Addressing IP and Technology Challenges to Pandemic Protection: A Need for Global Coordination to Promote National Security

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ABSTRACT

This Article argues that effective national security mandates protection against the spread of infectious diseases, which requires addressing intellectual property (IP) and technology obstacles. Without modification, IP laws can bar the manufacture of needed treatments by anyone besides the IP owner and its licensees. Although there was some recognition during the COVID-19 pandemic that existing IP laws should be modified, there was strong resistance not only by IP-owning companies, but also by individual countries that impeded the ability to manufacture needed vaccines during the height of the pandemic.

Many global leaders have recognized that future pandemics are inevitable and that a more collaborative approach is necessary to avoid repeating the problems of the COVID pandemic in the future. Negotiations on a pandemic agreement since 2021 under the auspices of the World Health Organization (WHO) are a concrete manifestation of this realization. Although recognizing a need to change is an important step, not all even agree that IP laws need to be modified for future pandemics. This Article explains how usual IP norms can frustrate public health and national security, why current proposals for a pandemic agreement are largely inadequate, as well as what countries can and should do to protect national security even if there is not adequate consensus for binding obligations in an international pandemic agreement.

I. INTRODUCTION

As the COVID pandemic demonstrated, infectious disease does not recognize territorial boundaries, and challenges traditional notions of national security. As repeatedly stated during the COVID pandemic, "no one is safe until everyone is safe" with respect to a highly contagious virus that can continue to mutate with inadequate vaccinations.[1] After

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[1] *E.g.*, EUR. PARL. ASS., *Declaration Adopted by Comm. On Social Affairs, Health and Sustainable Development: The Covid-19 Situation: "No-One is Safe Until Everyone is Safe,"* Doc. No.

all, when COVID infections were uncontrolled in some parts of the world, mutation risk increased, which promoted variants that jeopardized the health of even those vaccinated.[2] A pandemic can kill more than a war, and can make a nation vulnerable to more traditional threats of national security by compromising military readiness, economic progress, and political development.[3]

The COVID pandemic obviously underscores the threat of pandemics to national security. However, for more than twenty years some have recognized that infectious diseases impact national security and some have even argued that addressing such diseases should affirmatively be considered part of national security.[4] For example, in 2005, then-Senator Barack Obama and Senator Richard Lugar noted that contrary to threats to national security that most think of, such as global terrorism and rogue states, an important threat lies in pandemics.[5] At the time, the pandemic was the avian flu; the Director of the Centers for Disease Control and Prevention (CDC) warned that the flu could spread around the world in days, crippling economies in Southeast Asia and elsewhere.[6] Although the United States and many other countries were lucky to not succumb to either HIV/AIDS or the avian flu, the warning that infectious pandemics can cause "direct and immediate threats to security and prosperity here at home" did come to pass in 2020 with the COVID pandemic.[7]

Although some have recognized that addressing infectious pandemics is a national security concern that requires global coordination, addressing intellectual property (IP) as a barrier to national security is less often recognized as an issue. When the U.N. General Assembly

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AS/Soc (2021) 54rev, (2021); Keizo Takemi & Achim Steiner, *Covid-19: Nobody is Safe Until Everyone is Safe*, U.N. DEV. PROGRAMME (Dec. 9, 2020), https://www.undp.org/asia-pacific/blog/covid-19-nobody-safe-until-everyone-safe [https://perma.cc/7AGF-7RVQ].

[2] *E.g.*, Dany Bahar, *Is the World Now Paying the Price of Not Doing Enough to Help Developing World COVID-19 Vaccination Efforts?*, BROOKINGS (Jan. 7, 2022), https://www.brookings.edu/blog/up-front/2022/01/07/are-rich-countries-sufficiently-helping-the-developing-world-in-its-vaccination-efforts/ [https://perma.cc/7ZNT-DXRC] (noting that inequitable COVID vaccine distributions likely encouraged new COVID variants).

[3] *See, e.g.*, Segun Oshewolo & Agaptus Nwozor, *COVID-19: Projecting the National Security Dimensions of Pandemics*, 44 STRATEGIC ANALYSIS 269, 270–71 (2020); James G. Hodge Jr. & Kim Weidenaar, *Public Health Emergencies as Threats to National Security*, 9 J. NAT'L SEC. L. & POL'Y 81, 85 (2016); David P. Fidler, *Public Health and National Security in the Global Age: Infectious Diseases, Bioterrorism and Realpolitik*, 35 GEO. WASH INT'L. L. REV. 787, 791–92 (2023).

[4] *See* Hodge & Weidanaar, *supra* note 3, at 83; Fidler, *supra* note 3, at 792–94. *See generally* JENNIFER BROWER & PETER CHALK, THE GLOBAL THREAT OF NEW AND REEMERGING INFECTIOUS DISEASES: RECONCILING UNITED STATES NATIONAL SECURITY AND PUBLIC HEALTH POLICY (2003).

[5] *See* Barack Obama & Richard Lugar, *Grounding a Pandemic*, N.Y. TIMES (June 6, 2005), https://www.nytimes.com/2005/06/06/opinion/grounding-a-pandemic.html [https://perma.cc/N558-Y9DB].

[6] *See id.*

[7] *Id.*

adopted a 2020 resolution that global solidarity was necessary to fight COVID, it did not mention IP barriers.[8] In addition, pharmaceutical companies and even some countries in the Global North argued against changing IP rights during the pandemic, suggesting that IP fostered rapid development of COVID vaccines.[9] But, these arguments ignored the fact that such treatments were cold comfort to the many individuals that had no access to them. IP rights permitted companies to set their own prices and, in some cases, counterintuitively charge higher prices to poor countries.[10] Moreover, even when companies could not meet vaccine demand, their IP rights legally barred others from supplementing production to ensure adequate supplies for all. Since the COVID pandemic prompted world leaders to recognize the need for a global, rather than a nationalistic response, countries embarked on negotiating an international pandemic agreement under the auspices of the World Health Organization (WHO) to better prepare for inevitable future infectious pandemics.[11] This provides an opportunity to address IP

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[8] *See* G.A. Res. 74/270, ¶¶ 6, 8 (Apr. 2, 2020) (recognizing importance of global solidarity to fight COVID-19 without mention of IP).

[9] *E.g.*, *Innovative Pharmaceutical Industry Statement on Draft WHO Pandemic Treaty: We Need to Preserve What Went Well and Address What Went Wrong*, INT'L FED. PHARM. MFRS. & ASS'NS. (Oct. 17, 2023), https://www.ifpma.org/news/innovative-pharmaceutical-industry-statement-on-draft-who-pandemic-treaty-we-need-to-preserve-what-went-well-and-address-what-went-wrong/ [https://perma.cc/45SX-PYBJ] (stating that new vaccines and treatments "at record speed" were enabled by an "ecosystem that incentivized innovation," and arguing that the proposed text would have a "chilling effect on the innovation pipeline"); Robert Grant, *4 Things to Know About Intellectual property and COVID-19 Vaccines*, U.S. CHAMBER COM. (Dec. 9, 2021), https://www.uschamber.com/intellectual-property/4-things-to-know-about-intellectual-property-and-covid-19-vaccines [https://perma.cc/79NE-V8VV] (stating that vaccines were the product of research that "wouldn't have been viable without strong IP protections" in the context of arguing against waiver of IP rights to permit countries to make needed treatments).

[10] *E.g.*, Rebecca Martin et al., *Lessons Learnt from COVID-19 to Reduce Mortality and Morbidity in the Global South: Addressing Global Vaccine Equity for Future Pandemics*, BMJ GLOB. HEALTH, Nov. 6, 2023, at 1, 2–3, https://gh.bmj.com/content/bmjgh/9/1/e013680.full.pdf [https://perma.cc/QW3W-U2W4].

[11] *E.g.*, J.V. Bainimarama et al., *COVID-19 Shows Why United Action is Needed for More Robust International Health Architecture*, WORLD HEALTH ORG. (Mar. 30, 2021), https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture [https://perma.cc/HUX6-JGMC] (noting twenty-five heads of state recommending that WHO develop a pandemic treaty); Catherine Thomlinson, *The Politics and Promise of a Pandemic Treaty*, NEWS24 (Apr. 16, 2021), https://www.news24.com/life/archive/analysis-the-politics-and-promise-behind-a-proposed-pandemic-treaty-20210414 [https://perma.cc/X82B-6JXC] (noting support by developed and developing countries such as Germany, the U.K., and South Africa); Prime Minister's Office, 10 Downing Street & The Rt. Hon. Boris Johnson, *No Government Can Address the Threat of Pandemics Alone - We Must Come Together*, GOV.UK (Mar. 30, 2021), https://www.gov.uk/government/speeches/no-government-can-address-the-threat-of-pandemics-alone-we-must-come-together [https://perma.cc/H3VB-T5AL]; *see also* EUR. PARL. DOC. (A9-0217) 529 (2023) (observing that "countries cannot fight a global emergency alone" and that international cooperation and coordination is essential). These efforts were preceded by commentary earlier in the pandemic by some who argued for global cooperation to ensure equitable distribution of treatments to prevent hoarding of vaccines that happened with prior treatments such as the 2009 H1N1 pandemic. *E.g.*, Thomas J. Bollyky & Chad Brown, *Tragedy of Vaccine Nationalism*, 99 FOREIGN AFFS. 96, 103

barriers, and in doing so, to promote more equitable access to vaccines and treatments.[12] However, the need to arrive at consensus on many different provisions including, but not limited to IP and technology sharing, may result in commitments that fail to prevent the distribution inequities prevalent during the COVID pandemic.[13] This is despite stated agreement that greater global solidarity is necessary. Countries in the Global North focus primarily on the need for prevention and preparedness whereas countries in the Global South are highly concerned about equitable access to treatments, including how to overcome IP barriers to manufacture such treatments.[14] Some countries have opposed the inclusion of any IP obligations even though IP can, and in fact did, bar equitable and timely access to COVID treatments.[15] Even if the IP provisions remain in an eventual pandemic agreement, unless something dramatically changes, this will likely be a missed opportunity since proposed IP provisions thus far are primarily tepid suggestions

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(2020); Frederick M Abbott & Jerome H Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT'L ECON. L. 535, 543 (2020). However, some have suggested that there is no true consensus on solidarity. *E.g.*, Clare Wenham et al., *The Futility of the Pandemic Treaty: Caught Between Globalism and Statism*, 98 INT'L AFFS. 837, 843–44 (2022).

[12] Countries have debated the form this agreement may take. *E.g.*, Priti Patnaik, *Pandemic Regulations or Pandemic Agreement? Growing Affinity for Article 21 Over Article 19 of WHO Constitution as Some "Treaty" Proponents Rethink Underlying Legal Provisions of New Rules*, GENEVA HEALTH FILES (Feb. 24, 2024), https://genevahealthfiles.substack.com/p/pandemic-regulations-or-treaty-who-19-or-21-ihr [https://perma.cc/6MEJ-KA6Y]. In addition, the agreement being negotiated with the WHO that involves IP is being negotiated in conjunction with a separate amendment to the International Health Regulations. *E.g.*, Haik Nikogosian, *Pandemic Treaty – Will it Fragment or Consolidate the Global Health Emergency Infrastructure?*, 1 OXFORD OPEN INFRASTRUCTURE HEALTH 1, 1 (2003).

[13] *E.g.*, Jon Cohen, *A Treaty to Prepare the World For the Next Pandemic Hangs in the Balance*, SCIENCE (Mar. 15, 2024, 4:55 PM), https://www.science.org/content/article/treaty-prepare-world-next-pandemic-hangs-balance [https://perma.cc/YU84-3FR6]; Ian Schofield, *Time Pressures May Result in Diluted Global Pandemic Treaty*, PINK SHEET (Dec. 11, 2023), https://pink.citeline.com/PS149481/Time-Pressures-May-Result-In-Diluted-Global-Pandemic-Treaty [https://perma.cc/ANK4-4DXF]; Jenny Lei Ravelo, *What is the Pandemic Treaty and What Would It Do?*, DEVEX (Dec. 4, 2023), https://www.devex.com/news/what-is-the-pandemic-treaty-and-what-would-it-do-106577 [https://perma.cc/PG5S-XS68].

[14] *E.g.*, Annegret Mathari, *WHO Members Meet – Again – to Discuss a Pandemic Treaty*, SWISSINFO.CH (Dec. 4, 2023), https://www.swissinfo.ch/eng/politics/who-members-meet---again---to-discuss-a-pandemic-treaty/49029890 [https://perma.cc/2EX8-EK59]; Vijay Balakrishnan, *WHO Pandemic Treaty: The Good, the Bad, & The Ugly – An Interview with Larry Gostin*, HEALTH POL'Y WATCH (Sept. 14, 2023), https://healthpolicy-watch.news/who-pandemic-treaty-the-good-the-bad-the-ugly-an-interview-with-larry-gostin/ [https://perma.cc/N3GV-5BJ5] (noting that whereas high income countries prioritize access to scientific data to develop treatments, lower income countries view this information as their only bargaining chip to obtain equitable access to treatments).

[15] *E.g.*, Kerry Cullinan, *Intellectual Property Negotiations Belong at the WTO, European Countries Tell Pandemic Accord Negotiations*, HEALTH POL'Y WATCH (Nov. 6, 2023), https://healthpolicy-watch.news/intellectual-property-negotiations-belong-at-wto-european-countries-tell-pandemic-accord-negotiations/ [https://perma.cc/MRG3-9DZ8] (noting that U.S., E.U. and Switzerland have expressed reservations about modifying IP rights as well as technology transfer with European countries arguing that changes to IP are inappropriately addressed under the WHO and the United States arguing that limiting IP rights would actually diminish access during an pandemic).

for voluntary actions.[16] Notably, even the tepid suggestions are contentious and part of the reason that countries failed to come to an agreement on most provisions by the original May 2024 deadline, such that WHO extended the timeline for negotiations.[17]

Even if a pandemic agreement fails to establish necessary new norms concerning pandemic IP, a better understanding of how IP can compromise global as well as domestic security is important to help address inevitable future pandemics.[18] Part II explains how pandemics challenge national security using the COVID-19 pandemic as an example. Part IIA briefly reviews how nationalistic responses during COVID-19 compromised global security and Part IIB explains how IP issues can pose a barrier to addressing pandemics. Part IIC then explains how there was limited, but inadequate, recognition of IP issues during COVID-19.

After explaining the inadequate response to IP problems during COVID-19, Part III focuses on how we can better address future pandemics. Part IIIA explains that the ideal would be for all countries to broadly share relevant IP rights. Part IIIB explains that although there is recognition of the need for global coordination to address future pandemics, current negotiations on a pandemic agreement are likely to fall short of the ideal. Part IIIC explores why the draft WHO proposals for the IP and technology provisions of the pandemic agreement have been inadequate and also suggests what individuals, countries, and organizations can do even if not formally required in a pandemic agreement.

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[16] *E.g.*, Gabrielle Emanuel, *The Deadline is Nearly Here. Will the Global Pandemic Treaty be Finished in Time?*, NPR (May 23, 2024, 6:19 pm ET), https://www.npr.org/sections/goats-and-soda/2024/05/23/g-s1-319/the-deadline-is-nearly-here-will-the-global-pandemic-treaty-be-finished-in-time [https://perma.cc/T8PZ-X7AH]; Jenny Lei Ravelo, *Latest Pandemic Treaty Still has Many Weaknesses*, DEVEX, (Mar. 13, 2024), https://www.devex.com/news/latest-pandemic-treaty-draft-text-still-has-many-weaknesses-107223 [https://perma.cc/WH3J-X8NW]; *see also* Priti Patnaik, *Pandemic Agreement Talks "Difficult" Amidst Polarisation, Pressure Builds for a "Lite" Accord by May 2024 sans Contentious Provisions*, GENEVA HEALTH FILES (Dec. 8, 2023), https://genevahealthfiles.substack.com/p/pandemic-agreement-talks-difficult [https://perma.cc/3NKV-6BDA] (noting challenges of completing negotiations with divergent views by May unless parties agree to text that mostly reflects the status quo).

[17] WHO, Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response, Report by the Director-General, seventy-seventh World Health Assembly, Provisional Agenda Item 13.4, Doc A77/10, Appendix (May 27, 2024) (providing draft text indicating what parts have initial agreement or convergence, as well as test for which there is no consensus) [hereinafter *Pandemic Agreement May Draft*]; WHO, Intergovernmental Negotiating Body, Seventy-Seventh World Health Assembly Agenda Item 13.4, Doc. A77/A/CONF./15 (June 1, 2024) (extending negotiating process to 2025, or earlier if possible); *see also* Kat Lay, *Global Pandemic Treaty Could be More than a Year Away after Deadline Missed*, GUARDIAN (May 29, 2024, 5:30 EDT), https://www.theguardian.com/global-development/article/2024/may/29/global-pandemic-treaty-could-be-more-than-a-year-away-after-deadline-missed [https://perma.cc/8922-U322].

[18] *E.g.*, U.N. DEV. PROGRAMME, NEW THREATS TO HUMAN SECURITY IN THE ANTHROPOCENE: DEMANDING GREATER SOLIDARITY 14 (Feb. 8, 2022), https://hs.hdr.undp.org/pdf/srhs2022.pdf [https://perma.cc/X2J2-B8JS] (stating that global infectious disease crises should be anticipated).

II. HOW A PANDEMIC CHALLENGES NATIONAL SECURITY

Using the COVID pandemic as an example, this section provides some background on how infectious diseases can compromise national security and discusses why effective pandemic responses require global coordination. This section begins by reviewing how some domestic actions, arguably taken to promote traditional measures of security concerning territorial boundaries, in fact compromised national and global security. It then explains why addressing IP related to pandemic treatment is necessary to promote national security. Finally, it concludes by addressing specific actions taken during COVID.

A. The Scope of National Security and How Nationalistic Responses Compromise Domestic and Global Security

Although national security has traditionally been narrowly defined to focus on physical threats to domestic borders such as traditional warfare, this Article agrees with others who recognize that national security should encompass a wider array of activities that can challenge the physical integrity of a country, including infectious diseases.[19] Not only can a pandemic be tied to social, economic and political instability similar to traditional armed warfare, but it can be even deadlier.[20] Moreover, unlike conventional warfare that typically has clear borders and alliances, infectious diseases are not easily stopped at geographic borders. The COVID pandemic is a recent and potent illustration of how infectious diseases are a threat to national security. However, during the COVID pandemic, many domestic responses did not properly address this threat.

Domestic actions that were arguably undertaken to promote traditional conceptions of national security during COVID might have actually compromised security. For example, nations stockpiled vaccines and closed borders to reduce infection transmissions, alleging that it was to promote their *own* interests.[21] However, these steps undermined

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[19] *E.g.*, Craig Albert et al., *Human Security is Biosecurity: Reconceptualizing National Security Threats in the Time of COVID-19*, 40 POL & LIFE SCIS. 83 (2021); RAJAT KUMAR KUJUR, CRITICAL CONNECTION: COVID-19 PANDEMIC AND NATIONAL SECURITY (2020); *see also supra* note 3 (collecting works of scholars supporting this view).

[20] *E.g.*, Kujur, *supra* note 19, at 2–3 (noting political instability, economic implications of HIV/AIDS). During the COVID pandemic over one million U.S. citizens died, more than the deaths from the September 11 terrorist attacks; Albert, *supra* note 19, at 83. *See also* Pietro D. Marghella, *Public Health is a National Security Issue*, U.S. NAVAL INST. PROC. (Aug. 2023), https://www.usni.org/magazines/proceedings/2023/august/public-health-national-security-issue [https://perma.cc/DD6Z-PP4W] (noting that one million deaths is more than twice the number of citizens killed as a result of every war fought the United States in the 20th and 21st centuries).

[21] *See, e.g.*, Nelson Aghogho Evaborhene et al., *The Pandemic Treaty, the Pandemic Fund and the Global Commons: Our Scepticism,* BMJ GLOB. HEALTH, Feb. 8, 2023, at 1, 3,

global security and health, which in turn likely compromised domestic security.[22] For example, the fact that wealthy nations engaged in vaccine nationalism by purchasing far more vaccines than they needed meant that other countries were deprived of the ability to purchase them.[23] From a domestic perspective, it is arguably rational that countries purchased advance orders of vaccines in development from multiple companies when it was unclear which, if any, would be effective. However, given a limited supply of vaccines, this behavior resulted in more mutations, infections, deaths, and unnecessary harm to the global economy.[24] Moreover, even if there might have been some logic to originally purchasing more vaccines than necessary, the fact that some countries destroyed rather than donated unused doses seems to undermine global security.[25]

Along similar lines, international travel bans were arguably instituted to promote national security in terms of protecting domestic health, but they may have undermined domestic and global security. WHO recommends against travel measures.[26] There is no data showing effectiveness of such bans; this is likely because banning travel after infected individuals have transmitted a virus is not effective.[27]

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https://gh.bmj.com/content/8/2/e011431.long [https://perma.cc/8XBJ-YLUY] (noting that vaccine stores were suppressed by "buyers by richer countries who stockpiled doses that were in excess of their population need"). Nations also barred or limited exports of essential medical supplies that included vaccines, raw materials to make vaccines, as well as supplies of personal protective equipment like masks that were in short supply. *E.g.*, CHRISTOPHER A. CASEY & CATHLEEN D. CIMINO-ISAACS, CONG. RSCH. SERV. IF11551, EXPORT RESTRICTIONS IN RESPONSE TO THE COVID-19 PANDEMIC 1 (2021).

[22] Evaborhene, *supra* note 21, at 2 (noting that shutdown of borders and vaccine nationalisms conflict with science and result in inequitable outcomes); Wenham et al., *supra* note 11, at 839 (noting that many countries engaged in an "ineffective nation-state first approach" contrary to WHO guidance and even obligations under the IHR).

[23] *E.g.*, MARCO HAFNER ET AL., COVID-19 AND THE COST OF VACCINE NATIONALISM, RAND CORP. 29 (2020), https://www.rand.org/pubs/research_reports/RRA769-1.html [https://perma.cc/RJ6E-CU9Y]; Bollyky & Brown, *supra* note 11, at 103.

[24] *E.g.*, Cynthia Ho, *Confronting Intellectual Property Nationalism*, 100 DENV. L. REV. 109, 126 (2022).

[25] Kerry Cullinan, *EU Hoarding Then Dumping COVID Vaccines Highlights Pandemic Accord Equity Challenge*, HEALTH POL'Y WATCH (Dec. 19, 2023), https://healthpolicy-watch.news/eu-hoarding-then-dumping-covid-vaccines/ [https://perma.cc/Q8GZ-CQ93].

[26] *WHO Director-General's Statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV)*, WORLD HEALTH ORGANIZATION [WHO] (Jan. 30, 2020), https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ihr-emergency-committee-on-novel-coronavirus-(2019-ncov) [https://perma.cc/XXV9-FG7Z] (stating that the "WHO does not recommend limiting trade and movement").

[27] *E.g.*, Laurence O. Gostin & Meryl Justin Chertoff, *Lockdowns, Quarantines And Travel Restrictions, During COVID And Beyond: What's the Law, And How Should We Decide?*, HEALTH AFFS. (Mar. 24, 2021), https://www.healthaffairs.org/content/forefront/lockdowns-quarantines-and-travel-restrictions-during-covid-and-beyond-s-law-and-should [https://perma.cc/C2T3-P7PF] (noting that many countries barring international travel or restricting travel to and from certain countries, despite WHO historic rejection of travel restrictions). There is mixed evidence on effectiveness of travel bans. *E.g.*, Lama Bou-Karroum et al., *Public Health Effects of Travel-Related*

Moreover, banning travel from countries that have engaged in conspicuous efforts to help promote global security is particularly concerning and counterproductive. For example, many countries issued travel bans against South Africa after it identified a new COVID variant and shared its genetic sequence data of this variant to the benefit of all.[28] These travel bans likely reduced incentives for other countries to engage in global cooperation.

B. IP Reform for Pandemics is Needed to Promote National and Global Security

Since national security deals with protecting the state from a variety of issues, including infectious diseases, it is important for countries to have the means to combat such diseases. This includes overcoming IP barriers that may limit the availability of treatments. A country cannot effectively protect its citizens against an infectious disease if it lacks adequate vaccines, medicine, and supplies. As seen during COVID, there may be inadequate treatments available to purchase if some countries engage in nationalistic hoarding of supplies and IP prevents countries needing supplies from making them. Accordingly, in order to protect national security interests, it is necessary to understand what IP is needed to address an infectious disease during a global pandemic.

There are several different types of IP that may be needed for countries to make treatments or other medical supplies during a pandemic. Manufacturing needed supplies may require use of patented inventions. Other IP that might be needed are trade secret methods, and an additional IP-related protection in regulatory law that practically delay approval of competing products often called "data exclusivity".[29]

Policies on the COVID-19 Pandemic: A Mixed Methods Systemic Review, 83 J. INFECTION 413, 420–421 (2021) (finding that border closure may decrease number of infections, but effectiveness depends on compliance and enforcement, with a border closure more effective if followed by testing).

[28] *E.g.*, Keymanthri Moodley et al., *Ethics and Governance Challenges Related to Genomic Data Sharing in Southern Africa: The Case of SARS-CoV-2*, 10 LANCET GLOB. HEALTH e1855, e1856 (2022) (noting unscientific travel bans after South Africa shared the genome sequence of Omicron); Kenichi Serino, *Travel Bans Punish Countries for Doing Necessary Work During the Pandemic, South African Epidemiologist Says*, PBS NEWS HOUR (Dec. 2, 2021, 6:54 PM), https://www.pbs.org/newshour/health/outrageous-and-an-overreaction-south-africas-top-epidemiologist-responds-to-omicron-travel-ban [https://perma.cc/AS3B-ZTHP].

[29] *E.g.*, Cynthia Ho, *Beyond Traditional IP: Addressing Regulatory Barriers*, *in* INTELLECTUAL PROPERTY, COVID-19, AND THE NEXT PANDEMIC: DIAGNOSING PROBLEMS, DEVELOPING CURES 195, 196 (Haochen Sun & Madhavi Sunder eds.) (forthcoming 2025). Although data exclusivity is not always considered a traditional type of IP, the pharmaceutical industry as well as the U.S. government consider this part of IP that is often included in free trade agreements that require IP. *See, e.g.*, Michael Palmedo, *Evaluating the Impact of Data Exclusivity on the Price Per Kilogram of Pharmaceutical Imports* (Glob. Dev. Pol'y Ctr., Working Paper No. 048, 2021), https://www.bu.edu/gdp/files/2021/04/GEGI_WP_048_Palmedo_FIN.pdf [https://perma.cc/PH44-4B2W] (noting that free trade agreements requiring IP frequently require data exclusivity); *Data Exclusivity in International Trade Agreements: What Consequences for access to medicines?*,

Understanding what each of these requires and the scope of their rights is important to understand how to address pandemic needs. Also, although IP rights are governed by domestic law, most countries today must provide patents and trade secrets (or similar protection for undisclosed information) pursuant to international agreements such as the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[30]

Before discussing the scope of these rights, it is necessary to first briefly explain what is covered by each. A patent is generally only granted for inventions that meet requirements of being useful, new and nonobvious, and only when the inventor is willing to disclose the invention to the public. A trade secret, on the other hand, protects a broader array of information; any information can be a trade secret if it has value from not being generally known and is in fact kept reasonably secret. Whereas most IP is privately enforced by its owner, data exclusivity is not because it is enforced by government agencies that approve new drugs for sale. Data exclusivity bars competitors from relying on clinical data previously submitted to government agencies in seeking regulatory approval of a drug during the term of its exclusivity.

Patents generally provide their owners with the strongest rights because they may exclude others from making the patented invention, including even those who independently develop the invention later. However, issued patents are also public knowledge; publication of how to make the inventions is considered part of the justification for granting this exclusivity.[31] In addition, although patents usually require exclusivity, most nations have laws permitting exceptions from patents, such as the ability to grant a compulsory license to use a patented invention.

The other types of relevant IP do not provide the same kind of exclusivity that patents do. The trade secret right does not exclude all others; rather, it is a more limited claim against *unauthorized misappropriation,* such as stealing the invention. Data exclusivity does not bar the making of an invention but can be a practical barrier to entry for lower cost versions, such as generic versions of a brand name drug. In countries where this exclusivity exists, subsequent manufacturers cannot rely on clinical data previously submitted by the first manufacturer to expedite approval of similar drugs, thus removing a short-cut

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MEDECINS SANS FRONTIERES, May 2004, at 1, https://www.citizen.org/wp-content/uploads/dataexclusivitymay04.pdf [https://perma.cc/7AHH-MS9D] (comparing data exclusivity to more traditional intellectual property rights).

[30] *E.g.*, *infra* notes 55–56 and accompanying text.

[31] *E.g.*, 35 U.S.C. § 271 (providing exclusivity against others); Bonito Boats v. ThunderCraft Boats, Inc, 489 U.S. 141, 149 (1989) (noting that patents are a carefully crafted bargain).

for establishing regulatory approval.[32] Although second entrants could create their own studies to directly establish that their proposed drug is safe and effective, they generally do not because they are unable to obtain a patent on an existing drug to recover the costs of these studies.[33]

Although trade secrets and data exclusivity do not technically provide the same type of exclusive rights as patents, it can be more challenging to overcome these protections than circumventing patent protections. After all, whereas patents are public documents, trade secret information is by definition secret, and thus not public knowledge.[34] Similarly, data exclusivity protects clinical data from reliance by generic companies and can be barred from disclosure to the public even after the exclusivity period ends.[35] Moreover, there is generally no exception from trade secrets or data exclusivity, unlike compulsory license to patent rights.[36] In addition, even if there was an exception to trade secret rights, such an exception would not result in *disclosure* of the trade secret without the creation of additional laws. This is because the

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[32] The general regulatory standard nations use to establish whether drugs can be sold in a country are that they are safe and effective. Generic companies can more efficiently establish this by relying in part on clinical data submitted by earlier company in conjunction with limited data that the generic is bioequivalent to the previously approved drugs such that it can be inferred that the generic will be safe and effective without direct proof. *See, e.g.*, Ho, *Beyond Traditional IP*, *supra* note 29.

[33] Since this company would be duplicating what another had done, this would fail the "new" requirement for a patentable invention. In addition, in an earlier era when countries barred subsequent entrants from ever relying on earlier clinical data, there were few generic versions of drugs even after their patents had expired because of the cost of engaging in these clinical studies. *E.g.*, Gerard J. Mossinghoff, *Overview of the Hatch-Waxman Act and its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999) (noting 150 drugs whose patents had expired, but for which there were no generics).

[34] *E.g.*, 18 U.S.C. § 1389; *see also* MELVIN F. JAGER, TRADE SECRETS LAW § 6.4 (2022) (stating that "[i]t is hornbook law that trade secrets are entitled to protection . . . until they are publicly disclosed").

[35] Whereas a fundamental policy reason for granting patents is to provide an incentive to publicly share knowledge that might otherwise be kept as a trade secret, there is no similar justification for data exclusivity. *See, e.g.*, Ho, *Beyond Traditional IP*, *supra* note 29. Accordingly, countries have historically not disclosed this data. *See, e.g.*, Alexander C. Egilman et al., *Transparency of Regulatory Data Across the European Medicines Agency, Health Canada and US Food and Drug Administration*, 49 J. L., MEDICINE & ETHICS 456, 456 (2021) (noting that "sponsors and regulatory agencies have kept confidential much of the clinical data generated to support the approval and continued monitoring of small molecule and biologic drugs").

[36] There are a few countries that have exceptions from data exclusivity, but not the U.S. or countries in the E.U. *E.g.*, Ellen 't Hoen, *Protection of Clinical Data and Public Health: The Need to Remove the Stronghold of Data Exclusivity*, *in* ACCESS TO MEDICINE AND VACCINES 183, 191–93 (C.M. Correa & R.M. Hilty eds. 2022). In addition, an exception to trade secret rights is generally only an exception from liability for taking or using trade secrets without authorization, and until recently, although there was a prior amorphous exception, there was no exception even for a whistleblower of illegal activity in the U.S. *See, e.g.*, Peter Menell, *Tailoring a Public Policy Exception to Trade Secret Law*, 105 CAL. REV. 1, 5–7, 30–31, 61–62 (2017).

trade secret rights provide protection only against improperly obtaining the trade secret.

Some pandemic products only involve one issue, whereas others will require overcoming all three aforementioned IP issues. For example, during COVID, some engineers who successfully designed three-dimensional printed valves for respirators that were in short supply were reluctant to share their design, despite great interest, due to fear of IP liability.[37] In this case, the manufacturing of valves would seem to only involve potential patent liability for making the valves—if they were patented—but not implicate a trade secret method and definitely not data exclusivity since the valves are not a drug. However, a pill that treats COVID could be patented *and* protected from competition by data exclusivity. mRNA COVID vaccines as well as biological treatments such as monoclonal antibodies were protected by all three types of IP. Patents protected the underlying technology, and the method of making the vaccine was separately protected by trade secret. In addition, the first company to obtain regulatory approval for each type of vaccine would have data exclusivity barring subsequent companies from immediately obtaining regulatory approval for a similar version.

The COVID pandemic provides a useful illustration of how trade secrets alone can be a barrier to making needed vaccines. In particular, although Moderna claimed that it would not enforce patent(s) on its COVID vaccine, it nonetheless did not share its trade secret-protected methods of making the vaccine.[38] To be sure, scientists can and do create workarounds to trade secret methods. During COVID, some scientists in South Africa were able to eventually do so after more than a year, but this obviously consumed valuable time.[39] These efforts were

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[37] Communication from South Africa, *Intellectual Property and Public Interest: Beyond Access to Medicines and Medical Technologies Towards a More Holistic Approach to TRIPS Flexibilities*, WTO Doc. IP/C/W/666, at 3 (July 17, 2020); *see also* Dana Mahr & Sascha Dickel, *Rethinking Intellectual Property Rights and Commons-Based Peer Production in Times of Crisis: The Case of COVID-19 and 3D Printed Medical Devices*, 15 J. INTELL. PROP. L. & PRAC. 711 (2020) (suggesting that IP rights associated with 3-D printing should be reconceived for pandemics).

[38] *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-Property-Matters-during-the-COVID-19-Pandemic/default.aspx [https://perma.cc/A56B-5T57]; *Moderna's Updated Patent Pledge*, MODERNA (Mar. 7, 2022), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx [https://perma.cc/MZV7-QSFH]; Alice Park, *Moderna is Sharing its Vaccine Technology with Low-income Countries. But that Doesn't Mean Locally Produced Shots are Coming Soon*, TIME (Mar 9, 2022, 12:07 PM), https://time.com/6155934/moderna-covid-19-vaccine-patent/ [https://perma.cc/X8QC-QF8M]; All Things Considered, *Moderna Won't Share Its Vaccine Recipe. WHO Has Hired an African Startup to Crack It*, NPR (Oct. 19, 2021, 6:27 PM), https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun [https://perma.cc/5JTP-MGYZ].

[39] *E.g.*, Amy Maxmen, *South African Scientists Copy Moderna's COVID Vaccine*, 602 NATURE 372, 372 (2022); *mRNA Technology Transfer Moves to the Next Step*, WORLD HEALTH ORG. (April

not helpful for addressing the pandemic because by the time scientists created a workaround, there was substantial vaccine hesitancy. Also, although the South African scientists had adequate technical experience to develop an alternative, that will not necessarily always be true. In fact, IP owning companies often asserted that there was no need to share their IP more broadly because many countries lacked adequate technical expertise to use their trade secrets. So, adequate technical expertise is necessary. In addition, time is of the essence to overcoming these barriers during a pandemic. And, of course, failure to timely address barriers to treating infectious diseases can compromise national and global security.

C. Failure to Fully Address IP Barriers During COVID

1. WHO call for global solidarity rejected

Relatively early during the COVID pandemic, the WHO recognized that IP rights could be a problem and issued a solidarity call to action in May 2020 that requested all countries and IP owners take steps to reduce IP barriers to addressing COVID.[40] Although the WHO statement recognized IP was an issue, it simply requested IP owners *consider* voluntary sharing of IP and suggested that nations funding COVID research include provisions in funding agreements to promote affordable and accessible health products.[41] However, even those modest recommendations were supported primarily by countries from the Global South.[42]

The WHO call to action was issued alongside a newly created COVID-19 Technology Access Pool (C-TAP) to share all relevant IP relating to COVID products to promote equitable global access. This new

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20, 2023), https://www.who.int/news/item/20-04-2023-mrna-technology-transfer-programme-moves-to-the-next-phase-of-its-development [https://perma.cc/5QK8-KMPB] (noting mRNA vaccination development success in less than two years).

[40] *Making the Response to COVID-19 a Public Common Good: Solidarity Call to Action*, WORLD HEALTH ORG. (May 29, 2020), https://www.who.int/publications/m/item/solidarity-call-to-action [https://perma.cc/4YZV-WA59] [hereinafter *WHO Call to Action*]; *see also Medicines Law and Policy Welcomes WHO Solidarity Call to Action to Realize Equitable Global Access to COVID-19 Health Technologies Through Pooling of Knowledge, IP 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/92C2-PK3L].

[41] *WHO Call to Action*, *supra* note 40.

[42] *Id.* at 2 (listing a few dozen countries of the Global South supporting the recommendation and only including a few global North countries such as Norway, Spain and Portugal and the Netherlands). In addition, the statement was supported by some intergovernmental organizations such as UNDP as well as nongovernment organizations. *See Endorsements of the Solidarity Call to Action*, WORLD HEALTH ORG. (Apr. 13, 2024, 2:23 PM), https://www.who.int/initiatives/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action [https://perma.cc/8DTA-T5VY].

pool was suggested by Costa Rica and endorsed by nearly 100 public health organizations and experts.[43] Although some public health advocates hoped that the new pool could help further innovation for not yet developed treatments by creating a one-stop-shop to use such innovation, they recognized that the effectiveness of the pool would depend on whether IP owners would volunteer to share their IP.[44] Manufacturers of the most effective mRNA vaccines declined to share their IP with the pool and were highly critical and misleading concerning the WHO effort.[45] The CEO of Pfizer stated that the pool was "nonsense" and that it was "dangerous" to take away IP rights after investments had been made.[46] But, since the pool was voluntary, the suggestion that IP would be taken away was misinformation.

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[43] Letter from Carlos Alvarado Quesada, Presidente de la República, and Daniel Salas Peraza, Ministro de Salud, of Costa Rica to Dr. Tedros Adhanom Ghebreyesus, Director-General World Health Organization (Mar. 23, 2020) (https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf [https://perma.cc/6HXB-MNHS]); 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/9FHC-KPMB].

[44] *See* MEDS. L. & POL'Y, *supra* note 40.; *see also Medicines Patent Pool and Unitaid Respond to Access Efforts for COVID-19 Treatments and Technologies*, MEDICINES PATENT POOL (Mar. 21, 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/7FAF-GSFA] (noting that Medicines Patent pool that was created before COVID expanding mandate to include COVID treatments and also offering licensing expertise to the WHO).

[45] After COVID ceased to be a global threat, one small company shared IP relating to a vaccine. Ian Schofield, *WHO Working on Evolved Model for COVID-19 Licensing Platform*, PINKSHEET (Nov. 16, 2023), https://pink.citeline.com/PS149365/WHO-Working-On-Evolved-Model-For-COVID-19-Licensing-Platform [https://perma.cc/4AH5-7L6S] (noting that Medigen Vaccine Biologics was the first private manufacturer to offer a patent for a COVID-19 vaccine in August 2023).

[46] Ed Silverman, *Pharma Leaders Shoot Down WHO Voluntary Pool for Patent Rights on Covid-19 Products*, STAT (May 28, 2020), https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/ [https://perma.cc/J4GX-QUMA]; Steve Brachmann, *WHO's C-TAP Initiative Pushes for Non-Exclusive Licensing Amid Pharma Industry Concerns*, IPWATCHDOG (May 31, 2020), https://ipwatchdog.com/2020/05/31/whos-c-tap-initiative-pushes-non-exclusive-global-licensing-amid-pharmaceutical-industry-concerns/id=122041/ [https://perma.cc/HY7K-EV6V].

The WHO request for solidarity was largely unheeded.[47] Countries did not impose conditions on funding.[48] Companies alleged that they did voluntarily share IP, asserting that they had licensed all capable manufacturers of COVID vaccines, even though independent studies found over 100 untapped facilities and news articles reported reputable manufacturers denied licenses.[49] The licenses were denied even though IP owning companies and their licensees could not provide adequate vaccines to meet demand. The C-TAP pool also languished. Despite public pressure for companies with substantial public funding to contribute to the pool,[50] there was no sharing of vaccines by multinational companies.[51] Two years into the pandemic some manufacturers shared IP related to the COVID *treatments*, but only for the poorest countries; the manufacturers intentionally excluded most middle-income countries.[52] One company "shared" a treatment, but only with the condition that the licensees be deprived of the usual legal right to challenge patent validity.[53] These actions were not only contrary to the WHO request for

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[47] In addition, beyond self-interested pharmaceutical companies, some others also suggested actions inconsistent with global solidarity. For example, the Bill & Melinda Gates foundation pressured a university to exclusively license its vaccine without restriction on price. *See* Jay Hancock, *Rather Than Give Away Its COVID Vaccine, Oxford Makes Deal with Drugmaker*, HEALTH NEWS FLA. (Aug. 25, 2020, 9:56 AM), https://health.wusf.usf.edu/health-news-florida/2020-08-25/rather-than-give-away-its-covid-vaccine-oxford-makes-deal-with-drugmaker [https://perma.cc/EYR4-ZNRN] (describing Oxford University's decision to retract its promise to donate the rights to its COVID-19 vaccine after urging by the Bill & Melinda Gates Foundation); *see also* Alexander Zaitchik, *How Bill Gates Impeded Access to COVID Vaccines*, NEW REPUBLIC (Apr. 12, 2021), https://newrepublic.com/article/162000/bill-gates-impeded-global-access-covid-vaccines [https://perma.cc/GS9J-P9E8] (noting the Foundation's strong IP stance). After substantial public pressure, the Gates foundation eventually reversed course on the need to modify patent protections for COVID. *See* Catherine Cheney, *Gates Foundation Reverses Course on COVID-19 Vaccine Patents*, DEVEX (May 7, 2021), https://www.devex.com/news/gates-foundation-reverses-course-on-covid-19-vaccine-patents-99810 [https://perma.cc/D7DE-7KAC].

[48] In fact, U.S. contracts funding COVID research were more restrictive than usual. *See* Ho, *Confronting Intellectual Property Nationalism*, *supra* note 24, at 146–47.

[49] *E.g.*, Ashleigh Furlong, *Big Vaccine Makers Reject Offers to Help Produce More Jabs*, POLITICO (May 14, 2021, 12:21 PM), https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/ [https://perma.cc/8UEA-PRDX]; *see also Experts Identify 100 Plus Firms to Make Covid-19 mRNA Vaccines*, HUM. RIGHTS WATCH (Dec. 15, 2021), https://www.hrw.org/news/2021/12/15/experts-identify-100-plus-firms-make-covid-19-mrna-vaccines [https://perma.cc/2F46-ZM4J] (noting over 100 firms that could make mRNA vaccines).

[50] *E.g.*, *MSF: Following Full FDA Approval, Pfizer-BioNTech Must Share COVID-19 Vaccines to Boost Global Supply*, MEDECINS SANS FRONTIERES (Aug. 23, 2021), https://www.doctorswithoutborders.org/latest/msf-following-full-fda-approval-pfizer-biontech-must-share-covid-19-vaccine-technology-boost [https://perma.cc/BNF2-5FH4].

[51] *E.g.*, Schofield, *supra* note 13.

[52] *E.g.*, *Pandemic Accord: MSF's Comments on Equity Provisions in Zero Draft: Technical Brief*, MEDECINS SANS FRONTIERES, Apr. 2023, at 11, https://msfaccess.org/sites/default/files/2023-04/TechBrief_MSF-AC-Pandemic-Accord-Zero-Draft_EN_April2023.pdf [https://perma.cc/KT4E-G6SY] ("All three licenses offered by companies Merck, Pfizer and Shionogi exclude many middle-income countries from the license territories.").

[53] *E.g.*, *id.* (describing Merck's licensing of its molnupiravir license with the "unacceptable clause that undermines the legitimate right to challenge the validity of patents held by the

solidarity, but they also undermined national security with respect to protection from infectious disease, as well as global security for all countries.

2. International IP obligations complicate pandemic options

In light of inadequate voluntary sharing of IP that compounded the problem of vaccine nationalism, overcoming the IP rights that usually preclude making IP-protected treatments became necessary. After all, a patent typically permits its owner to bar all others from making a patented invention. Although each nation can technically modify its laws to permit overriding IP rights for emergency purposes, most nations must maintain certain IP obligations due to international agreements, and are subject to sanctions if they do not.[54] Since South Africa was previously pressured to modify its domestic laws intended to address an HIV epidemic as allegedly incompatible with international laws, it is not surprising that developing countries sought to suspend international obligations to provide domestic IP rights for members of the WTO. Although there are other international agreements requiring or protecting IP rights, the WTO has the broadest membership with over one hundred sixty country members.[55] In particular, the WTO Agreement on TRIPS generally requires WTO members, except least-developed countries (LDC), to provide minimal levels of intellectual property rights, such as patents and trade secrets, in their domestic law.[56] If countries do not meet this minimum standard, they are subject to challenges from other countries that can lead to withdrawal of WTO benefits.[57]

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licensor").

[54] *E.g.*, *infra* notes 55–56.

[55] *WTO Members*, WORLD TRADE ORGANIZATION [WTO] (2021), https://www.wto.org/english/res_e/booksp_e/sli_e/4wtomembers.pdf [https://perma.cc/86GT-6KRD]. Other international free trade agreements concluded since the WTO/TRIPS often require more protection of IP rights. *E.g.*, Md. Deen Islam et al., *Impacts of Intellectual Property Provisions in Trade Treaties on Access to Medicine in Low and Middle Income Countries: A Systematic Review*, 15 GLOBALIZATION & HEALTH, no. 88, 2019, at 1, 2; Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TTP*, 18 J. INTELL. PROP. L. 447 (2011). In addition, there are some international agreements protecting investments of foreign companies that also restrict countries from modifying IP rights that could negatively impact these investments. *E.g.*, Cynthia Ho, *A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings*, 6 U.C. IRVINE L. REV. 395 (2017).

[56] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 1.1, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter *TRIPS*]. Technically, TRIPS requires protection of undisclosed information without mandating that a specific type of form be used, such as trade secrets. *See id.* art. 39.

[57] Understanding on the Rules and Procedures Governing the Settlement of Disputes, art. 22, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401.

India and South Africa proposed waiving IP obligations under TRIPS as a first step to enable countries to make pandemic products such as COVID vaccines.[58] Notably, any waiver of TRIPS obligations would not automatically change domestic IP laws. So, countries that did not want to modify their own domestic laws would not be obligated to do so. However, a waiver is an important step for nations desiring to modify domestic laws without international liability under the WTO as well as without unilateral pressure from other countries.[59] This request was strongly opposed by a few countries, including Germany, that are home to multinational pharmaceutical companies.[60] Although the United States typically promotes strong IP rights, it was an early proponent of a TRIPS waiver—but only for vaccines, not treatments.[61] Around the time that the United States noted support to waive TRIPS provisions for vaccines, an independent report commissioned by the WHO noted an urgent need for countries and manufacturers to voluntarily license COVID vaccines, or otherwise to promptly waive IP obligations pursuant to TRIPS.[62]

a. The inadequacy of the 2022 TRIPS COVID waiver agreement

In 2022, more than eighteen months into the pandemic, countries reached a limited waiver of TRIPS obligations to purportedly address COVID.[63] The only affirmatively waived obligation was a usual requirement for complex compulsory licensing of patented inventions for export to countries who could not manufacture the invention; the usual

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[58] Communication from 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).

[59] Even had this proposal been fully adopted, some nations may have needed to waive IP obligations required under other international agreements. *E.g.*, Carlos Correa et al., *Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements*, SOUTH CTR., Sep. 2021, at 5–7, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4083056 [https://perma.cc/6V96-XBTH].

[60] *E.g.*, Kerry Cullinan, *World Leaders Call on Future German Chancellor to Support TRIPS Waiver*, HEALTH POL'Y WATCH (Sept. 15, 2021), https://healthpolicy-watch.news/pressure-on-future-german-leader-to-support-trips-waiver/ [https://perma.cc/K63N-9QDX]; Samuel Horti et al., *Who Killed the Vaccine Waiver?*, BUREAU INVESTIGATIVE JOURNALISM (Oct. 11, 2022), https://www.thebureauinvestigates.com/stories/2022-11-10/who-killed-the-vaccine-waiver [https://perma.cc/B9WT-MVUD].

[61] *E.g.*, Andrea Shalal et al., *US Reverses Stance, Backs Giving Countries Access to COVID Vaccine Patents*, REUTERS (May 5, 2021, 2:10 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/ [https://perma.cc/BK5Y-LXHW].

[62] INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS & RESPONSE, COVID-19: MAKE IT THE LAST PANDEMIC 42–43, 63 (2021).

[63] *Ministerial Decision on the TRIPS Agreement*, WTO Doc. WT/MIN(22)/30 (June 22, 2022) [hereinafter *TRIPS COVID Waiver*].

requirement typically involves a number of steps for the exporting and importing countries.[64] This requirement is so cumbersome that it has only been used once in over twenty years.[65] Although waiving this requirement for all countries would be helpful, the actual TRIPS COVID waiver notably only applied to developing countries. Moreover, the waiver explicitly discouraged those most likely to have capacity to make exportable drugs from using it, thus further undermining its effectiveness.[66]

The waiver of this complex requirement only applies to COVID vaccines, not treatments. However, when WTO member countries finally adopted the 2022 waiver, there was little global demand for vaccines due to increased vaccine hesitancy compared to the height of the COVID pandemic.[67] In contrast, treatment was a priority for all countries, but was not covered by the waiver.[68] The agreement technically permitted countries to consider expanding its scope to include COVID treatments within six months, i.e. by December 2022.[69] This six-month deadline was at one point indefinitely extended due to differences of opinion; countries that had previously been resistant to adopt the original limited waiver, strongly opposed expansion.[70] After continued

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[64] *See TRIPS*, *supra* note 56, art. 31.

[65] *E.g.*, CYNTHIA HO, *Complicated Compulsory Licenses: The Waiver/Article 31bis 'Solution'*, *in* ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 195–217 (Oxford Univ. Press, 2011). Although there was interest in using this exception to import drugs made under compulsory license in Canada during COVID, it never happened because Canada's laws limit exports of drugs made under compulsory license for export to a limited number of conditions which were never amended to include COVID. *See* Arianna Schouten, *41 Canadian Experts Request Amendment to Schedule 1 of the Patent Act to Include COVID-19 Vaccines,* KNOWLEDGE ECOLOGY INT'L (Apr. 30, 2021), https://www.keionline.org/36017 [https://perma.cc/63FW-MRKW].

[66] *See TRIPS COVID Waiver*, *supra* note 63, ¶ 1 & n.1 (stating that "[d]eveloping country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves" of the waiver).

[67] In 2022, just a few months after the waiver was adopted, Gavi, a nonprofit that supplied vaccines to poor countries, ceased doing so due to lack of demand. *E.g.*, Stephanie Nolen, *Key Partner in Covax Will Stop Giving Free Vaccines to Middle-Income Nations*, N.Y. TIMES (Dec. 8, 2022), https://www.nytimes.com/2022/12/08/health/covid-vaccines-covax-gavi.html [https://perma.cc/SMD4-KTVJ].

[68] *TRIPS COVID Waiver*, *supra* note 63, ¶ 1 (covering COVID-19 vaccines only).

[69] The initial deadline was December 17, 2022, six months after the conclusion of the agreement. *See id.* ¶ 8.

[70] Report to the General Council, *Paragraph 8 of the Ministerial Decision on the TRIPS Agreement Adopted on 17 June 2022*, WTO Doc. IP/C/95 (Dec. 16, 2022); Communication from the Delegations of Bangladesh et al., *Decision Text on Extension of the June 17 Ministerial Declaration to COVID-19 Therapeutics and Diagnostics*, WTO Doc. WT/GC/W/913 (Dec. 4, 2023); *WTO Members Meet External Stakeholders to Continue Discussion on Extending TRIPS Decision*, WORLD TRADE ORG. (Sep. 28, 2023), https://www.wto.org/english/news_e/news23_e/trip_28sep23_e.htm [https://perma.cc/88M2-KUFM]; Thiru, *WTO: Prospects to Adopt Proposed Decision Text on the Extension of the 17 June 2022 Ministerial Decision to Covid-19 Therapeutics and Diagnostics Appear Grim*, KNOWLEDGE ECOLOGY INT'L (Dec. 13, 2023), https://www.keionline.org/39300 [https://perma.cc/GL8J-B3QD]; *see also* Letter from Council for Innovation Promotion to President

disagreements, the WTO then abandoned this attempt for expansion in February 2024.[71]

b. *Originally-proposed TRIPS waiver was still inadequate*

As countries consider how to avoid missteps during the COVID pandemic, they should recognize that even the originally proposed waiver was likely inadequate. The original proposal suggested waiving all TRIPS obligations regarding patents and trade secrets related to COVID treatments, diagnostics and personal protective equipment for three years from the date of decision.[72] However, as previously noted, the method of making complex biologic inventions, such as the mRNA vaccines for COVID, is typically protected as a trade secret. But waiver of trade secret "rights" does not result in automatic disclosure of the trade secret information. This is because trade secret "rights" only provide a right against someone who obtains the trade secret through improper actions such as stealing a trade secret. So, even if trade secret rights are waived under TRIPS and domestic laws, additional domestic laws are required to mandate disclosure of needed trade secrets. However, mandating disclosure of trade secrets would likely be highly controversial. Public disclosure would admittedly destroy the existence of a trade secret, because a trade secret loses its protection when it is publicly known. Trade secrets could be disclosed with safeguards for protection since this is the norm with voluntary sharing of trade secrets, and some scholars have argued that this should be done.[73] Considering that there were no known domestic laws requiring sharing of trade secrets at the time, this would likely be challenging to implement.[74]

Biden, (Dec. 4, 2023) (available at https://ipwatchdog.com/wp-content/uploads/2023/12/C4IP-Letter-on-Covid-19-IP-waiver.pdf [https://perma.cc/9A2H-GDV4]) (recommending that the United States formally oppose expansion of the waiver to COVID treatments as ineffective in addressing root problems); Guilherme Cintra, *Is an Extension of the TRIPS Waiver Needed for COVID-19 Tools?*, INT'L FED. PHARM. MFRS. & ASS'NS. (Oct. 13, 2022), https://www.ifpma.org/insights/is-an-extension-of-the-trips-waiver-needed-for-covid-19-tools/ [https://perma.cc/Q92A-GZ59] (arguing that supply of treatments exceeds demand).

[71] *E.g.*, Thiru, *WTO Charts a Course for Addressing the Role of IP in the Preparedness* for Future Pandemics, KNOWLEDGE ECOLOGY INT'L (Mar. 10, 2024), https://www.keionline.org/39490 [https://perma.cc/KS32-UDRE].

[72] Communication from 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); *e.g.*, Cullinan, *supra* note 60.

[73] *E.g.*, Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer*, 16 J. INTELL. PROP. L. & PRAC. 1242, 1243–44 (2021); David Levine & Joshua Sarnoff, *Compelling Trade Secret Transfers*, 74 HASTINGS L.J. 987 (2023).

[74] *E.g.*, Mark F. Schultz, *Trade Secrecy and COVID*, GENEVA NETWORK (Sept. 2021), https://geneva-network.com/wp-content/uploads/2021/09/Trade-secrets-and-Covid-19-1.pdf [https://perma.cc/5SWE-C53L]; Eric M. Solovy & Deepak Raju, *Recent Threats to Trade Secret Protection: Why Compulsory Licensing Is Not (and Should Not Be) a Viable Legal Option*, CTR. FOR

However, this could change. Brazil proposed such action during the COVID pandemic, and a proposed EU regulation for an EU-wide compulsory license to address emergencies also suggests requiring sharing of trade secrets necessary to effectively use compulsory license of a patent.[75]

In addition, as noted earlier, beyond trade secrets there is another legal barrier in the laws of countries that can pose a problem. Some countries recognize "data exclusivity" which can bar approval of a subsequent treatment based on clinical testing of the first approved drug. Although some companies claim this is required by TRIPS, others claim that TRIPS does not apply.[76] Technically, the TRIPS COVID waiver clarifies this is not an issue for the limited number of countries that can take advantage of the waiver.[77] However, there are other international agreements beyond TRIPS that mandate data exclusivity for some countries, but do not permit countries to create exceptions.[78] Accordingly, a waiver of these additional agreements would also be required.[79] Perhaps if the originally proposed waiver had been adopted, there would have been impetus to then negotiate additional waivers of these other agreements. However, without a waiver, there would still be a barrier to quick approval even if patent barriers were waived *and* trade secrets shared. Notably, the time to repeat these clinical studies can take several years, which could span the entirety of a pandemic.[80]

INTELL. PROP. x INNOVATION POL'Y (Oct. 2021), https://cip2.gmu.edu/wp-content/uploads/sites/31/2021/10/GMU-CIP2-Solovy-Raju-1021-WEB.pdf [https://perma.cc/PQD3-N85H].

[75] *E.g.*, European Commission, Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for Crisis Management and Amending Regulation (EC) 816/2006, COM/2023/224 final; Pimenta & DeMello, *infra* note 91.

[76] *E.g.*, CARLOS CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 388–391 (2007)(noting that although it would be permissible to provide data exclusivity as more than what TRIPS requires, TRIPS does not require data exclusivity); Cynthia M. Ho, *Avoiding the TRIPS Trap: A Path to Domestic Disclosure of Clinical Drug Data Consistent with International Norms*, 54 CORNELL INT'L L.J. 479, 483 (2021)(noting some countries and companies assume data exclusivity is required); Peter Yu, *Data Exclusivities and the Limits of TRIPS Harmonization*, 46 FL. STATE L. REV. 658–62 (2019) (noting that the provisions should be interpreted to mean that it does not require data exclusivity, contrary to positions of US and EU).

[77] *TRIPS COVID Waiver*, *supra* note 63, ¶ 4 (clarifying that "it is understood that Article 39.3 of the Agreement does not prevent an eligible member from enabling the rapid approval for use of a COVID-19 vaccine produced under this decision). However, this is not an actual change in the law. Rather, this simply reflects the position of many public health scholars and academics, even if it is contrary to the views of the pharmaceutical industry as well as some countries of the Global North.

[78] Only Malaysia, Chile and Columbia have exceptions to data exclusivity pursuant to trade agreements that permit exceptions. *E.g.*, 't Hoen, *Protection of Clinical Data*, *supra* note 36, at 192–93.

[79] *E.g.*, Ho, *Beyond Traditional IP*, *supra* note 29.

[80] Sara Jerving, *Without Shared Tech, South Africa's mRNA COVID-19 Jab Faces 2 Year Lag*, DEVEX (Feb. 4, 2022), https://www.devex.com/news/without-shared-tech-south-africa-s-mrna-covid-19-jab-faces-2-year-lag-102603 [https://perma.cc/NQA8-FCAK].

Moreover, there are international agreements protecting foreign investments that could result in substantial monetary damages if a country changes its domestic IP laws in a manner considered harmful to these investments. Even if there was an effective waiver of TRIPS, if a country then modified its domestic laws to take advantage of this waiver, this could result in domestic liability pursuant to these international agreements that protect IP as investments of foreign companies.[81] Moreover, whereas violations of TRIPS obligations do not immediately result in financial penalties, violation of agreements protecting foreign investments can and do result in substantial damages.[82] Although some scholars have suggested that companies would not bring such actions, or that a tribunal would not find liability, not all agree. Companies have brought actions against states in economic crises and it costs millions simply to defend against such suits.[83] Accordingly, a clear waiver or suspension of investment claims relating to IP during a pandemic is also needed as some recognized during COVID.[84] At bottom, the COVID pandemic demonstrated that not only is it inadequate to rely on voluntary actions by IP owning companies and countries, but that international agreements can constrain countries from addressing global public health concerns.

In addition to all of the above issues, another problem with the originally proposed TRIPS waiver during COVID was that although waiving IP rights was a needed first step, more would have been required to enable rapid manufacture of vaccines. Notably, creation of the most effective mRNA vaccines required adequate technological capacity that not all countries had, and some lacked any facilities to create vaccines.[85]

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[81] Cynthia Ho, *Potential Claims Related to IP and Public Health in Investment Agreements: COVID-19, the Proposed TRIPS Waiver and Beyond*, SOUTH CTR., Dec. 2021, at 3.

[82] *E.g.*, Jonathan Bonnitcha & Sarah Brewin, *Compensation under Investment Treaties: What Are the Problems and What Can Be Done?*, INT'L INST. FOR SUSTAINABLE DEV.,Dec. 202, at 1, https://www.iisd.org/system/files/2020-12/compensation-investment-treaties-en.pdf [https://perma.cc/48TZ-BE9J] (noting compensation can be in the millions or even billions, with over fifty cases of over 100 million); *see also* MATTHEW HODGESON ET AL., 2021 EMPIRICAL STUDY: COST, DAMAGES AND DURATION IN INVESTOR-STATE ARBITRATION (Brit. Inst. Int'l & Compar. L., 2021).

[83] *E.g.*, Correa, *supra* note 59, at 8.

[84] *E.g.*, PROPOSED TEXT AND COMMENTARY: AGREEMENT FOR THE COORDINATED SUSPENSION OF INVESTOR-STATE DISPUTE SETTLEMENT WITH RESPECT TO COVID-19-RELATED MEASURES AND DISPUTES, INT'L INST. FOR SUSTAINABLE DEV., at 2–3 (June 18, 2020), https://www.iisd.org/system/files/2021-02/suspension-isds-covid-19-en.pdf [https://perma.cc/UC5Z-4KE2]; Phil Bloomer et al., *Call for ISDS Moratorium During COVID-19 Crisis and Response*, COLUMBIA CTR. ON SUSTAINABLE INV. (May 6, 2020), https://www.bilaterals.org/?call-for-isds-moratorium-during [https://perma.cc/GZ7B-DTL6].

[85] *E.g.*, Xiaolan Fu et al., *The World has a Unique Opportunity: Accelerating Technology Transfer and Vaccine Production Through Partnerships*, 5 INT'L BUS. POL'Y 406, 407 (2022) (noting fewer than ten manufacturers in Africa with vaccine production capacity); Gregg Gonsalves & Gavin Yamey, *The Covid-19 Vaccine Patent Waiver: A Crucial Step Towards a "People's Vaccine"*, BRIT. MED. J., May 2021, at 1; Peter Hotez et al., *Producing a Vaccines Requires More Than a*

Although some opponents of a waiver considered this a reason to oppose any waiver, that is the wrong lesson. Rather, it is an important issue to consider in preparing for future pandemics, especially since developing adequate infrastructure takes time.[86] If more countries had technological capacity to make vaccines, this would help to not only create more overall capacity, but also avoid problems seen during COVID due to overreliance on a limited number of countries with manufacturing capacity. For example, although India had adequate technological capacity to make vaccines, when it imposed an export restriction due to a surge in domestic infections, this resulted in disruption of global supplies.[87]

III. LEARNING FROM THE COVID-19 PANDEMIC

A. Ideals for Addressing Pandemic IP

1. Pandemic IP should be a global public good

An optimal approach to providing adequate treatment for all would be to consider IP covering vaccines and treatments for a pandemic as "global public goods" that all would have access to, as I have previously argued.[88] A global public good refers to goods like air or knowledge which are freely available to all in that no one can be excluded; use by one does not diminish the good's availability to another.[89] IP is by definition an *intangible* property so its use does not limit its availability, unlike tangible property such as an apple or a vaccine dose. So, if IP for pandemic products were considered global public goods, everyone could use the IP necessary to create their own pandemic products and could satisfy demand—even if some countries engage in stockpiling.

Patent: Intellectual Property Is Just One Piece of an Elaborate Process, FOREIGN AFFS. (May 10, 2021), https://www.foreignaffairs.com/united-states/producing-vaccine-requires-more-patent [https://perma.cc/DR5T-E89B] (noting that only a handful of low- and middle-income countries currently have capacity to make new vaccines, with India being the largest).

[86] *E.g.*, Hotez, *supra* note 85 (noting that building adequate infrastructure for vaccine development takes time and requires thinking a decade ahead to properly invest).

[87] *E.g.*, *infra* notes 185–186 (noting problems with India export bans).

[88] *See* Ho, *Confronting Intellectual Property Nationalism*, *supra* note 24. Others also agree. *See, e.g.* Ellen 't Hoen, *The Pandemic Treaty and Intellectual Property Sharing: Making Vaccine Knowledge a Public Good*, BILL HEALTH (Oct. 15, 2021), https://blog.petrieflom.law.harvard.edu/2021/10/15/pandemic-treaty-intellectual-property/ [https://perma.cc/S5DV-Z8EA]; James Love, *Buying Know-How to Scale Vaccine Manufacturing*, MEDIUM (Mar. 20, 2021), https://jamie-love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36 [https://perma.cc/RGG7-SMK8]; Marianne Meijer et al., *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, 926 (2021).

[89] *E.g.*, Joseph E. Stiglitz, *Defining Global Public Goods*, *in* GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 308–10 (Inge Kaul et al. eds., 1999).

Of course, a tricky question is *how* to make needed IP a global public good completely free for use. Traditionally, IP rights are the exact opposite of public goods in that they often give their owners the right to exclude all others. Moreover, most nations are required to have certain IP rights in their domestic laws due to international obligations such as TRIPS. Nations could commit to preemptively waiving any international obligations regarding IP rights and then modify domestic laws.[90] However, the challenge with waiving just *one* international agreement during the midst of the COVID pandemic suggest that odds are low that waiver of IP obligations under all international obligations is possible. Moreover, as previously noted, even if international obligations regarding trade secrets are waived, nations must proactively enact additional laws to mandate that trade secrets be shared, which seems unlikely. During COVID there was only one country that suggested trade secrets be shared along with compulsory licensed patents, but that domestic legislation did not pass.[91]

An alternative method of enabling IP to be available for all to use, even if not a true public good at zero cost, would be to create mandatory pools of licensed IP that include not only patent rights, but also needed trade secrets and data exclusivity. A mandatory pool—with some reasonable compensation, as some scholars have suggested—would be a major step forward to ensuring that IP does not pose an unnecessary barrier to combatting a pandemic.[92] Although mandatory pools would admittedly be difficult to create, they could be consistent with international obligations if the license of each patent complied with relevant TRIPS obligations.

A mandatory IP pool for needed treatments has major benefits over individual compulsory licenses issued by separate countries for several reasons. First, although compulsory licenses exist in many nations, they are infrequently used and have cumbersome requirements imposed by international obligations that can create delays and complications. Second, even if compulsory licenses were more efficient and

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[90] *E.g.*, Paul Ogendi, *Addressing IP Barriers in the Context of a Pandemic Treaty*, BILL HEALTH (Dec. 22, 2021), https://blog.petrieflom.law.harvard.edu/2021/12/22/addressing-ip-barriers-in-the-context-of-a-pandemic-treaty/ [https://perma.cc/9GLX-H45Q] (arguing there is a need for a "radical paradigm shift" to enable suspension of IP rights during global pandemics); *No Pandemic Treaty Without Us (December Analysis)*, PUB. SERVS. INT'L (Dec. 7, 2023), https://publicservices.international/resources/digital-publication/no-pandemic-treaty-without-us-december-analysis?id=14291&lang=en [https://perma.cc/U3Z7-PN4A] (stating that all relevant technologies from public funded research should be unpatented and that should be a binding and automatic mechanism to waive IP during an emergency).

[91] *E.g.*, Machado Montaury Pimenta & Vieira de Mello, *New Bill About Compulsory License Sanctioned in Brazil*, LEXOLOGY (Sep. 3, 2021), https://www.lexology.com/library/detail.aspx?g=ed4922e6-357f-47de-bff5-9e1463eaec28 [https://perma.cc/37K9-P5TL].

[92] *See* Abbott & Reichman, *supra* note 11, at 543–44.

streamlined, a patent pool can provide a more effective global licensing scheme. In contrast to compulsory licenses that are issued by individual countries and thus only valid within those individual countries, a patent pool can aggregate licenses for multiple countries. Moreover, an additional benefit is that a patent pool enables pooling of IP beyond patents for which there are no compulsory license mechanisms. For example, the pool should include related trade secrets and regulatory marketing exclusivities such as data exclusivity. WHO recognized the need for these additional types of IP during COVID when it established C-TAP to accommodate all these types of IP. Of course, the problem with C-TAP was that companies declined to volunteer IP relating to any COVID vaccines.

Ensuring that IP essential to pandemics is a global public good is consistent not only with general human rights concerning the right to health and benefit from science, but especially with the concept of human security.[93] This concept focuses on individual security rather than territorial limits because individual security is often a function of interlinked global threats.[94] As stated recently in a U.N. Development Programme (UNDP) report concerning new threats to human security in the Anthropocene, global public goods can enhance, rather than constrain, sovereignty.[95] The report specifically recommended equity and universalism in healthcare,[96] recognizing that "not every 'security action' leads to greater human security, particularly if it leads to greater security for one group at the expense of the security of other groups."[97]

B. Pandemic Agreement Negotiations – A Potential Missed Opportunity

This section focuses on the proposed obligations for the WHO pandemic agreement primarily relating to IP and technology. Although a global public goods approach to pandemic IP would be optimal, that is nowhere close to reality. As will be discussed, the WHO Bureau of the Intergovernmental Negotiating Body draft IP provisions[98] are often

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[93] *E.g.*, U.N. DEV. PROGRAMME, *supra* note 18, at 3 (noting that the U.N. General Assembly endorsed the human security approach in 2012).

[94] *Id.* at 15.

[95] *Id.* at 27.

[96] *Id.* at 134.

[97] *Id.* at 24.

[98] The Intergovernmental Negotiating Body was established and charged with drafting and overseeing the pandemic agreement negotiations. *See Decision on Establishment of an Intergovernmental Negotiating Body to Strengthen Pandemic Prevention, Preparedness and Response*, World Health Organization [WHO] Doc. WHASS2/2021/REC/1, 6 (Dec. 1, 2021); *see also Intergovernmental Negotiating Body*, WORLD HEALTH ORG., https://inb.who.int [https://perma.cc/2KBW-JZAX].

diluted provisions which many see as inadequate, but which are nonetheless criticized as problematic by the pharmaceutical industry and some countries.[99] The proposed obligations are minimal and may even eventually be jettisoned since some countries have noted that they will not support an agreement that impacts IP rights.[100] Lack of support of IP provisions is not limited to countries in the Global North. Notably and somewhat surprisingly, after the December 2023 negotiations, WHO Director General Dr. Tedros, who previously strongly supported a broad TRIPS waiver during COVID, made statements indicating support for IP rights that seem to further undermine the likelihood of IP provisions that will promote greater global health.[101] Some countries made more aggressive suggestions during March 2024 negotiations, resulting in an unwieldy 100-plus pages of text, basically three times the length of the prior draft.[102] Some continued to oppose subsequent

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[99] *E.g.*, Aggrey Aluso, *An Equitable INB Pandemic Agreement: Deal or No Deal?*, PANDEMIC ACTION NETWORK (Mar. 15, 2024), https://www.pandemicactionnetwork.org/news/an-equitable-inb-pandemic-agreement-deal-or-no-deal/ [https://perma.cc/V8P3-EU64] (noting inadequate binding provisions to promote equity, especially regarding IP and technology transfer); Kerry Cullinan, *Time for Top Leaders to Join Pandemic Negotiations*, HEALTH POL'Y WATCH (Mar. 15, 2024), https://healthpolicy-watch.news/time-for-top-leaders-to-join-pandemic-negotiations/ [https://perma.cc/76E6-PF6T] (noting concern about IP provisions by some in civil society whereas the industry describes most recent language as a "step backwards"); Elaine Ruth Fletcher, *Exclusive: Updated Pandemic Accord Draft Sees Watered Down Text on Publicly-Funded R&D; Pathogen Access and 'Benefit Sharing' Linkage Remain*, HEALTH POL'Y WATCH (May 24, 2023), https://healthpolicy-watch.news/exclusive-updated-pandemic-accord-draft-sees-watered-down-text-on-publicly-funded-r-pathogen-access-and-benefit-sharing-linkage-remain/ [https://perma.cc/K34D-3JYV]. Steve Brachmann, *Updated WHO Pandemic Accord Retains Non-Exclusive Licensing and Royalty Waivers*, IPWATCHDOG (April 24, 2024, 3:15 PM), https://ipwatchdog.com/2024/04/24/updated-pandemic-accord-retains-commitments-non-exclusive-licensing-royalty-waivers [https://perma.cc/ZQ2Y-J2WT] (describing response to updated draft proposal).

[100] *E.g.*, Cullinan, *supra* note 15; *see also* Luke Taylor, *WHO Pandemic Treaty: Negotiations Falter as Pharma Companies Warn That Intellectual Property Rules Will Harm Profits*, BRIT. MED. J., Oct. 2023, at 1 (noting that Germany and most other European countries are opposed to any "major limitation" on IP); Mathari, *supra* note 14.

[101] Priti Patnaik, *WHO DG's Marked Shift on Intellectual Property: Cautions Against Undermining IP on Access to COVID-19 Tests & Treatments at WTO. Implications for "Equity" in Current Negotiations*, GENEVA HEALTH FILES (Dec. 20, 2023), https://genevahealthfiles.substack.com/p/who-dgs-marked-shift-on-intellectual [https://perma.cc/D6W7-PN4C]. Another factor undermining effective IP provisions an effective negotiator from the Global South withdrew from participation due to pressure from the Global North. *E.g.*, Priti Patnaik, *Exclusive: Did Some Developed Countries Oust Africa Group's Key Negotiator, a Forceful Voice on Equity Provisions in INB-IHR Negotiations?*, GENEVA HEALTH FILES (Dec. 1, 2023), https://genevahealthfiles.substack.com/p/us-eu-namibia-africa-pandemic-treaty-ihr-geneva [https://perma.cc/KAA8-9KDG] (noting pressure from United States and EU to replace effective negotiator from the influential Africa group); Jyotsna Singh, *Pandemic Treaty Continues to Negate Principles of Equity and Justice*, PEOPLES DISPATCH (Dec. 2, 2023), https://peoplesdispatch.org/2023/12/02/pandemic-treaty-continues-to-negate-principles-of-equity-and-justice/ [https://perma.cc/48RQ-L9N7] (noting the surprise withdrawal of delegate from Namibia who had previously been an effective response to high income country proposals).

[102] *E.g.*, Kerry Cullinan, *Pandemic (Dis) Agreement Talks Limp into Extra Time*, HEALTH POL'Y WATCH (Mar. 28, 2024), https://healthpolicy-watch.news/pandemic-dis-agreement-talks-limp-into-extra-time/ [https://perma.cc/98LZ-WH2X]; *see also March On Screen Draft Text*, World Health

streamlined WHO drafts with modest IP provisions, while others argued that they should be strengthened. [103] Most of the recently proposed provisions about IP and technology transfer are aspirational clauses, or only statements to consider action on topics such as promoting voluntary licensing[104] and relevant transfer of technology.[105] Nonetheless,

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Org. [WHO] Intergovernmental Negotiating Body (Mar. 27, 2024), https://keionline.org/misc-docs/who/inb9.wed.27march.pdf [https://perma.cc/J8B7-DXY3] [hereinafter *Pandemic Agreement March On Screen Draft*] (providing the March text as well as all proposals of countries).

[103] *See e.g.*, Brachmann, *supra* note 99 (describing response to updated draft proposal); Brett Schaefer & Steven Groves, *The WHO Pandemic Treaty Fails Again*, HERITAGE FOUND. (Apr. 19, 2024), https://www.heritage.org/global-politics/report/the-who-pandemic-treaty-fails-again [https://perma.cc/6ZMX-Z9BK] (same); Ellen 't Hoen, *The Last Mile: A Few Suggestions for the WHO Pandemic Agreement's Last Two Weeks of Talks*, MEDS. L. & POL'Y BLOG (Apr. 26, 2024). https://medicineslawandpolicy.org/2024/04/the-last-mile-a-few-suggestions-for-the-who-pandemic-agreements-last-two-weeks-of-talks/ [https://perma.cc/A9UW-FDX8] (providing insights into negotiations).

[104] *E.g.*, Seventh Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response: Provisional Agenda Item 2, *Proposal for Negotiating Text of the WHO Pandemic Agreement*, WORLD HEALTH ORGANIZATION [WHO] Doc. A/INB/7/3, art. 10(3), at 15 (Oct. 30, 2023), https://apps.who.int/gb/inb/pdf_files/inb7/A_INB7_3-en.pdf [https://perma.cc/DV9V-ZVSH] [hereinafter *Pandemic Agreement October Draft*] (encouraging promoting voluntary licensing and encouraging manufacturers and in particular those receiving significant funding to waive or manage royalties for pandemic related products); Ninth Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response: Provisional Agenda Item 2, *Revised Draft of the Negotiating Text of the WHO Pandemic Agreement*, WORLD HEALTH ORGANIZATION [WHO] Doc. A/INB/9/3, art. 11(3), at 12 (Mar. 13, 2024), https://apps.who.int/gb/inb/pdf_files/inb9/A_inb9_3-en.pdf [https://perma.cc/NS85-ZM87] [hereinafter *Pandemic Agreement March Draft*] (noting countries "shall . . . encourage" patent owners to forgo or charge reasonable royalties to developing country manufacturers, and especially those that received public funding); Resumed Ninth Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response: Provisional Agenda Item, *Proposal for the WHO Pandemic Agreement*, WORLD HEALTH ORGANIZATION [WHO] Doc. A/INB/9/3 Rev. 1, art. 11(1)(d)–(e), at 11 (Apr. 22, 2024), https://apps.who.int/gb/inb/pdf_files/inb9/A_inb9_3Rev1-en.pdf [https://perma.cc/VJT7-2MQL] [hereinafter *Pandemic Agreement April Draft*] (noting countries shall "encourage," but not require patent owners to forgo royalties or license patents at reasonable royalties and even for publicly funded patent owners this is only "where appropriate").

[105] *E.g.*, *Pandemic Agreement October Draft*, *supra* note 104, art. 11(1), at 15 (suggesting parties strengthen and develop mechanisms to pool IP and data that promote transfer of technology); *Pandemic Agreement March Draft*, *supra* note 104, art. 11(2), at 12 (stating countries shall "develop and strengthen, as appropriate . . . relevant technology transfer mechanisms " that including "pooling of knowledge, intellectual property, know-how and data); *Pandemic Agreement April Draft*, *supra* note 104, at art 11(1)(d), at 11 (requiring countries to "promote the transfer of relevant technology" but only on "mutually agreed terms and conditions"); *Pandemic Agreement May Draft, supra* note 17, at art 11(1)(suggesting that countries "promote" technology transfer and continuing to reference voluntary and mutually agreed terms, although there is no consensus on such language); *see also* Amnesty Int'l et al., *The Pandemic Treaty Zero Draft Misses the Mark on Human Rights: Joint Public Statement*, AMNESTY INT'L, at 3 (Feb. 24, 2023), https://www.amnesty.org/en/documents/ior40/6478/2023/en/ [https://perma.cc/FQ9N-5FVC] [hereinafter *Amnesty International Joint Public Statement*] (noting that article 7 on technology transfer fails to establish adequate obligations to promote human rights given language such as "strengthen," "promote" and "encourage" regarding any statements designed to ensure IP do not become a barrier to the right to health and science); MSF, Pandemic Agreement: MSF's Comments on Selected Provisions of the Draft Proposal Text, Briefing Document 3–4 (Sept. 2024), https://www.msfaccess.org/

this section examines recent proposals to understand what issues must be overcome to protect national security regardless of whether they are addressed in a pandemic agreement.

This section first explains international and domestic IP and technology barriers that should be addressed by an international pandemic agreement. Then, the section explains why trade secrets are a type of IP that require additional domestic laws during a pandemic. Lastly, this section addresses proposals concerning access and benefit sharing of technology that is related to contested IP issues.

1. International obstacles need to be addressed

Waiving international obligations that constrain nations from changing domestic IP laws is an important first step to addressing IP hurdles. Unfortunately, no WHO draft includes any language to suspend challenges under international investment agreements for modifications of IP rights.[106] In addition, even though countries have discussed a waiver of IP rights during a pandemic, some countries have objected to any inclusion. Recent proposals have either only modestly suggested that members "consider" a waiver, or do not even include any language concerning waivers at all.[107] Another prior proposal which

sites/default/files/2024-09/MSF-AC_Comments_INB_MayDraft_Final.pdf [https://perma.cc/PAL9-XR37] (noting weak obligations for ensuring public funding recipients share results and suggesting the need to delete provisions only requiring voluntary licensing of pandemic related health products).

[106] As some have noted, this should be included in article 11 to promote technology transfer. *E.g.*, Viviana Muñoz Tellez, *How Should the WHO Pandemic Treaty Negotiations Tackle Intellectual Property?*, 256 SOUTH CTR. 1, 2 (Feb. 22, 2024), https://www.southcentre.int/wp-content/uploads/2024/02/SV256_240222.pdf [https://perma.cc/G2DX-H85A]; *Backgrounder: Supporting Equitable Access to Medicine in the WHO Pandemic Agreement*, PUB. CITIZEN (Mar. 12, 2024), https://www.citizen.org/wp-content/uploads/Backgrounder-Supporting-Equitable-Access-to-Medicines-in-the-WHO-Pandemic-Accord.pdf [https://perma.cc/FU83-KEP2]; Letter from Cynthia Ho to Office of Global Affairs 4–5, 10 (Jan. 31, 2024) (available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4790210 [https://perma.cc/ZCV5-BUAW]) [hereinafter Letter from Cynthia Ho]. However, there are promising signs that such challenges could be eliminated from agreements in general. *E.g.*, Melanie Foley, *Victories in the Global Movement Against Corporate Globalization*, PUB. CITIZEN (Apr. 24, 2024), https://www.citizen.org/article/victories-in-the-global-movement-against-corporate-globalization/ [https://perma.cc/75TH-MYC5]. Notably, even the March document that contained specific language from different member countries designed to require countries to not exercise pressure on use of TRIPS flexibilities was silent on use of investment agreements. *See, e.g.*, *Pandemic Agreement March On Screen Draft*, *supra* note 102, art. 11, 4bis.

[107] *Pandemic Agreement March Draft*, *supra* note 104, art. 11(3)(b), at 12 (noting that members "consider supporting . . . time-bound waivers of intellectual property rights . . . [t]o increase the availability and adequacy of affordable pandemic-related products"); *Pandemic Agreement April Draft*, *supra* note 104, *passim* (containing no provision concerning waiver); *Pandemic Agreement, May Draft*, *supra* note 17, *passim* (containing no provision concerning waiver). In addition, the earliest WHO draft agreement modestly mentioned countries will take "appropriate measures" to support a waiver "to the extent necessary." Fourth Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response: Provisional Agenda Item 3, *Zero Draft of the WHO CA+ For the Consideration of the Intergovernmental Negotiating Body at its Fourth*

more forcefully stated that members would "commit to agree" to a time-bound waiver did so with the caveat that the waiver only apply "to the extent necessary."[108] This caveat is problematic since during the COVID pandemic some countries thought no waiver of TRIPS obligations was necessary.[109] Accordingly, a mandatory waiver of international agreements obligating IP laws, but without caveats concerning "the extent necessary" should be included, as well as suspension of challenges under international investment agreements.[110]

If an affirmative waiver of international obligations cannot be achieved, agreeing to not challenge countries that use flexibilities under international agreements such as TRIPS would be a next best step. However, recent proposals are not encouraging. The drafts from March and April 2024 acknowledge that countries have rights to use flexibilities under TRIPS to protect public health during pandemics.[111] No specific flexibilities or even references to specific TRIPS provisions are stated. However, clarification of the scope of flexibilities is important because these flexibilities technically existed during COVID, yet were considered inadequate on their own such that countries sought a waiver of TRIPS provisions.[112] Although some have suggested including specific TRIPS provisions that address flexibilities,[113] countries may

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Meeting: WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response ("WHO CA+"), WORLD HEALTH ORGANIZATION [WHO] Doc. A/INB/4/3 art. 7(4)(a) (Feb. 1, 2023), https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf [https://perma.cc/S7UX-R2QR] [hereinafter *Pandemic Agreement Zero Draft*].

[108] *Pandemic Agreement October Draft*, *supra* note 104, art. 11(3)(a), at 16.

[109] *E.g.*, Taylor, *supra* note 100.

[110] It would be desirable to clarify what IP obligations are waived and to waive them under TRIPS, as well as Free Trade Agreements, and also international obligations that protect IP, such as agreements protecting foreign investments. *E.g.*, Letter from Cynthia Ho, *supra* note 106, at 2–3.

[111] *Pandemic Agreement March 2024 Draft*, *supra* note 104, art. 11(4), at 12; *Pandemic Agreement April Draft*, *supra* note 104, art. 11(4), at 12 (stating that the party countries "reaffirm that they have the right to use, to the full, the flexibilities in the TRIPS Agreement, . . . which provide flexibility to protect public health in future pandemics, and shall fully respect the use of the TRIPS Agreement flexibilities by WTO members"). *See also Pandemic Agreement May Draft*, *supra* note 17, art 11(4), at 19 (noting some consensus, but not agreement for the word "Flexibilities" in TRIPS). In contrast, there is some mention of specific provisions such as article 30 and article 31 in an earlier draft. *Pandemic Agreement Zero Draft*, *supra* note 107, art. 7(4)(a), at 14.

[112] *E.g.*, Communication from India and South Africa, *supra* note 58 and accompanying text (noting proposal to waive TRIPS obligations during COVID); *see also* Carlos Correa, *Interpreting the Flexibilities under the TRIPS Agreement*, *in* ACCESS TO MEDICINES AND VACCINES (C.M. Correa & R.M. Hilty Eds., 2022) 1, 5–6 (noting lack of consensus concerning definition of TRIPS flexibilities, as well as the fact that developed countries resist use of these flexibilities).

[113] *See, e.g.*, *Response to U.S. Health and Human Services Department Request for Comments on Draft WHO Pandemic Agreement*, MEDS. L. & POL'Y, Jan. 22, 2024, at 1, 2, https://medicineslawandpolicy.org/wp-content/uploads/2024/01/Comments-by-MLP-for-US-RFC-Final.pdf [https://perma.cc/7FYZ-5XDC] (suggesting language referencing article 31 on compulsory licensing as well as article 73 on the security exception to TRIPS).

disagree on the relevant provisions, as well as their scope.[114] Accordingly, perhaps a pragmatic approach would be language requiring countries to refrain from formally challenging or even pressuring countries to avoid use of flexibilities.[115] This language was not in the April 2024 draft, but is included in the May 2024 draft, albeit that draft indicates there is no consensus on this language in contrast to some other provisions.[116] Inclusion of this explicit language to avoid indirect pressure on countries is preferable over ambiguous language in the April 2024 draft to simply "respect" use of flexibilities.[117] Moreover, there needs to be a bar on countries entering into new international agreements that would limit TRIPS flexibilities. Problematically such language was at one point included but has since been jettisoned from recent drafts.[118]

2. Domestic IP and technology barriers need to be addressed

In addition to removing international barriers to modifying domestic IP laws, an effective pandemic treaty should ensure that IP and technology barriers are overcome. An effective agreement could have countries agree to waive domestic IP laws for pandemic products and also

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[114] For example, although some scholars and health advocates have suggested that TRIPS article 30 can be broadly interpreted to provide exceptions from patent rights based on the Doha Public Health Declaration, that is a different interpretation than a WTO panel ruling that occurred before the Declaration was adopted. *E.g.*, Matthias Lamping, et al., *Declaration of Patent Protection: Regulatory Sovereignty Under TRIPS*, MAX PLANCK INST. FOR INNOVATION AND COMPETITION 4, 8 (2014) (explicitly stating that WTO panel was incorrect in its interpretation of TRIPS article 30 and that the factors stated in this article should not be viewed cumulatively on behalf of a number of scholars and advocates organized by the Max Planck Institute for Innovation and Competition), https://www.ip.mpg.de/fileadmin/ipmpg/content/forschung_aktuell/04_declaration_on_patent/patent_declaration_en.pdf [https://perma.cc/BX9K-MCUC]; Amy Tesoriero, *Using the Flexibilities of Article 30 TRIPS to Implement Patent Exceptions in Pursuit of Sustainable Development Goal 3*, 25 J. WORLD INTELL. PROP. 516, 519–21 (2022) (describing how article 30 can address the unbalanced effects of patents and that it should be interpreted differently today than the older panel ruling).

[115] *E.g.*, Thiru, *The WHO pandemic treaty: The Peace Clause and its discontents*, KNOWLEDGE ECOLOGY INT'L (Apr. 3, 2024), https://www.keionline.org/39585 [https://perma.cc/9JDC-GFSV] (quoting text proposed by some countries that proposes "[p]arties shall not challenge, or otherwise exercise any direct or indirect pressure on the Parties that undermine the right of WTO members to use TRIPS flexibilities" and noting that some health advocates endorsed this language).

[116] Pandemic Agreement *May Draft*, *supra* note 17, art 11(4), at 19; *Pandemic Agreement April Draft*, *supra* note 104, art 11, at 11–12 (containing no such language). Inclusion of this language is consistent with some prior proposals. *E.g.*, 't Hoen, *The Last Mile*, *supra* note 103.

[117] *Pandemic Agreement April Draft*, *supra* note 104, art. 11(4), at 12; *see also* Tellez, *supra* note 106, at 3–4 (recommending explicit language to not challenge actions under international obligations).

[118] *Compare Pandemic Agreement October Draft*, *supra* note 104, art. 11(4), at 16 (stating that parties shall, when engaged in bilateral or regional trade or investment negotiations, take steps so that the negotiated provisions do not interfere with the full use of the flexibilities provided in the TRIPS Agreement) *with Pandemic Agreement April Draft*, *supra* note 104, art. 11, at 11–12 (containing no such language) and *Pandemic Agreement May Draft*, *supra* note 17, art 11, at 17–20 (containing no such language).

amend domestic laws before a pandemic to ensure maximum flexibility during an emergency situation. Notably, although the March 2024 draft recognized the need for countries to update domestic laws for maximum flexibility under existing international agreements, such language is missing from the April 2024 draft.[119] Although some language requiring countries to review and consider amending domestic laws reappeared in the May 2024 draft, it remains unclear whether it will remain, especially since there is no consensus regarding the key language that this review should ensure use flexibilities under international agreements.[120] Moreover, overcoming IP is important, but not sufficient alone to enable manufacture of complex pharmaceutical products (such as vaccines or monoclonal antibody therapies) which require greater infrastructure and technical capacity than basic medicines. Accordingly, not just IP, but technology transfer—including knowledge about technological issues—is necessary. Technology transfer is especially important to ensure geographic diversity of production facilities that can overcome not only stockpiling, but also export bans. WHO drafts recognize this on some level in that there is a provision on transfer of technology for pandemic products; for example, the April 2024 draft states there is a need to "enable the sufficient, sustainable and geographically diversified production" of such products.[121] However, there is generally no proposed language requiring sharing of IP or technology transfer; most provisions are instead about encouraging action.[122]

Draft language suggests that countries will "promote or facilitate" transfer of technology and promote or incentivize public and private

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[119] *Compare Pandemic Agreement March Draft*, *supra* note 104, art. 11(5), at 12 *with Pandemic Agreement April Draft*, supra note 104, art. 11, at 11–12; *see also MSF's Comments on Selected Provisions of the Proposal for the WHO Pandemic Agreement*, MEDECINS SANS FRONTIERES, at 12–13 (Apr. 2024), https://msfaccess.org/msfs-comments-selected-provisions-proposal-who-pandemic-agreement [https://perma.cc/Q6B2-SZWR] (stating that omission is a "huge drawback" that should be reinstated).

[120] *Pandemic Agreement May Draft*, *supra* note 17, art 11(6), at 19.

[121] *E.g.*, *Pandemic Agreement April Draft, supra* note 104, art. 11(1), at 11; *see also Pandemic Agreement Zero Draft*, *supra* note 107, art. 7(1), at 14 (stating the Organization's recognition that inequitable access to pandemic products "should be addressed by increased manufacturing capacity that is more equitably, geographically and strategically distributed").

[122] *E.g.*, *Pandemic Agreement October Draft*, *supra* note 104, art. 10(3), at 15 (encouraging promoting voluntary licensing and encouraging manufacturers and in particular those receiving significant funding to waive or manage royalties for pandemic related products); *id.* art. 11(1) (suggesting parties strengthen and develop mechanisms to pool IP and data that promote transfer of technology); *Pandemic Agreement March Draft*, *supra* note 104, art. 11(3), at 12 (stating that countries "shall encourage" patent owners to forgo or charge reasonable royalties); *Pandemic Agreement April Draft, supra* note 104, art. 11(1)(d), at 11 (stating countries will "promote" technology transfer by private owners on "mutually agreed terms and conditions"); *see also Amnesty International Joint Public Statement*, *supra* note 105, at 3 (noting that article 7 of the Pandemic Agreement Zero Draft on technology transfer fails to establish adequate obligations to promote human rights given language such as "strengthen," "promote" and "encourage" regarding any statements designed to ensure IP do not become a barrier to the right to health and science).

investment aimed towards enabling facilities in developing countries.[123] However, having mechanisms to facilitate transfer of technology may not be adequate on its own. For example, during COVID there were multiple mechanisms to facilitate transfer of technology that were simply not used since they were voluntary. Stronger language should be included that specifies countries will affirmatively "take measures to facilitate, *or require*" transfer of technology.[124] Voluntary sharing is admittedly likely most efficient. However, language indicating that sharing could be required may prompt more voluntary sharing. After all, companies have provided substantial discounts on drug prices when faced with a potential compulsory license.[125] In fact, during the COVID pandemic after the first compulsory license in 2020 on an AbbVie drug, AbbVie promptly agreed to not enforce its patent at all, making it completely free during the pandemic.[126] Accordingly, the threat of required action can be effective at achieving desired results on promoting transfer of technology. Such transfer of technology is essential to promoting national security that depends on protecting public health.

To the extent that IP is owned by governments, or developed with government funding, governments have leverage to mandate sharing of IP, or to ensure pandemic products covered by IP are available at low-cost prices. However, negotiations to date have not resulted in optimal language in WHO drafts. The March 2024 draft states that countries shall make non-exclusive licenses available for government owned pandemic products and publish the terms in accordance with national law, without requiring terms be reasonable.[127] However, the April and May

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[123] *Pandemic Agreement May Draft*, *supra* note 17, art 11(1), at 17; *Pandemic Agreement March Draft*, *supra* note 104, art. 10(1)–(2), at 11; *Pandemic Agreement Zero Draft*, *supra* note 107, arts. 10.1(1)(e), 11(2), at 17, 19.

[124] *E.g.*, *Pandemic Agreement March Draft*, *supra* note 104, art. 11(1)(a), at 11; *see also The WHO Pandemic Instrument Must Address the Sharing of Knowhow/Trade Secrets: A Proposal for a New Measure.*, MEDS. L. & POL'Y (Sept. 25, 2023), https://medicineslawandpolicy.org/wp-content/uploads/2023/11/Revised-MLP-Proposal-for-knowhow-trade-secret-sharing_final.pdf [https://perma.cc/E6PN-F3WZ].

[125] *E.g.*, Charles Sauer, *Government May Attempt to Steal COVID Vaccine*, REALCLEAR HEALTH (June 17, 2020), https://www.realclearhealth.com/articles/2020/06/17/government_may_attempt_to_steal_covid_vaccine_111060.html [https://perma.cc/4V2P-6UEW] (noting a fifty percent price cut after the U.S. government threat to use patented drug without authority, subject only to reasonable compensation); *see also* Gorik Ooms & Johanna Hanefeld, *Threat of Compulsory Licenses Could Increase Access to Essential Medicines*, BRIT. MED. J., May 2019, at 1, 2–3 (suggesting threat of compulsory license could be effective).

[126] *E.g.*, Donato Paolo Mancini & Hannah Kuchler, *AbbVie Drops Patent Rights for Kaletra Antiviral Treatment*, FIN. TIMES (Mar. 23, 2020), https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b [https://perma.cc/7K6J-JBXV].

[127] *Pandemic Agreement March Draft*, *supra* note 104, art. 11(1)(c), at 12. It also required countries to "promote" publication of license agreements and technology transfer agreements for privately owned pandemic products. *Id.* art 11(1)(b). This is somewhat of an improvement over earlier drafts. *E.g.*, *Pandemic Agreement Zero Draft*, *supra* note 107, art. 11(1) (stating countries only "collaborate towards" licensing of government owned technologies on "mutually agreed terms");

2024 drafts have no language mandating countries make any licenses available, although it retains the obligation to publish terms of licenses in accordance with domestic law.[128] In addition, although governments should require effective sharing of government funded (but not completely government owned) pandemic products, the most recent drafts do not do so.[129] However, an earlier October draft required government-funded entities to waive or manage patent royalties of pandemic products for manufacturers in developing countries—although with the caveat that this would be "as appropriate."[130]

Given the modest provisions regarding IP owned by governments, or developed with government funding, it is perhaps not surprising that proposed language for technology sharing without any government financing is even weaker. For example, the March 2024 WHO draft merely suggests countries "encourage" companies that have patents on pandemic related products to *consider* forgoing or charging reasonable royalties, rather than actually sharing IP.[131] This minimal suggestion was proposed along with a suggestion for a limited duration waiver of IP to promote manufacture of pandemic related products.[132] However, the April 2024 draft removes mention of any waiver of IP, while still including a mere suggestion that "as appropriate" countries encourage patent owners not funded to consider this modest action.[133] This is admittedly in addition to a suggestion that countries consider supporting waivers of IP rights to permit manufacture of pandemic products. If the pandemic agreement has an affirmative requirement that IP rights will be waived, it would be less critical what prices patent owners charged for their products since others could make them. However, that language was eliminated in the April 2024 draft. Some language about a waiver reappeared in the May 2024 draft, although that language notably lacks agreement and only suggests inclusion "to the extent necessary."[134] Still, that is forward progress since the protracted negotiation

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Pandemic Agreement October Draft, *supra* note 104, art. 11(2)(b), at 19 (stating that countries would make non-exclusive licensing of government owned technologies available "on mutually agreed terms as appropriate").

[128] *Pandemic Agreement April Draft*, *supra* note 104, art 11(1)(b), at 11; *Pandemic Agreement May Draft*, *supra* note 17, art 11(1)(c), at 18; *see also MSF's Comments on Selected Provisions of the Proposal for the WHO Pandemic Agreement*, *supra* note 119, at 9–10 (recommending reinstatement of removed language).

[129] *E.g.*, *Pandemic Agreement March Draft*, *supra* note 104, art 11(1)(a), at 11; *Pandemic Agreement April Draft*, *supra* note 104, art 11(1)(a), at 11.

[130] *Pandemic Agreement October Draft*, *supra* note 104, art. 11(3)(b), at 16.

[131] *Pandemic Agreement March Draft*, *supra* note 104, art. 11(3)(a), at 12; *Pandemic Agreement April Draft*, *supra* note 104, art. 11(1)(e), at 11.

[132] *Pandemic Agreement March Draft*, *supra* note 104, art. 11(3)(b), at 12.

[133] *Pandemic Agreement April Draft*, *supra* note 104, art. 11, at 11–12.

[134] *Pandemic Agreement May Draft*, *supra* note 17, art 11(3), at 19 (referring to parties include "appropriate time-bound measures" to increase availability, accessibility, and affordability of

of the TRIPS waiver during COVID suggests that adopting an actual waiver during a pandemic is unlikely to be effective. Whereas the March 2024 draft countries were proposed to "promote" timely publication of terms of license and/or technology transfer agreements for pandemic-related products by private companies (without public funding), no such obligation exists in the April and May 2024 drafts.[135] Although transparency through publication of license terms might help ensure terms are reasonable, even without a specific obligation in an agreement, lack of any obligation to require actual publication of such licenses is problematic.

An effective international pandemic treaty should do more. For example, countries should be required to share government funded technology, and without caveats concerning potential limitations by national laws.[136] Obviously, nations must act consistently with domestic laws. However, to the extent current laws fail to properly promote adequate sharing, those laws should be amended, rather than be a shield that countries can use to avoid taking necessary action. In addition, countries should not only promote but *require* publication of terms of licenses by all companies.[137] Terms for at least publicly funded inventions should also require that pricing be affordable, as some have suggested.[138] In addition, countries should be required to retain the right to demand reasonably priced goods in the event that manufacturers fail to do so.

3. Trade secrets require special attention

Even if waiver of typical IP rights were required by a pandemic treaty, trade secrets pose an additional complication that has not been

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pandemic health products).

[135] *Pandemic Agreement March Draft*, *supra* note 104, art. 11(1)(b), at 12; *see also id.* art. 9(6)(b), at 10 (stating that parties "develop national policies" to publish terms of government funded research promoting equitable and timely access, but without any mandates for ensuring equitable and timely access); *Pandemic Agreement April Draft*, *supra* note 104, art. 11, at 11–12 (containing no requirement for publication of agreements by private companies, and instead only requiring publication of government license agreements); *id.* art. 9(4), at 10 (noting government funded research agreements might "as appropriate" include publication of "relevant information on research inputs and outputs"); *Pandemic Agreement May Draft*, *supra* note 17, art 11(1)(d), at 18 (noting encouragement for private right owners).

[136] *E.g.*, *MSF's Comments on Selected Provisions of the Proposal for the WHO Pandemic Agreement*, *supra* note 119, at 9.

[137] That would go farther than the March draft only suggesting countries "promote" publication of license agreements for pandemic products without public funding. *E.g.*, *Pandemic Agreement March Draft*, *supra* note 104, art 11(1)(b), at 12.

[138] *E.g.*, *Pandemic Accord: MSF's Comments on Equity Provisions in INB Proposal for Negotiating Text*, MEDECINS SANS FRONTIERES, Nov. 3, 2023, at 1, 8, (https://msfaccess.org/pandemic-accord-msfs-comments-equity-provisions-inb-proposal-negotiating-text [https://perma.cc/C7XK-84RD].

consistently recognized during negotiations. Even when patents are not a barrier, trade secrets alone can delay creation of needed treatments. Problematically, although the October 2023 draft for the first time expressly recognized the need to address trade secrets,[139] that language disappeared from the 2024 February draft.[140] The April 2024 draft resurrects language that could relate to trade secrets, but similar to the October language, it only modestly suggests manufacturers should be "encouraged" to share information.[141] However, the April draft only suggests companies to share information "as appropriate" if such information "hinders the urgent manufacture" of a pharmaceutical product that is "necessary" to respond to a pandemic.[142] The statement that companies be "encouraged" to share is not a requirement to do so; it is also exactly what the WHO Secretary had previously recommended during COVID, but did not happen.[143] Moreover, the caveat that only "necessary" information need to be shared is also troubling. As previously discussed, during the height of the COVID pandemic, some countries denied that any IP rights needed to be shared.[144] Moreover, this opposition was simply to the waiver of IP rights, and not even the admittedly more controversial suggestion of required disclosure of trade secrets. In addition, even after countries agreed to the TRIPS COVID waiver, the industry claimed that it was not "necessary" and continued to claim there was no need to expand the TRIPS waiver to include pharmaceuticals and diagnostics.[145] However, the industry position ignores

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[139] *Compare Pandemic Agreement Zero Draft*, *supra* note 107, art. 11, at 19–20 (providing no requirements concerning undisclosed information, and instead only singling out patents as a type of IP that must be addressed) *with Pandemic Agreement October Draft*, *supra* note 104, art. 11(3)(c), at 16 (stating that during pandemics countries are to encourage manufacturers to share undisclosed information with qualified third party manufacturers). The reference to "undisclosed information" is the same language used in TRIPS that is known to include trade secrets, which are by definition undisclosed under TRIPS art. 39(2). The term "undisclosed information" is arguably broader to include protection of information through other areas of law beyond IP.

[140] *See generally Pandemic Agreement March 2024 draft*, *supra* note 104; *Pandemic Agreement October Draft*, *supra* note 104 (including no language concerning undisclosed information).

[141] *Pandemic Agreement Pandemic Agreement April Draft*, *supra* note 104, art. 11(1)(f), at 11; *see also Pandemic Agreement May Draft*, *supra* note 17, art 11(1)(f), at 18 (including language, but without agreement on whether it is voluntarily shared or not).

[142] *Pandemic Agreement Pandemic Agreement April Draft*, *supra* note 104, art. 11(1)(f), at 11–12. This is somewhat similar to the October language except that the October language specifically referenced the relevant TRIPS article provision and also mentioned that the sharing was with "qualified" manufacturers. *Pandemic Agreement October Draft*, *supra* note 104, art. 11(3)(c), at 16. Although the unnecessary "qualified" caveat is removed, the addition of "as appropriate" seems to be a similar unnecessary caveat that might bar needed sharing.

[143] *Pandemic Agreement October Draft*, *supra* note 104, art. 11(3)(c), at 16.

[144] *E.g.*, Horti, *supra* note 60 (noting countries that opposed waiver of TRIPS obligations during COVID, a list that included wealthy countries as well as some low and middle income countries, with some lower income countries having been pressured to do so by pharmaceutical industry lobby).

[145] *Pharmaceutical Industry Expresses Deep Disappointment With Decision on Waiving*

that unvaccinated individuals unnecessarily risk mortality from COVID infections.[146]

To effectively address trade secret hurdles to ensure the stated goal of equitable access to treatments, a binding international agreement should require countries to share needed trade secrets. For example, an effective pandemic agreement could state that when the manufacture of pharmaceutical products is necessary to address a pandemic, but hindered through lack of access to trade secret, countries shall compel sharing of that information with qualified third parties and with adequate protection of their interests.[147]

4. Benefit sharing of technology and products

Another opportunity to promote equity for countries that would complement sharing IP and technology, or even be used in lieu of shared IP, would be mandatory benefit sharing of pandemic products. However, this is highly contentious.[148] Many developed countries are eager for a pandemic agreement to include provisions mandating the sharing of biologic material with pandemic potential that could then be used to develop treatments. However, they are less eager to agree to obligations to share treatments derived from such material, even though there are some international norms ratified by most WHO member states such as

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Intellectual Property Rights Adopted at the World Trade Organization Ministerial Conference, INT'L FED. PHARM. MFRS. & ASS'NS. (June 17, 2022), https://www.ifpma.org/news/pharmaceutical-industry-expresses-deep-disappointment-with-decision-on-waiving-intellectual-property-rights-adopted-at-the-world-trade-organization-ministerial-conference/ [https://perma.cc/U5LW-NE4V]; IFPMA et al., *WTO Ministerial Conference in Abu Dhabi is an Opportunity to Strengthen Trade and Health Agenda*, INT'L FED. PHARM. MFRS. & ASS'NS. (Feb. 23, 2024), https://www.ifpma.org/news/wto-ministerial-conference-in-abu-dhabi-is-an-opportunity-to-strengthen-trade-and-health-agenda/ [https://perma.cc/FZK3-8G9N].

[146] *E.g.*, *Three Reasons to Support TRIPS Decision Extension*, PUB. CITIZEN (Nov. 28, 2023), https://www.citizen.org/article/three-reasons-to-support-the-trips-decision-extension/ [https://perma.cc/Q33P-W4A4] (noting COVID deaths are four times higher in poor countries with low vaccination rates); Letter from Jan Schakowsky et al. to Ambassador Katherine Tai (Feb. 5, 2024) (available at https://schakowsky.house.gov/sites/evo-subsites/schakowsky.house.gov/files/evo-media-document/Letter%20Supporting%20TRIPS%20Waivers%20for%20COVID-19%20Therapeutics%20and%20Diagnostics.pdf [https://perma.cc/QYY2-9X2B]) (noting that individuals remain at risk of death from lack of access to COVID-19 therapeutics and diagnostics).

[147] *E.g.*, *Response to U.S. Health and Human Services Department Request for Comments on Draft WHO Pandemic Agreement*, *supra* note 113; Christopher Garrison, *It is Not Too Late to Solve the Know-How Problem in the WHO Pandemic Accord*, MED. L. & POL'Y (Mar. 5, 2024), *https://medicineslawandpolicy.org/2024/03/it-is-not-too-late-to-solve-the-know-how-problem-in-the-who-pandemic-accord/* [https://perma.cc/6SWQ-6VED]; 't Hoen, *The Last Mile*, *supra* note 103.

[148] *E.g.*, Cohen, *supra* note 13, at 1277 (noting this is a contentious issue). The E.U. omitted benefit sharing entirely from its December proposal while considering to "study the issue." Schofield, *supra* note 13. A group of members from the European Parliament criticized the E.U. position as inconsistent with recommendations of the European Parliament that there should be obligations, not just encouragement to transfer technology and know-how including trade secrets to maximize global production and supply. Schofield, *supra* note 13.

the Nagoya Protocol that suggests parties equitably share benefits with the country providing a genetic resource.[149]

The gist of the access and benefit sharing proposal is that consistent with these international norms, when countries share genetic material with pandemic potential, they are guaranteed to receive benefits in exchange for that contribution. WHO drafts suggest manufacturers will provide to the WHO 10% of treatments for free and 10% at not-for profit prices, as well as annual monetary contributions.[150] However, these amounts are likely insufficient to address needs for all developing countries if countries were to rely on them alone, which would be the case if they lacked the IP rights and technology to make their own products.[151] The March 2024 draft also suggests that individual countries set aside some pandemic products for countries facing challenges addressing domestic health needs, but without any specific obligations and only if a country was "in a position to do so." [152] This could simply replicate the inadequate and often untimely donations of COVID vaccines. However, even this vague suggestion does not exist in the April and May 2024 drafts.[153]

The contentious access and benefit sharing provisions are actually a second-best solution to mandating the provision of low-cost pandemic products or requiring sharing of IP and technology. After all, there is no true precedent for utilizing such a system and there could be some merit to the claims of industry that these provisions will impose cumbersome and time consuming measures.[154] There are also commentators that

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[149] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity art. 5(1), Oct. 12, 2014, 3008 U.N.T.S. 1. During COVID, China did share genetic material from COVID that was used by pharmaceutical companies to make highly profitable COVID vaccines, but China received no financial or other compensation. This is unfortunately often the case since there is no WHO mechanism requiring equitable sharing of benefits outside the WHO Pandemic Influenza Preparedness framework, which has not thus far resulted in actual benefit sharing. *E.g.*, Nirmalya Syam, *The WHO CA+ Discussions on Pathogen Access and Benefit Sharing: State of Play*, SOUTH CTR., at 2 (Dec. 14, 2023), https://www.southcentre.int/policy-brief-123-14-december-2023/ [https://perma.cc/D62P-8UT4].

[150] *Pandemic Agreement March Draft*, *supra* note 104, art. 12(6)(b), at 13; *Pandemic Agreement April Draft*, *supra* note 104, art. 12(3)(b), at 12.

[151] Some have suggested that a fixed proportion of total quantity is not desirable. *E.g.*, *Pandemic Agreement: MSF's Comments on Selected Provisions of Revised Draft of Negotiating Text*, MEDECINS SANS FRONTIERES, at 12 (Mar. 2024), https://msfaccess.org/sites/default/files/2024-03/MSF-AC-INB9%20text-selected%20provisions-comments_Final_Mar2024_ENG.pdf [https://perma.cc/C5HM-C75L].

[152] *Pandemic Agreement March Draft*, *supra* note 104, art. 12(9), at 14.

[153] *See generally Pandemic Agreement April Draft*, *supra* note 104, art. 12, at 12–13 (providing no mention of setting aside treatments); *Pandemic Agreement May Draft*, *supra* note 17, art 12, at 19–22 (providing no mention of countries setting aside treatments).

[154] IFPMA et al., *Delivering Equitable Access in Pandemics: Biopharmaceutical Industry Commitments*, INT'L FED. PHARM. MFRS. & ASS'NS. (Mar. 11, 2024), https://www.ifpma.org/news/delivering-equitable-access-in-pandemics-biopharmaceutical-industry-commitments/

suggest any mechanism for access and benefit sharing is fundamentally at odds with the principles of equity in suggesting a transactional approach.[155] However, the Global South may view such a mechanism as the best opportunity to obtain needed treatments in exchange for agreeing to provide the Global North access to genetic material from pathogens that is needed to create pandemic treatments. Even if this mechanism may be imperfect, it could be an additional opportunity to require sharing of IP and technology, especially if the eventual agreement has language similar to the April 2024 draft that suggests that the details of these mechanism will be finalized by 2026.[156] There remains an opportunity to require sharing of IP or technology with countries that contribute genetic material, as preferable to industry than cash payments.[157]

5. Enforceability

Even if ideal IP provisions were included, a critical issue is whether any obligations are enforceable.[158] This is a tough issue to address in many international agreements. The TRIPS/WTO framework is notable among other international agreements for having some semblance of enforceability because of its broad scope such that noncompliance with one aspect of the agreement can result in loss of benefits under another

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[https://perma.cc/5N5R-SYRH] (arguing that rapid access to genetic materials is needed and would be stymied by benefit sharing obligations); *see also* Abbie-Rose Hampton et al., *Equity in the Pandemic Treaty: Access and Benefit-Sharing as a Policy Device or a Rhetorical Device?*, 51 J. L. MED. & ETHICS 217, 219 (2023) (arguing that access and benefit sharing may encourage countries to withhold samples to secure better terms through bilateral agreements); Sally Mueni Katee & Christian Keambou Tiambo, *Discussing the Drawbacks of the Implementation of Access and Benefit Sharing of the Nagoya Protocol Following the COVID-19 Pandemic*, 9 FRONTIERS PUB. HEALTH, Dec. 2021, at 1, 7–9 (suggesting drawbacks to access and benefit sharing).

[155] Hampton et al., *supra* note 154, at 218 (arguing that such a system improperly suggests that equity is transactional).

[156] *Pandemic Agreement April Draft*, *supra* note 104, art. 12(6), at 13 (stating that terms will be defined in a legally binding instrument operational by May 31, 2026). However, this timeline does not exist in the May draft. *See generally Pandemic Agreement May Draft*, *supra* note 17, art. 12, at 22.

[157] *E.g.*, Elaine Ruth Fletcher, *Pharma Pivot on Pandemic Agreement, Free Access to Pathogens in Exchange for Binding Obligation on Equity*, HEALTH POL'Y WATCH (Mar. 21, 2024), https://healthpolicy-watch.news/industry-pivot-binding-obligation-on-equity-in-exchange-for-free-access-to-pathogens-in-pandemic-accord/ [https://perma.cc/4NZD-ZYP3].

[158] *E.g.*, Elliot Hannon et al., *WHO Member States are Negotiating a Pandemic Treaty. But Will Countries Follow the New Rules?*, BULL. ATOMIC SCIENTISTS (Feb. 15, 2024), https://thebulletin.org/2024/02/who-member-states-are-negotiating-a-pandemic-treaty-but-will-countries-follow-the-new-rules/ [https://perma.cc/HNE6-DL55]. Moreover, enforceability is notably only an issue for countries that actually agree to sign on to language of the concluded treaty. The U.S., for example, has often participated in treaty negotiations, but not signed on to concluded provisions. *E.g.*, German Velasquez, *Where is the Binding International Treaty Negotiated at the WHO Against Future Pandemics Going?*, SOUTH CTR. at 6 (Mar. 15, 2024), https://www.southcentre.int/wp-content/uploads/2024/03/SV259_240315.pdf [https://perma.cc/P3MN-6FP6] (noting the United States' refusal to ratify Framework Convention on Tobacco Control that it negotiated).

aspect of the agreement.[159] Enforceability of an international pandemic agreement is challenging in that unlike the TRIPS/WTO framework, it is focused on one area, making it more similar to international agreements before TRIPS that were effectively unenforceable.[160]

The May 2024 draft includes some aspect of governance that can promote accountability, but only in a modest form. The draft shows agreement for a "Conference" of the parties to review implementation of the agreement, but only every five years, rather than annually, or even every three years as previously proposed (although there can be extraordinary sessions as necessary).[161] This Conference of the parties is designed to adopt "appropriate measures" that are not defined. There is also a provision for dispute settlement, but the May 2024 draft notes countries have agreed to address disputes through "diplomatic channels."[162] This seems unlikely to provide adequate impetus for mandating compliance and also provides no means for an independent arbiter that might be especially helpful for disputes between countries with

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[159] Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 22.3(c), Apr. 15, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments – Results of the Uruguay Round, 33, ILM 1125 (1994). *See also* Cynthia Ho, An introduction to TRIPS, *in* ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 55, 58 (Oxford Univ. Press, 2011) (noting that enforcement of WTO agreements such as TRIPS is an improvement over prior international agreements that could not effectively sanction noncompliance since the process permits suspension of benefits under a different WTO agreement); Armal Vargas, *Cross-retaliation in IP Rights: Addressing Member Asymmetries and compliance at the WTO*, WOLF PUBLISHING, Jan. 2012, at 1, 108, 113, https://cris.maastrichtuniversity.nl/ws/portalfiles/portal/1131937/guid-328e1209-507e-4945-9d73-2a2f39b3bb6d-ASSET1.0.pdf [https://perma.cc/F5YH-9DH3] (explaining cross-retaliation option as potentially beneficial to developing countries); Int'l. Chamber Com. Comm'n. on Intell. Prop., *Cross-Retaliation under the WTO Dispute Settlement Mechanisms Involving TRIPS Provisions*, INT'L. CHAMBER COM. (June 29, 2012), https://www.wto.org/english/forums_e/ngo_e/cross_retaliation_2012_e.pdf [https://perma.cc/733S-W8QG] (advocating that countries not utilize this option). However, some have suggested that the benefits are more theoretical than practical with respect to suspending IP obligations for violations of other parts of WTO agreements. *E.g.*, Sarah R. Wasserman Rajec, *The Intellectual Property Hostage in Trade Retaliation*, 76 MARYLAND L. REV 169 (2016).

[160] The predecessor of the TRIPS/WTO framework had a dispute settlement system that was considered ineffective. *E.g.*, CHRISTOPHER A. CASEY & CATHLEEN D. CIMINO-ISAACS, CONG. RSCH. SERV. IF10645, DISPUTE SETTLEMENT IN THE WTO AND U.S. TRADE AGREEMENTS 1 (2021) (noting that predecessor to TRIPS/WTO framework was ineffective); Hanz P. Kunz-Hallstein, *The United States Proposal for a GATT Agreement on Intellectual Property and the Paris Convention for the Protection of Industrial Property*, 22 VAND. J. TRANSNAT'L L. 265, 278–282 (1989) (describing enforcement issues with Paris Convention for IP that preceded TRIPS/WTO); *see also* Steven J. Hoffman et al., *International Treaties Have Mostly Failed to Produce their Intended Effects*, PROC. NAT'L ACAD. SCIS., Aug. 2022, at 5–6.

[161] *Pandemic Agreement May Draft*, *supra* note 17, art 21(2); *Pandemic Agreement March Draft*, *supra* note 104, art. 21(2), at 23 (establishing Conference frequency of once every three years) *with Pandemic Agreement October Draft*, *supra* note 104, art. 21(4)(a), at 25 (establishing annual Conference frequency); *see also Pandemic Agreement March Draft*, *supra* note 104, art. 21(4), at 24 (providing for extraordinary sessions); *see also* Aluso, *supra* note 99 (noting reintroduction of conference of Parties governance structure).

[162] *Pandemic Agreement May Draft*, *supra* note 17, art. 25 (1), at 31. This is similar to a prior draft. *Pandemic Agreement March Draft*, *supra* note 104, art. 25(1), at 25.

power imbalances. Without any true repercussions for noncompliance, even stronger obligations concerning IP sharing are likely of no real utility.

Although it is very late to introduce effective enforcement mechanisms, this is an issue that is sorely in need of resolution and should build upon prior lessons. Leveraging different interests within the pandemic agreement could be utilized similar to the different sectors of the WTO framework. For example, perhaps noncompliance with sharing of IP could result in a member country being denied access to their desired pathogen samples. This would somewhat parallel the situation under the dispute process of the WTO where noncompliance under one provision, such as IP, could result in loss of benefits under another, such as trade. This seems unlikely to be included in the actual agreement given the many other issues to address in the final days of negotiation. However, perhaps this is something that the Conference of the parties can address in the future.

C. Addressing Incomplete Consensus on IP and Technology for an International Pandemic Agreement

1. Reasons for disagreement and implications

A fundamental reason for the lack of progress, and even backsliding of IP provisions in the pandemic agreement language, is an absence of consensus. In particular, there seems to be disagreement concerning the need to even address IP in future pandemics.[163] Despite alleged recognition of gross inequity during the COVID pandemic for timely and equitable access that requires a "comprehensive international response," the role of IP barriers in providing a response is disputed.[164] Draft preambular language states that "protection of intellectual property rights is important for the development of new medical products" before stating that such rights "do not and should not" prevent public health measures.[165] This fails to recognize that IP can, and in fact did, prevent countries from protecting public health during COVID when capable suppliers could not make vaccines due to COVID. In addition, draft language has consistently recognized "concerns about the effects of intellectual property rights on prices." But for some countries, there were no COVID vaccines available at any price.

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[163] Considering that countries disagree on the need to even address IP, that means that there is also an implicit rejection of the idea that pandemic IP should be a global public good.

[164] *E.g.*, *Pandemic Agreement March Draft*, *supra* note 104, art. 3, at 4 (noting equity as goal and outcome of pandemic prevention, preparedness, and response).

[165] *Id.* pmbl., at 2.

Pharmaceutical companies and many countries home to such companies assert that any change to IP rights, including changes far more modest than IP being a global public good, will harm innovation for needed treatments.[166] Some corporate assertions seem inconsistent with reality. For example, companies alleged that IP "resulted in global equitable access to COVID-19 therapeutics at breakthrough speed."[167] However, even though treatments were developed at breakthrough speed, the need for a pandemic treaty to address widespread global inequities seems to clearly contradict the assertion that there was equitable access.

The claim that waiving IP will harm innovation is likely a red herring. First, IP alone may not result in socially needed innovation. As many developing countries know, IP has not been an adequate incentive to develop treatments for neglected diseases that predominantly impact these countries. Companies are not interested in developing treatments for countries that lack resources to pay the premium associated with new, typically patented treatments.[168] Inadequate profit incentives also result in inadequate new antibiotic development—even though countries with adequate resources would be interested in these—because it is challenging to charge high prices for antibiotics as opposed to gene therapy or cancer treatments.[169] Second, although companies claim that IP is essential to promote allegedly risky and expensive research, the reality is that only a fraction of new drugs are expensive to develop and companies actually spend substantial amounts of money not on innovative research, but on advertising and executive compensation.[170]

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[166] *E.g.*, Cintra, *supra* note 70; Fabi Fugazza, *Delay Likely on WTO Decision to Extend IP Waiver to COVID Therapeutics*, ITALIAN COAL. FOR C.L. & RTS. (Dec. 14, 2022), https://cild.eu/en/2022/12/14/delay-likely-on-wto-decision-to-extend-ip-waiver-to-covid-therapeutics/ [https://perma.cc/ZF95-GSNS]; Jake Johnson, *WTO Pens 'Love Letter to Patents' as World Suffers from Big Pharma Greed*, COMMON DREAMS (Feb. 14, 2024), https://www.commondreams.org/news/wto-patents-big-pharma [https://perma.cc/XB8X-TGW9].

[167] *Impact of a Waiver of Intellectual Property Rights for COVID-19 Therapeutics*, INT'L FED. PHARM. MFRS. & ASS'NS. (Dec. 5, 2022), https://www.ifpma.org/resources/impact-of-a-waiver-of-intellectual-property-rights-for-covid-19-therapeutics/ [https://perma.cc/C2K4-WSGM]. In addition, other claims are even more tenuous, such as the assertion that modifying IP rights poses a danger to public health. *E.g.*, Ho, *Confronting Intellectual Property Nationalism*, *supra* note 24, at 162 (describing such assertions as "groundless red herrings"). Domestic regulatory agencies, not IP owners or IP rights are what protects public health and safety.

[168] *E.g.*, Frank Mueller-Langer, *Neglected Infectious Diseases: Are Push and Pull Incentives Mechanisms Suitable for Promoting Drug Development Research?*, 8 HEALTH ECON. POL'Y & L. 185, 188–190 (2013); Gavin Yamey et al., *Funding Innovation in Neglected Diseases*, BRIT. MED. J., Mar. 2018, at 1.

[169] *E.g.*, Michael Anderson et al., *Challenges and Opportunities for Incentivizing Antibiotic Research and Development in Europe*, LANCET, Oct. 2023, at 9–10; Chantal M. Morel, *Industry Incentives and Antibiotic Resistance: An Introduction to the Antibiotic Susceptibility Bonus*, 73 J. ANTIBIOTICS 421, 421 (2020).

[170] MAJORITY STAFF OF H. COMM. ON OVERSIGHT AND REFORM, 107TH CONG., REP. ON DRUG PRICING INVESTIGATION 41 (2021) (finding companies are spending substantial money not on

Disagreements on changing IP rights may also reflect different views regarding whether addressing infectious diseases is fundamentally an issue of national security. Although this Article is premised on the assumption that national security requires addressing infectious diseases, that may not be the view of all countries. Some countries that oppose modifying IP laws to address infectious disease may assume that there will be no harm to their domestic interests, even though infectious diseases that only impact some countries (such as HIV/AIDS) can still indirectly impact national security of other countries. Unless countries recognize that changing IP rights is necessary to promote domestic as well as global security, to inequitable access to needed pandemic treatments will remain a problem. In addition, as discussed earlier, inequitable access to treatments for an infectious global pandemic threatens domestic and global security for all. Accordingly, failure to acknowledge and address IP barriers to effective treatment for all is short sighted.

2. Beyond the pandemic treaty

Although the pandemic treaty currently being negotiated is unlikely to require significant changes, countries can and should do more than what may be required, including stronger versions of suggestions in an agreement, or even jettisoned prior language. This section will mention some of these issues, as well as others that were not specifically proposed. Whereas WHO drafts have mildly proposed that countries promote or encourage sharing of technology and low or no cost licensing of IP, countries can do more.[171] For example, even though the pandemic treaty does not contemplate a mandatory IP pool, countries could create such pools.[172] In addition, individual countries could and should require as a condition of public funding that products developed through such funding are either free, or at least licensed on equitable terms. There is nothing to prevent countries from taking such an approach for all pandemic treatments, or even all inventions that are government funded, so that there is no need to argue about changing norms during a pandemic.[173] If governments are hesitant to incorporate such language in

research, but on executive compensation, stock buybacks and dividends); JISHIAN RAVINTHIRAN, PROFITS OVER PATIENTS: SPENDING ON SELF-ENRICHMENT EXCEEDS RESEARCH AND DEVELOPMENT COSTS FOR MANY MANUFACTURERS OF IRA DRUGS 3 (Alan Zibel et al. eds., 2024).

[171] *E.g.*, *Pandemic Agreement April Draft*, *supra* note 104, art. 11(d)–(f), at 11.

[172] *E.g.*, Abbott & Reichmann, *supra* note 11.

[173] The United States seems to be taking this approach to its contracts. *E.g.*, *New HHS Actions and Research Highlight How President Biden's Administration is Lowering Prescription Drug Costs*, U.S. DEP'T HEALTH & HUM. SERVS. (Dec. 14, 2023), https://www.hhs.gov/about/news/2023/12/14/new-hhs-actions-and-research-highlight-how-president-bidens-administration-lowering-prescription-drug-costs.html [https://perma.cc/N5F4-K6U5] (indicating the Biden administration's plans to make fair pricing a standard part of contracts for medical products that are federally funded by the Administration for Strategic Preparedness and Response).

agreements, there are exceptions to IP rights that can sometimes be used, such as compulsory licenses. However, because nations are generally reluctant to use these exceptions even during a pandemic, affirmative clauses in funding contracts seem to be the most effective approach.[174]

Countries can and should also review their own domestic legislation to enable maximum flexibility for addressing emergency situations. For example, countries could amend domestic laws to mandate sharing of trade secrets and technology voluntarily even if no international agreement demands this. In addition, countries that have compulsory license laws that permit exports to countries in need should ensure that they are not unduly limited to specific diseases. If Canada's compulsory license law to permit export had omitted restrictions to certain diseases, it would have enabled a Canadian company to help another country during COVID. In addition, countries may currently be constrained from helping even their own citizens due to unduly restrictive domestic laws, such as laws that have no exceptions from data exclusivity even for an emergency.[175] As noted earlier, although patent laws generally have exceptions such as for compulsory licenses, there are no similar laws in most countries for data exclusivity. This can and should be changed.

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[174] For example, during the COVID pandemic, there were only a handful of countries that issued licenses. *E.g.*, Sapna Kumar, *Compulsory Licensing of Patents During Pandemics,* 54 CONN. L. REV. 60 (2022) (noting that Israel, Hungary and Russia issued pandemic related compulsory licenses). India did not issue a license despite pleas from many, including its own judiciary. *E.g.*, Zuliquar Memon et al., *The Indian Dilemma on Compulsory Licensing of the COVID-19 Vaccines*, MONDAQ (Nov. 4, 2021), https://www.mondaq.com/india/operational-impacts-and-strategy/1126130/the-indian-dilemma-on-compulsory-licensing-of-the-covid-19-vaccines [https://perma.cc/V2FW-4GAJ]. The United States recently issued a proposal that would permit the federal government to override domestic patent rights for federally funded inventions due to high cost. That is an improvement over a proposal from the prior administration that suggested cost was never an issue. *See* Request for Information Regarding the Draft IP Guidance Framework for Considering the Exercise of Rights, 88 Fed. Reg. 85593 (Dec. 8, 2023); *see also Fact Sheet: Biden-Harris Administration Announces New Actions to Lower Health Care Prescription Drug Costs by Promoting Competition*, WHITE HOUSE (Dec. 7, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/ [https://perma.cc/KK5T-G9N3]. Although this would only permit an agency such as the NIH to act, rather than require any such action, it was still strongly opposed. *See e.g.*, Steve Brachmann, *Public Comments Reveal Widespread Objection to NIST's March-in Rights Framework*, IPWATCHDOG (Feb. 5, 2024), https://ipwatchdog.com/2024/02/05/public-comments-reveal-widespread-unity-opposition-nists-march-rights-framework/id=172851/ [https://perma.cc/RGT9-C9S2]. Accordingly, even if this rule is not jettisoned after public comments, it may be an exception to patent rights that technically exist, but remains unused to date. *E.g.*, KEVIN J. HICKEY, CONG. RSCH. SERV. IF12582, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT: DRAFT GUIDANCE 1 (2024).

[175] *E.g.*, Ellen 't Hoen et al., *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in The European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation,* 10 J. PHARM. POL'Y & PRAC. 1, 6 (2017).

Countries in the Global North could also contemplate more incentives to encourage owners of IP for needed treatments to share them. Although countries have thus far not taken any serious steps to encourage IP owning companies to share IP, there is precedent for providing more incentives to companies beyond IP to promote desired innovation. For example, academics as well as policymakers have recognized that incentives are necessary to promote socially needed treatments that patent incentives fail to adequately promote in certain areas such as so-called "orphan drugs" that only impact a small number of citizens, as well as treatments for neglected disease.[176] Countries have granted incentives beyond IP such as additional market protection or priority in regulatory review of other drugs. These are admittedly imperfect tools that can arguably over-reward companies when effective, or alternatively fail to provide adequate incentive.[177] Still, they provide a template for considering new incentives to encourage IP owners to share IP. For example, similar to how companies that engage in researching typically neglected tropical disease are provided the benefit of priority review of a profitable drug, perhaps companies that willingly share IP for pandemics could be granted similar priority review of drug approval, patent application, or some other desired incentive.

Even if countries of the Global North are unwilling to permit wide-scale modification of IP norms to let other countries make needed pandemic products, there are other things that could promote equitable outcomes even if not formally mandated by an international agreement. At a bare minimum, countries should avoid entering into new international agreements that impose additional IP norms that could erode existing flexibilities under TRIPS. Along similar lines, countries should avoid pressuring or criticizing other countries for taking steps to address pandemics. Although this may seem obvious, in 2020 the U.S. criticized some countries for contemplating compulsory licenses without recognition or even mention of the COVID epidemic, seemingly just copying language from the year before the pandemic.[178] Such action should not be repeated.[179]

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[176] *E.g.*, Taeho Greg Rhee, *Policymaking for Orphan Drugs and its Challenges*, 17 AM. MED. ASS'N. J. ETHICS 776, 777–78 (2015); *see also* Aiden Hollis, *The Health Impact Fund: A Useful Supplement to the Patent System?*, 1 PUBLIC HEALTH ETHICS 124, 124 (2008) (proposing new mechanism to promote development of socially desirable treatments).

[177] Celine Aerts, *The Impact of the Priority Review Vouchers on Tropical Disease*, 36 PHARM. MED. 189 (2022); Sean Tu et al., *Five-Year Sales for Newly Marketed Prescription Drugs With and Without Initial Orphan Drug Act Designation*, 329 J. AM. MED. ASS'N 1607 (2023).

[178] Luis Gil Abinader, *2020: USTR Publishes a Tone-Deaf Special 301 Report, Repeats Old Complaints*, KNOWLEDGE ECOLOGY INT'L (Apr. 30, 2020), https://www.keionline.org/32862 [https://perma.cc/B7XZ-MZUU].

[179] The most recent U.S. annual report concerning inadequate IP norms of other countries takes a promising step in this direction by noting that it will not challenge countries for using

There are a number of additional steps countries of the Global North should take to promote more equitable outcomes in pandemics, as well as to promote their own national security interests by reducing infectious diseases worldwide. First, they should not engage in nationalistic purchases of treatments that would result in inadequate supplies for others. Second, they should help fund purchases for poorer countries which would be in the interest of all since protection of these countries also helps reduce further mutations that can impact all. Of course, such funding needs to be more organized than the irregular and unpredictable donations during COVID (that often included donations close to expiry).[180] Funding and/or supply of treatments could occur through a reconfigured version of the COVID-19 Vaccines Global Access (COVAX)[181] that was intended to improve the bargaining power of poor countries by acting on their behalf,[182] but was thwarted by wealthy nations acting outside of COVAX to purchase their own doses.[183] Alternatively, countries could demand that companies within their jurisdiction provide reasonably priced goods for pandemic treatment and prevention. Third, wealthy countries or even philanthropic individuals could affirmatively purchase IP rights so that IP does not pose a barrier to creating

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TRIPS flexibilities. *USTR Respects Fight for Medicines Access, Within WTO Rules*, PUB. CITIZEN (Apr. 25, 2024), https://www.citizen.org/news/ustr-respects-fight-for-medicine-access-within-wto-rules/ [https://perma.cc/P7WD-55H6].

[180] *E.g.*, E. Richard Gold, *What the COVD-19 Pandemic Revealed about Intellectual Property*, 40 NATURE BIOTECH 1428, 1429 (2022) (noting that donations often are inadequate in ensuring steady and affordable supply); Martin, *supra* note 10, at 3. IP owning companies have suggested that countries supply relevant doses instead of modifying IP rights. *See e.g.*, Maria Cheng & Lori Hinnant, *Countries Urge Drug Companies to Share Vaccine Know-How*, AP (Mar. 1, 2021, 10:38 AM), https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92afbc3ea9ed519be007f8887bcf6 [https://perma.cc/N6BU-QD48].

[181] COVAX is coordinated by not only the WHO, but also the Global Alliance for Vaccines and Immunization (GAVI) as well as the Coalition for Epidemic Preparedness Innovations. *See* PHILIP LOFT, COVAX AND GLOBAL ACCESS TO COVID-19 VACCINES 8 (House of Commons Library, 2022).

[182] *Id.*; *see also* Geoffrey York, *Rich Countries are Undercutting COVAX's Ability to Get COVID-19 Vaccines to Developing World, Critics Say*, GLOBE & MAIL (Mar. 4, 2021), https://www.theglobeandmail.com/world/article-rich-countries-are-undercutting-covaxs-ability-to-get-covid-19/ [https://perma.cc/69GY-N5M6]; *Will Low-Income Countries Be Left Behind When COVID-19 Vaccines Arrive?*, DUKE GLOB. HEALTH INST. (Nov. 9, 2020), https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive [https://perma.cc/7YJG-NQRB]; Seth Berkley, *COVAX Explained*, GAVI (Sept. 3, 2020), https://www.gavi.org/vaccines-work/covax-explained [https://perma.cc/98K2-BEBX].

[183] *See, e.g.*, Megan Twohey et al., *With First Dibs on Vaccines, Rich Countries Have 'Cleared the Shelves'*, N.Y. TIMES (Dec. 18, 2020), https://www.nytimes.com/2020/12/15/us/coronavirus-vaccine-doses-reserved.html [https://perma.cc/YD64-BQ3D]; Jamie Ducharme, *COVAX Was a Great Idea, But is Now 500 Million Doses Short of its Vaccine Distribution Goals. What Exactly Went Wrong?*, TIME (Sept. 9, 2021, 7:00 AM), https://time.com/6096172/covax-vaccines-what-went-wrong/ [https://perma.cc/CP4V-4NJF]; Eric Friedman et al., *Pandemic Treaty: The Conceptual Zero Draft*, O'NEILL INST. FOR NAT'L GLOB. HEALTH L. (Dec. 5, 2022), https://oneill.law.georgetown.edu/publications/pandemic-treaty-the-conceptual-zero-draft/ [https://perma.cc/X8W2-HZJK] (noting that COVAX goals were undermined because countries were not barred from engaging in bilateral deals with vaccine manufacturers).

pandemic treatments. Even if only IP rights on some innovations were purchased, this could drive down prices for other products.[184] Of course, there would also be no need to purchase IP rights for government funded innovations if at the outset governments mandated licenses of IP associated with such innovation. Although these actions would be expensive, a global pandemic takes a financial toll on all in terms of lost productivity.

Beyond providing doses to countries and citizens in need, vaccine production and technology capacity should also be decentralized such that manufacturing capacity is not limited to a few, mostly high-income countries even if this is not mandated by an international pandemic agreement. This would help to avoid replicating the situation during the COVID pandemic where India was barred from exporting vaccines for five months due to a surge in domestic infections, resulting in a halt of desperately needed supplies to developing countries.[185] India's export bar was very problematic during the COVID pandemic because even when companies voluntarily licensed IP for COVID treatments, the vast majority of the licenses were with Indian companies.[186] Current centralization is a function not only of a lack of IP rights, but also inadequate technological capacity and resources.[187] This is something that the pandemic treaty nods towards, but with inadequate requirements concerning IP rights as well as technical skill.[188] Nonetheless, progress on this front is possible, even if there are hurdles to doing so in that technological capacity is often needed to create vaccines. Even before negotiations began on the pandemic agreement, the WHO recognized

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[184] James Love, *Buying Know-How to Scale Vaccine Manufacturing*, MEDIUM (Mar. 20, 2021), https://jamie-love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36 [https://perma.cc/S8ME-AE2J].

[185] Jeffrey Gettleman et al., *India Cuts Back on Vaccine Exports as Infections Surge at Home*, N.Y. TIMES (Apr. 22, 2021), https://www.nytimes.com/2021/03/25/world/asia/india-covid-vaccine-astrazeneca.html [https://perma.cc/KH8M-GBBY]; Sameer Yasir, *India Plans to Resume Vaccine Exports Starting Next Month*, N.Y. TIMES (Sep. 20, 2021), https://www.nytimes.com/2021/09/20/world/asia/india-covid-vaccine-exports.html [https://perma.cc/JAK7-6DYP] (noting that India was to be a major source for COVAX).

[186] *E.g.*, *Impact of a Waiver of Intellectual Property Rights for COVID-19 Therapeutics*, INT'L FED. PHARM. MFRS. & ASS'NS., Dec. 2022, at 1, 2, https://www.ifpma.org/resources/impact-of-a-waiver-of-intellectual-property-rights-for-covid-19-therapeutics/ [https://perma.cc/E75R-QXA6] (noting India as the top location for licenses that exceeded China, the second location by three times).

[187] *E.g.*, Ganesh Kumraj et al., *Capacity Building for Vaccine Manufacturing: The Way Forward*, HUM. VACCINES & IMMUNOTHERAPEUTICS, no. 1, 2022, at 3.

[188] For example, the October draft said parties "shall cooperate to build, strengthen and sustain geographically diverse capacities and institutes for research and development," including promoting technology co-creation and joint ventures. *Pandemic Agreement October Draft*, supra note 104, art. 9, at 12–14. However, these clauses do not mandate any actual action, similar to provisions in TRIPS that suggest technology sharing with LDC that have not come to fruition. *E.g.*, *TRIPS*, *supra* note 56, art. 66(2), at 25; Ellen 't Hoen, *Protecting Public Health through Technology Transfer: The Unfulfilled Promise of the TRIPS Agreement*, 24 HEALTH & HUM. RTS. J. 211 (2022).

the need for greater diversification in vaccine manufacturing and accordingly partnered with Biovac to create an mRNA vaccine manufacturing center in South Africa.[189] The center was successful in reproducing mRNA vaccines, which is a promising start to more developments.[190] In addition, on a broader level, scientific knowledge relevant to creating vaccines and treatments needs to be shared. Again, the pandemic treaty somewhat recognizes this, but efforts can and have been taken by institutions and scientists, as the WHO has previously recommended.[191] Admittedly, an international agreement mandating technology sharing with developing countries would be most comprehensive and efficient. However, considering existing language is weak, countries and entities should share needed technology outside of mandates. Although this did not happen during the COVID pandemic, it is possible if nations recognize that their national security depends upon greater diversity of technological capacity and sharing IP to adequately address pandemics.

Finally, civil society groups can help to propel greater actions on the part of countries, as they have previously done. Such groups have previously been successful in mobilizing forces to help reduce IP barriers to enable access to affordable HIV treatments and thus reduce unnecessary deaths.[192] The Doha Declaration, which is frequently noted as recognizing flexibilities under the existing TRIPS agreement, came about in part due to the efforts of not only developing countries, but public health groups.[193] These groups lobbied for the need to clarify

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[189] Martin, *supra* note 10, at 3

[190] *See* Martin, *supra* note 10, at 3. On the other hand, other efforts to create mRNA vaccine facilities have recently stalled in light of low demand for COVID vaccines. *E.g.*, Zoey Becker, *Facing Uncertain Vaccine Demand, Moderna halts mRNA plant buildout in Kenya*, FIERCE PHARMA (Apr. 11, 2024, 10:40 AM), https://www.fiercepharma.com/manufacturing/facing-uncertain-vaccine-demand-moderna-halts-mrna-plant-buildout-kenya [https://perma.cc/52M5-QARF].

[191] *E.g.*, Adam Taylor, *A New Coronavirus Vaccine Headed to India 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/T6UZ-9VAU] (noting that the hospital would share technology for Corbevax vaccine free of patent or IP issues); Martin, *supra* note 10, at 5–6 (noting that NIH provided training to Afrigen scientists, a scientist from Duke university shared technology with South Africa and Thailand, and AstraZeneca shared knowledge with a public lab in Brazil); Rick A. Bright, *Efforts Against Flu Show Developing Nations Can Make Vaccines*, THINK GLOB. HEALTH (Feb. 27, 2024), https://www.thinkglobalhealth.org/article/efforts-against-flu-show-developing-nations-can-make-vaccines [https://perma.cc/MZ78-86VZ] (noting that WHO recent initiative with mRNA vaccines builds upon its prior success in building capacity to make flu vaccines in Vietnam).

[192] *E.g.*, Ellen 't Hoen et al., *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines For All*, 14 J. INT'L AIDS SOC'Y, no. 15, 2011, at 1; *see also* Sharifah Sekalala & Belinda Rawson, *The Role of Civil Society in Mobilizing Human Rights Struggles for Essential Medicines: A Critique from HIV/AIDS to COVID-19*, 24 HEALTH & HUM. RTS. J. 177, 179–181 (2022) (arguing that civil society groups go beyond focusing on IP to embrace broader narratives).

[193] Cynthia Ho, *A History of Access to Medicine through the Lens of Patent Protection*, *in* ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED

exceptions from patent rights in the face of pressure from the countries of the Global North and the pharmaceutical industry. Continued lobbying is necessary to persuade countries that IP and inadequate technology capacity are barriers to national and global security.

IV. CONCLUSION

Although COVID has increased recognition that infectious pandemics can compromise domestic security, fully addressing IP issues that undermine tackling such pandemics is essential. The negotiation of a pandemic treaty provides some acknowledgement of the need for global solidarity. However, unless and until all countries recognize that IP can thwart effective action against a pandemic by limiting needed medical supplies, national and global security remain at risk. Hopefully, this Article has helped to illustrate current barriers seen during COVID as well as suggest what can be done to help move towards greater consensus to fight future pandemics.

RIGHTS 335–39 (Oxford Univ. Press, 2011).