-19 Vaccines 4, 14 (2020), https://www.hrw.org/sites/default/files/media_2020/10/globalvaccine1020_web.pdf; Amnesty Int'l, A Fair Shot: Ensuring Universal Access to COVID-19 Diagnostics, Treatments, and Vaccines 4–5 (2020), https://www.amnesty.org/download/Documents/POL3034092020ENGLISH.PDF; Int'l Comm'n of Jurists, Living Like People Who Die Slowly: The Need for Right to Health Compliant COVID-19 Responses, 39–40 (2020), https://www.icj.org/wp-content/uploads/2020/09/Universal-Global-Health-COVID-19-Publications-Reports-Thematic-Reports-2020-ENG.pdf; Nuffield Council on Bioethics, Fair and Equitable Access to COVID-19 Treatments and Vaccines 5–6 (2020), https://www.nuffieldbioethics.org/assets/pdfs/Fair-and-equitable-access-to-COVID-19-treatments-and-vaccines.pdf.

91 "With control over the production of these vaccines, these companies will largely

as are prominent politicians.[92] This call has a new urgency, given evidence that death rates will be two times higher if vaccines are hoarded rather than shared globally.[93] Some of these initiatives are discussed at length in Part II.

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 the point of use, most certainly for poor people and people living in LMICs.

---

provide them on their own schedule, using their own factories or licensed producers – while other facilities around the world sit idle. Governments will almost certainly order more of the approved vaccines in the weeks and months to come, but the production capacity for each company is limited. Companies should not only pledge to waive their patents but to also share all their technical knowledge so that other manufacturers can help produce the much-needed vaccines." Stephen Buranyi, *Big Pharma Is Fooling Us*, N.Y. TIMES (Dec. 17, 2020), https://www.nytimes.com/2020/12/17/opinion/covid-vaccine-big-pharma.html?smid=tw-share; Achal Prabhala et al., *Want Vaccines Fast? Suspend Intellectual Property Rights*, N.Y. TIMES (Dec. 7, 2020), https://www.nytimes.com/2020/12/07/opinion/covid-vaccines-patents.html; Arnab Acharya & Sanjay G. Reddy, *It's Time to Use Eminent Domain on the Coronavirus Vaccines*, FOREIGN POL'Y (Dec. 29, 2020), https://foreignpolicy.com/2020/12/29/its-time-to-use-eminent-domain-on-the-coronavirus-vaccines/?utm_source=PostUp&utm_medium=email&utm_campaign=28865&utm_term=Editors%20Picks%20OC&?tpcc=28865.

92 *E.g.*, Clive Lewis, *Rich Countries Should Scale Up Production of the Coronavirus Vaccine, Not Stockpile It*, INDEPENDENT (Dec. 10, 2020), https://www.independent.co.uk/voices/coronavirus-vaccine-distribution-patents-pharma-b1769212.html; Lloyd Doggett & Charles Duan, *How to Protect Taxpayers' Investments in COVID-19 Vaccines*, USA TODAY (Dec. 18, 2020), https://www.usatoday.com/story/opinion/2020/12/17/why-patents-covid-19-vaccines-treatments-should-lifted-column/3919600001/?fbclid=IwAR0i47Yk1cO-3TNoxyP7ocaM_uiM6QAgXJ0vzDh0xiI7jfrmnCpQor_MJSg; *MSPs Call on Westminster to Back Suspension of Patents on Covid-19 Vaccines*, GLOB. JUST. NOW (Dec. 9, 2020), https://www.globaljustice.org.uk/news/2020/dec/9/msps-call-westminster-back-suspension-patents-covid-19-vaccines; Hugo Gye, *Covid Vaccines: Poor Countries Will Miss Out Unless the Global Patent Rules Are Changed, MPs Warn Government*, I (Nov. 24, 2020), https://inews.co.uk/news/politics/covid-vaccines-poor-countries-miss-out-global-patent-rules-771046; Global Justice Now, *Politicians from the Global South Call for Support to Suspend Patents on Covid-19 Vaccines*, YOUTUBE (Dec. 8, 2020), https://www.youtube.com/watch?v=qOehyKq_WhA&feature=youtu.be.

93 Matteo Chinazzi et al., *Estimating the Effect of Cooperative Versus Uncooperative Strategies of COVID-19 Vaccine Allocation: A Modeling Study*, NE. UNIV. NETWORK SCI. INST. 5 (2020), https://www.mobs-lab.org/uploads/6/7/8/7/6787877/global_vax.pdf; Emily Arntsen, *If Rich Countries Monopolize COVID-19 Vaccines, It Could Cause Twice as Many Deaths as Distributing Them Equally*, NEWS@NORTHEASTERN (Sept. 14, 2020), https://news.northeastern.edu/2020/09/14/if-rich-countries-monopolize-covid-19-vaccines-it-could-cause-twice-as-many-deaths-as-distributing-them-equally/.

G. *Nationalistic Hoarding and Commercial Control over Distribution vs. Fair and Equitable Access*

Biopharmaceutical companies typically sell their products at higher prices in rich countries,[94] 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 also gives them near-total control over which customers to prioritize.[95] Particularly in periods of scarcity, this can lead to bidding wars,[96] which certainly occurred with respect to global supplies of personal protective equipment, and to export controls as well.[97]

In the wake of anticipated supply shortages, the world is experiencing an explosion of vaccine and therapeutics nationalism[98] by the U.S., U.K., European Union (E.U.), Canada, Japan, and other countries that have entered into preferential advance purchase agreements.[99] Researchers at Duke University are updating information on vaccine nationalism and grossly disproportionate supply to rich countries and, as of March 19, 2021, reported that 8.6 billion doses of vaccines had been purchased and

94 Judith L. Wagner & Elizabeth McCarthy, *International Differences in Drug Prices*, 25 Ann. Rev. Pub. Health 475, 483–84 (2004); *2019 Medicine Price Index*, Medbelle, https://www.medbelle.com/medicine-price-index-usa/ (last visited Feb. 24, 2021).

95 *See High Drug Prices and Monopoly*, Open Mkts., https://www.openmarketsinstitute.org/learn/drug-prices-monopoly (last visited Feb. 24, 2021) (stating that big pharmaceutical companies operate as monopolies and this practice allows them the ability to charge high drug prices).

96 Shawn Tully, *Inside the Surreal 'Mask Economy': Price-Gouging, Bidding Wars, and Armed Guards*, Fortune (Apr. 14, 2020), https://fortune.com/2020/04/14/coronavirus-face-masks-n95-respirators-price-gouging-ppe-medical-supplies-covid-19/.

97 *Id.*; WTO Secretariat, *Export Prohibitions and Restrictions* (Apr. 23, 2020), https://www.wto.org/english/tratop_e/covid19_e/export_prohibitions_report_e.pdf (noting such restrictions in 80 countries).

98 Brook K. Baker, *U.S.-, China- and EU-First Nationalism and COVID-19 Technology Hoarding Push the Rest of the World to the End of the Line*, Health GAP (June 5, 2020), https://healthgap.org/u-s-china-and-eu-first-nationalism-and-covid-19-technology-hoarding-push-the-rest-of-the-world-to-the-end-of-the-line/ [hereinafter Baker, *U.S.-, China- and EU-First Nationalism*]; David P. Fidler, *Vaccine Nationalism's Politics*, 369 Science 749, 749 (2020); Alexandra L. Phelan et al., *Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access*, 396 Lancet 800, 800–802 (2020).

99 Grace Ren, *Scramble to Preorder COVID-19 Vaccines May Leave Poorer Countries Behind*, Health Pol'y Watch (Aug. 14, 2020), https://healthpolicy-watch.news/scramble-to-preorder-covid-19-vaccines-may-leave-poorer-countries-behind-threatening-global-response/; Mohga Kamal-Yanni, *Solidarity or Nationalism?*, Access 2 HealthCare https://www.access2healthcare.net/post/solidarity-or-nationalism (last updated Sept. 22, 2020).

6.3 billion are under negotiation or reserved[100]: "High-income countries currently hold a confirmed 4.6 billion doses, upper-middle-income countries hold 1.5 billion doses, lower-middle-income countries hold 703 million doses, and low-income countries hold 670 million;" the COVAX Facility has reserved 1.1 billion confirmed doses, the majority of which will go to ninety-two lower-income and concessionary loan eligible countries.[101] As a consequence, "[m]any high-income countries have hedged their bets by advance purchasing enough doses to vaccinate their population several times over," whereas middle- and lower-middle-income countries do not "have enough [doses] to vaccinate their entire populations" and may not until 2023 or 2024.[102]

Similarly, the U.S. sequestered initial supplies of Gilead's remdesivir. First, Gilead increased its initial donation "to the federal government from 607,000 to around 940,000," and then 90+% of Gilead's initial commercial sales through July, August, and September of 2020 were secured by the Trump Administration.[103] The U.S. has also contracted to receive up to 300,000 doses of Regeneron's antibody treatment if used for sick patients or up to 1.3 million doses as a preventive treatment, and another 300,000 doses of Eli Lilly's monoclonal antibody with an option for an additional 650,000 doses.[104] 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 rightsholders, 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

100 Duke Glob. Health Innovation Ctr., *Vaccine Procurement*, LAUNCH & SCALE SPEEDOMETER, https://launchandscalefaster.org/covid-19/vaccineprocurement (last visited Mar. 22, 2021) (providing data visualizations of inequitable distribution of COVID-19 vaccines, including advance market commitments for COVID-19 vaccines).

101 Duke Glob. Health Innovation Ctr., *COVID-19*, LAUNCH & SCALE SPEEDOMETER, https://launchandscalefaster.org/COVID-19 (last visited Mar. 22, 2021).

102 *Id.*

103 Eric Boodman, *Gilead Ups Its Donation of the COVID-19 Drug Remdesivir for U.S. Hospitals*, STAT (May 18, 2020), https://www.statnews.com/2020/05/18/coronavirus-gilead-ups-remdesivir-donation/; *Trump Administration Secures New Supplies of Remdesivir for the United States*, U.S. DEP'T HEALTH & HUM. SERVS. (June 29, 2020), https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html.

104 Nathan-Kazis, *supra* note 86; Press Release, Eli Lilly, Lilly Announces Agreement with U.S. Government to Supply 300,000 Vials of Investigational Neutralizing Antibody Bamlanivimab (LY-CoV555) in an Effort to Fight COVID-19 (Oct. 28, 2020), https://investor.lilly.com/node/43881/pdf.

lifesaving and life-enhancing vaccines and medicines will be eviscerated.

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 "U.K. 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.

II. 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.

A. *TRIPS Waiver Proposal*

One of the most far-reaching proposals is a request from India and South Africa to the World Trade Organization (WTO) that it adopt a waiver to the enforcement of relevant international IP obligations. These obligations arise under the TRIPS Agreement,[105] which establishes minimum global requirements relating to the recognition and enforcement of IP rights. The waiver proposal provides that the obligations of members to implement or apply designated IP rights on COVID-19-related health technologies be waived "until widespread vaccination is in place globally, and the majority of the world's population has developed immunity."[106] The waiver proposal relies on Article IX of the Marrakesh Agreement Establishing the WTO, which allows waivers of obligations under the Agreement in exceptional circumstances for a set period of time.[107] Although decision by consensus is preferred, if the waiver request comes to vote, it could pass with a three-quarter majority of a Ministerial Council or General Council meeting of the WTO.

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,

105 Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 8(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

106 Council for Trade-Related Aspects of Intellectual Prop. Rights, *Waiver from Certain Provisions of the TRIPS Agreement for Prevention, Treatment and Containment of COVID-19, Communication from India and South Africa*, WTO Doc. IP/C/W/669, at 1–2 (Oct. 2, 2020), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True; *see* Ann Danaiya Usher, *South Africa and India Push for COVID-19 Patents Ban*, 396 LANCET 1790 (2020).

107 Marrakesh Agreement Establishing the World Trade Organization, art. IX § 3(a)–(b), Apr. 15, 1994, 1867 U.N.T.S. 154, 159–60; *Waiver from Certain Provisions of the TRIPS Agreement for Prevention, Treatment and Containment of COVID-19*, *supra* note 106, at 3.

manufacturing and supply of medical products essential to combat COVID-19."[108] 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 [copyright and related rights], 4 [industrial designs], 5 [patents], and 7 [protection of undisclosed information] of Part II of the TRIPS Agreement in relation to prevention, containment, or treatment of COVID-19."[109] In paragraph thirteen, they specify that "[t]he 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."[110]

The waiver request received a mixed reaction from the TRIPS Council meeting in mid-October 2020.[111] South Africa and India spoke forcefully in favor of the waiver request.[112] The vast majority of countries that supported the waiver request were least developed and developing countries, including Tanzania on behalf of the 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.[113] A number of other countries welcomed the proposal, including Nigeria, the Philippines, Turkey, Ecuador, China, Thailand, Senegal, Jamaica, Colombia, Costa Rica, Chile, and El Salvador, but some requested clarifications and expressed a need to consult with their capitals.[114]

It was predominantly rich countries that expressed their opposition to the request: the E.U., U.S., Switzerland, Norway, Australia, Canada,

108 *Waiver from Certain Provisions of the TRIPS Agreement for Prevention, Treatment and Containment of COVID-19*, *supra* note 106, at 1.

109 *Id*. at 2.

110 *Id.*

111 For a verbatim transcript of countries' positions, see WTO Council on Trade Related Aspects of Intellectual Property Rights, *Advance Minutes of Agenda Item 15*, WTO Doc. JOB/IP/41 (Nov. 5, 2020) (on file with author) [hereinafter WTO Waiver Minutes Oct 2020].

112 Thiru, *WTO TRIPS Council (October 2020): South Africa Issues Clarion Call Urging Support for TRIPS Waiver Proposal*, Knowledge Ecology Int'l (Oct. 16, 2020), https://www.keionline.org/34235; Communication from India and South Africa, *Proposal for a Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 16, 2020), https://pmindiaun.gov.in/public_files/assets/pdf/TRIPS_Agreemnet.pdf; D. Ravi Kanth, *South Africa, India Strongly Rebut Arguments Against TRIPS Waiver*, Third World Network (Oct. 20, 2020), https://www.twn.my/title2/wto.info/2020/ti201021.htm.

113 WTO Waiver Minutes Oct. 2020, *supra* note 111; *see* Kanth, *supra* note 112.

114 WTO Waiver Minutes Oct. 2020, *supra* note 111; *see* Kanth, *supra* note 112.

Japan, and the U.K.; they were also joined by Brazil.[115] The E.U. expressed a "commit[ment] to work with all Members on this global challenge," pointing to "[r]esearchers and [the] pharmaceutical industry, supported by public funding, [that] have put extraordinary efforts into the development of future treatments and vaccines against COVID-19."[116] The E.U. argued that "[a] well-functioning intellectual property rights system is crucial to ensure that [industry's R&D] efforts are adequately incentivized and rewarded."[117] Further, the E.U. stated that "[t]here is no indication that IPR issues have been a genuine barrier in relation to COVID-19-related medicines and technologies."[118] The E.U. noted that while "maintaining continued supply of such medicines and technologies is a difficult task[,] . . . non-efficient and underfunded healthcare and procurement systems, spike in demand and lack of manufacturing capacity or materials are much more likely to have an impact on the access to those medicines and technologies."[119] It concluded that "[a] well-functioning IPRs system, including its wide range of exceptions and flexibilities" under the TRIPS Agreement, "is part of the solution rather than an obstacle." [120]

The U.S. confirmed its goal of "ensur[ing] the swift delivery of potential COVID-19 therapeutics and vaccines around the globe," stating a belief that providing "incentives for innovation . . . respecting intellectual property rights, and supporting industry-led collaboration and voluntary knowledge sharing, will best achieve [the] shared objective."[121] For the U.S., "IP is important, but, ultimately, it is only one piece of addressing access to potential therapies."[122] The U.S. also noted that "IP has not been an obstacle in addressing the pandemic, but rather has incentivized global efforts to find treatments and cures."[123] It went on, saying that "[l]imits to manufacturing capacities and supply chain issues . . . are of much greater concern, especially for vaccines, given the need to provide access to the

115 WTO Waiver Minutes Oct. 2020, *supra* note 111; *see* Thiru, *WTO TRIPS Council (October 2020): European Union Dismisses Concerns that IPRs Are a Barrier to COVID-19 Medicines and Technologies*, KNOWLEDGE ECOLOGY INT'L (Oct. 20, 2020), https://www.keionline.org/34275.

116 WTO Waiver Minutes Oct. 2020, *supra* note 111. (For more on the European Union's assertion that "[t]here is no indication that IPR issues have been a genuine barrier in relation to COVID-19-related medicines and technologies, see Thiru, *supra* note 115.)

117 WTO Waiver Minutes Oct. 2020, *supra* note 111.

118 *Id.*

119 *Id.*

120 *Id.*

121 *Id.*

122 *Id.*

123 *Id.*

entire global population."[124]

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."[125] An informal meeting to further discuss the waiver proposal was held on November 20, 2020, with many developed countries raising multiple questions, opposing the waiver, or both.[126] Most of the questions raised had arguably been addressed or rebutted in the pre-meeting briefing document[127] and were rebutted by South Africa.[128] An additional TRIPS Council meeting was held on December 10, 2020, with some increased support from developing countries but little apparent change of developed country positions, which prompted a wide range of critical commentary.[129] The resulting factual report was delivered at a meeting of the WTO General Council that took place December 16–17, 2020; additional consultations were to take place back at the TRIPS Council in early 2021, followed by additional discussions at the General Council as

124 *Id*.

125 *Members Discuss Intellectual Property Response to the COVID-19 Pandemic*, World Trade Org. (Oct. 20, 2020), https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm.

126 D. Ravi Kanth, *Developed Countries Continue to Block TRIPS Waiver Proposal*, Third World Network (Nov. 24, 2020), https://www.twn.my/title2/intellectual_property/info.service/2020/ip201108.htm; Priti Patnai, *TRIPS Waiver: The Needle Has Moved, but the Fight Is On*, Geneva Health Files (Nov. 26, 2020), https://genevahealthfiles.substack.com/p/trips-waiver-discussions-moving-the.

127 *India and South Africa Proposal for WTO Waiver from Intellectual Property Protections for COVID-19-Related Medical Technologies: Briefing Document*, Medecins Sans Frontieres (updated Nov. 18, 2020), https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf.

128 Thiru, *WTO TRIPS Council – 20 November 2020 – South Africa's Defense of TRIPS Waiver*, Knowledge Ecology Int'l (Nov. 21, 2020), https://www.keionline.org/34708.

129 Andrew Green, *At WTO, A Battle for Access to COVID-19 Vaccines*, Devex (Dec. 15, 2020), https://www.devex.com/news/at-wto-a-battle-for-access-to-covid-19-vaccines-98787; D. Ravi Kanth, *TRIPS Waiver Gains More Support Despite Efforts to Stall Its Passage*, Third World Network (Dec. 14, 2020), https://www.twn.my/title2/health.info/2020/hi201208.htm; *see* James Hacker et al., *WHO Calls on World Leaders to "Honor Their Pledge" to Fund COVID-19 Vaccines; South Africa Raises Spectre of "Vaccine Apartheid,"* Health Pol'y Watch (Nov. 12, 2020), https://healthpolicy-watch.news/who-honor-pledge-south-africa/; Ed Silverman, *World Trade Council Fails to Act on Proposal to Waive IP Rights to COVID-19 Drugs and Vaccines*, STAT (Dec. 11, 2020), https://www.statnews.com/pharmalot/2020/12/11/wto-patents-covax-who-south-africa-india/?utm_campaign=stat_plus_today&utm_medium=email&_hsmi=102714445&_hsenc=p2ANqtz-_Z_pp6Obra-vERjN0baE5DP8YBd-WDtBXuNSpnMXDgEr3RvKfEE3p6jSU5wo30d4OcY68TaNfkEMD0QTziIatDPmcmQw&utm_content=102714445&utm_source=hs_email; Priti Patnaik, *Countries Fail to Reach Consensus on TRIPS Waiver Proposal*, Geneva Health Files (Dec. 10, 2020), https://genevahealthfiles.substack.com/p/no-consensus-on-trips-talks-who-foundation.

needed.[130]

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.[131]

B. *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.[132] This waiver relieves LDC Members of the obligations to adopt or enforce any IP protections whatsoever except with respect to most favored nation and national treatment protections for any IP rights they do recognize. The LDC general transition period under Article 66.1 of the TRIPS Agreement has been previously extended on two occasions, first in 2005 until 2013 and then in 2013 until 2021.[133] On each of those occasions, LDCs had sought an extension for LDC Members for as long as they were LDCs.[134] Even though Article 66.1 states that requested extensions "shall" be granted upon well-motivated requests, LDCs were granted time-limits for relatively shorter periods of time only.[135] This time, LDCs have more forcefully articulated their need for an extension as long as an LDC Member retains that status, but they also argued that they

130 *Members to Continue Discussion on Proposal for Temporary IP Waiver in Response to COVID-19*, WORLD TRADE ORG. (Dec. 10, 2020), https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm.

131 Brook Baker, *South Africa and India's Proposal to Waive Recognition and Enforcement of COVID-19 Intellectual Property Rights for COVID-19 Medical Technologies Deserves Universal Support, but Countries Also Have to Take Domestic Measures*, HEALTH GAP (Oct. 10, 2020), https://healthgap.org/south-africa-and-indias-proposal-to-waive-recognition-and-enforcement-of-intellectual-property-rights-for-covid-19-medical-technologies-deserves-universal-support-but-countries-also-have-to/.

132 Council for Trade-Related Intellectual Property Rights, *Extension of the Transition Period Under TRIPS Article 66.1 for Least Developed Country Members: Communication from Chad on Behalf of the LDC Group*, 3, 5 WTO Doc. IP/C/W/668 (Oct. 1, 2020).

133 *Id.* at 2.

134 *See id.*

135 *Id.* at 3.

need a further transition period of twelve years before needing to enforce TRIPS IP protections.[136] In paragraphs four and five of their request, LDCs draw special attention to the additional challenges they face from COVID-19.[137] One thing they could have perhaps made clearer is that the general waiver will be needed for them to have IP-free access to COVID-19 health products other than "pharmaceuticals," which are already covered by their 2033 pharmaceutical-product transition period under Article 66.1. Even though the LDC general transition-period extension request was not acted upon at the October 2020 TRIPS Council meeting, it too requires urgent passage before July 1, 2021, when the existing transition period expires.

C. *TRIPS Article 73 Security Waiver*

South Centre, an international organization of developing nations, 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.[138] Article 73 of the TRIPS Agreement reads: "*Nothing in this Agreement shall be construed . . . (b) to prevent a member from taking any action which it considers necessary for the protection of its essential security interests . . . (iii) taken in time of war or other emergency in international relations*."[139] 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*."[140] Similarly, Articles 7 and 8 of the TRIPS Agreement provide further support for the argument that member

136 *Id.* at 4–5.

137 *Id.*

138 Carlos Correa, *COVID-19 Pandemic: Access to Prevention and Treatment Is a Matter of National and International Security,* S. Ctr. (Apr. 4, 2020), https://www.southcentre.int/wp-content/uploads/2020/04/COVID-19-Open-Letter-REV.pdf; *see* Frederick Abbott, S. Ctr., The TRIPS Agreement Article 73 Security Exception and the COVID-19 Pandemic (Sept. 2020), https://www.southcentre.int/wp-content/uploads/2020/08/RP-116.pdf (concluding that the COVID-19 pandemic provides a sufficient basis for WTO nations to invoke art. 73 of the TRIPS Agreement to override intellectual property rights).

139 TRIPS Agreement, *supra* note 105, at art. 73.

140 World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002).

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.[141] 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.

D. *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, and Chile, Ecuador, Brazil, and even the U.S. are considering proposals for the issuance of compulsory licenses to address COVID-19.[142] 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.[143] Countries have historically faced political and trade threats arising from resort to compulsory licenses even though such measures are fully legal under Articles 31, 31b, and 44.2 of the TRIPS Agreement.[144] 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

141 TRIPS Agreement, *supra* note 105, at arts. 7–8.

142 *The TRIPS Agreement and COVID-19: Information Note*, WORLD TRADE ORG. 9 (Oct. 15, 2020), https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf; *People Over Patents: How Governments are Preparing to Make COVID-19 Medicines Available*, PUB. CITIZEN (Aug. 10, 2020), https://www.citizen.org/wp-content/uploads/Global-survey-of-IP-and-COVID-final.pdf.

143 *Making the Most of the EU's Innovative Potential – An Intellectual Property Action Plan to Support the EU's Recovery and Resilience*, at 12, COM (2020) 760 final; Thiru Balasubramaniam, *The European Commission Action Plan on Intellectual Property – Of COVID-19, TRIPS, EU BARDA, March-in Rights, Patent Pools, and Compulsory Licensing*, KNOWLEDGE ECOLOGY INT'L EUROPE (Nov. 25, 2020), https://keieurope.org/2020/11/24/leaked-eu-action-plan-on-intellectual-property-covid-19-of-trips-eu-barda-march-in-rights-patent-pools-and-compulsory-licensing/.

144 *See* TRIPS Agreement, *supra* note 105, at art. 31, 31b, 44.2; Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 249 (2009).

establishment of global or regional platforms for coordinated issuance of compulsory licenses and for procurement of resulting generic products.[145] It does seem clear that countries will need to act more proactively on their own behalf—including by establishing mandatory, automatic, or presumptive compulsory licenses for COVID-19 health products—if they want to overcome pricing and supply constraints.

E. *People's Vaccine Campaign*

The People's Vaccine campaign was launched by 140 global luminaries and organizations in May 2020 and has been calling for vaccines to be freely and equitably distributed globally.[146] The campaign has five principal goals: (1) governments and pharmaceutical companies must make vaccines free of patents and other monopolies and companies should freely 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, 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 (5) the people's vaccine should be used to fight poverty and inequality, including that arising from the pandemic itself.[147] The campaign had a day of action, and a demand letter was sent to the CEOs of major COVID-19 vaccine manufacturers on December 14, 2020.[148]

F. *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

145 Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supply of Patented Pharmaceuticals: The Case of COVID-19*, 23 J. Int'l Econ. L. 535 (2020).

146 *Uniting Behind a People's Vaccine Against COVID-19*, UNAIDS (May 14, 2020), https://www.unaids.org/en/resources/presscentre/featurestories/2020/may/20200514_covid19-vaccine-open-letter.

147 *What's a People's Vaccine, and How Can We Get One?*, Oxfam (Sept. 17, 2020), https://www.oxfamamerica.org/explore/stories/whats-a-peoples-vaccine-and-how-can-we-get-one/.

148 *Global Day of Action for a #PeoplesVaccine*, Glob. Just. Now, https://www.globaljustice.org.uk/join-peoples-vaccine-day-action (last visited Apr. 7, 2021); *100 Signature Letter to CEOs of Vaccine Companies*, Health Gap, https://healthgap.org/wp-content/uploads/2020/12/100-signature-letter-to-CEOs-of-vaccine-companies.pdf (last visited Feb. 21, 2021).

that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic."[149] Subsequently, thirty-seven countries and the WHO jointly issued The Solidarity Call to Action on May 29, 2020,[150] which established the COVID-19 Technology Access Pool (C-TAP),[151] a platform for sharing IP on COVID-19 treatments, vaccines, and health technologies. C-TAP finally announced its implementation plan on October 27, 2020.[152] In addition to the Medicines Patent Pool expanding its mandate to address COVID-19,[153] other initiatives to pool IPRs and to facilitate more open science, more supply, and lower prices, include the early Open COVID Pledge,[154] the university-based COVID-19 Technology Access Framework,[155]

149 Carlos Alvardo Quesada, President, Costa Rica, & Daniel Salas Peraza, Minister of Health, Costa Rica, to Dr. Tedro Adhanom Ghebreyesus, Dir. Gen. of the World Health Org. (Mar. 23, 2020), https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf.

150 *Medicines Law & Policy Welcomes WHO's Solidarity Call to Action to Realise Equitable Global Access to COVID-19 Health Technologies Through Pooling of Knowledge, Intellectual Property and Data*, MEDS. L. & POL'Y (May 29, 2020), https://medicineslawandpolicy.org/2020/05/medicines-law-policy-welcomes-whos-solidarity-call-to-action-to-realise-equitable-global-access-to-covid-19-health-technologies-through-pooling-of-knowledge-intellectual-property-and-data/; *Solidarity Call to Action*, WORLD HEALTH ORG., https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action (last visited Apr. 7, 2021).

151 *COVID-19 Technology Access Pool*, WORLD HEALTH ORG., https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool (last visited Oct. 21, 2020).

152 *Operationalising the COVID-19 Technology Access Pool (C-TAP)*, WORLD HEALTH ORG. (Oct. 27, 2020), https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9_36&download=true.

153 *Governance Board Resolution on Temporarily Expanding MPP's Remit to Include Any Health Technology That Could Contribute to the Global Response to COVID-19*, MEDS. PAT. POOL (Mar. 31, 2020), https://medicinespatentpool.org/uploads/2020/04/Governance-Board-Resolution-31-March-2020_final.pdf; *The Medicines Patent Pool and Unitaid Respond to Access Efforts for COVID-19 Treatments and Technologies*, MEDS. PAT. POOL (Mar. 31, 2020), https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-covid-19-treatments-and-technologies/.

154 OPEN COVID PLEDGE, https://opencovidpledge.org (last visited Oct. 21, 2020); Jorge L. Contreras et al., *Pledging Intellectual Property for COVID-19*, 38 NATURE BIOTECH. 1146, 1146–49 (2020), ("[V]oluntary pledges to make IP broadly available to address urgent public health crises can overcome administrative and legal hurdles faced by more elaborate legal arrangements such as patent pools and achieve greater acceptance than governmental compulsory licensing.").

155 *COVID-19 Technology Access Framework*, STAN. UNIV., https://otl.stanford.edu/covid-19-technology-access-framework (last visited Oct. 21, 2020); *COVID-19 Technology Access Framework*, NAT'L ACADS. SCI. ENG'G & MED. (Apr. 29, 2020), https://www.nationalacademies.org/event/04-29-2020/covid-19-technology-access-framework (webinar explaining the Framework).

Japanese Open COVID-19 Declaration,[156] and the COVID-19 Clinical Research Coalition.[157]

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.[158] More significantly, open licensing of all rights needed to allow full technology transfer would greatly expand supply beyond the limitations of single-source suppliers.[159] Allowing licensed manufacturers to expand production would help counteract the impulse to hoard and would also accelerate equitable distribution globally while assuring more affordable pricing.[160] Although C-TAP is promising in theory, it is disappointing that no biopharmaceutical company has contributed to the pool.[161] 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.[162] Industry and rich countries may warm to the idea of voluntary efforts if countries become more resolute in

156 Hirohisa Suzuki, *Japanese Companies' Contribution Against COVID-19 by IPs*, Mondaq (July 13, 2020), https://www.mondaq.com/patent/964756/japanese-companies39-contribution-against-covid-19-by-ips.

157 COVID-19 Clinical Research Coalition, *supra* note 54, at 234–35.

158 James Love, *Open Letter to the World Health Organization (WHO) and Its Member States on the Proposal by Costa Rica to Create a Global Pool for Rights in the Data, Knowledge and Technologies Useful in the Prevention, Detection and Treatment of the Coronavirus/COVID-19 Pandemic*, Knowledge Ecology Int'l (Mar. 27, 2020), https://www.keionline.org/32599.

159 *Id.* ("Such a pool would allow for competitive and accelerated production of needed COVID-19 technologies, and expand our capacity to address the need for affordable products for all.").

160 Brook Baker, *Rationale for Supporting Costa Rica's Proposal for Emergency COVID-19 Technology IP Pool for All Countries*, Health GAP (Mar. 25, 2020), https://healthgap.org/rationale-for-supporting-costa-ricas-proposal-for-emergency-covid-19-technology-ip-pool-for-all-countries/; Ellen 't Hoen, *Protect Against Market Exclusivity in the Fight Against COVID-19*, 26 Nature Med. 813, 813 (2020); Luca Li Bassi & Lenias Hwenda, *COVID-19: Time to Plan for Prompt Universal Access to Diagnostics and Treatments*, 8 Lancet Glob. Health e756, e756 (2020); Muhammad Zaheer Abbas, *Treatment of the Novel COVID-19: Why Costa Rica's Proposal for the Creation of a Global Pooling Mechanism Deserves Serious Consideration?*, 7 J.L. & Biosciences (forthcoming 2020) (manuscript at 1, 4), https://doi.org/10.1093/jlb/lsaa049; *see* Katrina Perehudoff & Jennifer Sellin, *COVID-19 Technology Access Pool (C-TAP): A Promising Human Rights Approach*, Health & Hum. Rts. J. (June 4, 2020), https://www.hhrjournal.org/2020/06/covid-19-technology-access-pool-c-tap-a-promising-human-rights-approach/.

161 Grace Ren, *Progress on COVID-19 Technology Access Pool Inches Along as Sister Initiative to Pool Vaccine Procurement Accelerates*, Health Pol'y Watch (Sept. 25, 2020), https://healthpolicy-watch.news/progress-on-covid-19-technology-pool-inches-along-as-sister-initiative-to-pool-vaccine-procurement-accelerates/.

162 *See* Ed Silverman, *Pharma Leaders Shoot Down WHO Voluntary Pool for Patent Rights on COVID-19 Products*, STAT (May 28, 2020), https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/.

seeking IP waivers and use of compulsory licensing mechanisms.

G. *ACT-Accelerator*

The initiative that has received the most fanfare to date is 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.[163] The ACT-Accelerator, relying on a partnership framework, "is organized into four pillars of work: diagnostics, treatment, vaccines and health system strengthening."[164] With respect to vaccines, the ACT-Accelerator has pre-established goals of accelerating the 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 2021, to be split equitably between (1) low-income and lower-middle-income countries, and (2) upper-middle-income and upper-income countries.[165] Its ambitions for therapeutics were initially to identify more effective treatments and catalyze manufacturing, procurement, and delivery of safe, effective, and quality assured therapeutics for 245 million courses of treatment within its first year.[166] For diagnostics, its goals were 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.[167] The health systems connector was to be principally focused on enabling the effective deployment of COVID-19 tools and delivery of essential health services, including supplying personal protective equipment and oxygen to those in need.[168] WHO was specifically tasked with adopting

163 *See ACT Accelerator, Status Report & Plan September 2020 – December 2021*, WORLD HEALTH ORG. (Sept. 25, 2020), https://www.finddx.org/wp-content/uploads/2021/03/Status-Report-Plan-FINAL-v2.pdf; *The Access to COVID-19 Tools (ACT) Accelerator*, WORLD HEALTH ORG., https://www.who.int/initiatives/act-accelerator (last visited Dec. 30, 2020).

164 *What Is the ACT-Accelerator*, WORLD HEALTH ORG., https://www.who.int/initiatives/act-accelerator/about (last visited Dec. 30, 2020).

165 Seth Berkley, *COVAX Explained*, GAVI (Sept. 3, 2020), https://www.gavi.org/vaccineswork/covax-explained.

166 ACT Accelerator Therapeutics P'ship, *COVID-19 Therapeutics Investment Case*, UNITAID, https://unitaid.org/assets/Therapeutics-Partnership-Investment-Case.pdf (last visited Feb. 21, 2021).

167 Access to COVID-19 Tool (ACT) Accelerator Diagnostics P'ship, *Investing in Diagnostics to Manage the Course of the COVID-19 Pandemic*, FIND (May 2020), https://www.finddx.org/wp-content/uploads/2020/05/ACT-A-Dx_Investment-Case_FINAL.pdf.

168 ACT Accelerator, *Status Report & Plan: September 2020 – December 2021*, *supra* note 163, at 14–15, 20, 21, 23.

a framework and guidelines for equitable access and fair allocation of COVID-19 tools.[169]

The ACT-Accelerator, conceptualized by the WHO, European Commission, France, and The Bill & Melinda Gates Foundation,[170] was launched in April 2020, "bring[ing] together governments, health organizations, scientists, businesses, civil society, and philanthropists[.]"[171] 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.[172] CEPI's work focuses on identifying and supporting promising vaccine candidates and reserving manufacturing capacity for proven vaccines.[173] 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.[174] Although Gavi COVAX

169 *See id*. at 15, 24–26; *Fair Allocation Mechanism for COVID-19 Vaccines Through the COVAX Facility*, World Health Org. at 9 (Sept. 9, 2020), https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility (click "Download (929.7 kB)").

170 *The ACT-Accelerator Frequently Asked Questions*, World Health Org., https://www.who.int/initiatives/act-accelerator/faq (last visited Feb. 21, 2021). For more information on the ACT Accelerator, *see* White Paper on COVID-19 Product Needs and Response: Vaccines, Diagnostics, and Therapeutics 8 (2020) (detailing the basic architecture and proposed strategy for the Access to COVID-19 Tools Accelerator) (on file with the author).

171 *The ACT-Accelerator Frequently Asked Questions*, *supra* note 170; *see* World Health Org. et al., Commitment and Call to Action (2020), https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator (click "Download (204.1 kB)").

172 *The Bill and Melinda Gates Foundation*, Gavi (last updated July 29, 2020), https://www.gavi.org/operating-model/gavis-partnership-model/bill-melinda-gates-foundation (reporting that the Gates Foundation pledged $750 million in 1999 to set up Gavi and has invested over $4 billion to date); *Responding to COVID-19*, Gavi, https://www.gavi.org/covid19 (last updated Dec. 2, 2020); *Coalition for Epidemic Preparedness Innovations (CEPI)*, Devex, https://www.devex.com/organizations/coalition-for-epidemic-preparedness-innovations-cepi-72733 (last visited Jan. 10, 2021) (reporting that "CEPI was founded in 2016 by the Government of Norway, the Bill & Melinda Gates Foundation, the Wellcome Trust, the World Economic Forum, and India's Department of Biotechnology"); *see What Is the ACT-Accelerator*, *supra* note 164; CEPI, https://cepi.net (last visited Feb. 21, 2021).

173 *See COVAX: CEPI's Response to COVID-19*, CEPI, https://cepi.net/COVAX/ (last visited Oct. 25, 2020).

174 Berkley, *supra* note 165; Seth Berkley, *The Gavi COVX AMC Explained*, Gavi, https://www.gavi.org/vaccineswork/gavi-covax-amc-explained (last visited Oct. 13, 2020); *COVAX Facility Explainer: Participation Arrangement for Self-Financing Economies*, Gavi, https://www.

AMC was initially slow in reserving needed doses and was projected to fail,[175] it announced major new supply deals on December 18, 2020.[176]

One promising development is that some rich countries may be willing to donate or transfer excess vaccine doses to Gavi COVAX AMC, and they are encouraged to do so in accordance with five criteria.[177] Within 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.[178] Likewise, within the diagnostics pillar, the Gates Foundation executed a volume guarantee for 120 million rapid diagnostic antigen tests.[179] Despite its ambition, the ACT-Accelerator is grossly under-resourced to achieve its goals. Out of an estimated budget need of $33.2 billion by the end of 2021, the ACT-Accelerator had raised only $11 billion as of March 4, 2021.[180] A more recent analysis still shows a $28 billion funding shortfall after several

gavi.org/sites/default/files/covid/covax/COVAX_Facility_Explainer.pdf (last visited Feb. 21, 2021).

175 Francesco Guarascio, *Exclusive–WHO Vaccine Scheme Risks Failure, Leaving Poor Countries with No COVID Shots Until 2024*, REUTERS (Dec. 16, 2020), https://www.reuters.com/article/health-coronavirus-who-vaccines-exclusiv-idUSKBN28Q1LF; Peter Beaumont, *Scheme to Get Covid Vaccine to Poorer Countries at 'High Risk' of Failure*, GUARDIAN (Dec. 16, 2020), https://www.theguardian.com/world/2020/dec/16/scheme-to-get-covid-vaccine-to-poorer-countries-at-high-risk-of-failure; Maria Cheng & Anniruddha Ghosal, *Poor Countries Face Long Wait for Vaccines Despite Promises*, ASSOCIATED PRESS (Dec. 15, 2020), https://apnews.com/article/poorer-countries-coronavirus-vaccine-0980fa905b6e1ce2f14a149cd2c438cd.

176 CEPI et al., *COVAX Announces Additional Deals to Access Promising COVID-19 Vaccine Candidates; Plans Global Rollout Starting Q1 2021* (Dec. 18, 2020), https://www.gavi.org/news/media-room/covax-announces-additional-deals-access-promising-covid-19-vaccine-candidates-plans (announcing agreements in place to access nearly two billion doses of several promising COVID-19 vaccine candidates, and laying the groundwork for further doses to be secured through contributions from donors).

177 COVAX, *Principles for Sharing COVID-19 Vaccine Doses with COVAX*, GAVI (Dec. 18, 2020), https://www.gavi.org/sites/default/files/covid/covax/COVAX_Principles-COVID-19-Vaccine-Doses-COVAX.pdf.

178 Eli Lilly, *Lilly Announces Arrangement* for *Supply* of *Potential COVID-19 Antibody Therapy* for *Low- and Middle-Income Countries*, CISION PR NEWSWIRE (Oct. 8, 2020), https://www.prnewswire.com/news-releases/lilly-announces-arrangement-for-supply-of-potential-covid-19-antibody-therapy-for-low--and-middle-income-countries-301148217.html.

179 *Global Partnership to Make Available 120 Million Affordable, Quality COVID-19 Tests for Low- and Middle-Income Countries*, WORLD HEALTH ORG. (Sept. 28, 2020), https://www.who.int/news/item/28-09-2020-global-partnership-to-make-available-120-million-affordable-quality-covid-19-rapid-tests-for-low--and-middle-income-countries.

180 ACT Accelerator, *ACT-Accelerator Prioritized Strategy and Budget for 2021*, WORLD HEALTH ORG. 26–29 (Mar. 12, 2021), https://www.who.int/publications/m/item/act-a-prioritized-strategy-and-budget-for-2021.

months of intensive resource mobilization.[181]

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.[182] Thus, for example, the Accelerator limits its ambition to facilitating supply sufficient to meet only 20% of projected vaccine need in LMICs and similar proportions of short-term needs for therapeutics and diagnostics. The ACT-Accelerator apparently 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 commitments, 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, such as 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 supply needs 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% of their population need instead of the 20% maximum for the ninety-two countries covered by the Advance Market Commitment;

181 ACT Accelerator, *A Financing Framework for the 2021 Act-A Funding Gap*, World Health Org. (Dec. 14, 2020), https://www.who.int/publications/m/item/a-financing-framework-for-the-2021-act-a-funding-gap (click "Download (820 kB)"); *see* ACT Accelerator, *Urgent Priorities and Funding Requirements at 10 November 2020*, World Health Org. (Nov. 12, 2020), https://www.who.int/publications/m/item/urgent-priorities-financing-requirements-at-10-november-2020 (click "Download (1.3 MB)"); ACT Accelerator, *supra* note 180.

182 ACT Accelerator, *supra* note 180.

(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.[183] Although not all of the ACT-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.

H. *Regional Solidarity Efforts*

In addition to these global efforts, regional mechanisms have also been established to promote collaboration and sharing. For example, the Association of Southeast Asian Nations (ASEAN) 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).[184] 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.[185] Similarly, within the WHO South-East Asia 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.[186] Subsequently, in June, African Union ministers of health

183 *See* Priti Patnaik, *COVAX in 2021: Will the Pieces Come Together?*, GENEVA HEALTH FILES: COVAX 2021: THE GAVI BOARD DOSSIERS (Dec. 25, 2020), https://genevahealthfiles.substack.com/p/covax-2021-the-gavi-board-dossiers?token=eyJ1c2VyX2lkIjoxNzE0ODUyNiwicG9zdF9pZCI6MjgwMDQ2MDAsIl8iOiJqalFSZSIsImlhdCI6MTYwOTM2NDYxMSwiZXhwIjoxNjA5MzY4MjExLCJpc3MiOiJwdWItNzkzOTYiLCJzdWIiOiJwb3N0LXJlYWN0aW9uIn0.uvVY7oO0ALL7zMCs06UN_QxC_IhBlseT85pxyJ5DFvA.

184 *Declaration of the Special ASEAN Summit on Coronavirus Disease 2019 (COVID-19)*, ASEAN (Apr. 14, 2020), https://asean.org/storage/2020/04/FINAL-Declaration-of-the-Special-ASEAN-Summit-on-COVID-19.pdf.

185 *Id.*

186 World Health Org. Comm. For S.E. Asia Res. SEA/RC73/R1 (Sept. 10, 2020), https://apps.who.int/iris/bitstream/handle/10665/334243/sea-rc73-r1-eng.pdf?sequence=1&isAllowed=y.

committed to pursuing local manufacturing of COVID-19 vaccines using flexibilities in the TRIPs Agreement.[187] In addition, the African Union Centre for Disease Control has been quite proactive in organizing regional distribution of scarce supplies. 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.[188]

187 *Communiqué from Africa's Leadership in COVID-19 Vaccine Development and Access Virtual Conference*, Africa CDC (June 30, 2020), https://africacdc.org/news-item/covid-19-vaccine-development-and-access-virtual-conference/.

188 *Cooperation in Latin America: Responses to COVID-19 Expose Existing Cracks in Regional Infrastructure*, Pol. Settlements Rsch. Program (July 16, 2020), https://www.politicalsettlements.org/2020/07/16/cooperation-in-latin-america-responses-to-covid-19-expose-existing-cracks-in-regional-infrastructure/.

Conclusion

IPRs, 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 also 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 research wastage and delay, fewer sources of supply, higher prices, insufficient quantities, 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.