FROM BUSINESS AS USUAL TO HEALTH FOR THE FUTURE: CHALLENGING THE INTELLECTUAL PROPERTY REGIME TO ADDRESS COVID-19 AND FUTURE PANDEMICS

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I. INTRODUCTION

A global respiratory pandemic, COVID-19, has been met by an international legal and policy regime that instantiates closed science, intellectual property ("IP") monopolies, and privatized control over the testing, supply, price, and distribution of life-saving health technologies. As a result, we have had avoidable delays in biopharmaceutical preparedness, COVID-19 medical technologies that are not optimized for use in resource poor settings, inconclusive and non-comparative clinical evidence, artificially restricted supplies, needlessly high prices, and grotesquely inequitable distribution.[1] IP right holders have preferentially and disproportionately supplied richer countries paying high prices at the same time that those countries have stockpiled excessive quantities of COVID-19 health technologies, resulting in what is now known as vaccine/therapeutic/diagnostic apartheid.[2]

Despite the remarkable effectiveness of the currently available vaccines, almost one-third of the world remains totally unvaccinated, allowing the virus to run rampant in many low- and middle-income countries ("LMICs"),[3] and increasing the likelihood that newer, post-Omicron variants will emerge.[4] The same is true of therapeutics. While many are being developed for in-

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[1] Brook K. Baker, *Hamstringing the Health Technology Response to Covid-19: The Burdens of Exclusivity and Policy Solutions*, 13 NE. L. REV. 689, 731 (2021).

[2] Brook K. Baker, *Access-to-Medicines Activists Demand Health Justice During COVID-19 Pandemic*, BILL OF HEALTH: EXAMINING THE INTERSECTION OF HEALTH L., BIOTECHNOLOGY, AND BIOETHICS (Aug. 12, 2021), https://blog.petrieflom.law.harvard.edu/2021/08/12/access-to-medicines-activists-covid-health-justice/ [https://perma.cc/PFE6-MJQY].

[3] Hannah Ritchie et al., *Coronavirus Pandemic (COVID-19)*, OUR WORLD IN DATA, https://ourworldindata.org/covid-vaccinations [https://perma.cc/5F8P-A8HK].

[4] Joia Mukherjee, Haniya Abbasi & Michelle Morse, *Global Vaccine Inequity Led to the COVID-19 Omicron Variant: It's Time for Collective Action*, HEALTH AFFS. FOREFRONT (Jan. 26, 2022), https://www.healthaffairs.org/do/10.1377/forefront.20220124.776516/full/ [https://perma.cc/Z4BK-6ADY].

patient and more recently out-patient use,[5] they remain elusive for people in LMICs.[6] Moreover, both polymerase chain reaction ("PCR") lab tests and antigen rapid diagnostic tests have been vastly more available in high-income countries than low-income countries—where almost half of the global population has received around twenty percent of the tests to date.[7] In light of these realities, it is increasingly important that countries work together to overcome health inequality in the short- and long-term.

In the following pages, this article seeks to explain the legal, political, and commercial obstacles that bar low- and middle-income countries from getting access to the pharmaceutical products needed to protect their populations during a pandemic. It begins by providing a summary of the reasons that access to medicines is fraught, even in ordinary times. It then describes how these dynamics have played out in the context of COVID-19, analyzing the successes and shortcomings of four levels of public and private action aimed at increasing access to COVID-19 products during the pandemic. It concludes by introducing some possible ways forward, all in nascent stages, that would enable us to face the next pandemic more effectively and equitably. Much has changed over the past three years as country representatives, regional organizations and institutions, civil society, and academics have attempted to tackle the difficult problem of addressing COVID-19 health inequality. As the following sections show, despite the many changes made to the global legal landscape, much more must be done to establish a more resilient and equitable response to this pandemic and those that will inevitably emerge in the future.

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[5] Emi Takashita et al., *Correspondence: Efficacy of Antibodies and Antiviral Drugs Against Covid-19 Omicron Variant*, 386 NEW ENG. J. MED. 995, 997 (2022).

[6] Andres Taylor, Beth Boyer & Krishna Udayakumar, *COVID GAP Accountability Report*, COVID GAP (May 25, 2022), https://covid19gap.org/assets/publications/COVID-GAP-Accountability-Report---May-2022-Issue-2-(3).pdf [https://perma.cc/UA7Z-EW3H] (documenting purchase of 36,564,000 courses of out-patient antiviral therapies by high-income countries; 250,000 by upper-middle-income countries; 1,320,000 by lower-middle-income countries; and zero by low-income countries).

[7] *SARS-COV-2 Test Tracker*, FIND, https://www.finddx.org/tools-and-resources/dxconnect/test-directories/covid-19-test-tracker/ [https://perma.cc/2HWA-5NJ5]; Carolina Batista et al., *The Silent and Dangerous Inequity Around Access to COVID-19 Testing: A Call to Action*, 43 ECLINICALMEDICINE 1 (2022); Fifa Rahman, Brook K. Baker & Carolyn Gomes, *COVID Testing Equity: A Reflection Based on 1.5 Years in the ACT-Accelerator*, PLOS BLOGS: SPEAKING OF MEDICINE AND HEALTH (Jan. 24, 2022), https://speakingofmedicine.plos.org/2022/01/24/covid-testing-equity-a-reflection-based-on-1-5-years-in-the-act-accelerator/ [https://perma.cc/TF9U-P4EU].

II. BARRIERS TO EQUITABLE PHARMACEUTICAL ACCESS

A. The World Trade Organization and the TRIPS Agreement

Prior to 1995, there was no universally accepted standard of pharmaceutical patent protection, and countries had different rules regarding patent terms, product versus process patents, and more.[8] The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement" or "TRIPS") then introduced new globalized minimum standards of intellectual property protection, including a mandatory twenty-year patent term,[9] a mandatory minimum protection for copyright (fifty years),[10] industrial designs (ten years),[11] and many other forms of intellectual property protection. It also introduced protection for the test data submitted to apply for marketing approval for new chemical entities (often pharmaceuticals) and additional protections for confidential information.[12] To provide teeth to these new commitments, TRIPS included minimum enforcement provisions (both civil and criminal)[13] and state-to-state dispute settlement[14] for alleged violations.

Although many developing country members of the WTO were discontented with the new standards as they applied to health technologies, TRIPS also established some key flexibilities.[15] The best known of these allow countries to determine what constitutes a patentable innovation and how to protect it.[16] More specifically, the TRIPS Agreement allowed countries to uphold strict standards on patentability and disclosure,[17] to adopt patent exclusions and limited exceptions,[18] and to implement expansive options for patent opposition and revocation.[19] In addition to patent-related

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[8] Kenneth C. Shadlen, Bhaven N. Sampat & Amy Kapczynski, *Patents, Trade and Medicines: Past, Present and Future*, 27 REV. INT'L POL. ECON. 75, 79 (2020).

[9] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 33, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [WTO], Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

[10] *Id*. art. 12.

[11] *Id*. art. 26.

[12] *Id*. art. 39.

[13] *Id*. arts. 41–47, 61.

[14] *Id*. art. 64.

[15] RACHEL D. THRASHER ET AL., WORKING GRP. ON TRADE, INV. TREATIES & ACCESS TO MEDS., RETHINKING TRADE TREATIES AND ACCESS TO MEDICINES: TOWARD A POLICY ORIENTED RESEARCH AGENDA 6, 8 (Oct. 2019), http://www.bu.edu/gdp/files/2019/11/Trade-Report-2019-GDP-Center-3.pdf [https://perma.cc/372N-XQGK].

[16] *Id*. at 10

[17] *Id*. at 10, 16; *see id*. at 21.

[18] TRIPS Agreement, *supra* note 9, art. 30.

[19] *See infra* Annex Table 1.

flexibilities, the TRIPS Agreement provision covering data protection[20] allows medicines regulatory authorities to rely on innovators' regulatory submissions or the fact of prior registration to grant marketing approval for generic equivalents of similar quality.[21] Compulsory or government-use licensing[22] also allow states to design their own policies facilitating access to important medicines and health-related technologies, especially in public health emergencies and other crises. Furthermore, the combination of minimum enforcement standards with permission to use competition policies to reign in IP rights abuses that artificially constrained supply of essential products[23] allows states to strike their own balance in protecting and defending IP rights, while still protecting and defending consumer welfare. Overall, WTO members retain quite a bit of discretion in designing their own IP policies.

In 2001, at the initiation of the Doha ("Development") Round of WTO negotiations, member states demanded a clarifying statement about the policy flexibility available to countries to promote access to medicines.[24] The Doha Declaration on TRIPS and Public Health affirmed the rights of parties to balance the interests of intellectual property rights holders and the public's need to gain access to essential medicines by confirming countries' broad discretion to define grounds for compulsory licenses, including identification of what constitutes an emergency that would permit expedited licensing.[25] An important modification was then introduced: WTO members could issue compulsory licenses, previously limited to production "predominantly" for domestic consumption, to allow export of even predominant quantities to

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[20] TRIPS Agreement, *supra* note 9, art. 39.3.

[21] CARLOS CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 14, 31 (2001); Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 309, 310–12, 323 (2008); Jerome H. Reichman, *The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?*, *in* NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 133, 133, 141 (Pedro Roffe, Geoff Tansey & David Vivas Eugui eds., 2006); Peter Yu, *Data Exclusivities in the Age of Big Data, Biologics, and Plurilaterals*, 6 TEX. A&M L. REV. 22, 23 (2019).

[22] TRIPS Agreement, *supra* note 9, art. 31.

[23] *Id*. arts. 8.2, 40.

[24] *See* Council for Trade-Related Aspects of Intellectual Property Rights, *Proposal by the African Group, et al*., IP/C/W/312, WT/GC/W/450, (Oct. 4, 2001), https://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm [https://perma.cc/V5QP-JVPN]; Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 935 (2007) (extensively analyzing this proposal).

[25] WTO, Ministerial Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha TRIPS Declaration].

other countries without sufficient manufacturing capacity.[26]

Least developed countries ("LDCs") have enjoyed additional flexibilities over the past twenty years. Beyond the initial eleven year transition period (the same as other countries without established pharmaceutical patenting programs), they were allowed an automatic right of further extension.[27] That transition period has so far been extended three times—in 2005, 2013, and 2021.[28] In each case, the full demands of LDCs have not been met, but the most recent extension was slightly longer than those in previous iterations, and the current pharmaceutical transition period ends in 2033.[29]

B. Legal and Practical Realities That Interfere with the Proper Exercise of TRIPS Flexibilities

Although the need for flexibilities was foreseen and built into the TRIPS agreement, several legal and practical realities interfere with WTO member countries exercising those flexibilities. First, TRIPS is not the only game in town. A parallel and growing regime of bilateral, regional, and mega-regional free trade agreements has further ratcheted up the rules governing global protection of IP rights. Second, historical and on-going political pressure on developing countries to not use existing flexibilities has kept countries from adopting IP measures that would otherwise be allowed. If that was not enough, patent complexity specific to COVID-19, including overlapping and multi-component technology and global production chains, means that many different patents protect each final product, which in turn makes country-by-country and product-by-product solutions exceedingly difficult.

1. Free Trade Agreements and TRIPS-Plus Standards

Research has found that approximately ninety percent of all regional and mega-regional free trade agreements ("FTAs") signed since 2009 include IP rules, and of those, at least one-third increase IP protection for pharmaceuticals over above the standards in the TRIPS Agreement.[30] The

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[26] TRIPS Agreement, *supra* note 9, art. 31*bis*. Although the revision was proposed and adopted initially on a temporary basis in 2005, it wasn't ratified by the required super-majority of the WTO membership until 2017.

[27] *Id*. art. 66.

[28] *WTO Members Agree to Extend TRIPS Transition Period for LDCs Until 1 July 2034*, WTO (June 29, 2021), https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm [https://perma.cc/5HST-MXBP].

[29] *Responding to Least Developed Countries' Special Needs in Intellectual Property*, WTO, https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm [https://perma.cc/EAC7-M7ZQ] (Oct. 16, 2013).

[30] Mark Wu, *Intellectual Property Rights*, *in* HANDBOOK OF DEEP TRADE AGREEMENTS 201, 205 (Aaditya Mattoo, Nadia Rocha & Michele Ruta eds., 2020).

provisions that increase IP protection are called "TRIPS-plus" provisions and vary widely among a diverse set of treaties.[31] Some of these new rules simply ratchet-up standards under existing rules, while others introduce new rules altogether or require amplified enforcement mechanisms.[32]

There is a wealth of literature analyzing and critiquing the TRIPS-plus standards in FTAs.[33] Generally speaking, the literature points out that these treaties require lower standards of patentability, increase the rights and enforcement powers of patent holders, and decrease the scope of available exceptions.[34] One TRIPS-plus standard that is particularly important for the COVID-19 context demands complete data exclusivity for all clinical trial data—no disclosure, reference to, or reliance upon regulatory data, for any reason even to register a generic equivalent—for five to twelve years, even if the product is not protected by patent.[35] There is also an increased emphasis on enforcement such that country parties must impose more deterrent civil remedies, specifying damages based on the average retail price of original goods.[36] Other treaties demand that counterfeit goods are not only seized but destroyed in transit if they are found to infringe patents.[37]

Beyond traditional provisions requiring ratcheted IP protection in FTAs, a much older regime protects IP owned by foreign investors more directly. Almost ninety-eight percent of all international investment agreements ("IIAs") in force today make some mention of intellectual property as a

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[31] World Health Org. [WHO], *Impact Assessment of TRIPS Plus Provisions on Health Expenditure and Access to Medicines*, at 2, WHO Doc. SEA/AIDS/176 (2007).

[32] RACHEL D. THRASHER, *Trade-Related Aspects of Intellectual Property Investment Rules and Access to Medicines*, *in* CONSTRAINING DEVELOPMENT: THE SHRINKING OF POLICY SPACE IN THE INTERNATIONAL TRADE REGIME 41, 55–56 (2021).

[33] *See, e.g.*, Gaëlle P. Krikorian & Dorota M. Szymkowiak, *Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine*, 10 J. WORLD INTELL. PROP. 388 (2007); Deborah Gleeson et al., *Analyzing the Impact of Trade and Investment Agreements on Pharmaceutical Policy: Provisions, Pathways, and Potential Impacts*, 15 GLOBALIZATION & HEALTH 1 (2019); Nusaraporn Kessomboon et al., *Impact on Access to Medicines from TRIPS-Plus: A Case Study of Thai-US FTA*, 41 SE. ASIAN J. TROPICAL MED. & PUB. HEALTH 667, 668–75 (2010).

[34] *See infra* Annex Table 1.

[35] Agreement Between the European Union and Japan for an Economic Partnership, EU-Japan, art. 14.37, July 17, 2018, 2018 O.J. (L 330) 1 [hereinafter EU-Japan Agreement]; Comprehensive Economic Trade Agreement (CETA), Can.-EU, art. 20.29, Oct. 30, 2016, 2017 O.J. (L 11) 23 [hereinafter CETA]; Agreement Between the United States of America, the United Mexican States, and Canada, art. 20.48.1, Nov. 30, 2018, https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between [https://perma.cc/E89E-7JQE].

[36] *See, e.g.*, Free Trade Agreement Between the United States of America and the Republic of Korea, U.S.-S. Kor., art. 18.10.5, June 30, 2007, 46 I.L.M. 642; CETA, *supra* note 35, art. 20.48.

[37] *See, e.g.*, EU-Japan Agreement, *supra* note 35, arts. 14.42, 14.51.

covered investment.[38] Where IP is a protected asset, public health policies which undermine the value of that investment by allowing diminution of patent or data exclusivity rights, for example, might run afoul of investor protections under the agreement, including indirect expropriation and unfair or inequitable treatment. Furthermore, unlike the WTO and FTA IP provisions, IIAs subject countries to direct suit by the affected investors under investor-state dispute settlement ("ISDS") provisions[39] and pharmaceutical companies have begun to utilize this system to defend their IP, most in a claim by Eli Lilly against Canada.[40] In another instance, Novartis threatened to sue Colombia on the basis of a proposed compulsory license,[41] which is particularly troubling given the legality of such a measure under the TRIPS Agreement.[42]

These legal obstacles are not the only hurdles facing these countries, however. As discussed in the following section, historical and current political pressure, as well as the realities of the complex global patent regime

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[38] Wolfgang Alschner et al. *Introducing the Electronic Database of Investment Treaties (EDIT): The Genesis of a New Database and Its Use*, 20 WORLD TRADE REV. 73, 77–94 (2021); CARLOS M. CORREA, NIRMALYA SYAM & DANIEL URIBE, SOUTH CENTRE, IMPLEMENTATION OF A TRIPS WAIVER FOR HEALTH TECHNOLOGIES AND PRODUCTS FOR COVID-19: PREVENTING CLAIMS UNDER FREE TRADE AND INVESTMENT AGREEMENTS 8 (2021), https://www.southcentre.int/research-paper-135-september-2021/ [https://perma.cc/556L-3TDA]. It is also important to note that many modern FTAs which have IP provisions also include these provisions on IP as a protected investment.

[39] *See Primer on International Investment Treaties and Investor-State Dispute Settlement*, COLUM. CTR. ON SUSTAINABLE INV., https://ccsi.columbia.edu/content/primer-international-investment-treaties-and-investor-state-dispute-settlement [https://perma.cc/6X5F-CAQD] (Jan. 2022).

[40] *See* Gleeson et al., *supra* note 33, at 7; Brook K. Baker & Katrina Geddes, *The Incredible Shrinking Victory:* Eli Lilly v. Canada*, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS*, 49 LOY. UNIV. CHI. L.J. 479, 496–98 (2017).

[41] *See* LORA VERHEECKE ET AL., *How Big Pharma Sabotaged the Struggle for Affordable Cancer Treatment*: *Novartis vs Colombia*, *in* RED CARPET COURTS: 10 STORIES OF HOW THE RICH AND POWERFUL HIJACKED JUSTICE 20, 22 (2019), https://10isdsstories.org/cases/case2/ [https://perma.cc/Y5YZ-EPM9].

[42] Although many IIAs carve out compulsory licenses from certain claims under the treaty, scholars have pointed out that they may still be challengeable by firms on the grounds that the compulsory license is not TRIPS compliant due to a lack of "adequate" compensation or failure to fulfill all the procedural requirements. *See* CYNTHIA HO, SOUTH CENTRE, POTENTIAL CLAIMS RELATED TO IP AND PUBLIC HEALTH IN INVESTMENT AGREEMENTS: COVID-19, THE PROPOSED TRIPS WAIVER AND BEYOND 2–4 (2021), https://www.southcentre.int/wp-content/uploads/2021/11/IPB24_Potential-Claims-related-to-IP-and-Public-Health-in-Investment-Agreements_EN.pdf [https://perma.cc/EC5N-NQDP]; Cynthia Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERKELEY TECH. L.J. 213, 287–88 (2014); Carlos Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. INT'L L. 331, 350–51 (2004).

for COVID-19 products, also play an important role.

2. Political Pressure Stymying the Development of Domestic Measures for TRIPS Flexibilities

One of the major flexibilities built into TRIPS, commonly brought into FTAs with IP commitments, is Article 31 ("Other Use Without Authorization of the Right Holder").[43] Under Article 31, in circumstances of "national emergency" or "extreme urgency," the government may issue a compulsory license so that patented products can be produced without infringing patents.[44] Article 31*bis* allows countries, in theory, to also export predominant quantities of those products to countries with no manufacturing capacity.[45] Unfortunately, this process requires national governments to establish a domestic process for issuing such licenses—an area of legal reform many countries have not undertaken.[46] This is due in part to unilateral pressure from both the U.S. and the EU.[47]

Relying on its Special 301 authority,[48] the U.S. has been most persistent with respect to countries' deployment of stringent patentability standards, adoption and use—or threatened use—of compulsory licenses,[49] and refusals to adopt data exclusivity and patent-registration linkage.[50] Some of the most

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[43] TRIPS Agreement, *supra* note 9, art. 31. *See generally* Peter Drahos, Expanding Intellectual Property's Empire: The Role of FTAs (Nov. 2003) (unpublished manuscript), https://www.grain.org/media/W1siZiIsIjIwMTEvMDcvMjUvMDZfMjhfMjRfNzUxX2RyYWhvc19mdGFfMjAwM19lbi5wZGYiXV0 [https://perma.cc/J4PN-U9L6].

[44] TRIPS Agreement, *supra* note 9, art. 31.

[45] *Id*. art. 31*bis*.

[46] WTO, *Members' Laws Implementing the 'Paragraph 6' System*, https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm [https://perma.cc/9WYP-B7JC] (listing only twenty-two countries as having notified the WTO about having amended their laws).

[47] *See infra* Annex Figure 1.

[48] Sean M. Flynn, *Special 301 of the Trade Act of 1974 and Global Access to Medicines*, 7 J. GENERIC MED. 309, 315 (2010).

[49] *See* Brook K. Baker, *Don't Be Afraid of Compulsory Licenses Despite US Threats: Special 301 Reports 1998-2017 – Listing Concerns but Taking Little Action*, INFOJUSTICE (Feb. 20, 2018), http://infojustice.org/archives/39594 [https://perma.cc/D8AP-UZPV]. The case of India is especially instructive as it has long been targeted by Special 301 Reports because of its strength as a major generic producer. *See* Aswathy Asok, *Compulsory Licensing for Public Health and USA's Special 301 Pressure: An Indian Experience*, 42 J. INTELL. PROP. RTS. 125, 127, 129 (2019).

[50] *See* Baker, *supra* note 21. Unsurprisingly, the adoption of data exclusivity has clear upward impacts on the price of pharmaceutical products. Michael Palmedo, *Evaluating the Impact of Data Exclusivity on the Price per Kilogram of Pharmaceutical Imports* 10, 14 (B.U. Glob. Dev. Pol'y Center, Working Paper No. 048, 2021), https://www.bu.edu/gdp/files/2021/04/GEGI_WP_048_Palmedo_FIN.pdf [https://perma.cc/PT83-3LUX].

vituperative Special 301 complaints have involved the issuance of compulsory licenses by Thailand,[51] Brazil[52] and India.[53] The EU also closely polices the IP performance of other countries through regular reports on recognition and enforcement of EU-style IP rules.[54] These explicit forms of monitoring other countries' IP performance are matched by other forms of diplomatic pressure, perhaps most acutely in India.[55] These unilateral measures have resulted in a chilling effect so that many countries do not take advantage of the flexibilities they have under the TRIPS Agreement.[56]

3. Patent Realities: Patent "Thickets" and the Limitations of Patent Information

Even if a country could overcome this political pressure to issue compulsory licenses for essential medical products, the interplay of overlapping and multiple IP rights, multicomponent COVID-19 health technologies, and complex global supply chains renders individual-product and country-by-country initiatives ineffectual. The International Federal of Pharmaceutical Manufacturers and Associations ("IFRMA") has explained the complexities of the supply chain for messenger RNA ("mRNA") and viral vector vaccines: "Vaccine supply chains are international. The BioNTech/Pfizer vaccine contains 280 ingredients sourced from 19 countries. Moderna's, AstraZeneca's and Johnson & Johnson's are similarly complex."[57] The patent landscape of COVID-19 vaccines and medicines is

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[51] *See* Suwit Wibulpolprasert et al., *Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership*, GLOBALIZATION & HEALTH, Sept. 12, 2011, at 1, 5.

[52] *See* Vera Zolotaryova, *Are We There Yet? Taking "TRIPS" to Brazil and Expanding Access to HIV/AIDS Medication*, 33 BROOK. J. INT'L L. 1099, 1100 (2008).

[53] *See* Asok, *supra* note 49, at 127. Michael Palmedo has completed one of the most complete analyses of U.S. Special 301 reports from 2009 to 2020 with key findings summarized in the Annex Figure 1. Michael Palmedo, *Analysis of Special 301 Listings, 2009-2020* 15–16 (Texas A&M Univ. Sch. L. Working Paper No., 2020), https://ssrn.com/abstract=3680332 [https://perma.cc/ZL5X-ESSG].

[54] *See, e.g., Communication from the Commission to the European Parliament, the Commission and the European Economic and Social Committee, Trade, Growth* and *Intellectual Property - Strategy for the Protection and Enforcement of Intellectual Property Rights in Third Countries*, COM (2014) 389 final (July 1, 2014).

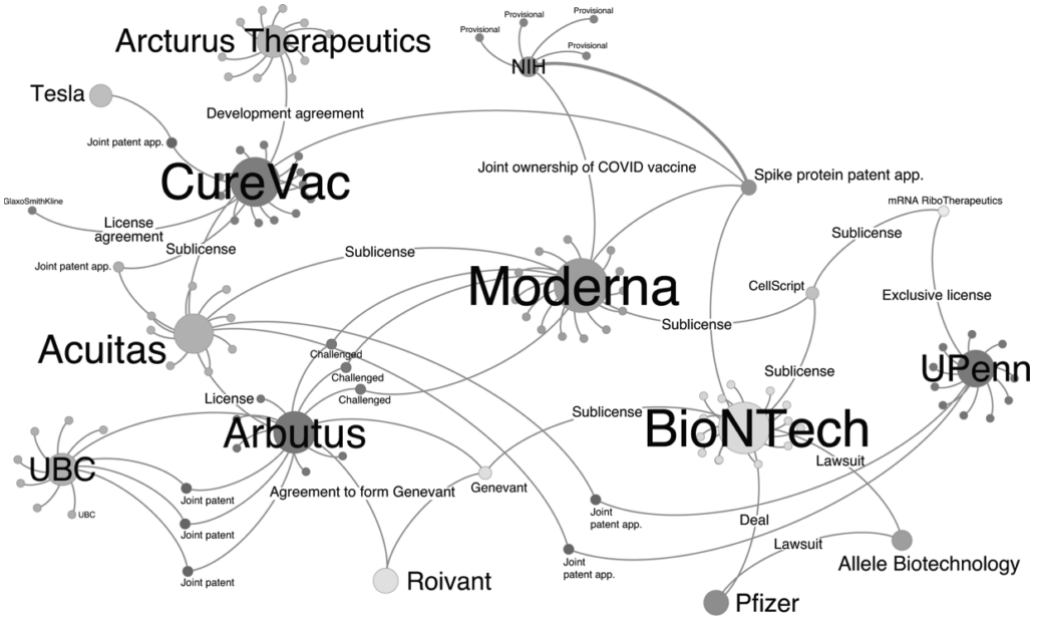
[55] *See* Brook K. Baker, *Will the Modi Government Succumb to US and Industry Pressure to Modify its Pro-Access Pharmaceutical Patent Policy?*, 25 EXPERT OP. ON THERAPEUTIC PATS. 625, 626 (2015).

[56] John S. Odell & Susan K. Sell, *Reframing the Issue: Intellectual Property and Public Health, 2001*, *in* NEGOTIATING TRADE DEVELOPING COUNTRIES IN THE WTO AND NAFTA 85, 86 (John S. Odell ed., 2006).

[57] Thomas B. Cueni, *Challenges and Solutions to Scaling-up COVID-19 Vaccine Manufacturing Capacity*, INT'L FED'N PHARM. MFRS. & ASS'NS.: GLOB. HEALTH MATTERS

likewise extensive and labyrinthine.[58] Although researchers are still discovering how extensively vaccine originators have been patenting, early reports show that there is a convoluted web of patents on COVID-19 vaccine technologies and that they have been filed in many countries capable of producing components and vaccines (See Figure 1 below).

Figure 1: Network Analysis of COVID-19 mRNA Vaccine Patents[59]



(Apr. 29, 2021), https://www.ifpma.org/global-health-matters/challenges-and-solutions-to-scaling-up-covid-19-vaccine-manufacturing-capacity/ [https://perma.cc/WM77-K5BW].

[58] *See, e.g., What We Do: VaxPaL*, MEDS. PAT. POOL, https://medicinespatentpool.org/what-we-do/vaxpal [https://perma.cc/B3KA-THLZ]; Dan Shores, Dylan Haversack & Andrew J. Storaska, *The mRNA IP and Competitive Landscape Through One Year of the COVID-19 Pandemic – Part I*, IPWATCHDOG (Apr. 11, 2021, 12:15 PM), https://www.ipwatchdog.com/2021/04/11/mrna-ip-competitive-landscape-one-year-covid-19-pandemic-part/id=132130/ [https://perma.cc/87R7-C2ER]; Ahmed S. Alshrari et al., *Innovations and Development of Covid-19 Vaccines: A Patent Review*, 15 J. INFECTION & PUB. HEALTH 123, 126 (2022); WORLD INTELL. PROP. ORG. [WIPO], PATENT LANDSCAPE REPORT: COVID-19-RELATED VACCINES AND THERAPEUTICS: PRELIMINARY INSIGHTS ON RELATED PATENTING ACTIVITY DURING THE PANDEMIC 12–16 (2021), https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_covid_ge_22/publication_1075_e.pdf [https://perma.cc/R77P-AJ7W].

[59] Mario Gaviria & Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NATURE BIOTECHNOLOGY 546, 546 (2021). Large nodes represent the relevant entities while the edges represent agreements or patents between two entities. Smaller nodes around the entities represent patents that were identified as being relevant to the underlying vaccine technology.

This very complexity makes country-by-country patent opposition and compulsory licenses relatively ineffective and difficult-to-use policy tools in this context. Even though pre- and post-grant opposition procedures[60] can theoretically be used to weed out unmeritorious patents, oppositions are largely unavailing in the context of pandemics because they are time-delayed. Pre-grant oppositions must wait until patents are published and examination initiated while post-grant oppositions must wait even longer until patents are granted; moreover, opposition procedures themselves entail long timelines.[61] Oppositions might need to be filed in multiple jurisdictions and on dozens of patent-protected components, not to mention the finished product. Furthermore, not all countries have even domesticated effective patent opposition procedures.

Reliance on compulsory licenses is similarly fraught.[62] For each patented component or component-process where the patent-owner is not willing or able to sell sufficient quantities, to do so at an affordable price, or not willing to grant a voluntary license, the manufacturer that wishes to use the patented component for its own biopharmaceutical manufacturing processes must find another producer in a country without a blocking license or with a producer willing to apply for a compulsory license on that component. If that patent-blocked component producer is in another country, there must be a compulsory license that would allow for both production and export, and there would need to be a different compulsory license issued in the importing country. The complexity compounds if the next stage of the vaccine manufacturing process must take place in yet another country besides the final destination importing country.[63] In sum, at least for a compulsory license-dependent vaccine manufacturer that is not completely "vertically

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[60] Standing Committee on the Law of Patents, *Opposition System and Other Administrative Revocation and Invalidation Mechanisms, SCP/18/4* (2012), https://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_4.pdf [https://perma.cc/2BAT-ANN8].

[61] Stuart J. H. Graham et al. *Patent Quality Control: A Comparison of U.S. Patent Re-examinations and European Patent Oppositions*, 74, 94, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (reporting 4.8 years between patent filing and initiation of post-grant opposition at the European Patent Office and 7 years to final decision).

[62] *See* MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN, COMPULSORY LICENSES, THE TRIPS WAIVER AND ACCESS TO COVID-19 MEDICAL TECHNOLOGIES 6–9 (2021), https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies [https://perma.cc/PPW3-LYFB].

[63] Jill Whitley et al., *Development of mRNA Manufacturing for Vaccines and Therapeutics: mRNA Platform Requirements and Development of a Scalable Production Process to Support Early Phase Clinical Trials*, 242 TRANSLATIONAL RSCH. 38 (2022) (describing the multiple stages of mRNA vaccine production). Notably, not all countries have adopted rules allowing compulsory license for export as Article 31*bis* is not self-implementing.

integrated" (all component and final formulation phases in a single plant), a harrowing number of labyrinthine notices and compulsory licenses would have to be coordinated and granted in multiple countries.[64]

Finally, compulsory licenses on patents alone would not be enough. For every country that introduced such a license, they would also have to enact a *sui generis* set of rules overriding additional IP protections such as protected confidential information, trade secrets, regulatory data, copyright protected software, industrial designs, and more.[65] They would also have to navigate how to force technology transfer for confidential information, trade secrets, and biologic resources that might be held in other countries—a serious territoriality issue.[66]

III. POLICY RESPONSES AND CHALLENGES

All told, despite acknowledged flexibilities present in the TRIPS Agreement, patent complexity and global IP standards as defended by most developed countries have presented a real threat to countries attempting to respond in real time to the COVID-19 pandemic.[67] Given these seemingly insurmountable challenges, public and private actors worldwide have mobilized to respond to the dilemmas of securing adequate, affordable, and equitably distributed COVID-19 health technologies.[68] Some of these responses have been implemented, some are languishing, and others demand heightened advocacy and political will. In addition, new proposals leverage insights about the inequitable response to the COVID-19 pandemic to create new rules of engagement in preparation for and response to future pandemics.[69]

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[64] Brook K. Baker, *The Impracticality of Relying on Compulsory Licenses to Expand Production Capacity for COVID-19 Vaccines*, HEALTH GAP (June 6, 2021), https://healthgap.org/the-impracticality-of-relying-on-compulsory-licenses-to-expand-production-capacity-for-covid-19-vaccines/ [https://perma.cc/GET9-VUF2].

[65] *Id*.; *See, e.g*., Joseph E. Stiglitz et al., *Patents vs. the Pandemic*, COLUM. BUS. SCH. (Apr. 23, 2020), https://www8.gsb.columbia.edu/articles/chazen-global-insights/patents-vs-pandemic [https://perma.cc/TWD4-8CG9].

[66] *See infra* note 171; *see, e.g*., THE EXTRATERRITORIALITY OF LAW: HISTORY, THEORY, POLITICS (Daniel S. Margolies et al. eds., 2019); Caroline Omari Lichuma, *(Laws) Made in the 'First World': A TWAIL Critique of the Use of Domestic Legislation to Extraterritorially Regulate Global Value Chains*, 81 ZaöRV 497 (2021) (highlighting the practical and political difficulty of applying domestic laws outside of a territory).

[67] Stiglitz, *supra* note 65.

[68] *See, e.g.,* Press Release, The White House, 2nd Global Covid-19 Summit Commitments (May 12, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/12/2nd-global-covid-19-summit-commitments/ [https://perma.cc/QWP6-W4M2].

[69] *See, e.g.,* WHO, *Conceptual Zero Draft for Consideration the International*

A. Public Financing of R&D for Pandemic Countermeasures

One of the boldest and most impactful responses to the COVID-19 pandemic was the decision by governments to significantly expand public funding for product development, clinical trials, expanded manufacturing capacity, and at-risk production of the vaccine, diagnostic, and therapeutic countermeasures needed to prevent, contain, and treat SARS-CoV-2.[70] The public funding for research upon which novel COVID-19 vaccines depended far pre-dated the detection of SARS-CoV-2.[71] The U.S. National Institutes of Health invested at least $17.2 billion in vaccine research in the time period between 2000 and 2019, including on every vaccine technology platform currently in use against COVID-19 and on coronaviruses as a class,[72] though funding was sporadic given other viral outbreaks.[73]

Once countries declared COVID-19 to be a global pandemic, the public purse opened even further, though calculations of the amount of public support varies between researchers. The U.S. and Germany were by far the major funders.[74] By mid-2021, the public sector and Coalition for Epidemic Preparedness Innovations ("CEPI") had invested $5.6 billion in developing COVID-19 vaccines, and more than $51.1 billion when counting advanced purchase agreements.[75] Much of this money poured out of the U.S. Treasury with few, if any, strings attached.[76] Universities Allied for Essential Medicines found that the U.S. invested more than $16 billion on R&D: $11.38 billion on vaccines, $2.53 billion on therapeutics, and $2.27 on diagnostics, much of this focused on Moderna's development of its mRNA

Negotiating Body at Its Third Meeting, A/INB/3/3 (Nov. 25, 2022), https://apps.who.int/gb/inb/pdf_files/inb3/A_INB3_3-en.pdf [https://perma.cc/Q7YF-F6DS].

[70] *See* James C. Robinson, *Funding of Pharmaceutical Innovation During and After the COVID-19 Pandemic*, 325 J. AM. MED. ASSOC. 825, 825–26 (2021) (celebrating this expanded public funding and its role in incentivizing innovation).

[71] *See* Elie Dolgin, *The Tangled History of mRNA Vaccines*, 597 NATURE 318 (2021).

[72] Anthony E. Kiszewski et al., *NIH Funding for Vaccine Readiness Before the COVID-19 Pandemic*, 39 VACCINE 2458, 2458–65 (2021). Some of that spending was on specific vaccine technology platforms, like messenger RNA ($943 million) and other spending could be allocated to specific epidemic threats, like coronavirus ($767 million). *Id*. at 2640.

[73] *Id*. at 2464.

[74] *COVID-19 Vaccine R&D Funding*, GLOB. HEALTH CTR.: KNOWLEDGE PORTAL ON INNOVATION & ACCESS TO MEDS., https://www.knowledgeportalia.org/covid-19-vaccine-r-d-funding [https://perma.cc/SZ93-NS7U] (July 8, 2021).

[75] *Id*.

[76] *See* Stephanie Baker & Cynthia Koons, *Inside Operation Warp Speed's $18 Billion Sprint for a Vaccine*, BLOOMBERG (October 29, 2020, 4:00 AM), https://www.bloomberg.com/news/features/2020-10-29/inside-operation-warp-speed-s-18-billion-sprint-for-a-vaccine [https://perma.cc/HN9M-Y5XS].

vaccine.[77] BioNTech, likewise, received significant support in the amount of €375 million from the German government,[78] and ninety-seven to ninety-nine percent of Oxford/AstraZeneca's vaccine research was publicly funded.[79] As icing to their cakes, both Moderna and BioNTech have received priority review vouchers worth as much as $100 million from the U.S. for their mRNA vaccine innovations.[80] When looking at support for COVID-related clinical trials specifically, the International Monetary Fund ("IMF") has found that public research institutions accounted for seventy percent of COVID-19 clinical trials.[81] Public investments to expand manufacturing capacity were also significant and relatively unprecedented. Related investments under the Defense Production Act supported scaled-up manufacturing and prioritized access to critical supplies for domestic COVID vaccine manufacturers.[82]

Despite laudable increases in public funding, however, recent critiques have exposed weaknesses in the public funding model. The key critique addressed the need to impose access conditions in funding agreements, including requirements on recipient firms to share or license technology, price fairly, and ensure equitable distribution.[83] Paradoxically, instead of imposing such conditions, the U.S., for example, contracted away some of

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[77] *COVID Mapping: Dashboard*, UNIVS. ALLIED FOR ESSENTIAL MEDS., https://publicmeds4covid.org/dashboard [https://perma.cc/KQD9-82UG]; Chad P. Bown & Thomas J. Bollyky, *Here's How to Get Billions of COVID-19 Vaccine Doses to the World*, PETERSON INST. FOR INT'L ECON. (Mar. 18, 2021, 12:00 PM), https://www.piie.com/blogs/trade-and-investment-policy-watch/heres-how-get-billions-covid-19-vaccine-doses-world [https://perma.cc/6K9P-WWRT]. *See infra* Annex Table 2.

[78] Press Release, BioNTech, BioNTech to Receive up to €375 in Funding from German Federal Ministry of Education and Research to Support COVID-19 Vaccine Program BNT162 (Sept. 15, 2020), https://investors.biontech.de/news-releases/news-release-details/biontech-receive-eu375m-funding-german-federal-ministry [https://perma.cc/CGV9-NP5S].

[79] Samuel Cross et al., *Who Funded the Research Behind the Oxford-AstraZeneca COVID-19 Vaccine?*, 6 BRIT. MED. J. GLOB. HEALTH e007321, 1 (2021).

[80] Zachary Brennan, *Exclusive: The Curious Case of the BioNTech Priority Review Voucher*, ENDPOINTS NEWS (Feb. 2, 2022, 3:58 PM), https://endpts.com/the-curious-case-of-the-biontech-priority-review-voucher/ [https://perma.cc/E4ES-R4SU].

[81] Ruchir Agarwal & Patrick Gaulé, *What Drives Innovation? Lessons from COVID-19 R&D*, (IMF, Working Paper No. 2021/048, 2021), https://www.imf.org/en/Publications/WP/Issues/2021/02/20/What-Drives-Innovation-Lessons-from-COVID-19-R-D-50096; Richard G. Frank et al., *It Was the Government That Produced COVID-19 Vaccine Success*, HEALTH AFFS. FOREFRONT (May 14, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210512.191448/full/ [https://perma.cc/K6AU-44X9].

[82] U.S. GOV'T ACCOUNTABILITY OFF., GOA-21-443, COVID-19: EFFORTS TO INCREASE VACCINE AVAILABILITY AND PERSPECTIVES ON INITIAL IMPLEMENTATION 23, 27 (2021), https://www.gao.gov/assets/gao-21-443.pdf [https://perma.cc/W7SX-JFT5].

[83] Suerie Moon et al., *Embedding Global Access in Development of Future Pandemic Vaccines*, 374 BRIT. MED. J. n2256, 1 (2021).

the access rights it has under federal law.[84] A second critique argued that clinical trial design,[85] reporting, and funding[86] diminished the public ownership of trial data and restricted head-to-head trials to help develop the most promising products or a more complex treatment regimens. This critique also focused on the need to increase transparency and public reporting/sharing of clinical trial data.[87] A third critique advocated that all public funding agreements must be transparent with full disclosure of relevant terms and conditions to ensure accountability.[88]

Although public funding had an enormous impact on the pandemic, it was also a primary source of vaccine, therapeutic, and diagnostic inequity, pitting the political pressures of governments to care for their citizens and residents against the need for widespread access to these products.[89] Especially in the

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[84] *See* Selam Gebrekidan & Matt Apuzzo, *Rich Countries Signed Away a Chance to Vaccinate the World*, N.Y. TIMES (Mar. 25, 2021, 10:40 PM), https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html [https://perma.cc/9TSR-4SS2]; KATHRYN ARDIZZONE & JAMES LOVE, OTHER TRANSACTION AGREEMENTS: GOVERNMENT CONTRACTS THAT ELIMINATE PROTECTIONS FOR THE PUBLIC ON PRICING, ACCESS AND COMPETITION, INCLUDING IN CONNECTION WITH COVID-19 VACCINES AND TREATMENTS (2020), https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf [https://perma.cc/S7FB-BU3Y]; *see also* 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 [https://perma.cc/VJ7U-4D88]. *See generally* 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 [https://perma.cc/4KJS-NMTV] (under the Bayh-Dole Act "the U.S. government can leverage its substantial, multi-billion dollar funding towards providing competitive access to inventions that the government has not funded, including, but not limited to, existing patent rights.").

[85] *See generally* Jay J.H. Park et al., *How COVID-19 Has Fundamentally Changed Clinical Research in Global Health*, 9 LANCET GLOB. HEALTH e711, e711–13 (2021).

[86] *See* DEAN BAKER, THE BENEFITS AND SAVINGS FROM PUBLICLY-FUNDED CLINICAL TRIALS OF PRESCRIPTION DRUGS, CTR. FOR ECON. & POL'Y RSCH. 2–3 (2008), https://cepr.net/documents/publications/clinicaltrials_2008_03.pdf [https://perma.cc/33VZ-TSGH].

[87] Sarah Tanveer et al., *Transparency of COVID-19 Vaccine Trials: Decisions Without Data*, 27 BRIT. MED. J. EVIDENCE-BASED MED. 199, 199 (2022).

[88] TRANSPARENCY INT'L GLOB. HEALTH, FOR WHOSE BENEFIT? TRANSPARENCY IN THE DEVELOPMENT AND PROCUREMENT OF COVID VACCINES 17 (2021), http://ti-health.org/wp-content/uploads/2021/05/For-Whose-Benefit-Transparency-International.pdf [https://perma.cc/2RHS-VUKN].

[89] *See, e.g.*, Elisabeth Mahase, *Covid-19: Public Vaccine Funding Needs "Strings Attached" for Equitable Access, Say Campaigners*, 376 BRIT. MED. J. o565, 1 (2022); Glob. Pub. Health Convention, Summary Report for Consultation with NGO and Civil Society Representatives (Nov. 2021), https://oneill.law.georgetown.edu/wp-content/uploads/2021/11/Panel-ONeill-NGO-Consultation_Annex-to-Report-on-Legal-Tools-for-Pandemic_November-2021.pdf [https://perma.cc/VA66-5KDR].

context of vaccines, advanced purchase agreements by developed countries ensured that the vast majority of early vaccines produced would go directly to them.[90]

B. Collective Purchasing, Donations, and COVAX

Anticipating the built-in inequity of relying on the vast amount of public funds to innovate and produce essential COVID-19 products, the World Health Organization ("WHO") developed the Access to COVID-19 Tools (ACT) Accelerator ("ACT-A") partnership, including its vaccine pillar, COVAX.[91] ACT-A and COVAX aimed to distribute diagnostic tools, treatments, and vaccines worldwide more equitably by pooling purchase of those products and distributing them according to need.[92] Early on, COVAX sought to deliver two billion vaccines to low-income countries by the end of 2021.[93] The process was straightforward: high income countries would pay into the COVAX lending facility and secure a certain percentage of the vaccines purchased by COVAX.[94] COVAX would procure vaccines from the manufacturers with the money paid into the facility, and those vaccines would be distributed to both the donor countries and the low-income participants.[95] Donor countries were also able to donate vaccine doses directly to be distributed through COVAX.[96]

Unfortunately, this process was fraught from the beginning. The facility for purchasing vaccines was under-funded because the potential donor countries were buying up as much of the newly manufactured vaccines as they could.[97] Those same countries did not want to engage in pool purchasing because that would slow down their own access to vaccines. Moreover, they were reluctant to donate large numbers of vaccines given the political pressure to vaccinate their own populations first.[98]

In the fall of 2021, once potential donors had vaccinated as much of their

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[90] *See* Alexandra L. Phelan et al., *Legal Agreements: Barriers and Enablers to Global Equitable Vaccine Access*, 396 LANCET 800, 800 (2020).

[91] *What is COVAX?*, GAVI, THE VACCINE ALLIANCE, https://www.gavi.org/covax-facility#what [https://perma.cc/FL2C-BBQW].

[92] *Id.*

[93] *Why a Pioneering Plan to Distribute COVID Vaccines Equitably Must Succeed*, NATURE (Jan. 13, 2021), https://www.nature.com/articles/d41586-021-00044-9 [https://perma.cc/QB4V-NZ34].

[94] *Id.*

[95] *Id.*

[96] *Id.*

[97] *Id.*

[98] *See id.*; Jennifer Rigby & Sarah Newey, *Norway to Share Covid-19 Vaccine with Poorer Countries at Same Time as Protecting Its Own Citizens*, TELEGRAPH (Jan. 20, 2021), https://www.telegraph.co.uk/global-health/science-and-disease/norway-share-covid-19-vaccine-poorer-countries-time-protecting [https://perma.cc/7DYJ-STHR].

populations as they could, they became more amenable to donations, making larger commitments to do so.[99] Unfortunately, by that time, recipient countries began to experience waning demand from a combination of factors: mistrust of Western governments,[100] inconsistent and delayed donation shipments, and donations received too close to their expiry dates.[101] These factors made it nearly impossible to plan vaccination campaigns in much of Africa.

One promising development, however, to come out of COVAX was the Manufacturing Task Force.[102] The Task Force is spearheaded by the co-leads of COVAX[103]—CEPI, WHO, Gavi, and UNICEF—which work in partnership with the Bill & Melinda Gates Foundation, the International Federation of Pharmaceutical Manufacturers & Associations ("IFPMA"), the Developing Countries Vaccine Manufacturers Network ("DCVMN"), and the Biotechnical Innovation Organization ("BIO"). The Task Force was designed to "leverage the capabilities of the global vaccine community . . . to address short-term, medium-term, and long-term COVID-19 vaccine manufacturing challenges and bottlenecks."[104] In the short term, it sought to overcome trade obstacles to access to COVID-19-related products and facilitate increased manufacturing capacity.[105] Over the longer term, the Task Force would seek to build a resilient global health structure for future pandemics.[106] The major achievement of the Task Force to date, however, is the launch of a new COVAX Marketplace that primarily meets the needs of proprietary vaccine manufacturers by matching suppliers and buyers of critical vaccine components.[107] This Task Force's expanded manufacturing element eventually evolved into the COVID-19 Technology Transfer Hub,

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[99] Antoine de Bengy Puyvalee & Katerini Tagmatarchi Storeng, *COVAX, Vaccine Donations and the Politics of Global Vaccine Inequity*, 18 GLOBALIZATION & HEALTH 1, 4–5, (2022).

[100] *See* Camila Carvalho de Souza Amorim Matos et al., *Vaccine Hesitancy in the Global South: Towards a Critical Perspective on Global Health*, 17 GLOBAL PUB. HEALTH 1087 (2022).

[101] *See* de Bengy Puyvalee & Storeng, *supra* note 99, at 6, 9.

[102] CEPI, *COVAX Manufacturing Task Force to Tackle Vaccine Supply Challenges*, GAVI, THE VACCINE ALLIANCE (May 14, 2021), https://www.gavi.org/vaccineswork/covax-manufacturing-task-force-tackle-vaccine-supply-challenges [https://perma.cc/G7F5-G8RE].

[103] *See id*.; *What Is COVAX?*, *supra* note 91.

[104] CEPI, *supra* note 102.

[105] *See id*.

[106] *See id*.

[107] *COVAX Launches Marketplace to Match Buyers and Sellers of Critical Manufacturing Suppliers and Speed up Global Access to COVID-19 Vaccines Through COVAX*, INT'L FED'N PHARM. MFRS. & ASS'NS (July 15, 2021), https://www.ifpma.org/resource-centre/covax-launches-marketplace-to-match-buyers-and-sellers-of-critical-manufacturing-suppliers-and-speed-up-global-access-to-covid-19-vaccines-through-covax/ [https://perma.cc/623V-VNMS].

discussed in more detail below.

C. COVID-19 Technology Access Pool and the Medicines Patent Pool

Another collective effort to increase equitable supply and distribution of COVID-19 products was through a mechanism called a patent or technology "pool." Shortly after the declaration of the global pandemic, Costa Rica sent a letter to the WHO advocating for the establishment of a voluntary IP pool for "technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic."[108] In response, thirty-seven countries and the WHO issued the Solidarity Call to Action,[109] which established the COVID-19 Technology Access Pool ("C-TAP"),[110] a platform for sharing IP on COVID-19 treatments, vaccines, and health technologies. Civil society activists immediately supported the establishment of C-TAP to enable faster and higher quality open-science research and product development[111] and to significantly expand supply beyond the limitations of exclusive right holders.[112] It was hoped that licensing additional manufacturers would help counteract hoarding and accelerate equitable global distribution and more affordable pricing.[113] Unfortunately, the biopharmaceutical industry opposed

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[108] Letter from Carlos Alvardo Quesada, President, Costa Rica, & Daniel Salas Peraza, Minister of Health, Costa Rica, to Tedro Adhanom Ghebreyesus, Dir.-Gen. of WHO (Mar. 23, 2020), https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf [https://perma.cc/82L4-HEME].

[109] *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/ [https://perma.cc/944G-Z238]; *Solidarity Call to Action*, WHO, https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action [https://perma.cc/9EP9-6R5R].

[110] *COVID-19 Technology Access Pool,* WHO, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool [https://perma.cc/MJ8G-KTK2].

[111] 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 [https://perma.cc/FKM7-APVG].

[112] *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.").

[113] Brook K. 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-

C-TAP from the very beginning.[114] Despite welcoming eighteen generic companies available to manufacture C-TAP licensed products,[115] C-TAP did not receive any in-licensed technology until November 23, 2021, when it signed an agreement with the Spanish National Research Council for a COVID-19 serological antibody test.[116] There are rumors that C-TAP is involved in additional license negotiations, including with vaccine manufacturers, but that information has not been confirmed. More recently, however, the National Institutes of Health licensed eleven COVID-19 research tools and early-stage vaccine and diagnostic candidates to C-TAP.[117]

The Medicines Patent Pool ("MPP") was established ten years before C-TAP and has a positive history of bringing HIV medicines, and more recently

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technology-ip-pool-for-all-countries/ [https://perma.cc/MZ5H-HV6V]; 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); SUDIP CHAUDHURI, MAKING COVID-19 MEDICAL TOOLS AFFORDABLE: VOLUNTARY PATENT POOLS AND TRIPS FLEXIBILITIES, SOUTHVIEWS (2020), https://www.southcentre.int/wp-content/uploads/2020/06/SouthViews-Chaudhuri.pdf [https://perma.cc/C7WY-CJFH]; 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 1, 4, 7 (2020); *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/ [https://perma.cc/2VMZ-BYL3].

[114] *See* Ed Silverman, *Pharma Leaders Shoot Down WHO Voluntary Pool for Patent Rights on COVID-19 Products*, STAT: PHARMALOT (May 28, 2020), https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/ [https://perma.cc/6UM3-KN23].

[115] *C-TAP Welcomes Open Pledge by 18 Generic Companies to Increase Access to COVID-19 Health Tools*, WHO (Nov. 13, 2020), https://www.who.int/news/item/13-11-2020-c-tap-welcomes-open-Pledge-by-18-generic-companies-to-increase-access-to-covid-19-health-tools [https://perma.cc/B6W3-9Z75].

[116] *WHO and MPP Announce the First Transparent, Global, Non-Exclusive Licence for a COVID-19 Technology*, WHO (Nov. 23, 2021), https://www.who.int/news/item/23-11-2021-who-and-mpp-announce-the-first-transparent-global-non-exclusive-licence-for-a-covid-19-technology [https://perma.cc/WGT7-HT2V].

[117] News Release, U.S. Dep't Health and Hum. Servs., NIH Licenses COVID-19 Research Tools and Early-Stage Technologies to WHO Program (May 12, 2022), https://www.hhs.gov/about/news/2022/05/12/NIH-Licenses-COVID-19-Research-Tools-Early-Stage-Technologies-WHO-Program.html [https://perma.cc/SP2K-RHPU]; Ed Silverman, *National Institutes of Health Licenses Nearly a Dozen Covid-19 Technologies to a WHO Program*, STAT: PHARMALOT (May 12, 2022), https://www.statnews.com/pharmalot/2022/05/12/nih-covid19-vaccines-who-patents/ [https://perma.cc/V79X-2NN8]. The NIH/MPP license agreements can be accessed at https://medicinespatentpool.org/progress-achievements/licences [https://perma.cc/BT3Q-QFLJ].

hepatitis C and tuberculosis medicines, to LMICs.[118] In a recent study of the impact of just two MPP licenses, researchers found that the dolutegravir license had the projected impact of saving 151,839 lives and $3.074 billion compared to the counterfactual of no MPP license.[119] In March of 2020, the MPP expanded its mandate to address COVID-19,[120] and since then has entered into several voluntary agreements on COVID-19 countermeasures.[121]

As an enabling mechanism, the MPP established VaxPaL,[122] a free-online service that provides worldwide information on the status of patents on COVID-19 vaccine. Shortly thereafter, it joined the launch of the WHO COVID-19 Technology Transfer Hub whereby the MPP would provide legal support on governance matters, relations with technical partners, and intellectual property and voluntary licensing issues.[123] The MPP would play a leading role in cross-licensing agreements involving the countries announced as "spokes" of the Hub.[124]

In the fall of 2021, for example, MPP concluded important voluntary licenses with Merck and Pfizer for production of their promising

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[118] Brook K. Baker, *A Sliver of Hope: Analyzing Voluntary Licenses for Medicines*, 10 NE. L. REV. 691, 695, 709 (2018).

[119] Sébastien Morin et al., *The Economic and Public Health Impact of Intellectual Property Licensing of Medicines for Low-Income and Middle-Income Countries: A Modelling Study*, 7 LANCET PUB. HEALTH e169, e169, e173 (2022).

[120] *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 [https://perma.cc/4NM3-YGDX]; *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/ [https://perma.cc/5UXD-MJJU].

[121] *MPP's Contribution to the Global Response to COVID-19*, MEDS. PAT. POOL, https://medicinespatentpool.org/covid-19 [https://perma.cc/23GK-D4U9].

[122] *See* MEDS. PAT. POOL, *supra* note 58; *see also* VaxPaL, MEDS. PAT. POOL, https://www.vaxpal.org/?page=1 [https://perma.cc/QU8Z-ZETE].

[123] *See mRNA Technology Transfer Hub Programme*, MEDS. PAT. POOL, https://medicinespatentpool.org/covid-19/mrna-technology-transfer-hub-programme [https://perma.cc/7PUP-5XGV]; *FAQ - The mRNA Vaccine Technology Transfer Hub*, WHO, https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/faq [https://perma.cc/3EHL-SWSH].

[124] *WHO Announces First Technology Recipients of mRNA Vaccine Hub with Strong Support from African and European Partners*, WHO (Feb. 18, 2022), https://www.who.int/news/item/18-02-2022-who-announces-first-technology-recipients-of-mrna-vaccine-hub-with-strong-support-from-african-and-european-partners [https://perma.cc/NS8V-D8EB] (announcing that Egypt, Kenya, Nigeria, Senegal, South Africa, and Tunisia will establish mRNA manufacturing facilities).

therapeutics.[125] The licenses allow sub-licenses and sale for exports in the majority of the world's LMICs.[126] Although the MPP licenses with Merck and Pfizer do eventually provide access to generic medicines for low- and lower-middle-income countries and a very small subset of upper-middle income countries, concerns have been expressed that the licenses maintain control over large portions of the world's population where the companies can sell at prices they alone will set.[127] In sum, although the MPP licenses

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[125] News Release, Merck, The Medicines Patent Pool (MPP) and Merck Enter into License Agreement for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine, to Increase Broad Access in Low- and Middle-Income Countries (Oct. 27, 2021, 6:00 AM), https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countri/ [https://perma.cc/MYQ4-ER39]; Press Release, Pfizer, Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries (Nov. 16. 2021, 06:45 AM), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing [https://perma.cc/HY7B-DR4W].

[126] *See* News Release, Merck, *supra* note 125; Press Release, Meds. Pat. Pool, 35 Generic Manufacturers Sign Agreements with MPP to Produce Low-Cost, Generic Versions of Pfizer's Oral COVID-19 Treatment Nirmatrelvir in Combination with Ritonavir for Supply in 95 Low- and Middle-Income Countries (Mar. 17, 2022), https://medicinespatentpool.org/news-publications-post/35-generic-manufacturers-sign-agreements-with-mpp-to-produce-low-cost-generic-versions-of-pfizers-oral-covid-19-treatment-nirmatrelvir-in-combination-with-ritonavir-for-supply-in-95-low-and [https://perma.cc/9GLX-FY5Q]. For more information on the license agreements, see *MOLNUPIRAVIR (MOL),* MEDS. PAT. POOL., https://medicinespatentpool.org/licence-post/molnupiravir-mol [https://perma.cc/WEY8-H2JG] and *NIRMATRELVIR,* MEDS. PAT. POOL, https://medicinespatentpool.org/licence-post/pf-07321332 [https://perma.cc/S666-KSGJ].

[127] *MSF Responds to FDA Approval of COVID-19 Drug Molnupiravir*, MÉDECINS SANS FRONTIÈRES (Dec. 23, 2021), https://www.doctorswithoutborders.org/what-we-do/news-stories/story/msf-responds-fda-approval-covid-19-drug-molnupiravir [https://perma.cc/826T-5XU8]; *MSF Responds to Pfizer's and Medicines Patent Pool License for New COVID-19 Treatment*, MÉDECINS SANS FRONTIÈRES (Nov. 16, 2021), https://www.doctorswithoutborders.org/what-we-do/news-stories/news/msf-responds-pfizer-and-medicines-patent-pool-license-new-covid-19 [https://perma.cc/EV5H-MSNQ]; *Reaction to Pfizer's Announcement of Voluntary Licenses for Its COVID-19 Oral Antiviral Treatment Paxlovid to the Medicines Patent Pool*, OXFAM INT'L (Nov. 16, 2021), https://www.oxfam.org/en/press-releases/reaction-pfizers-announcement-voluntary-licenses-its-covid-19-oral-antiviral [https://perma.cc/39UH-VUKY]. For a more favorable view on the MPP licenses, see John Cohen, *Once a 'Crazy Idea,' Patent-Pooling Nonprofit Will Help Bring COVID-19 Pills to World's Poor*, SCIENCE (Dec. 29, 2021, 5:00 PM), https://www.science.org/content/article/once-crazy-idea-patent-pooling-nonprofit-will-help-bring-covid-19-pills-world-s-poor [https://perma.cc/69MX-MGR2]. For an even more trenchant critique, see *MPP-Merck Molnupiravir License Reveals the Limits of Voluntary*

may result in more affordable generic antivirals, there are LMIC populations at risk because of delayed generic entry, limited production capacity, high tiered-prices in upper-middle-income countries, and disproportionate distribution to high-income countries.

D. Bilateral Voluntary Licenses and Other Voluntary Undertakings by Private Actors

The business-as-usual approach touted by developed countries and their pharmaceutical firms asserts that voluntary efforts by private firms and countries are the best way to ensure the future of innovation and expand access to COVID-19 products.[128] A review of bilateral voluntary efforts finds a few examples in the vaccine space, a handful of examples in the therapeutics space, and only two examples in the diagnostics space.

With respect to voluntary measures relating to vaccines, the first that came closest to voluntary licensing was Oxford-AstraZeneca's license and technology transfer agreements with Serum Institute of India, previously the world's largest vaccine producer, which has separately registered its trademarked vaccine, COVISHIELD™.[129] A similar contract has been negotiated between Johnson & Johnson ("J&J") and Aspen Pharmacare ("Aspen") in South Africa that will allow Aspen to produce its own branded version of J&J's vaccine.[130] Much more recently, a Brazilian company has concluded a technology transfer agreement concerning Russia's Sputnik

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Measures During a Pandemic, MAKE MEDS. AFFORDABLE (Oct. 29, 2021), https://makemedicinesaffordable.org/mpp-merck-molnupiravir-license-reveals-the-limits-of-voluntary-measures-during-a-pandemic/ [https://perma.cc/PAS7-798V].

[128] *See* Yaniv Heled et al., *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, 7 J.L. & BIOSCIENCES 1, 2–4 (2020) (discussing United States' profit driven pharmaceutical system).

[129] Press Release, AstraZeneca, AstraZeneca Takes Next Steps Towards Broad and Equitable Access to Oxford University's Potential COVID-19 Vaccine (June 4, 2020), https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html [https://perma.cc/F4NV-QLTY]; *India's Serum Institute Applies for Full Approval of Covishield Vaccine*, REUTERS (Dec. 31, 2021), https://www.usnews.com/news/world/articles/2021-12-31/indias-serum-institute-applies-for-full-approval-of-covishield-vaccine. AstraZeneca has established a manufacturing capacity with a total of 25 manufacturing sites in 15 countries. *Making the COVID-19 Vaccine*, ASTRAZENECA (Feb. 2021), https://www.astrazeneca.com/content/dam/az/what-science-can-do/stories/delivering-covid-19-vaccine-across-the-globe/MakingTheCOVID19Vaccine_Factsheet_V5.pdf [https://perma.cc/GYA9-EB42].

[130] Tamar Kahn, *Aspen Agrees Terms with Johnson & Johnson for Own Brand of Covid-19 Vaccine*, BUS. DAY (Nov. 30, 2021, 7:13 PM), https://www.businesslive.co.za/bd/national/health/2021-11-30-aspen-agrees-terms-with-johnson-johnson-for-own-brand-of-covid-19-vaccine/ [https://perma.cc/7GMG-RKFC].

Light vaccine that allows supply to other Latin American countries,[131] while Cuba has also promised to transfer its COVID-19 vaccine technologies to other manufacturers.[132] Likewise, the Texas Children's Hospital Center for Vaccine Development and the Baylor College of Medicine have promised to make their prospective protein sub-unit vaccine, Corbevax, freely available and have already licensed it to Biological E. Limited in India, which has conducted initial clinical trials and received emergency use authorization in India, as well as to companies in Indonesia, Bangladesh, and Africa.[133] ImmunityBio, a newer company to Cape Town headed by Patrick Soon-Shiong, is working on another COVID-19 vaccine as well as setting up new production facilities and investing in education for "a new generation of African scientists" so that the continent is more resilient the next time around.[134]

However, major mRNA vaccine manufacturers Moderna and BioNTech/Pfizer have been unwilling to transfer their platform technologies, presumably because they expect greater expanded sales from new mRNA vaccines and therapeutics addressing many other health needs. Moderna issued an early statement declaring that it would not enforce its COVID-19 mRNA vaccine patents against LMICs for the duration of the pandemic.[135]

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[131] Anthony Boadle, *Brazilian Firm to Make Russia's Sputnik Light COVID Vaccine for Export*, REUTERS (Feb. 17, 2022, 10:28 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/brazilian-firm-make-russias-sputnik-light-covid-vaccine-export-2022-02-17/ [https://perma.cc/U6TB-WKVB].

[132] *Cuba Pledges "Lifesaving Package" of Covid-19 Vaccine Support to Global South at Progressive International Briefing*, PROGRESSIVE INT'L (Jan. 25, 2022), https://progressive.international/wire/2022-01-25-cuba-pledges-lifesaving-package-of-covid-19-vaccine-support-to-global-south-at-progressive-international-briefing/en [https://perma.cc/BD2L-K22A].

[133] Peter J. Hotez & Maria Elena Bottazzi, *A COVID Vaccine for All*, SCI. AM. (Dec. 30, 2021), https://www.scientificamerican.com/article/a-covid-vaccine-for-all/ [https://perma.cc/7NEA-VXLP]; Elaine Ruth Fletcher, *'Vaccine for the World' Gets Emergency Use Authorization in India; Texas Children's Hospital Grants Non-Exclusive License to Biological E*, HEALTH POL. WATCH (Dec. 28, 2021), https://healthpolicy-watch.news/vaccine-for-world-gets-emergency-use-authorization-in-india-texas-childrens-hospital-grants-non-exclusive-license-to-biological-e/ [https://perma.cc/YW8P-6NKG]; Adam Taylor, *A New Coronavirus Vaccine Was Developed by a Small Team in Texas. It Expects Nothing in Return*, WASH. POST (Dec. 30, 2021, 8:03 AM), https://www.washingtonpost.com/world/2021/12/30/corbevax-texas-childrens-covid-vaccine/ [https://perma.cc/25VK-U663].

[134] Tommy Trenchard, *South Africa Hails New COVID Jab Plant in Fight for Self-Reliance*, AL JAZEERA (Jan. 29, 2022), https://www.aljazeera.com/news/2022/1/29/south-africa-hails-new-covid-jab-plant-in-fight-for-self-reliance [https://perma.cc/UHJ7-MUKX].

[135] *Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic,* MODERNA (Oct. 8, 2020), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-

At the same time, Moderna has steadfastly refused to allow technology transfer to non-affiliate producers. It has refused technology transfer requests from the U.S.,[136] the WHO Technology Transfer Hub,[137] the WHO COVID-19 Technology Access Pool,[138] the People's Vaccine Alliance,[139] and many others.[140] Moderna, Pfizer, and other mRNA innovators are hard at work

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Property-Matters-during-the-COVID-19-Pandemic/default.aspx [https://perma.cc/PV2D-HQ6N]. Recently, Moderna has made an updated statement of commitment to "equitable access" and confirmed "that its intellectual property will not create a barrier to COVID vaccine distribution . . . by Afrigen Biologics," although subsequent statements have cast confusion on that statement. Pfizer has likewise made mixed public statements. Wendell Roelf & Julie Steenhuysen, *Moderna Patent Application Raises Fears for Africa COVID Vaccine Hub*, REUTERS (Feb. 17, 2022, 1:36 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-patent-application-raises-fears-africa-covid-vaccine-hub-2022-02-17/ [https://perma.cc/PS2F-8KDY]; Ludwig Burger, *BioNTech Says It Won't Challenge Vaccine Copying in Africa*, REUTERS (Feb. 16, 2022, 10:00 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/biontech-pledges-african-access-its-future-cancer-drugs-2022-02-16/ [https://perma.cc/GH4W-6SEV].

[136] Stephanie Nolen & Sheryl Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, N.Y. TIMES (Sept. 22, 2021), https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html [https://perma.cc/9VS9-KQQF]; Adam Taylor, *Biden's Plan to Vaccinate the World Faces an Obstacle: Vaccine Manufacturers*, WASH. POST (Nov. 18, 2021, 12:01 AM), https://www.washingtonpost.com/world/2021/11/18/bidens-plan-vaccinate-world-faces-an-obstacle-vaccine-manufacturers/ [https://perma.cc/NG48-QRBJ]; Peter Sullivan, *Biden Official Warns Moderna to 'Step-Up' on Vaccine Doses for the World*, HILL (Oct. 13, 2021, 2:38 PM), https://thehill.com/policy/healthcare/576599-biden-official-warns-moderna-to-step-up-on-vaccine-doses-for-the-world [https://perma.cc/694M-U6JY].

[137] David Meyer, *Moderna Wouldn't Share Its Vaccine Technology, So South Africa and the WHO Made a COVID Jab Based on It Anyway*, FORTUNE (Feb. 4, 2022, 6:59 AM), https://fortune.com/2022/02/04/south-africa-afrigen-moderna-covid-vaccine-mrna-who-hotez-corbevax/ [https://perma.cc/95PA-5XJ6].

[138] Emily Baumgaertner, *Vaccine Companies and U.S. Government Snubbed WHO Initiative to Scale-Up Global Manufacturing*, L.A. TIMES (Apr. 30, 2021), https://www.latimes.com/world-nation/story/2021-04-30/vaccine-companies-and-the-u-s-government-snubbed-who-initiative-to-scale-up-global-manufacturing [https://perma.cc/EFV9-UPBY].

[139] *See* Kevin Dunleavy, *Moderna, Amid Mounting Pressure to Address Vaccine Inequality, Says It's Working on a New COVAX Deal*, FIERCE PHARMA (Nov. 16, 2021, 4:22 PM), https://www.fiercepharma.com/pharma/under-pressure-moderna-talks-to-pledge-covid-19-vaccines-to-poor-countries-report [https://perma.cc/PW7P-R5BD]; *see also* ROHIT MALPANI & ALEX MAITLAND, PEOPLE'S VACCINE ALL., DOSE OF REALITY: HOW RICH COUNTRIES AND THEIR CORPORATIONS ARE BREAKING THEIR VACCINE PROMISES (2021), https://webassets.oxfamamerica.org/media/documents/A_Dose_of_Reality-Briefing_Note_kOW1yUs.pdf [https://perma.cc/ZNK2-V9TN].

[140] *See, e.g.*, *4 Reasons Why Pfizer, BioNTech and Moderna Must Share COVID-19 mRNA Vaccine Technology Now!*, MÉDECINS SANS FRONTIÈRES (Sept. 8, 2021),

exploring new vaccine and therapeutics options.[141]

The earliest quasi-voluntary action (see discussion above) by a pharmaceutical company with respect to therapeutics was the decision of AbbVie to declare that it would not enforce patents on its antiretroviral medicine, Kaletra—later proved ineffective against SARS-CoV-2—after Israel issued a compulsory license.[142] Another early voluntary license was issued when the U.S. Food & Drug Administration ("FDA") granted emergency use authorization to Gilead's remdesivir and the firm offered a total of nine Indian, Pakistani, and Egyptian companies licenses to supply to 127 LMICs.[143] Other firms like Eli Lilly and Merck have offered voluntary licenses for their COVID-19 therapeutics, with various limitations on where

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https://msfaccess.org/4-reasons-why-pfizer-biontech-and-moderna-must-share-covid-19-mrna-vaccine-technology-now [https://perma.cc/PW7P-R5BD]; Zain Rizvi, *Sharing the NIH-Moderna Vaccine Recipe*, PUB. CITIZEN (Aug. 10, 2021), https://www.citizen.org/article/sharing-the-nih-moderna-vaccine-recipe/ [https://perma.cc/U9FA-RTSH]; JAMES KRELLENSTEIN ET AL., PREP4ALL, 22 BILLION IN THE HOLE: OMICRON'S IMPLICATIONS FOR GLOBAL MRNA VACCINE NEEDS IN 2022 (2022), https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/61d5aa06cc6f013a1c76e374/1641392648217/PrEP4All+Omicron+Report+1-5-22.pdf [https://perma.cc/4DZL-AGXF]; Amnesty Int'l, *A Double Dose of Inequality: Pharma Companies and the COVID-19 Vaccine Crisis*, AI Index POL 40/4621/2021, at 5, 7–9 (2021), https://www.amnesty.org/en/wp-content/uploads/2021/09/POL4046212021ENGLISH.pdf [https://perma.cc/X9E6-HLRV]; Amnesty Int'l, *Money Calls the Shots: Pharma's Response to the COVID-19 Vaccine Crisis*, AI Index POL 40/5140/2022, at 5, 7 (Feb. 14, 2022), https://www.amnesty.org/en/documents/pol40/5140/2022/en/ [https://perma.cc/S5QW-E6XK].

[141] Molly Campbell, *The Spotlight on mRNA: A Conversation with Moderna*, TECH. NETWORKS (Apr. 26, 2022) https://www.technologynetworks.com/biopharma/blog/the-spotlight-on-mrna-a-conversation-with-moderna-360947 [https://perma.cc/8WPB-234M] (discussing research plans for HIV, tuberculosis, influenza, cancer, antibiotic resistant enteric diseases, and rare diseases); *Harnessing the Potential of mRNA*, PFIZER, https://www.pfizer.com/science/innovation/mrna-technology [https://perma.cc/MU8G-KASR].

[142] Ed Silverman, *AbbVie Will Allow Generic Copies of Its HIV Pill in Israel After the Government Approves a License*, STAT: PHARMALOT (Mar. 20, 2020), https://www.statnews.com/pharmalot/2020/03/20/abbvie-israel-hiv-kaletra-coronavirus-covid19/ [https://perma.cc/2PQ8-3XM3]; *Israel Issues Compulsory License to Allow the Government to Import Generic Versions of Kaletra*, KNOWLEDGE ECOLOGY INT'L (Mar. 23, 2020), https://www.keionline.org/32503 [https://perma.cc/A28S-54QU].

[143] Ed Silverman, *Gilead Signs Licenses for Generic Companies to Make and Sell Remdesivir in 127 Countries*, STAT: PHARMALOT (May 12, 2020), https://www.statnews.com/pharmalot/2020/05/12/gilead-generics-remdesivir-covid19-coronavirus-licenses/ [https://perma.cc/2RA6-FQF2]. The agreement was heavily criticized by activists for excluding 48 percent of the world's population. Sara Jerving, *Gilead's Closed-door Deal Sets Precedent for COVID-19 Drug Access*, DEVEX (June 16, 2020), https://www.devex.com/news/sponsored/gilead-s-closed-door-deal-sets-precedent-for-covid-19-drug-access-97214.

supply may be shipped.[144] Voluntary measures in the diagnostics space have been even sparser. Unitaid and FIND have engineered the only publicly reported voluntary licensing initiative for antigen rapid diagnostic tests with two companies that have agreed to share their diagnostic technology with producers in LMICs.[145]

E. Leveraging Compulsory Licensing at a Domestic Level

Another pandemic response at the national level has been to make changes to domestic IP frameworks in order to make compulsory licenses more accessible. Despite the above-mentioned limitations to the use of compulsory licensing, a handful of countries have made legal changes to their compulsory licensing regime and even issued limited compulsory licenses to address gaps in access to medicines, with a note of success.[146] These have largely involved potential treatments to COVID-19, however, and have not stretched into the area of vaccines or other health technologies.[147]

A small number of countries have made subtle changes to their existing IP laws to make it easier to issue effective compulsory licenses during the pandemic.[148] The changes are small and range from declarations that the COVID-19 pandemic constitutes a sufficient reason to issue related licenses, to introductions of new measures allowing compulsory and government uses licenses in the first instance.[149] Among the most interesting is a bill introduced in Brazil and passed with a partial veto by former President Jair Bolsonaro.[150] The Act allows for the licensing of a group of technologies

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[144] Press Release, Eli Lilly, Lilly Accelerating Baricitinib's Availability in India Following Receipt of Permission for Restricted Emergency Use as a COVID-19 Therapy via Donations and Licensing Agreements (May 4, 2021), https://investor.lilly.com/news-releases/news-release-details/lilly-accelerating-baricitinibs-availability-india-following; Press Release, Merck, Amid Humanitarian Crisis in India, Merck Announces Voluntary Licensing Agreements with Five Indian Generics Manufacturers to Accelerate and Expand Global Access to Molnupiravir, an Investigational Oral Therapeutic for the Treatment of COVID-19 (Apr. 27, 2021), https://www.merck.com/news/amid-humanitarian-crisis-in-india-merck-announces-voluntary-licensing-agreements-with-five-indian-generics-manufacturers-to-accelerate-and-expand-global-access-to-molnupiravir-an-investigational-ora/ [https://perma.cc/9TV8-TXSW].

[145] Press Release, Unitaid, FIND and Unitaid Invest to Support Technology Transfer and Boost Local Production of COVID-19 Rapid Tests in Low- and Middle-Income Countries (July 15, 2021), https://unitaid.org/news-blog/find-unitaid-technology-transfer-covid-19/#en [https://perma.cc/N8RW-PZKG].

[146] *See* MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN, *supra* note 62.

[147] *Id*. at 6.

[148] *Id*. at 3.

[149] *See id*. at 2–3.

[150] Lei No. 14.200, de 3 de Setembro de 2021, Diário Oficial da União [D.O.U.] de

thereby acknowledging the patent web that surrounds many of these new innovations; however, the original Brazilian proposal creating mechanisms to access trade secret information was removed as was the portion of the bill designating COVID-19 as a public health emergency of national importance.[151] Even Germany made a change to its IP law, facilitating government use licensing for patented products related to COVID-19—including a list of products that looks substantially similar to those included in the most recent TRIPS Waiver proposal (see below).[152] Several other countries took steps to simply resort to compulsory licenses in response to the COVID pandemic.[153]

An even smaller group of countries have actually issued compulsory licenses or initiated the process of doing so.[154] When Israel issued a compulsory license to import generic versions of Kaletra (lopinavir/ritonavir) as an experimental COVID-19 treatment and an essential treatment for HIV, the patent holder, AbbVie, announced that it would no longer enforce those patents for any indication—an outcome long sought after by HIV/AIDS advocates.[155] In response to its territorial exclusion from Gilead's voluntary licenses on remdesivir, Russia granted a compulsory license,[156] as did Hungary, but only for a very short time.[157] Since these early efforts, there

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3.9.2021 (Braz.) ("Amends Law No. 9,279, of May 14, 1996 (Industrial Property Law), to provide for the compulsory license of patents or patent applications in cases of declaration of national or international emergency or public interest, or of recognition of a national state of public calamity.").

[151] *Id*.

[152] *See* MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN, *supra* note 62, at 4; *see also* Patentgesetz [PatG] [Patent Act], May 25, 1877, RGBl at 501, last amended by Gesetz [G], Aug. 30, 2021, BGBl I at 4074, § 24 (Ger.), https://www.gesetze-im-internet.de/patg/BJNR201170936.html#BJNR201170936BJNG000100311 [https://perma.cc/J2KM-FZWA] (section of German Patent Act on compulsory licenses).

[153] *See COVID-19: Measures Regarding Trade-Related Intellectual Property Rights*, WTO, https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm [https://perma.cc/NX6D-LVSL] (listing with respect to compulsory licensing measures [not yet referenced with respect to a granted compulsory license]: Antigua and Barbuda, Bolivia, Canada, Indonesia, and Italy).

[154] *See id*.

[155] Katrina Perehudoff, Ellen 't Hoen & Pascale Boulet, *Overriding Drug and Medical Technology Patents for Pandemic Recovery: A Legitimate Move for High-income Countries, Too*, 6 BRIT. MED. J. GLOB. HEALTH e005518, 3 (2021).

[156] *Russia Court Rejects U.S. Firm's Lawsuit Over COVID-19 Drug Remdesivir*, REUTERS (May 28, 2021, 6:02 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/russian-supreme-court-rejects-gilead-lawsuit-over-covid-19-drug-2021-05-27/ [https://perma.cc/9J8B-PZD2].

[157] *COVID-19 and Trade - Hungary*, WTO, https://www.wto.org/english/tratop_e/covid19_e/covid_details_by_country_e.htm?country=HUN [https://perma.cc/9SSP-PJCB].

have been additional compulsory licenses on remdesivir and another COVID-19 medicine in Indonesia,[158] and first steps to issue compulsory licenses on Pfizer's Paxlovid in the Dominican Republic,[159] Colombia,[160] Peru,[161] and Chile.[162] Nevertheless, successes in compulsory licensing have proved the exception rather than the rule, as obstacles discussed above have kept most countries from issuing them. Pfizer for example, has issued an aggressive human/fundamental rights defense against the compulsory license application in the Dominican Republic.[163]

F. TRIPS Waiver

Given the paucity of voluntary licensing initiatives and the difficulty of issuing compulsory licenses, it is unsurprising that some countries attempted to accomplish a broader waiver of IP rights for COVID-19 products. India and South Africa proposed, in October of 2020, to temporarily suspend certain provisions of the TRIPS Agreement for COVID-19 products.[164] By spring of 2021, they had been joined by more than 100 nations in support of

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Even though the compulsory license was short-lived, it drew negative responses from industry. *Hungarian Compulsory License for Remdesivir Raises a Stir with BIO, PhRMA and the US Chamber of Commerce*, KNOWLEDGE ECOLOGY INT'L (Mar. 8, 2021), https://www.keionline.org/35558 [https://perma.cc/KEQ3-5KDC].

[158] *Indonesia Issues Government Use Licenses for Remdesivir and Favipiravir*, MAKE MEDS. AFFORDABLE (Dec. 8, 2021), https://makemedicinesaffordable.org/indonesia-issues-government-use-licenses-for-remdesivir-and-favipiravir/ [https://perma.cc/9QXK-VHCJ].

[159] Mari Serebrov, *Promising Results Drive Push for Paxlovid Compulsory License*, BIOWORLD (Dec. 7, 2021), https://www.bioworld.com/articles/514050-promising-results-drive-push-for-paxlovid-compulsory-license?v=preview.

[160] Letter from the Glob. Humanitarian Progress Corp. et al. to Iván Duque Márquez, President of Colom. 2 (Mar. 14, 2022), https://www.ghpcorporation.co/_files/ugd/706fd7_2b10a060d5bc453196e7ead33ab4c022.pdf [https://perma.cc/FZ4G-ZGHB].

[161] Letter from Asociación Acción Internacional para la Salud et al. to Pedro Castillo Terrones, President of Peru (May 5, 2022), https://aisperu.org.pe/wp-content/uploads/2022/05/Solicitud-de-Uso-Gubernamental-Covid_-PRESIDENCIA.pdf [https://perma.cc/9NMM-HBBF].

[162] Ed Silverman, *Chilean Health Ministry Is Urged to Issue a Compulsory License for the Pfizer Covid Pill*, STAT: PHARMALOT (Jan. 6, 2022), https://www.statnews.com/pharmalot/2022/01/06/pfizer-covid-paxlovid-chile-pandemic-coronavirus/ [https://perma.cc/9UCY-6FGK].

[163] Ed Silverman, *Pfizer Faces Criticism for Arguing That Intellectual Property for Its Covid-19 Pill is a Human Right*, STAT: PHARMALOT (Apr. 20, 2022), https://www.statnews.com/pharmalot/2022/04/20/patent-pfizer-covid19-patent-paxlovid-dominican-republic/ [https://perma.cc/ZDK5-U43B].

[164] Request for Waiver by India and South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020).

such a waiver and a revised waiver text was submitted.[165] However, the European Commission, influenced by Germany, strongly opposed the proposed waiver and counter-offered a tightly limited compulsory-license based approach.[166] Through delay and intransigence, this proposal became the basis for "compromise" negotiations involving the U.S., EU, South Africa, and India, and eventually for the Twelfth Session of the WTO Ministerial Decision on the TRIPS Agreement.[167]

The undergirding rationale for the original TRIPS Waiver proposal was that, even if we support traditional rules protecting intellectual property, the pandemic had changed the calculus.[168] During a pandemic, the emergency nature of the situation demanded sharing ideas, technology, and know-how. Temporarily waiving commitments to protect IP could make space for countries to mobilize generic pharmaceutical producers to manufacture these products without the threat of domestic lawsuits, complaints at the WTO, or (possibly) investor-state disputes.[169] This had become especially important in the context of vaccines in light of the supply gap that has resulted in grossly inequitable distribution.[170] While advocates had not ignored other supply chain bottlenecks—domestic implementation, technology and know-how transfer, and regulatory processes[171]—some critics have argued that these hurdles are too high for most firms, especially given the lack of cooperation from key pharmaceutical giants.[172]

When the United States Trade Representative came out in support of the Waiver in May 2021, many supporters were optimistic that a waiver could be negotiated and signed in time to make a significant difference in ramping

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[165] Request for Waiver by the African Group et al., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19,* WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021).

[166] *See infra* notes 176–78 and accompanying discussion.

[167] WTO, Ministerial Decision on the TRIPS Agreement of 17 June 2022, WTO Doc. WT/MIN(22)/30, WT/L/1141 [Ministerial Decision on TRIPS].

[168] Rachel D. Thrasher, *Why Innovation Would Survive a COVID-19 TRIPS Waiver*, IPWATCHDOG (Mar. 24, 2021, 12:15 PM), https://www.ipwatchdog.com/2021/03/24/innovation-survive-covid-19-trips-waiver/id=131194/ [https://perma.cc/E6KW-HREX].

[169] *Id*.

[170] *Id*.

[171] KATIE GALLOGLY-SWAN & RACHEL D. THRASHER, THREE PILLARS OF VACCINE EQUITY: TRIAGING THE GLOBAL VACCINATION CHALLENGE 3 (2021), https://www.bu.edu/gdp/files/2021/09/GEGI_PB_016_FIN.pdf [https://perma.cc/TN87-ACTL].

[172] Ken Shadlen, *To Speed New COVID Drugs and Vaccines, Look to Patenting*, ISSUES IN SCI. & TECH. (Aug. 11, 2020), https://issues.org/covid-vaccines-development-distribution-patenting-shadlen/ [https://perma.cc/5SS7-6ZH2].

up supply to the developing world.[173] Proponents followed with a minor modification of their original proposal,[174] after which the EU laid out a patent-only counter-proposal, couched as a "clarification" of existing compulsory licensing rules, which simply stated that the pandemic reaches the threshold of a "national emergency" and that remuneration for compulsory licenses should reflect affordable prices for developing countries.[175] Following additional months of bilateral talks producing no progress, the Chairperson of the TRIPS Council initiated discussions involving the U.S., European Union, India, and South Africa ("the Quad").[176] A so-called "compromise" text appeared to come out of those discussions, which bore much more similarity with the EU's counterproposal than the original waiver proposal.[177] The "compromise" text appeared based on the TRIPS Chairperson's own interpretation of areas of convergence that did not, in fact, have the direct support of any of the Quad members other than the EU.[178]

Even so, there were multiple bracketed areas of disagreement in the released text; the basics of the proposed text was a vast departure from the comprehensive waiver proposal submitted by South Africa, India, and their

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[173] Rachel D. Thrasher, *What Happens Now That the US Supports the TRIPS Waiver?*, OPEN ACCESS GOV'T (May 7, 2021), https://www.openaccessgovernment.org/us-trips-waiver/109897/ [https://perma.cc/8EKJ-EMZL].

[174] *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID*-19, *supra* note 165.

[175] Communication from the European Union, *Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property*, at 1–2, COM (2021), 159606 final (June 4, 2021); *see also* Brook K. Baker, *Disinformation, Diversion, and Delay: The Real Text of the European Union's Communication to the WTO TRIPS Council – Urgent Trade Policy Responses to the COVID-19 Crisis*, HEALTH GAP (June 7, 2021), https://healthgap.org/disinformation-diversion-and-delay-the-real-text-of-the-european-unions-communication-to-the-wto-trips-council-urgent-trade-policy-responses-to-the-covid-19-crisis/ [https://perma.cc/Y5NY-MMXG].

[176] Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the Chairperson*, WTO Doc. IP/C/W/688 (May 3, 2022) [hereinafter *Communication from the Chairperson*].

[177] *Trade and Health: WTO Response to the COVID-19 Pandemic,* WTO, https://www.wto.org/english/thewto_e/minist_e/mc12_e/briefing_notes_e/bftrade_and_health_e.htm [https://perma.cc/9WZ7-9CJH].

[178] *Communication from the Chairperson, supra* note 176.

65 supporters.[179] The text addressed vaccines[180] only and proposed postponing a decision on whether to include diagnostics and therapeutics.[181] It did not waive trade secret protection, which is essential information for expanding vaccine manufacturing, although it did include an exception to the usual data protection rules, where applicable.[182] It limited developed countries and China from eligibility to produce vaccines and export vaccines to eligible developing county Members.[183] It proposed the impractical and, in some cases, impossible listing of all pending and granted patents not only on the vaccines but on their components and manufacturing processes.[184] It adopted onerous anti-diversion[185] and advance notification requirements[186] on any and all uses of the very slightly revised compulsory licensing authorization mechanism. Finally, its duration was quite short,[187] meaning that entry of alternative producers might be disincentivized and that any new

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[179] *Members Continue Discussions on IP COVID-19 Response as High-Level Engagement Intensifies*, WTO (Dec. 16, 2021), https://www.wto.org/english/news_e/news21_e/trip_16dec21_e.htm [https://perma.cc/SML7-WQDW]; *TRIPS Council Hears Initial Reactions to Quad's Outcome Document on IP COVID-19 Response*, WTO (May 6, 2022), https://www.wto.org/english/news_e/news22_e/trip_06may22_e.htm [https://perma.cc/9HEX-6DKU].

[180] *Communication from the Chairperson, supra* note 176, ¶ 1.

[181] *Id*. ¶ 8. WTO Member States failed to meet the original six-month deadline for deciding whether or not to extend the WTO Ministerial Decision to cover diagnostics and therapeutics. The same day that proponents filed a document proposing a *mutatis mutandis* extension of the Decision, the United States notified the WTO that it intended to refer outstanding issues to a study by the United States International Trade Commission. After inconclusive negotiations for a time-limited extension, the issue of putting a time limit on the extension decision was postponed until March 2023. *See* Priti Patnaik, *WTO Could Defer Decision on COVID-19 Tests & Treatments, Fueled by American Resistance to Ease IP Rules*, GENEVA HEALTH FILES (Dec. 7, 2022), https://genevahealthfiles.substack.com/p/wto-could-defer-decision-on-covid [https://perma.cc/R5KR-RCXR]; Priti Patnaik, *Hours to Deadline, Countries Remain Divided at WTO on Extending Temporary Easing of IP Rules for COVID-19 Tests & Treatments*, GENEVA HEALTH FILES (Dec. 16, 2022), https://genevahealthfiles.substack.com/p/hours-to-deadline-countries-remain [https://perma.cc/KWN8-U35L]; Priti Patnaik, *High Drama, But No Outcome at the WTO: TRIPS Extension Decision for COVID-19 Tests & Treatment*, GENEVA HEALTH FILES (Dec. 22, 2022), https://genevahealthfiles.substack.com/p/high-drama-but-no-outcome-at-the [https://perma.cc/2RZZ-UWFD].

[182] *Communication from the Chairperson, supra* note 176, ¶ 4.

[183] *Id*. ¶ 1, n.1 (bracketed); *see also* Michael Igoe, *How WTO Got Its TRIPS Waiver Compromise*, DEVEX (June 17, 2022), https://www.devex.com/news/devex-newswire-how-wto-got-its-trips-waiver-compromise-103477 (discussing China's exclusion).

[184] *Communication from the Chairperson, supra* note 176, ¶ 3(a) (bracketed).

[185] *Id*. ¶ 3(d).

[186] *Id*. ¶ 5 & n.5.

[187] *Id*. ¶ 6.

manufacturing capacity might not be sustainable. The only true waiver in the proposed text was a highly conditionalized exception to TRIPS Art. 31(f) to allow unlimited export to eligible countries.[188]

At this point, the access-to-medicines outcry against the draft text was almost universal.[189] Civil society groups condemned it as "worse than nothing"[190] and "an abomination"[191] and predicted that it would set a negative precedent for dealing with future pandemics and systemic access-to-medicines concerns.[192] Even so, the WTO employed green room negotiations involving thirty only Member States to try to reach final agreement, a process made harder by even more restrictive proposals put forth by the U.K. and Switzerland.[193] On the eve of the WTO Ministerial, the Director-General issued a Draft Ministerial Decision showing some progress but still multiple bracketed provisions.[194] After the Ministerial was extended two days to finalize negotiations, the WTO Ministerial Decision on the TRIPS Agreement was formally adopted.[195] It contained essentially all of the elements of the WTO May 3 draft text with only seven textual changes, the most significant of which was probably the elimination of the near impossible patent listing requirement.[196]

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[188] *Id*. ¶ 3(c).

[189] *See WTO Text Would Undermine Global Access to Medicines,* PUB. CITIZEN (May 20, 2022), https://www.citizen.org/article/leaked-wto-proposal-is-not-the-covid-19-medicines-waiver-we-need/ [https://perma.cc/WL4Z-S725] (listing multiple critical perspectives from civil society organizations and academics).

[190] *Id*.

[191] Brook K. Baker, *The Quad TRIPS Waiver Text is Not a Compromise; It Is an Abomination,* HEALTH GAP (Mar. 16, 2022), https://healthgap.org/the-quad-trips-waiver-text-is-not-a-compromise-it-is-an-abomination/ [https://perma.cc/6F7E-ATQ3].

[192] Ellen 't Hoen, *A Plan to Fix Vaccine Inequity Offers False Hope*, BARRON'S (May 9, 2022, 1:51 PM), https://www.barrons.com/articles/trips-waiver-quad-compromise-wto-covid-vaccines-equity-51652118609 [https://perma.cc/6S7L-HQW5].

[193] *See* Priti Patnaik, *So Close, Yet So Far: TRIPS Waiver at the WTO*, GENEVA HEALTH FILES (June 11, 2022), https://genevahealthfiles.substack.com/p/so-close-yet-so-far-trips-waiver?s=r [https://perma.cc/3CCH-XXKA]; *WTO: UK & Switzerland Attempt to Limit Scope of COVID-19 TRIPS Decision*, THIRD WORLD NETWORK (June 7, 2022), https://www.twn.my/title2/wto.info/2022/ti220605.htm [https://perma.cc/D5VC-DDJT].

[194] WTO, Draft Ministerial Decision of 10 June 2022, WTO Doc. WT/MIN(22)/W/15.

[195] Ministerial Decision on TRIPS, *supra* note 167; *see WTO Members Secure Unprecedented Package of Trade Outcomes at MC12*, WTO (June 17, 2022), https://www.wto.org/english/news_e/news22_e/mc12_17jun22_e.htm [https://perma.cc/BJ9A-NY79].

[196] For a detailed discussion of the waiver negotiations and of the seven textual changes, see Peter Yu, *The COVID-19 TRIPS Waiver and the WTO Ministerial Decision*, *in* IPR IN TIMES OF CRISIS: LESSONS LEARNED FROM THE COVID-19 PANDEMIC (Jens Schovsbo ed., Edward Elgar Publ'g forthcoming 2023),

Public condemnation was intense and quick.[197] Almost 300 civil society organizations condemned the decision and called for country campaigns to overcome intellectual property barriers and a ceasefire from counteractions that might be taken by rich countries challenging measures taken by countries to override intellectual property protections on all COVID-19 countermeasures.[198] Activists from South Africa called the decision "a massive step back" and "slap in the face," demanding immediate action by the South African government to override IP barriers to COVID-19 health technologies.[199] Although the Decision is largely regarded as a defeat, access-to-medicines activists and others are pressing for the Decision to be extended to cover diagnostics and therapeutics and for true waiver provisions, that extend beyond patents and think outside of the box of compulsory licensing mechanisms, to be included in the ongoing WHO Pandemic Accord process.

IV. HEALTH FOR THE FUTURE: BUILDING RESILIENCE FOR OUR NEXT PANDEMIC

The failure of the international legal regime to reform its IP and commercial distribution regimes in the face of the COVID-19 pandemic will be an enduring tragedy and a negative precedent. Although it is far too early to give up on reform efforts outlined above, many access-to-medicines advocates and pandemic preparedness proponents are simultaneously turning their attention to establishing a new legal framework to address future global emergencies such as a framework convention proposed by the Independent Panel for Pandemic Preparedness and Response.[200] It is beyond the scope of

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https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4150090 [https://perma.cc/96QT-RRQU].

[197] *See CSO Statements in Response to Shameful Results on Intellectual Property and Covid at 12th WTO Ministerial*, PUB. CITIZEN (June 17, 2022), https://www.citizen.org/news/cso-statements-in-response-to-shameful-result-on-intellectual-property-and-covid-at-12th-wto-ministerial/ [https://perma.cc/H9QR-AZLG].

[198] *See id*.; *GLOBAL CALL TO ACTION: Governments Must Break Big Pharma-WTO Stranglehold on Access to Medicine by Taking Immediate Action to Prioritize Human Lives Over Pharmaceutical Monopolies*, TRADE JUST. EDUC. FUND (June 16, 2022), https://tradejusticeedfund.org/governments-must-break-big-pharma-wto-stranglehold-on-access-to-medicine/ [https://perma.cc/T63L-4ELW].

[199] Yousuf Vawda, Fatima Hassan & Tian Johnson, *New WTO Deal Is a Slap in the Face for Poorer Countries,* NEWS24 (June 18, 2022), https://www.news24.com/fin24/opinion/opinion-new-wto-deal-is-a-slap-in-the-face-for-poorer-countries-20220618 [https://perma.cc/5TL3-TTNJ].

[200] THE INDEP. PANEL FOR PANDEMIC PREPAREDNESS & RESPONSE, COVID-19: MAKE IT THE LAST PANDEMIC 45–46 (2021), https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf [https://perma.cc/Y8Y6-4PT9] (proposing the adoption of a Pandemic Framework

this paper to detail the morphing positions that countries, treaty proponents, and skeptics are espousing on the mechanisms and processes for creating formal and potentially binding rules to deal with future pandemics[201] and the

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Convention). The Recommendations of the Panel and its calls for reform, including adoption of a TRIPS Waiver and a Pandemic Framework Convention, was reiterated by the Panel's co-chairs. ELLEN JOHNSON SIRLEAF & HELEN CLARK, LOSING TIME: END THIS PANDEMIC AND SECURE THE FUTURE 28–30 (2021), https://live-the-independent-panel.pantheonsite.io/wp-content/uploads/2021/11/COVID-19-Losing-Time_Final.pdf.

[201] Relevant discussion focuses on whether there should be a formal United Nations or WHO treaty, reform of International Health Regulations, global surveillance, access to pathogens, and benefit sharing, and provisions for technology transfer and equitable access. *See, e.g.*, Jonathan H. Duff et al., *A Global Public Health Convention for the 21st Century*, 6 LANCET PUBL. HEALTH e428, e428–e429 (2021); *see also* Ronald Labonté et al., *A Pandemic Treaty, Revised International Health Regulations, or Both?*, 17 GLOBALIZATION & HEALTH 1 (2021); Lawrence O. Gostin et al., *An International Agreement on Pandemic Prevention and Preparedness*, 326 J. AM. MED. ASS'N 1257, 1257 (2021); Amy Maxmen, *World Commits to a Pandemic Response Pact: What's Next*, NATURE (Dec. 1, 2021), https://www.nature.com/articles/d41586-021-03596-y [https://perma.cc/8QUS-5XDU]; LAWRENCE O. GOSTIN ET AL., O'NEILL INST. FOR NAT'L & GLOB. HEALTH L. & FOUND. FOR NAT'L INSTS. HEALTH, LEGAL TOOLS FOR PANDEMIC PREPAREDNESS: WHO COLLABORATING CENTER SUPPORT FOR NEW COORDINATING MECHANISMS 10–18 (2021), https://oneill.law.georgetown.edu/wp-content/uploads/2021/11/ONL_Pandemic_Prep_D1_P5.pdf [https://perma.cc/7UT6-C5XB] (reporting results from multistakeholder consultations); Tamara Luciana Bustamante et al., *A New Treaty on Pandemics: Some Key Issues from a Global South Perspective* 9–17 (Univ. of Buenos Aires L. Sch., Working Paper 2021) https://www.southcentre.int/wp-content/uploads/2021/11/WP_A-New-Treaty-on-Pandemics_UBA-TradeLab_EN-1.pdf [https://perma.cc/46JL-RCDW]; GERMÁN VELÁSQUEZ & NIRMALYA SYAM, SOUTH CENTRE, A NEW WHO INT'L TREATY ON PANDEMIC PREPAREDNESS AND RESPONSE: CAN IT ADDRESS THE NEEDS OF THE GLOBAL SOUTH? 3–6 (2021), https://www.southcentre.int/wp-content/uploads/2021/05/PB-93-A-New-WHO-International-Treaty-on-Pandemic-Preparedness-and-Response-REV-2.pdf [https://perma.cc/QS8N-LZMW]; Tedros Adhanom Ghebreyesus, *What Is the Missing Ingredient in Global Pandemic Preparedness and Response?*, 375 BRIT. MED. J. n2800 (2021); Haik Nikogosian & Ilona Kickbusch, *Confronting Future Pandemics: What Could a New Treaty Resolve Beyond the IHR?*, 375 BRIT. MED. J. n2801 (2021); Allen Donnelly, *Creating a New Global Treaty to Minimise Future Pandemic Risks*, 375 BRIT. MED. J. n2784 (2021); Ogerta Manastirliu et al., *The World Must Act Now to Be Prepared for Future Health Emergencies*, 375 BRIT. MED. J. n2879 (2021); Katharina Kummer Peiry, *Triggers for Treaty Negotiations: Could Lessons from Environmental Protection Inform a Prospective Pandemic Treaty?*, 375 BRIT. MED. J. e068903 (2021); Ilona Kickbusch & Anna Holzscheiter, *Can Geopolitics Derail the Pandemic Treaty?*, 375 BRIT. MED. J. e069129 (2021); THOMAS F. MCINERNEY, GLOB. HEALTH CTR., FACTORS CONTRIBUTING TO TREATY EFFECTIVENESS: IMPLICATIONS FOR A POSSIBLE PANDEMIC TREATY (2021), https://www.graduateinstitute.ch/sites/internet/files/2021-10/PolicyBrief2.pdf [https://perma.cc/Q8L9-BRJK]; NATALIE RHODES, PEOPLE'S HEALTH MOVEMENT, DO WE NEED A PANDEMIC TREATY NOW? 5–8 (2021), https://phmovement.org/wp-content/uploads/2021/11/Do-we-need-a-Pandemic-Treaty-now_-A-PHM-Policy-Brief_2mb.pdf [https://perma.cc/V92D-89YD].

general concept of global health security.[202] However, it is appropriate to briefly outline the proposals being advanced to make IP reform central to the project. One positive in this respect is that the most recent draft report from the WHO Working Group on Strengthening WHO Preparedness and Response to Health Emergencies included a principle on equity that recognized the need, among others, to address IP barriers.[203]

There are proposals for pandemic-preparedness IP reform from many quarters. The most prescient proposals focus on both funding for innovation and technology sharing—essentially making pandemic countermeasures global public goods.[204] These proposals advocate for predictable and sufficient funding for pandemic preparedness; conditioning funding on information and technology sharing; incentivizing or compelling sharing through buyouts of and/or compulsory access to all needed inventions, information, biologic resources, and technology platforms; supporting expansion of independent component and final product manufacturing in all

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[202] *See* Sakiko Fukuda-Parr, Paulo Buss & Alicia Ely Yamin, Editorial, *Pandemic Treaty Needs to Start with Rethinking the Paradigm of Global Health Security*, 6 BRIT. MED. J. GLOB. HEALTH e006392 (2021).

[203] WHO, *WGRP Interim Report to EB150*, ¶ 12(d), A/WGPR/6/3 (Jan. 10, 2022), https://apps.who.int/gb/wgpr/pdf_files/wgpr6/A_WGPR6_3-en.pdf [https://perma.cc/6HSH-EA7Q].

[204] *See* Tedros Adhanom Ghebreyesus, WHO Dr.-Gen., WHO Director-General's Speech at the Paris Peace Forum Panel: ACT-A: Covid-19 Vaccines, Tests and Therapies, the Global Public Good Solution (Nov. 12, 2020), https://www.who.int/director-general/speeches/detail/who-director-general-s-speech-at-the-paris-peace-forum-panel-act-a-covid-19-vaccines-tests-and-therapies-the-global-public-good-solution---12-november-2020 [https://perma.cc/L5L8-G9L9]; Press Release, Secretary-General, COVID-19 Vaccines Must Be Global Public Good, Secretary-General Says, Announcing 'Only Together' Campaign to Encourage Sharing of Technology, Doses, U.N. Press Release SG/SM/20620 (Mar. 11, 2021), https://www.un.org/press/en/2021/sgsm20620.doc.htm [https://perma.cc/G7AH-JUWX]; David J. Hunter et al., *Addressing Vaccine Inequity – COVID-19 Vaccines as Global Public Goods*, 386 NEW ENG. J. MED. 1176, 1177–78 (2022); Marianne Meijer, Marieke Verschuuren & Ella Weggen, *COVID-19 Vaccines a Global Public Good? Moving Past the Rhetoric and Making Work of Sharing Intellectual Property Rights, Know-how and Technology*, 31 EUR. J. PUB. HEALTH 925, 925 (2021); Stuart J. Peacock, *Vaccine Nationalism Will Persist: Global Public Goods Need Effective Engagement of Global Citizens*, 18 GLOBALIZATION & HEALTH 1, 1–5 (2022); James Love, *The Use and Abuse of the Phrase "Global Public Good"*, GLOB. POL'Y (Sept. 28, 2020), https://www.globalpolicyjournal.com/blog/28/09/2020/use-and-abuse-phrase-global-public-good [https://perma.cc/S44P-AQXN]; *cf.* Govind Persad & Ezekiel J. Emanuel, *Can Covid-19 Vaccine Be Global Public Goods?*, BMJ OPIN. (July 22, 2021), https://blogs.bmj.com/bmj/2021/07/22/can-covid-19-vaccines-be-global-public-goods/ [https://perma.cc/5XYV-EXMP] (arguing that vaccines are rival and excludable and that arguing that they are public goods diverts attention from the real challenges of achieving universal vaccination).

regions of the world; and guaranteeing equitable access to all populations.[205] A particularly detailed proposal has come out of a consultation of an Expert Working Group, which recommends seven areas of action, including: sufficient financing for biomedical R&D, creating conditions for licensing government-funded R&D, mandating technology transfer, sharing IP, data and knowledge needed for the production and supply of products, streamlining regulatory standards and procedures, greater transparency, and inclusive governance.[206] The policy proposals of this group have been seconded and expanded upon by other authors who recommend to countries and other actors:

> (1) Implementing alternative incentive and funding mechanisms to develop new scientific innovations to address infectious diseases with pandemic potential; (2) Voluntary and involuntary initiatives to overcome IP barriers including pooling IP, sharing data and vesting licences for resulting products in a globally agreed entity; (3) Transparent and accountable collective procurement to enable equitable distribution; (4) Investments in regionally distributed research and development (R&D) capacity and manufacturing, basic health systems to expand equitable access to essential health technologies and non-discriminatory national distribution; (5) Commitment to strengthen national (and regional) initiatives in the areas of health system development, health research, drug and vaccine manufacturing and regulatory oversight and (6) Good governance of the convention on pandemic preparedness and response. It is important to articulate principles for deals that include reasonable access conditions, and transparency in negotiations.[207]

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[205] Ellen 't Hoen, *The Pandemic Treaty and Intellectual Property Sharing: Making Vaccine Knowledge a Public Good*, PETRIE-FROM CTR.: BILL OF HEALTH (Oct. 15, 2021), https://blog.petrieflom.law.harvard.edu/2021/10/15/pandemic-treaty-intellectual-property/ [https://perma.cc/E3UF-Y7AA]; Timothy Fish Hodgson et al., *Human Rights Must Guide a Pandemic Treaty*, HEALTH & HUM. RTS. J. (Nov. 20, 2021), https://www.hhrjournal.org/2021/11/human-rights-must-guide-a-pandemic-treaty/ [https://perma.cc/2JX9-9KG8] (arguing for a human rights focus on participation, equality, and access to health technologies); Yousuf A. Vawda, *Global Health Equity – An Unfulfilled Promise*, 52 INT'L REV. INTELL. PROP. & COMPETITION L. 1287, 1289 (2021); ABHA SAXENA ET AL., GLOB. HEALTH IMPACT, PANDEMIC PREPAREDNESS AND RESPONSE: KEY PROVISIONS FOR A NEW TREATY (2022), https://www.global-health-impact.org/static/docs/povax2reportcover2.pdf [https://perma.cc/N7EG-YSQE].

[206] Katrina Perehudoff et al., *A Pandemic Treaty for Equitable Global Access to Medical Countermeasures: Seven Recommendations for Sharing Intellectual Property, Know-how and Technology*, 7 BRIT. MED. J. GLOBAL HEALTH e009709 (2022).

[207] Abha Saxena, Brook K. Baker, Amanda Banda et al., *Pandemic Preparedness and Response: Beyond the WHO's Access to COVID-19 Tools Accelerator*, 8 BRIT. MED. J. GLOB. HEALTH (forthcoming 2023).

Parallel domestic and regional efforts to address vaccine and medicine shortages are garnering increasing attention in the media. African institutions have taken steps to change the way the continent responds to the next pandemic, such as the Africa Centres for Disease Control and Prevention launching the Partnerships for African Vaccine Manufacturing in April of 2021.[208] The WHO's Director-General, Dr. Tedros Adhanom Ghebreyesus, has emphasized the importance of local production of vaccines, and Africa CDC Director, Dr. John Nkengasong, articulated an agenda that would place not only the final vaccines but also more supply chains in Africa before the next pandemic hits.[209] Even private actors may play a role in this, as ImmunityBio founder, Patrick Soon-Shiong, seeks to build more health resilience on the continent.[210] Aspen's J&J license resulted in expanding manufacturing capacity on the continent, although a recent uptick in donations have begun to outcompete Aspen's domestic production.[211] BioNTech and Moderna are also taking steps to establish satellite, company-controlled mRNA production facilities in Africa.[212]

Perhaps one of the most promising, forward-thinking initiatives to emerge from the pandemic is the WHO mRNA Vaccine Technology Transfer Hub,[213] which announced remarkable progress in reverse engineering the Moderna mRNA vaccine and is now looking to insource or independently develop commercial manufacturing know-how.[214] One important step in developing a second-generation vaccine and building commercial capacity is the newly

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[208] Sara Jerving & Jenny Lei Ravelo, *Prospects for Local Manufacturing of COVID-19 Vaccines in Africa*, DEVEX (Jan. 6, 2022), https://www.devex.com/news/prospects-for-local-manufacturing-of-covid-19-vaccines-in-africa-102300.

[209] *Id*.

[210] *See* Janice Kew & Antony Sguqzzin, *Billionaire Soon-Shiong Launches 1 Billion-Dose Vaccine Plant in Cape Town*, BLOOMBERG (Jan. 19, 2022, 4:11 AM), https://www.bloomberg.com/news/articles/2022-01-19/soon-shiong-launches-1-billion-dose-vaccine-plant-in-cape-town [https://perma.cc/KF6Q-32YK].

[211] Paul Adepoju, *Lack of Orders Could Halt COVID-19 Vaccine Production in South Africa*, DEVEX (Apr. 14, 2022), https://www.devex.com/news/lack-of-orders-could-halt-covid-19-vaccine-production-in-south-africa-103052.

[212] Mandy Parrett, *BioNTech Launches African Vaccine Production in Rwanda*, EUR. PHARMACEUTICAL. REV. (June 24, 2022) https://www.europeanpharmaceuticalreview.com/news/172615/biontech-launches-african-vaccine-production-in-rwanda/ [https://perma.cc/9XU2-CFGE] (announcing BioNTainer manufacturing plans for Rwanda, Senegal, and South Africa); Sarah Jerving, *Moderna's First African mRNA Vaccine Facility Will Be in Kenya*, DEVEX (Mar. 7, 2022), https://www.devex.com/news/moderna-s-first-african-mrna-vaccine-facility-will-be-in-kenya-102808.

[213] *The mRNA Vaccine Technology Transfer Hub*, WHO, https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub [https://perma.cc/4SHS-KQGS].

[214] Amy Maxmen, *South African Scientists Copy Moderna's COVID Vaccine*, 602 NATURE 372, 372–73 (2022).

announced agreement between Afrigen Biologics and the Univercells group involving the development of a novel heat-stable mRNA vaccine and sharing of Univercells's production technology.[215] The Hub has been established on a hub-and-spoke model where two generations of COVID-19 mRNA vaccines are being developed. Beyond the two COVID-19 vaccines in development, the sharing will include both the commercial scale know-how with all required quality assurance protocols and a basic mRNA technology platform adaptable to other products and diseases.[216] Thirteen spoke countries have already been identified and a biomanufacturing training hub has also been established.[217] Not only will "spokes" receive these mRNA technologies and platforms,[218] but they will essentially be recruited into a new innovation ecology whereby further innovations and improved know-how will be shared back to the Hub and with other spokes. Although there are still intellectual property quandaries to be resolved, resources to be mobilized, and demand from regional buyers for future products to be cultivated, the Hub is providing new optimism about the potential of Southern governments to cooperate and free themselves from Big Pharma monopolies and the failed, trickle-down, charity-based model that delayed vaccine and medicines delivery to LMICs.[219]

The COVID-19 pandemic has offered an opportunity for countries to take

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[215] Raisa Santos, *Biotech Companies' Agreement Paves the Way for First African-Owned COVID-19 Vaccine*, HEALTH POL'Y WATCH (June 21, 2022), https://healthpolicy-watch.news/biotech-companies-agreement-paves-way-for-first-african-owned-covid-19-vaccine/ [https://perma.cc/S6J8-YBYM].

[216] Ed Silverman, *The WHO's Chief Scientist on COVID-19 Vaccines, Patent Battles, and Speeding Up Access in Africa*, STAT: PHARMALOT (Feb. 22, 2022), https://www.statnews.com/pharmalot/2022/02/22/covid19-vaccine-who-africa-moderna-biontech-mrna/ [https://perma.cc/2CJA-84TP].

[217] Zachary Brennan, *mRNA for All: WHO Establishes Biomanufacturing Training Hub in Korea*, ENDPOINTS NEWS (Feb. 23, 2022), https://endpts.com/mrna-for-all-who-establishes-biomanufacturing-training-hub-in-korea/ [https://perma.cc/7ZYW-R42L] (identifying Argentina, Brazil, Egypt, Kenya, Nigeria, Senegal, South Africa, Tunisia, Bangladesh, Indonesia, Pakistan, Serbia, and Vietnam as spokes, and establishing biomanufacturing workforce training hub in South Korea); *Moving Forward on Goal To Boost Local Pharmaceutical Production, WHO Establishes Global Biomanufacturing Training Hub in Republic of Korea*, WHO (Feb. 23, 2022), https://www.who.int/news/item/23-02-2022-moving-forward-on-goal-to-boost-local-pharmaceutical-production-who-establishes-global-biomanufacturing-training-hub-in-republic-of-korea [https://perma.cc/6PD6-MH4X].

[218] *South Africa's mRNA Hub Progress is Foundation for Self-Reliance*, WHO (Feb. 11, 2022), https://www.who.int/news/item/11-02-2022-south-africa-s-mrna-hub-progress-is-foundation-for-self-reliance [https://perma.cc/UBX8-8SG9].

[219] *See* Peter Drahos, *Public Lies and Public Good: Ten Lessons from When Patients and Pandemics Meet* 9–10 (Eur. Univ. Inst., Working Paper No. 2021/5, 2021), https://cadmus.eui.eu/bitstream/handle/1814/71560/EUI_WorkingPaper_Law_2021_5.pdf [https://perma.cc/G8JZ-2R3P] (proposing robust South-South collaboration).

a hard look at the existing reality of health inequity in the world and the multiple systems that reinforce that inequality. Nevertheless, the business-as-usual operation of international trade rules, especially those governing IP, has resulted in perpetuating vast health system inequality. The changes that have been made amount to tinkering at the margins, and other legal developments suggest that the international trade rules as written are more likely to present as obstacles rather than opportunities for the remainder of this pandemic, perhaps in the next.[220] The prospects for a multilateral treaty to improve pandemic preparedness and for regional efforts to ramp up pharmaceutical manufacturing capacity are uncertain though some progress has been made.[221] What is clear is that future pandemic responses should include major IP reform, adequate financing, and assurance of equitable distribution of pandemic countermeasures by prepared and capacitated health systems.

[220] We already see gross inequality in access to mpox vaccines and therapies. *See* Paul Adepoju, *Monkeypox: African CDC Demands Equal Treatment in Global Allocation of Limited Vaccine Doses*, HEALTH POL'Y WATCH (June 16, 2022), https://healthpolicy-watch.news/monkeypox-who-limited-vaccine-doses/ [https://perma.cc/DK7E-B3FH].

[221] WHO, *supra* note 69.

ANNEX

Table 1: Key Patent-Related Public Health Flexibilities[222]

Flexibilities Affecting Grants of Patents	
Exclusions from Patentability[223]	No patents required on: ⇒ mere discoveries; ⇒ surgical, diagnostic and therapeutic methods; ⇒ plants or animals, except sui generis system for plant varieties; ⇒ genes or extractions from naturally occurring matter; ⇒ abstract ideas, discoveries, theories of nature, computer software or business methods; and ⇒ new uses and methods of use of known substances (incl. admixtures, combinations or rearrangements and variations).
Standards of Patentability[224]	Requires strict standards of patentability, especially concerning combinations of prior art, novelty, inventive step, and industrial applicability.
Disclosure[225]	May require applicant to disclose: ⇒ all known practical methods of carrying out the invention, and the "best known mode"; ⇒ corresponding applications and patents in other jurisdictions; and ⇒ the international nonproprietary name (INN) for pharmaceuticals.
Opposition Procedures and Grounds for Revocation[226]	⇒ Permits states to implement pre- and post-grant patent opposition procedures with broad standing rights and easy-to-use administrative procedures. ⇒ Permits states to establish broad grounds for revoking patents including inequitable conduct, fraud, failure to make required disclosures and failure to satisfy requirements/standards of patentability, among others.

[222] Brook K. Baker, *International Collaboration on IP/Access to Medicines: Birth of the South Africa's Fix the Patents Law Campaign*, 60 N.Y. L. SCH. L. REV. 309, 315–18 (2015/16) (detailing most of this chart and the legal basis for such flexibilities in the context of South Africa's Patents Law).

[223] TRIPS Agreement, *supra* note 9, art. 27.3.

[224] *Id*. art. 27.

[225] *Id*. art. 29.

[226] *Id*. arts. 32, 62.4; *see also id*. arts. 41.2, 41.4.

Patent Term[227]	No requirement of patent term extensions for regulatory delays or for delays in granting patents.
LDC Transition Period and Pharmaceutical Extension[228]	⇒ 2013 to 2021 general LDC TRIPS transition period would allow avoidance of all IP rights obligations; and ⇒ 2015 to 2033 pharmaceutical transition period would allow avoidance of pharmaceutical patents, data protection, mailbox obligations, and market exclusivity.

Flexibilities Creating Limitations and Exceptions	
Limited Exceptions[229]	⇒ Commercial and non-commercial research rights and educational use rights; prior use and private, non-commercial use; ⇒ Early working/Bolar exception allowed both domestically and for export for the purpose of obtaining regulatory approval; ⇒ Other limited exceptions as needed, including allowing unlimited export to countries with insufficient manufacturing capacity that have issued compulsory licenses.
Parallel Importation[230]	Permits states to adopt international exhaustion rule for IP rights and easy procedures for parallel importation.[231]
Compulsory Licenses and Government Use[232]	States may adopt broad grounds for issuing a compulsory license, such as: ⇒ excessive pricing, refusal to license/denial of access to an essential facility, failure to work or supply sufficient quantities and others or for any other matter of public interest or public health, as well as: ⇒ clear, easy-to-use remuneration guidelines established; ⇒ efficient and easy-to-use administrative procedures. States may allow without prior negotiation: ⇒ licenses based on emergencies or matters of extreme urgency, including national security and public health crises; ⇒ public, non-commercial-use licenses without prior negotiation;

[227] *Id*. art. 37 (identifying the twenty-year patent term but making no reference to patent term extensions for regulatory delays).

[228] *Id*. art. 66.1.

[229] *Id*. art. 30.

[230] *Id*. art. 6; Doha TRIPS Declaration, *supra* note 25, ¶ 5(d).

[231] May also permit restrictions on contractual limitations on export in support of parallel importation.

[232] TRIPS Agreement, *supra* note 9, arts. 31, 31*bis*, 44.2; Doha TRIPS Declaration, *supra* note 25, ¶¶ 4, 5(a)–(b).

	⇒ production for export licenses either pursuant to Art. 31*bis* or Art. 30; ⇒ judicial licenses allowed pursuant to Art. 44.2, among others; and ⇒ presumptive and even mandatory compulsory licenses may be lawful.

Flexibilities Affecting Enforcement	
Enforcement Flexibilities[233]	Compensatory damages and injunctions must be available remedies, but: ⇒ no border measures required for suspected patent infringement of goods in transit;[234] ⇒ no criminal penalties required for patent violations; [235] ⇒ may limit remedies to adequate remuneration in certain cases; [236] ⇒ provision measures must be possible, but use is not mandatory; [237] and ⇒ alternative damages measures based on market value, selling price, deterrence not required. [238]
Competition Policies[239]	Allows states to: ⇒ prevent abuse of IP rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect international transfer of technology; and ⇒ prevent licensing practices or IP rights conditions that restrain competition or adversely affect trade and may impede transfer of technology.

[233] TRIPS Agreement, *supra* note 9, arts. 44.2, 45, 50, 51, 61.

[234] *Id*. art. 51.

[235] *Id*. art. 61.

[236] *Id*. art. 44.

[237] *Id*. art. 50.

[238] *Id*. art. 45.

[239] *Id*. arts. 8.2, 40.

Table 2: Trade Secret, Data Protection, and Copyright Flexibilities

Exceptions to Confidential Information / Trade Secret Protection Under Art. 39.2 and Art. 39.3	Overcoming confidential information/trade secret barriers: ⇒ public interest and public health exceptions to confidential information/trade secret protections, including for clinical trial related data; ⇒ compulsory licenses on confidential information/trade secrets with or without adequate remuneration; ⇒ exception to government protection of confidential information/trade secrets submitted to regulatory authorities allowing disclosure to patent licensees.
Avoidance of Data Exclusivity Under Art. 39.3	⇒ Article 39.3 requires data protection, not data exclusivity, allowing regulatory authorities to reference or rely on otherwise confidential regulatory data to register equivalent medical products; ⇒ Disclosure of such data when in the public interest.
Exceptions to Copyright	⇒ Fair use or limited exceptions to copyright protected content, including for data analysis, research, and educational purposes.

When it comes to data protection, trade secrets, and copyright, COVID-19 has made the need for additional public health flexibilities abundantly clear. Exceptions to patent rights alone do not provide alternative producers with sufficient information to manufacture commercial batches of vaccines and other biologic medicines. The kind of deep technology transfer that would expedite development, registration, and marketing of near-identical vaccines—in particular those using new mRNA technology—depends on access to data, reagent formulas, manufacturing know-how and quality assurance specifications, specialized equipment, software, operating manuals, and even cell lines and other biologic products. While TRIPS Article 39.2 does not directly specify pathways for exceptions to confidential-information/trade-secret rights, it does not prevent such exceptions either. Indeed, statements in the Agreement's preamble, Articles 7, 8 and 66.2, as well as the Doha Declaration on TRIPS and Public Health indirectly support exceptions that would encourage this technology transfer, and multiple jurisdictions have adopted public interest exceptions to confidential-information/trade-secret protections.[240] Moreover, although this has not been tested in WTO jurisprudence, there is a plausible argument that Article 39.3 could be construed to allow disclosure of "other data" held by regulatory authorities in order to "protect the public" so long as steps are

[240] David S. Levine & Joshua Sarnoff, *Compelling Trade Secret Transfers*, 75 HASTINGS L.J. 39–54, 66–79 (forthcoming 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4311880 [https://perma.cc/SX9M-TH3F].

taken to prevent "unfair commercial use."[241]

Finally, Flynn and others are drawing attention to the possibility of drawing on Article 17 of the Berne Convention and Article 13 of the TRIPS Agreement to allow compulsory licensing, fair use, and other limited exceptions to copyright that are necessary to advance collaborative scientific research, data mining, product development, marketing, and repair of COVID countermeasures and equipment.[242] In this regard it is interesting to note that even the European Union has recognized the need to create mandatory exceptions to copyright for text and data mining.[243]

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[241] TRIPS Agreement, *supra* note 9, art. 39.3. *See* K. M. Gopakumar, Chetali Rao & Sangeeta Shashikant, *Trade Secrets Protection and Vaccines: The Role of Medicine Regulatory Agencies*, THIRD WORLD NETWORK: BRIEFING PAPER (June 2021), https://twn.my/title2/briefing_papers/twn/Trade%20secrets%20TWNBP%20Jun%202020%20Gopakumar%20et%20al.pdf [https://perma.cc/5SPJ-YRLD]. Notably, many regulatory authorities receive such detailed data from patent holders, which would otherwise be confidential, concerning manufacturing processes, quality control systems and other protocols, some of which may continue to be updated.

[242] *See* Sean Flynn et al., *Non-Patent Intellectual Property Barriers to COVID-19 Vaccines, Treatment and Containment*, PIJIP/TLS RSCH. PAPER SERIES, Nov. 2021, at 14–20, https://digitalcommons.wcl.american.edu/research/71 [https://perma.cc/76J7-AUFM].

[243] *See* Directive 2019/790, of the European Parliament and of the Council of 17 April 2019 on Copyright and Related Rights in the Digital Single Market and Amending Directives 96/9/EC and 2001/29/EC, 2019 O.J. (L 130), ¶¶ 5, 9, 11, 18.

Figure 1: Frequency of TRIPS Flexibilities Cited in Countries Identified by PhRMA and Listed by USTR (%)[244]

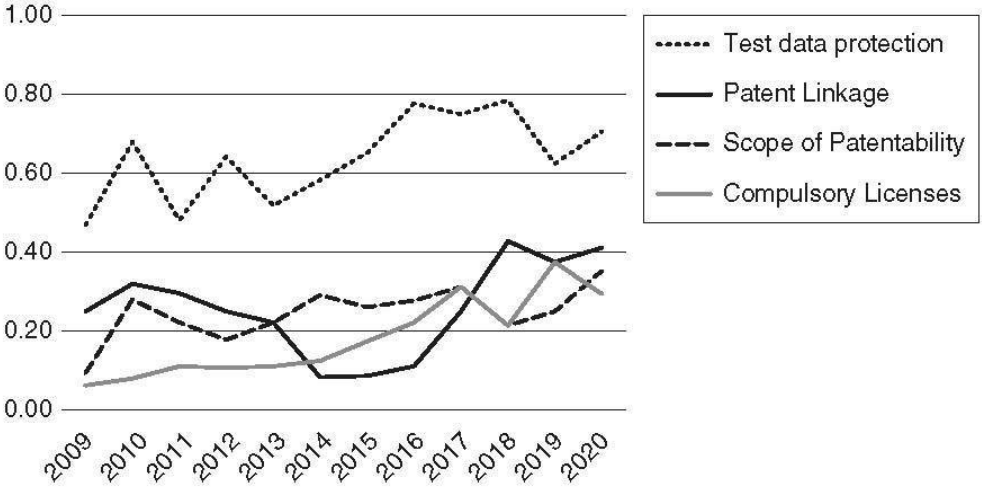

Table 3: U.S. Federal Subsidies and Contracts to Moderna[245]

Amount	**Date**	**Task**
$430 million	April 16, 2020	Accelerate development of vaccine candidate
$53 million	May 24, 2020	Expand manufacturing capacity
$472 million	July 25, 2020	Support Phase 3 clinical trial
$1.53 billion	August 11, 2020	Support Lonza's manufacturing, 100 million doses
$1.67 billion	December 11, 2020	100 million doses
$1.75 billion	February 11, 2021	100 million doses

[244] Palmedo, *supra* note 53; *see also* Michael Palmedo, *Promotion of TRIPS-Plus Intellectual Property Provisions Through the Special 301 Review: How Did It Change During the Covid-19 Pandemic?*, INFOJUSTICE (Aug. 17, 2022), https://infojustice.org/archives/43369 [https://perma.cc/YM9Z-ZYH2].

[245] *See* Bown & Bollyky, *supra* note 77.