

CONFRONTING INTELLECTUAL PROPERTY NATIONALISM

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ABSTRACT

Stories about nations engaging in vaccine (and medical) nationalism by hoarding limited COVID-19 vaccines and treatments are widespread, but there is a hidden phenomenon that has exacerbated vaccine nationalism and prolonged the pandemic: intellectual property nationalism or “IP nationalism.” This Article coins and explains this term and highlights its negative impacts. Essentially, some nations, primarily of the Global North, are hoarding essential knowledge protected by intellectual property (IP). This Article argues that IP nationalism has contributed to millions of unnecessary deaths and limited the growth of the global economy. Meanwhile, countries and pharmaceutical companies obscure the role of IP nationalism by highlighting red herrings as the alleged main barriers to vaccine access.

This Article advocates that countries jettison IP nationalism in favor of a polar-opposite framework—a “global public goods” approach, where IP on essential medical treatments is freely available to all. The global public goods approach goes beyond the (original) waiver of international IP obligations proposed by India and South Africa that simply removes liability. Instead, a global public goods approach would involve actively sharing knowledge on COVID-19 treatments. In most instances, the proposed waiver alone would not facilitate creation of COVID-19 vaccines by new manufacturers. Especially for effective mRNA vaccines, manufacturing involves trade secret processes that are, by definition, secret; a waiver of liability for stealing trade secrets does not grant other companies access to trade secrets. On the other hand, if the trade secrets were considered global public goods and policy makers enacted laws accordingly, then companies would be forced to share them. This approach is consistent with historical policy underlying IP norms, which recognizes that IP exclusivity sometimes needs to yield to other interests such as public health.

Recognizing the existence and influence of IP nationalism is an essential first step to better address IP constraints and distortions in the context of public health. This is a timely issue now that the World Health Organization has begun negotiations for a global pandemic treaty, with the

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goal of being better prepared for inevitable future pandemics. Hopefully, by considering IP on pandemic treatments as global public goods, this treaty could help prevent another global vaccine apartheid. This Article provides concrete suggestions to meet this goal while still ensuring adequate incentives for innovation. Moreover, the Article also recommends complementary modifications to domestic law to similarly promote affordable essential treatments while preserving innovation even in non-pandemic situations.

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INTRODUCTION

COVID-19 (COVID) has created a multiyear global health crisis and has caused over eighteen million unnecessary deaths—and counting.¹ Was this inevitable? Not necessarily. To some extent it is a crisis of our own making. Many would say that the unnecessary deaths were due to vaccine nationalism. Because wealthy nations snatched up COVID vaccines and treatments, this resulted in inadequate global vaccination rates, which in turn resulted in continuous mutation of the virus that threatens even the vaccinated.² However, this Article argues that the crisis highlights a different yet related problem that not only exacerbates vaccine nationalism but results in perpetual unaffordable access to essential treatments even in non-pandemic contexts—a phenomenon this Article calls intellectual property nationalism or “IP nationalism.”³

This Article argues that just as some nations engage in vaccine nationalism by hoarding scarce vaccine supplies, so too some nations engage in IP nationalism, a currently underrecognized phenomenon which further limits supplies. IP nationalism refers to actions by countries to protect their domestic economic self-interest with respect to IP rights. For example,

1. COVID-19 Excess Mortality Collaborators, *Estimating Excess Mortality Due to the COVID-19 Pandemic: A Systematic Analysis of COVID-19-Related Mortality, 2020–21*, 399 LANCET 1513, 1513 (2022); see also Luke Taylor, *COVID-19: True Global Death Toll from Pandemic Is Almost 15 Million, Says WHO*, 377 BRIT. MED. J. 1144, 1144 (2022) (noting nearly fifteen million deaths from COVID-19 in 2020 and 2021, which is more than three times official reports, and with over 80% of the deaths in middle-income countries).

2. See, e.g., Rogelio Mayta, KK Shailaja, & Anyang’ Nyong’o, *Vaccine Nationalism is Killing Us. We Need an Internationalist Approach*, GUARDIAN (June 17, 2021, 6:13 AM), <https://www.theguardian.com/commentisfree/2021/jun/17/covid-vaccine-nationalism-internationalist-approach>; see also 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/> (noting that inequitable COVID vaccine distribution likely encouraged new COVID variants).

3. The concept of IP nationalism is related to, yet distinct from, the concept of innovation nationalism. See Sapna Kumar, *Innovation Nationalism*, 51 CONN. L. REV. 205, 205, 208–09 (2019). Whereas innovation nationalism is premised on a national identity based on a country being innovative, IP nationalism includes, but is not limited to this; national identity need not be tied to innovation to embrace IP nationalism which is more a function of embracing strong IP rights. See *infra* Section II.A.

wealthy countries of the “Global North” engaged in IP nationalism by opposing modification of usual IP rights to address COVID,⁴ which benefited their IP-owning pharmaceutical companies that profit handsomely from IP rights on COVID treatments.⁵ Without modification of IP rights, companies can legally prevent otherwise available and capable manufacturers from making vaccines and treatments, resulting in inadequate supplies.⁶ This benefits countries in the Global North where these companies are located. Inadequate physical supplies, of course, are also exacerbated by vaccine nationalism, which includes stockpiling more booster shots than necessary.⁷ However, IP nationalism exacerbated vaccine nationalism. After all, hoarding of vaccines would not have been as problematic if other companies could have made them. Moreover, during the continuing COVID crisis, IP nationalism still precludes making necessary treatments because of resistance to modifying IP rights to permit more creation of IP-protected treatments.⁸ Recognizing and combatting IP nationalism is important because, unlike its well-recognized counterpart, vaccine nationalism, IP nationalism is an ever-present issue that contributes to the longstanding inequity between the Global North and Global South in terms of access to affordable treatment, which results in unnecessary death and suffering.⁹

Although poor countries of the Global South arguably also engaged in IP nationalism by advocating for modified IP rights to enable them to create their own treatments, this Article focuses primarily on the IP nationalism wielded by the Global North, as it is those nationalist views exacerbating the current crisis. With COVID, no one is safe until everyone is safe and inadequate vaccination rates result in more mutations that endanger the global community. Refusing to change IP norms to combat a highly contagious pathogen is extremely problematic for all. Moreover,

4. See *infra* Section III.B.

5. E.g., Julia Kollewe, *Pfizer Accused of Pandemic Profiteering as Profits Double*, *GUARDIAN* (Feb. 8, 2022, 12:26 PM), <https://www.theguardian.com/business/2022/feb/08/pfizer-covid-vaccine-pill-profits-sales> (noting Pfizer had \$37 billion in vaccine sales in 2021 and expects record revenues in 2022 of \$100 billion).

6. See, e.g., Mayta et al., *supra* note 2. This is because IP rights such as patents permit the owner to bar all others from making the patented invention. E.g., 35 U.S.C. § 271(a) (2022). Although countries finally agreed to a minimal modification of IP norms in June 2022, treatments are excluded and IP nationalism was still responsible for delayed creation of vaccines and unnecessary deaths. See *infra* note 242. See also *infra* Subsection III.B.2. for discussion of how countries engaged in IP nationalism up to and including the minimal modification.

7. E.g., Olivia Goldhill, *We Have Enough COVID Vaccines for Most of the World. But Rich Countries are Stockpiling More than They Need for Boosters*, *STAT* (Dec. 13, 2021), <https://www.statnews.com/2021/12/13/we-have-enough-covid-vaccines-for-most-of-world-but-rich-countries-stockpiling-more-than-they-need/>; Ann Danaiya Usher, *The Global COVID-19 Treatment Divide*, 399 *LANCET* 779, 779–80 (2022); Andrew Green & Carmen Paun, *The Battle for Paxlovid*, *POLITICO* (May 19, 2022, 10:34 AM), <https://www.politico.com/newsletters/global-pulse/2022/05/19/the-battle-for-paxlovid-00033516>.

8. E.g., Stephanie Nolen, *Will New COVID Treatments Be as Elusive for Poor Countries as Vaccines?*, *N.Y. TIMES* (Oct. 27, 2021), <https://www.nytimes.com/2021/10/17/health/covid-treatment-access-molnupiravir.html>; Green & Paun, *supra* note 7.

9. Of course, this is a broad generalization because there are poor citizens in wealthy countries.

economic studies indicate that all countries suffer in today's interconnected global economy where supply chains are disrupted when individual countries suffer from the pandemic.¹⁰

Admittedly, focusing IP nationalism on the actions of the Global North means that the IP nationalism definition overlaps some with imperialism and colonialism. For example, the IP nationalism embraced by wealthy countries is consistent with imperialism to the extent that wealthy countries have used their power to extract economic profits from the Global South, which includes COVID vaccine profits.¹¹ However, it is not a complete overlap. As explained below, even countries in the Global South can exhibit IP nationalism for strategic reasons. This Article consciously focuses on principles of nationalism because it is widely recognized as a barrier for COVID treatments, whereas a focus on imperialism would likely prompt defensiveness, detracting from the focus of solving inequitable access to COVID treatments.

This Article argues that nations should reject IP nationalism and view IP, at least for essential medicines, as a “global public good” that is freely available to all. In other words, if IP on essential medicines (essential medicine IP) was a global public good, countries would not only be willing to jettison the exclusivity attendant with IP rights but would also be willing to proactively share IP for those medicines so that they can be truly accessible to all.¹² Some scholars and policy makers already recognize that widespread COVID immunization should be a global public good.¹³ As such, the next step should be that IP on COVID vaccines (COVID IP), which is necessary to obtain widespread COVID immunization as quickly as possible, should also be a global public good. Indeed, the World Health Organization (WHO) and some world leaders have argued that COVID IP should be shared.¹⁴

Treating COVID IP as a global public good is far superior to suspending IP rights. For example, suspending rights alone does not enable additional companies to efficiently create effective messenger ribonucleic

10. See *infra* note 93.

11. E.g., Amaka Vanni, *On Intellectual Property Rights, Access to Medicines and Vaccine Imperialism*, THIRD WORLD APPROACHES TO INT'L L. REV.: REFLECTIONS (Mar. 23, 2021), <https://twair.com/on-intellectual-property-rights-access-to-medicines-and-vaccine-imperialism/>; Mohit Mookim, *The World Loses Under Bill Gates' Vaccine Colonialism*, WIRED (May 19, 2021, 9:00 AM), <https://www.wired.com/story/opinion-the-world-loses-under-bill-gates-vaccine-colonialism/>.

12. This is because a “public good” in economic theory is a good that cannot exclude others, in contrast to a private good, and is “non-rivalrous,” meaning it is a good that does not reduce in quantity, such as clean air. E.g., Gregory Shaffer, *International Law and Global Public Goods in a Legal Pluralist World*, 23 EUR. J. INT'L L. 669, 673 (2012).

13. E.g., G20 Riyadh Summit, *Leaders' Declaration*, at 1 (Nov. 21–22, 2020), http://www.g20.utoronto.ca/2020/G20_Riyadh_Summit_Leaders_Declaration_EN.pdf; see also Inge Kaul, Pedro Conceição, Katell Le Goulven, & Ronald U. Mendoza, *How to Improve the Provision of Global Public Goods*, in PROVIDING GLOBAL PUBLIC GOODS: MANAGING GLOBALIZATION 44, 58 (Inge Kaul ed., 2003) (citing U.N. Secretary-General, *Road Map Towards the Implementation of the United Nations Millennium Declaration*, ¶¶ 259–60, U.N. Doc. A/56/326 (Sept. 6, 2001) (recognizing universal access to health care as a global public good)).

14. See *infra* Subsection III.A.2.

acid (mRNA) vaccines unless IP-owning companies voluntarily share needed IP, including their trade secrets.¹⁵ After all, suspending liability for stealing trade secrets simply means that an opportunistic thief would not be liable, but such theft would be difficult because most companies employ a variety of techniques to protect their trade secrets.¹⁶ In addition, although companies could create their own methods without using trade secrets, as South Africa recently did with Moderna's mRNA vaccine, it takes precious time to do so; indeed, South Africa's success took more than a year.¹⁷ As a result, although South Africa can now make its own COVID vaccines, in that year momentum stalled, with many now opting out of receiving vaccines and governments focused on addressing other health needs.¹⁸ Although some surviving individuals have natural immunity after being exposed to COVID, that immunity is not as durable as vaccination-based immunity and provides no protection against new variants.¹⁹ An early embrace of a global public goods approach would have ensured trade-secret-protected methods were promptly shared to create vaccines when people were most motivated to get vaccinated. This approach could have happened by pressuring companies to do so, or alternatively, through legal action.²⁰

Admittedly, recognizing essential medicine IP as a global public good would not address all issues. For example, there have been problems distributing vaccines before they expire due to logistical challenges and delays caused by supply chain disruptions.²¹ However, these issues are ex-

15. E.g., Gareth Iacobucci, *COVID-19: How Will a Waiver on Vaccine Patents Affect Global Supply?*, 373 BRIT. MED. J. 1182, 1882–83 (2021).

16. By definition, a trade secret requires the information be subject to reasonable secrecy, which generally means owners of trade secrets use multiple techniques to protect their secrets including limiting physical access with passwords. E.g., MELVIN F. JAGER, 1 TRADE SECRETS LAW § 5:16 (2022) (discussing what constitutes reasonable measures, such as Coca-Cola only revealing formula to two people and keeping the written record in a security vault).

17. Amy Maxmen, *South African Scientists Copy Moderna's COVID Vaccine*, NATURE (Feb. 3, 2022), <https://www.nature.com/articles/d41586-022-00293-2>; see also *infra* note 226 (Moderna statement from October 2020 that it would not enforce patent rights).

18. Rebecca Robbins & Stephanie Nolen, *The Drive to Vaccinate the World Against Covid is Losing Steam*, N.Y. TIMES (Apr. 27, 2022), <https://www.nytimes.com/2022/04/23/health/covid-vaccines-world-africa.html>; Lynsey Chutel, *Africa's First Covid-19 Vaccine Factory Hasn't Received a Single Order*, N.Y. TIMES (May 12, 2022), <https://www.nytimes.com/2022/05/12/world/africa/south-africa-covid-vaccine-factory.html>.

19. See, e.g., Rahul K. Suryawanshi, Irene P. Chen, Tongcui Ma, Abdullah M. Syed, Noah Brazer, Prachi Saldhi, Camille R. Simoneau, Alison Ciling, Mir M. Khalid, Bharath Sreekumar, Pei-Yi Chen, G. Renuka Kumar, Mauricio Montano, Ronne Gascon, Chia-Lin Tsou, Miguel A. Garcia-Knight, Alicia Sotomayor-Gonzalez, Venice Servellita, Amelia Gliwa, Jenny Nguyen, Ines Silva, Bilal Milbes, Noah Kojima, Victoria Hess, Maria Shacreaw, Lauren Lopez, Matthew Brobeck, Fred Turner, Frank W. Soveg, Ashley F. George, Xiaohui Fang, Mazharul Maishan, Michael Matthey, Mary Kate Morris, Debra Wadford, Carl Hanson, Warner C. Greene, Raul Andino, Lee Spraggon, Nadia R. Roan, Charles Y. Chiu, Jennifer A. Doudna, & Melanie Ott, *Limited Cross-Variant Immunity From SARS-CoV-2 Omicron Without Vaccination*, 607 NATURE 351, 351–55 (2022).

20. See *infra* note 123 and accompanying text.

21. E.g., Edward McAllister, Libby George, & Stephanie Nebehay, *Exclusive: Up to 1 million COVID Vaccines Expired in Nigeria Last Month*, REUTERS (Dec. 7, 2021, 5:56 PM), <https://www.reu->

acerbated by usual IP norms. After all, it is difficult to establish an effective distribution system for irregular supplies of donated vaccines, which are sometimes donated close to their expiration date, whereas if IP were not at issue, distribution could be more easily planned.²² Similarly, supply chain disruptions may exist in part because of vaccination shortages that impact the work force. Moreover, unlike existing logistical issues involving infrastructure,²³ addressing IP barriers requires not only recognizing that there are barriers, which some deny,²⁴ but also depends on changing current laws, which is more challenging than addressing infrastructure issues.²⁵ Additionally, deciding which medicines are “essential” can be

ters.com/business/healthcare-pharmaceuticals/exclusive-up-1-million-covid-vaccines-wasted-nigeria-last-month-2021-12-08/; Nelson Naturinda, *Uganda to Destroy 400,000 Doses of Expired COVID-19 Vaccines*, E. AFR. (Jan. 14, 2022), <https://www.theeastafrican.co.ke/tea/news/east-africa/uganda-to-destroy-expired-covid-vaccines-3681852>. The unfortunate destruction of doses in Uganda was apparently, in part, due to vaccine hesitancy which exists even in wealthy countries. See Azfar Hossain, Stephen Asimwe, & Louise Ivers, *Claims of Vaccine Hesitancy in African Countries Are at Odds with the Reality on the Ground*, STAT (Dec. 21, 2021), <https://www.statnews.com/2021/12/21/claims-of-vaccine-hesitancy-in-african-countries-are-at-odds-with-the-reality-on-the-ground/>. However, vaccine hesitancy could be worse in poor countries with deeper distrust of governments and the shadow of colonialism. E.g., Lynsey Chutel & Max Fisher, *The Next Challenge to Vaccinating Africa: Overcoming Skepticism*, N.Y. TIMES (Dec. 1, 2021), <https://www.nytimes.com/2021/12/01/world/africa/coronavirus-vaccine-hesitancy-africa.html>.

22. E.g., Francesco Guarascio, *Poorer Nations Reject Over 100 mln COVID-19 Vaccine Doses as Many Near Expiry*, REUTERS (Jan. 14, 2022, 1:47 AM), <https://www.reuters.com/business/healthcare-pharmaceuticals/more-than-100-million-covid-19-vaccines-rejected-by-poorer-nations-dec-unicef-2022-01-13/>.

23. E.g., Allison Martell & Euan Rocha, *How the U.S. Locked Up Vaccine Materials Other Nations Urgently Need*, REUTERS (May 7, 2021, 9:15 AM), <https://www.reuters.com/business/healthcare-pharmaceuticals/how-us-locked-up-vaccine-materials-other-nations-urgently-need-2021-05-07/>; Chad P. Bown & Chris Rogers, *The U.S. Did Not Ban Exports of Vaccine Supplies. But More Help is Needed*, PETERSON INST. FOR INT’L ECON. (June 7, 2021, 5:00 AM), <https://www.piie.com/blogs/trade-and-investment-policy-watch/us-did-not-ban-exports-vaccine-supplies-more-help-needed>. There are several proposals to address infrastructure issues. E.g., Ruchir Agarwal & Gita Gopinath, *IMF Staff Discussion Note: A Proposal to End the COVID-19 Pandemic*, INT’L MONETARY FUND, May 19, 2021, at 19 (proposing global database); Juan Camilo Castillo, Amrita Ahuja, Susan Athey, Arthur Baker, Eric Budish, Tasneem Chipty, Rachel Glennerster, Scott Duke Kominers, Michael Kremer, Greg Larson, Jean Lee, Canice Prendergast, Christopher M. Snyder, Alex Tabarrok, Brandon Joel Tan, & Witold Wiecek, *Market Design to Accelerate COVID-19 Vaccine Supply*, SCI. (Feb. 25, 2021), <https://www.science.org/doi/10.1126/science.abg0889>; Prashant Yadav & Rebecca Weintraub, *4 Strategies to Boost the Global Supply of COVID-19 Vaccines*, HARV. BUS. REV. (May 6, 2021), <https://hbr.org/2021/05/4-strategies-to-boost-the-global-supply-of-covid-19-vaccines>; *The COVAX Marketplace*, COAL. FOR EPIDEMIC PREPAREDNESS INNOVATIONS, <https://cepi.net/the-covax-marketplace/> (last visited Nov. 30, 2022) (noting new method to improve COVAX supply distribution).

24. See *infra* Subsection IV.B.2; *Research-Based Biopharmaceutical Industry on the TRIPS Waiver Discussions at WTO Ministerial Conference (MC12)*, INT’L FED’N PHARM. MFRS. & ASS’NS (June 9, 2022), <https://www.ifpma.org/resource-centre/research-based-biopharmaceutical-industry-on-the-trips-waiver-discussions-at-wto-ministerial-conference-mc12/> [hereinafter IFPMA, *Trips Waiver*] (alleging no evidence that IP has been a barrier to vaccine production or access); see also Communication from Plurinational State of Bolivia et al., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19—Responses to Questions*, ¶¶ 36–53, WTO Doc. IP/C/W/672 (Jan. 15, 2021) [hereinafter Jan. 15, 2021 WTO Communication] (documenting evidence of IP as a barrier to accessing COVID treatments, contrary to claim by some countries that there is no such evidence).

25. See, e.g., Kristine Liao, *Prolonged Pandemic: How Vaccine Inequity is Keeping COVID-19 Alive*, GLOB. CITIZEN (Apr. 29, 2022), <https://www.globalcitizen.org/en/content/vaccine-inequity-prolonged-pandemic/> (noting efforts to scale up vaccination support in terms of logistics and delivery,

tricky. COVID vaccines clearly seem essential because without widespread immunization, all individuals are at risk²⁶ and inoculation remains elusive for many.²⁷ However, this Article defers to public health scholars and policy makers to define additional treatments. This Article focuses instead on arguing that essential medicine IP as a global public good should be recognized broadly by policy makers and countries so that these principles can be enshrined in domestic and international law.

IP nationalism provides new answers to an age-old question: how important is IP for promoting innovation? Countries embracing IP nationalism (and the companies in those countries) have repeatedly argued that without strong and secure IP rights, innovation will halt to the detriment of all.²⁸ However, the COVID pandemic suggests that this is untrue. Notably, although countries have been discussing a waiver of IP rights on COVID treatments since 2020, companies have continued to develop and obtain approval for COVID treatments and diagnostics.²⁹ This continued COVID innovation highlights that IP alone is not what promotes innovation. Indeed, some scholars and policy makers have long suggested that countries should proactively support innovation with both direct funding and advance purchase agreements, so that innovation is not distorted by

but a need for reduced IP to ensure production of life-saving resources); Megan Van Etten, *Intellectual Property Waiver on COVID-19 Innovation is Unnecessary and Harmful*, PhRMA (May 23, 2022), <https://catalyst.phrma.org/intellectual-property-waiver-on-covid-19-innovation-is-unnecessary-and-harmful> (opposing changing IP rights, but noting that distribution and supply chain are the issue). In addition, even if there is an international waiver of IP rights, domestic laws would also need to be changed.

26. See World Health Org., *Statement for Healthcare Professionals: How COVID-19 Vaccines Are Regulated for Safety and Effectiveness*, WHO (May 17, 2022), <https://www.who.int/news/item/17-05-2022-statement-for-healthcare-professionals-how-covid-19-vaccines-are-regulated-for-safety-and-effectiveness>.

27. E.g., World Health Org., *WHO Director-General's Opening Remarks at the WHO Press Conference*, WHO (Mar. 30, 2022), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-who-press-conference-30-march-2022> (noting one third of the global population lacks a single vaccine dose, including over 80% in Africa); *Global Dashboard for Vaccine Equity*, U.N. DEV. PROGRAMME, <https://data.undp.org/vaccine-equity/> (last visited Oct. 21, 2022) (noting that about 23% of individuals in poor countries have only had a single dose); World Health Org., *WHO Recommends Highly Successful COVID-19 Therapy and Calls for Wide Geographical Distribution and Transparency From Originator*, WHO (Apr. 22, 2022), <https://www.who.int/news/item/22-04-2022-who-recommends-highly-successful-covid-19-therapy-and-calls-for-wide-geographical-distribution-and-transparency-from-originator> (noting WHO recommendation that Paxlovid be broadly used to treat patients at high risk of hospitalization).

28. See *infra* Subsection IV.B.1.

29. E.g., Scott Hensley, *First Doses of Paxlovid, Pfizer's New COVID Pill, Are Released to States*, NPR (Dec. 23, 2021, 3:37 PM), <https://www.npr.org/sections/health-shots/2021/12/22/1066761436/fda-authorizes-1st-antiviral-pill-for-covid>; Press Release, FDA, *Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Diagnostic Test Using Breath Samples* (Apr. 14, 2022), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-diagnostic-test-using-breath-samples>; Jeanine Santucci, *FDA Grants Emergency Authorization for First COVID-19 Breathalyzer Test*, USA TODAY (Apr. 14, 2022, 7:58 PM), <https://www.usatoday.com/story/news/health/2022/04/14/covid-breathalyzer-test-fda-emergency-authorization/7325352001/>.

profit incentives that do not reflect societal needs.³⁰ Although countries generally have not adopted this approach, they have used several levers, noted in past scholarship, to promote innovation with remarkable results indicated by rapid development of multiple COVID vaccines and treatments.³¹ But, companies fail to recognize the importance of these levers and instead continue to claim that IP rights explain the rapid development of treatments.³²

Important benefits beyond the context of a pandemic are possible if IP nationalism was jettisoned in favor of viewing essential medicine IP as a global public good. Notably, the end goal is not the designation of *certain* IP as a global public good. Rather, if countries were persuaded that essential medicine IP should be shared by all, consistent with treating it as a global public good, that would make countries amenable to approaches supported by the United Nations (UN) and WHO concerning access to affordable drugs.³³ A global public goods approach could fundamentally alter global access to essential drugs, especially for those who often cannot afford them until the expiration of IP rights allows others to make and sell them as generics. Admittedly, it will be challenging to persuade all countries that currently embrace IP nationalism to reject it, even for essential drugs. After all, treating any IP as a global public good is, at first glance, contrary to traditional IP norms that are built on exclusivity. However, a deeper analysis reveals that all IP laws provide exceptions that recognize situations where exclusivity should give way to accommodate other socially desirable activity.³⁴ Historically, but contrary to current norms, IP focused on promoting information sharing rather than simply profiting the IP owner.³⁵ However, IP norms emanating from the Global North that emphasize exclusivity and benefits to the IP owner have become globally entrenched because IP nationalism has baked these norms into the current international infrastructure. As this Article discusses, IP nationalism is reflected by the efforts of IP-exporting countries that successfully tied IP to

30. E.g., Bénédicte Callan & Iain Gillespie, *The Path to New Medicines*, 449 NATURE 164, 164–65 (2007) (discussing need for new strategies to promote drug development aimed at the developing world where the usual market incentives do not work); Paul Grootendorst, Aidan Hollis, David K. Levine, Thomas Pogge, & Aled M. Edwards, *New Approaches to Rewarding Pharmaceutical Innovation*, 183 CAN. MED. ASS'N. J. 681, 683–84 (2011) (suggesting public subsidies of clinical trials to “push” drug discovery and various rewards to “pull” new drug development); Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 320–21 (2013).

31. See *infra* Subsection IV.B.1.

32. E.g., IFPMA, *Trips Waiver*, *supra* note 24.

33. A full discussion of these possibilities is beyond the scope of this Article, although they include alternative methods to fund drugs and “delinking” the cost of drugs from alleged research costs. E.g., Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies*, 29–32 (2016), [hereinafter UN HIGH LEVEL PANEL] (explaining mechanisms that delink the cost of research from ultimate prices and recommending a binding agreement to require delinking costs of research from end prices).

34. See *infra* Subsection IV.A.2.

35. See *infra* Subsection IV.A.3.

global trade agreements—an activity that began with the World Trade Organization (WTO).³⁶ However, long-held views can change; this is underscored by the fact that the United States, a major proponent of IP nationalism, surprisingly endorsed waiving IP rights for COVID vaccines.³⁷

The time is ripe not only to recognize IP nationalism as a major problem but also to acknowledge that essential medicine IP is a global public good. Timely recognition could ensure that the WHO's pandemic treaty negotiations avert another vaccine apartheid.³⁸ Because the treaty proposes to address a wide range of issues, including equitable access to medical treatments and the incompatibility of IP's exclusivity with affordable access to treatments, it is especially important to recognize essential medicine IP as a global public good.³⁹ Moreover, a global public goods approach would promote socially productive innovation. Recognizing that usual IP rules have unduly prolonged the COVID crisis reveals how to address this problem not only with future pandemics but also to promote a better balance of interests for essential medicines outside of pandemic situations.

I. TYPES OF NATIONALISM AND THEIR NEGATIVE IMPACT ON COVID SUPPLIES

This Part provides essential background on the principles of nationalism that are central to the thesis that it is time to move beyond nationalism to embrace a global public goods approach concerning essential medicine IP. This Part begins with an introduction to nationalism, including medical and vaccine nationalism.

36. See *infra* Section II.B.

37. E.g., Jorge L. Contreras, *US Support for a WTO Waiver of COVID-19 Intellectual Property*, 56 *INTERECONOMICS* 179, 179 (2021). In addition, sometimes public opposition leads to change in domestic policy; for example, although the EU used to be a staunch defender of so-called investor-state disputes, it changed its views due to strong public opposition. E.g., Cynthia M. Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 *BERKELEY TECH. L.J.* 213, 221 (2015).

38. World Health Org., *World Health Assembly Agrees to Launch Process to Develop Historic Global Accord on Pandemic Prevention, Preparedness and Response*, WHO (Dec. 1, 2021), <https://www.who.int/news/item/01-12-2021-world-health-assembly-agrees-to-launch-process-to-develop-historic-global-accord-on-pandemic-prevention-preparedness-and-response>; see also World Health Org., *Special Session of the World Health Assembly to Consider Developing a WHO Convention, Agreement or Other International Instrument on Pandemic Preparedness and Response*, at ¶¶ 1–3, A74/A/CONF./7 (May 25, 2021), https://apps.who.int/gb/eb-wha/pdf_files/WHA74/A74_ACONF7-en.pdf (requesting a special World Health Assembly session on this issue in November or December 2021); Germán Velásquez & Nirmalya Syam, *A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?*, 93 *S. CTR.* 1, 2–3 (2021).

39. World Health Org., *Draft Annotated Outline of a WHO Convention, Agreement or Other International Pandemic Prevention, Preparedness and Response*, Part II § 3, A/INB/1/12 (June 14, 2022), https://apps.who.int/gb/inb/pdf_files/inb1/A_INB1_12-en.pdf [hereinafter WHO Draft Outline].

A. Introduction to Nationalism

Although nationalism can have positive elements of shared culture and pride in national achievements,⁴⁰ it is often harmful.⁴¹ As repeatedly seen during COVID, nationalism has directly resulted in the stockpiling and hoarding of resources and export bans depriving other countries of needed supplies,⁴² and less directly, has resulted in some countries using inferior domestic vaccines.⁴³

Although nationalism has different definitions,⁴⁴ this Article defines nationalism as actions and policies that favor a nation consistent with the nation's culture and goals, generally without regard to potential negative impact on other nations.⁴⁵ This can include protectionist trade policies and tariffs against imports, whether done once or embodied in a domestic law.⁴⁶ Nationalism can include policies that require other countries to have strong IP norms that benefit domestic industries exporting IP goods, such as pharmaceuticals, movies, and books.⁴⁷ Nationalism in this sense benefits only some domestic industries, while for other industries, tariffs on

40. E.g., Remarks by President Biden on the COVID-19 Response and the Vaccination Program, Briefing Room (May 17, 2021) (transcript available at <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/05/17/remarks-by-president-biden-on-the-covid-19-response-and-the-vaccination-program-4/>) (emphasizing U.S. companies that made COVID vaccines and minimizing contribution of companies from other nations, such as German company, BioNTech, who collaborated with U.S. company, Pfizer).

41. Although this Article focuses on nationalism during COVID, nationalism obviously includes other situations. For example, arguments against influx of immigrants, and even refugees, reflect nationalism. Jiyoung Ko & Seung-Wan Choi, *Nationalism and Immigration Control*, 28 WILEY 12, 12–14 (2022).

42. E.g., Peter S. Goodman, Katie Thomas, Sui-Lee Wee, & Jeffrey Gettleman, *A New Front for Nationalism: The Global Battle Against a Virus*, N.Y. TIMES (Apr. 10, 2020), <https://www.nytimes.com/2020/04/10/business/coronavirus-vaccine-nationalism.html> (noting sixty-nine countries found to limit exports of COVID-related equipment and or drugs); Ross L. Denton, Sunny Mann, Tristan Grimmer, Anahita Thoms, Alexander Bychkov, Milena Hoffmanova, Wojciech Pfadt, Michael Perche, Martin Lazar, Alexander Ehrle, Andrew Rose, & Ross Evans, *New EU and National Export Controls on Face Masks and Medical Protective Equipment*, BAKER & MCKENZIE (Mar. 16, 2020), <https://sanctionsnews.bakermckenzie.com/new-eu-and-national-export-controls-on-face-masks-and-medical-protective-equipment/> (noting EU Regulation prohibiting export of personal protective equipment without a license).

43. E.g., James Griffiths, *China is Hitting Back at Criticism of Its Vaccines with a Dangerous Disinformation Campaign*, CNN (Jan. 19, 2021, 3:51 AM), <https://www.cnn.com/2021/01/19/china/china-vaccine-disinformation-intl-hnk/index.html>; Yvaine Ye, *China's First mRNA Vaccine is Close—Will that Solve Its COVID Woes?*, NATURE (June 27, 2022), <https://www.nature.com/articles/d41586-022-01690-3> (suggesting that China has failed to approve Moderna and Pfizer vaccines due to nationalism); see also Benjamin Mueller, *Western Warnings Tarnish Covid Vaccines the World Badly Needs*, N.Y. TIMES (May 4, 2021), <https://www.nytimes.com/2021/04/14/world/europe/western-vaccines-africa-hesitancy.html> (noting that developing countries primed by colonialism are concerned that they are being provided unsafe vaccines by AstraZeneca and Johnson & Johnson).

44. DUSAN KECMANOVIC, *THE MASS PSYCHOLOGY OF ETHNONATIONALISM* 15 (1996); Ernst B. Haas, *What is Nationalism and Why Should We Study It?*, 40 INT'L ORG. 707, 707 (1986).

45. Brandon M. Boylan, Jerry McBeath, & Bo Wang, *US-China Relations: Nationalism, the Trade War, and COVID-19*, 14 FUDAN J. HUM. & SOC. SCI. 23, 27 (2021).

46. 19 U.S.C. § 1337(a)(2) (1994) (permitting U.S. IP owners to exclude infringing imports from foreign countries).

47. E.g., CONG. RSCH. SERV., RL 34942, *INTELLECTUAL PROPERTY RIGHTS AND INTERNATIONAL TRADE* 6 (2020) (noting that IP-related exports were more than half of U.S. merchandise exports).

imports can have a negative impact by increasing business costs.⁴⁸ In addition, regardless of whether some domestic businesses benefit from strong IP rights for exports, those strong IP rights increase costs for individual citizens on goods, including life-sustaining drugs.⁴⁹ Similarly, strong IP laws worldwide that exist as a result of IP nationalism may make drugs expensive globally, reducing the ability of domestic citizens to import cheaper drugs from another country.⁵⁰ Nationalism can also include actions to promote domestic interests like public health. For example, countries that bar citizens of other countries from entering due to concern about the spread of COVID fit this definition.⁵¹

Nationalism also includes policies that can appear to prioritize the interests of a nation over others. For example, early in the pandemic when the Biden Administration opposed donating AstraZeneca vaccines that were not approved for use in the United States, the Administration's Press Secretary stated, "[W]e have not provided doses from the U.S. government to anyone," consistent with a nationalist approach of putting domestic interests first.⁵² This policy appeared to prioritize domestic interests by keeping vaccines for use in the United States, but lacked any domestic utility because AstraZeneca had not sought approval in the United States.⁵³ Similarly, the domestic announcement of COVID boosters prior to scientists evaluating whether boosters were needed to avoid hospitalization—or prior to considering global need for *initial* doses—also reflects nationalism.⁵⁴ Another example is Australia's cancellation of tennis star Novak Djokovic's visa, which appeared to prioritize the national public health interests of Australian citizens by excluding him for lack of COVID im-

48. Christopher West Davis, *Here's What Small Businesses, Slammed by China Tariffs, Are Doing to Minimize the Impact of the Trade War*, CNBC (Oct. 5, 2019, 9:53 AM), <https://www.cnbc.com/2019/10/05/us-china-trade-war-causing-small-biz-to-reinvent-customer-retention.html>.

49. Olga Gurgula & Wen H. Lee, *COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?*, 17 J. GENERIC MEDS. 61, 62 (2021).

50. *Id.*

51. *E.g.*, Shira Rubin, *Israel Bars All Foreigners, Reinstates Phone Surveillance in Effort to Contain Omicron Variant*, WASH. POST (Nov. 28, 2021, 4:55 AM), https://www.washingtonpost.com/world/israel-omicron-borders-coronavirus/2021/11/28/f315184a-5015-11ec-a7b8-9ed28bf23929_story.html.

52. Nathaniel Weixel, *US Comes Under Pressure to Share Vaccines with Rest of World*, HILL (Mar. 14, 2021, 8:00 AM), <https://thehill.com/policy/healthcare/543004-us-comes-under-pressure-to-share-vaccines-with-rest-of-world>.

53. Noah Weiland & Rebecca Robbins, *The US Is Sitting on Tens of Millions of Doses the World Needs*, N.Y. TIMES (Mar. 11, 2021), <https://www.nytimes.com/2021/03/11/us/politics/coronavirus-astrazeneca-united-states.html>.

54. *E.g.*, Helen Branswell, *U.S. Officials' Decision on COVID-19 Booster Shots Baffles—and Upsets—Some Scientists*, STAT (Aug. 18, 2021), <https://www.statnews.com/2021/08/18/u-s-decision-on-covid-19-booster-shots-baffles-and-upsets-some-scientists/>; Isabel Kershner, *Israel Considers 4th Vaccine Dose, but Some Experts Say It's Premature*, N.Y. TIMES (Dec. 25, 2021), <https://www.nytimes.com/2021/12/23/world/middleeast/israel-vaccine-4th-dose.html>.

munization, although some suggested that it was intended to make an example of him.⁵⁵ Curiously, the policy on which individuals would jeopardize Australian public health changed while he was en route to Australia.⁵⁶

Nationalism typically refers to actions and policies by nations, but it is not limited to that. Nationalism can be condoned and encouraged by entities or individuals.⁵⁷ A company can endorse a nationalist approach or take actions consistent with nationalism.⁵⁸ For example, AstraZeneca stated that its initial doses would be earmarked for the United Kingdom because it partnered with the University of Oxford in developing its vaccine.⁵⁹ Also, when U.S. vaccine manufacturers entered agreements with the federal government, those contracts limited vaccine use to the United States and barred donations abroad.⁶⁰ Although this was likely done to limit legal liability, it was also consistent with the Trump Administration's nationalist "America First" approach.⁶¹ Individual members of Congress

55. E.g., Damien Cave, *How the 'Djokovic Affair' Finally Came to an End*, N.Y. TIMES (Jan. 16, 2022), <https://www.nytimes.com/2022/01/16/world/australia/djokovic-deported.html>.

56. Tracey Holmes, *Novak Djokovic's 'Health Risk' to Australia Will Determine Fate of Serbian Tennis Star's Visa*, ABC (Jan. 13, 2022, 5:38 AM), <https://www.abc.net.au/news/2022-01-13/novak-djokovic-health-risk-to-determine-visa-decision/100753502>.

57. Although nationalism typically relates to actions of one country, it can also involve a group of countries with similar interests. KECMANOVIC, *supra* note 44, at 15–16. For example, one commentator incorrectly claimed that vaccine companies from North America and Western Europe, but not those from Russian, China, or India, were vulnerable to "affirmative expropriation" due to the proposed waiver. Hans Sauer, *Waiving IP Rights During Times of COVID: A 'False Good Idea'*, IPWATCHDOG (Apr. 9, 2021, 7:15 AM), <https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/>. The statement is false because waiver of international IP norms would impact owners of IP rights in all countries.

58. Corporate attempts at nationalism can also sometimes be rebuffed. For example, the United States attempted to purchase exclusive access to a vaccine in development by German company CureVac but the company rebuffed that attempt and German leaders criticized the U.S. effort as inconsistent with the need for global cooperation. Owen Dyer, *COVID-19: Trump Sought to Buy Vaccine Developer Exclusively for US, Say German Officials*, 368 BRIT. MED. J. 1, 1 (2020); Katrin Bennhold & David E. Sanger, *U.S. Offered 'Large Sum' to German Company for Access to Coronavirus Vaccine Research, German Officials Say*, N.Y. TIMES (June 16, 2021), <https://www.nytimes.com/2020/03/15/world/europe/coronavirus-vaccine-us-germany.html>. Sanofi's CEO, on the other hand, was initially receptive to providing the United States with initial doses of its vaccine-in-progress due to U.S. funding but the French government pressured Sanofi to change course, with French President Emmanuel Macron asserting that the vaccine should be a "public good," for the entire world. Hanna Ziady & Pierre Bairin, *France Piles Pressure on Sanofi Over Coronavirus Vaccine Plans*, CNN BUS. (May 15, 2020, 8:08 AM), <https://www.cnn.com/2020/05/15/business/sanofi-vaccine-coronavirus/index.html>.

59. E.g., Hans von der Burchard, *AstraZeneca Chief Says UK got 'Priority' Access to Coronavirus Vaccine*, POLITICO (May 22, 2021, 3:49 PM), <https://www.politico.eu/article/astrazeneca-pascal-soriot-uk-priority-access-coronavirus-vaccine/>; see also Angela Dewan, *AstraZeneca's Vaccine Contract with the UK is Based on 'Best Efforts,' Just Like Its Deal with a Frustrated EU*, CNN (Feb. 18, 2021, 1:54 AM), <https://www.cnn.com/2021/02/17/europe/uk-astrazeneca-vaccine-contract-details-intl/index.html> (suggesting UK had an interest in ensuring contract with AstraZeneca would prioritize UK). Similarly, the chief executive of Serum Institute of India, the world's largest producer of vaccines, stated that most of the vaccine "would have to go to our countrymen before it goes abroad." Rebecca Weintraub, Asaf Bitton, & Mark L. Rosenberg, *The Danger of Vaccine Nationalism*, HARV. BUS. REV. (May 22, 2020), <https://hbr.org/2020/05/the-danger-of-vaccine-nationalism>.

60. Katherine Eban, *"We Are Hoarding": Why the U.S. Still Can't Donate COVID-19 Vaccines to Countries in Need*, VANITY FAIR (Apr. 6, 2021), <https://www.vanityfair.com/news/2021/04/why-the-us-still-cant-donate-covid-19-vaccines-to-countries-in-need>.

61. Although the United States eventually donated doses to Mexico and Canada, these were technically "loans" to get around the contractual language barring donations to retain liability protection within the United States. *Id.*

have also supported a nationalist approach to keeping COVID vaccines for the United States and have opposed any modification to IP rights for fear that other countries will steal U.S. innovations. For example, Republican senators argued that waiving international IP obligations would “enable foreign competitors to effectively steal the crown jewels of many American businesses” and suggested that “[i]t is no coincidence that most of the IP rights the waiver sponsors are planning to bypass are owned by American companies.”⁶²

B. Medical and Vaccine Nationalism

This Section focuses on explaining a subset of nationalism commonly discussed during the pandemic—medical nationalism. This includes but is not limited to the more commonly known term vaccine nationalism.⁶³ Understanding medical nationalism during COVID sets the stage for understanding how IP nationalism exhibited by the Global North exacerbates scarcity of IP-protected products like vaccines.

Medical nationalism encompasses nationalist actions concerning any activities or protections related to medical treatment⁶⁴ that result in demand outstripping supply such that only some nations end up receiving adequate supplies.⁶⁵ Medical nationalism includes nationalist actions regarding personal protective equipment, diagnostics, ventilator supplies, drugs, vaccines, and raw materials.⁶⁶ The United States exemplified medical nationalism when it purchased virtually all available supplies of Remdesivir, an initially promising COVID treatment.⁶⁷ U.S. contracts to purchase COVID vaccines also reflect vaccine nationalism because the

62. Letter from the Subcomm. on Cts., Intell. Prop., & the Internet, U.S. H.R., to Ambassador Katherine C. Tai, U.S. Trade Rep. (May 4, 2021), <https://republicans-judiciary.house.gov/wp-content/uploads/2021/05/2021-05-04-GOP-Courts-IP-to-USTR-re-WTO-TRIPS-Waiver.pdf> [hereinafter Congressional Letter to Tai]; see also Letter from Thom Tillis, Tom Cotton, & Marsha Blackburn, U.S. S., to Gina Raimondo, Sec’y U.S. Dep’t Com. (Mar. 23, 2022), <https://patent-docs.typepad.com/files/2023-03-23-tillis-cotton-blackburn-letter.pdf> (alleging that “compromise” agreement to waive TRIPS would “enable . . . hostile actors like China and Russia [] to simply steal cutting-edge American technology.”).

63. It could also be referred to as health care nationalism. See William Fisher, Ruth L. Okediji, & Padmashree Gehl Sampath, *Fostering Production of Pharmaceutical Products in Developing Countries*, 43 MICH. J. INT’L L. 1, 7 (2022).

64. Medical nationalism could more broadly include not providing the same medical care for those who are not citizens, as well as preferences for domestically trained doctors in U.S. medical residency programs. Yusuke Tsugawa, Anupam B. Jena, & Ashish K. Jha, *Immigrant Doctors Provide Better Care, According to a Study of 1.2 Million Hospitalizations*, HARV. BUS. REV. (Feb. 3, 2017), <https://hbr.org/2017/02/immigrant-doctors-provide-better-care-according-to-a-study-of-1-2-million-hospitalizations>.

65. E.g., Jeremy Youde, *How ‘Medical Nationalism’ is Undermining the Fight Against the Coronavirus Pandemic*, WORLD POL. REV. (Mar. 23, 2020), <https://www.worldpoliticsreview.com/articles/28623/how-medical-nationalism-is-undermining-the-fight-against-the-coronavirus-pandemic>.

66. Ezekiel Boro & Beat Stoll, *Barriers to COVID-19 Health Product in Low- and Middle-Income Countries During the COVID-19 Pandemic: A Rapid Systematic Review and Evidence Synthesis*, 10 FRONTIERS IN PUB. HEALTH 1, 2, 11 (2022).

67. Judy Stone, *US Buys World Supply of Remdesivir for Coronavirus—What Does that Mean for Public Health and Our Future?*, FORBES (July 2, 2020, 4:10 PM), <https://www.forbes.com/sites/judydystone/2020/07/02/us-buys-world-supply-of-remdesivir-for-coronavirus-what-does-that-mean-for-public-health-and-our-future/>.

agreements mandated that the vaccines only be used within the United States rather than permitting donations.⁶⁸ In addition, once clinical testing showed promising results, wealthy nations preordered more vaccine doses than needed to fully vaccinate their populations.⁶⁹ For example, Canada secured enough COVID vaccine doses to inoculate its population five times over.⁷⁰ These purchases resulted in fewer doses available for poor countries. As a result, the WHO initiative COVID-19 Vaccines Global Access (COVAX),⁷¹ which was intended to improve the bargaining power of poor countries that lacked adequate funding to compete with countries of the Global North,⁷² was unable to secure vaccine doses early in the pandemic.⁷³ Vaccine nationalism continued even after wealthy countries knew they had more vaccines than needed; these nations neither promptly donated their excess doses⁷⁴ nor heeded pleas by the UN and WHO to stop ordering vaccines, including boosters, so that COVAX and poor countries could obtain desperately needed initial doses.⁷⁵

Medical nationalism is also evidenced by domestic export bans that include laws that prioritize domestic needs first, such as the U.S. Defense Production Act.⁷⁶ Wealthy nations have banned the export of COVID vaccines as well as the raw materials needed to manufacture them,⁷⁷ which is

68. Eban, *supra* note 60. This language is consistent with the Trump Administration's nationalist approach considering no geographic restrictions were imposed during the H1N1 flu outbreak. *Id.*

69. Ewen Callaway, *The Unequal Scramble for Coronavirus Vaccines—By the Numbers*, NATURE (Aug. 27, 2020), <https://www.nature.com/articles/d41586-020-02450-x>.

70. Stephanie Hegarty, *Covid Vaccine Tracker: How's My Country and the Rest of the World Doing?*, BBC (Feb. 12, 2021), <https://www.bbc.com/news/world-56025355>.

71. 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. PHILIP LOFT, COVAX AND GLOBAL ACCESS TO COVID-19 VACCINES 8 (2021).

72. *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/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>. COVAX did contemplate that participating nations could still procure their own contracts, perhaps in hopes of luring the participation of wealthy countries. Seth Berkley, *COVAX Explained*, GAVI (Sept. 3, 2020), <https://www.gavi.org/vaccineswork/covax-explained>.

73. See, e.g., Megan Twohey, Keith Collins, & Katie Thomas, *With First Dibs on Vaccines, Rich Countries Have 'Cleared the Shelves'*, N.Y. TIMES (Dec. 18, 2020), <https://www.nytimes.com/2020/12/18/us/coronavirus-vaccine-doses-reserved.html>; 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/>.

74. Sheryl Gay Stolberg, *U.S. and Novavax Will Aid Global Vaccination Campaign*, N.Y. TIMES (June 3, 2021), <https://www.nytimes.com/2021/02/18/us/politics/biden-novavax-covax-vaccinations.html> (discussing donations “once there is sufficient supply in the United States,” but not when it was expanding vaccinations in the United States).

75. WHO Warns Against Blanket Boosters, as Vaccine Inequity Persists, U.N. NEWS (Dec. 22, 2021), <https://news.un.org/en/story/2021/12/1108622>.

76. See, e.g., Agarwal & Gopinath, *supra* note 23, at 15–16 (noting delays in raw materials from the United States because the act prioritized manufacture of domestic vaccines).

77. Matina Stevis-Gridneff, *EU Will Curb COVID Vaccine Exports for 6 Weeks*, N.Y. TIMES (May 6, 2021), <https://www.nytimes.com/2021/03/23/world/europe/eu-curbs-vaccine-exports.html>

particularly problematic because the raw materials only come from a handful of countries.⁷⁸ However, wealthy nations are not the only ones—after a huge spike in COVID infections, India demonstrated medical nationalism by unofficially barring vaccine exports, disrupting the global supply chain for planned vaccines.⁷⁹

Although companies and countries may donate COVID vaccines or funding to humanitarian entities like COVAX, the gestures do not negate the existence of medical nationalism. First, not only are wealthy countries donating long after they had time to substantially vaccinate interested citizens, their actual donations lag far behind the doses pledged.⁸⁰ Moreover, by the time the donations reach poor countries, they are often close to expiration and thus unusable.⁸¹ Even if the doses were timely delivered, the pledged amounts are woefully inadequate for global needs; for example, the Group of Seven (G7) promised to donate one billion doses but the total global need is eleven billion doses to vaccinate 70% of the population.⁸² Minimal donations were particularly problematic when combined with the

(limiting the ability of EU manufacturers to export COVID vaccines to the UK); *Access to COVID-19 Vaccines: Looking Beyond COVAX*, 397 LANCET 941, 941 (2021) (noting that in March 2021, Italy blocked export of AstraZeneca vaccines for Australia following disagreements between manufacturer and EU); T.V. Padma, *COVID Vaccines Won't Reach Poorest Countries Before 2023*, 595 NATURE 342, 342–43 (2021) (noting the United States and EU prohibit exports of some vaccines and vaccine ingredients); see also Imad Antoine Ibrahim, *Overview of Export Restrictions on COVID-19 Vaccines and Their Components*, AM. SOC'Y INT'L L., June, 2021, at 1–2 (discussing EU, India, and U.S. export bans and how they are permissible under exceptions to WTO law regarding international trade).

78. Ralf Peters & Divya Prabhakar, *Export Restrictions Do Not Help Fight COVID-19*, UNCTAD (June 11, 2021), <https://unctad.org/news/export-restrictions-do-not-help-fight-covid-19> (noting that the United States and the EU account for half of key ingredients for vaccines, with smaller amounts from Japan, the UK, and China).

79. Grady McGregor, *The World's Largest Vaccine Maker Can't Keep Up with the World's Worst COVID Wave*, FORTUNE (Apr. 20, 2021), <https://fortune.com/2021/04/20/india-covid-cases-vaccine-vaccinations-serum-institute/>.

80. Uamir Irfan, *Why Are Rich Countries Still Monopolizing COVID-19 Vaccines?*, VOX (Nov. 9, 2021, 8:30 AM), <https://www.vox.com/22759707/covid-19-vaccine-gap-covax-rich-poor-countries-boosters>; *U.S. International COVID-19 Vaccine Donations Tracker*, KAISER FAM. FOUND. (Oct. 14, 2022), <https://www.kff.org/coronavirus-covid-19/issue-brief/u-s-international-covid-19-vaccine-donations-tracker/> (showing majority of pledged U.S. COVID vaccines have not been delivered).

81. Irfan, *supra* note 80; *Poor Nations Forced to Dump Close-to-Expiry COVID Vaccines*, ALJAZEERA (Jan. 13, 2022), <https://www.aljazeera.com/news/2022/1/13/poorer-nations-dump-close-to-expiry-covid-vaccines-unicef>; Lise Barnéoud, *The Huge Waste of Expired COVID-19 Vaccines*, LE MONDE (Apr. 4, 2022, 9:47 AM), https://www.lemonde.fr/en/science/article/2022/04/04/the-huge-waste-of-expired-covid-19-vaccines_5979632_10.html; Annalisa Merelli, *Europe Sent Nigeria Up to 1 Million Near-Expired Doses of COVID-19 Vaccine*, QUARTZ AFR. (July 20, 2022), <https://qz.com/africa/2100629/europe-donated-near-expired-doses-of-vaccine-to-african-countries/>.

82. E.g., Elizabeth Piper & Kate Holton, *"We Need More": UN Joins Criticism of G7 Vaccine Pledge*, REUTERS (June 12, 2021, 10:48 AM), <https://www.reuters.com/business/healthcare-pharmaceuticals/g7-donate-1-billion-covid-19-vaccine-doses-poorer-countries-2021-06-10/>; World Health Org., *WHO, UN Set Out Steps to Meet World COVID Vaccination Targets*, WHO (Oct. 7, 2021), <https://www.who.int/news/item/07-10-2021-who-un-set-out-steps-to-meet-world-covid-vaccination-targets>.

fact that wealthy countries with high vaccination rates purchased unnecessary doses beyond booster shots, such that few doses were available.⁸³

As with nationalism in general, medical nationalism also includes actions that are not strictly necessary to protect a nation's citizens but instead are done to create the perception that domestic interests are being prioritized. For example, as mentioned above,⁸⁴ the United States originally resisted donating AstraZeneca vaccines that were unauthorized for use in the United States and thus of no utility to American citizens.⁸⁵ Although the United States eventually donated these vaccines, they did so only after severe spikes in COVID infections in other countries, a drop in global supply, and pressure from both health experts and the manufacturer itself.⁸⁶ Further, the United States donated these doses only after it had vaccinated almost half of its adult population at least once.⁸⁷ The practice of administering booster shots, sometimes for a total of three to four doses per person, also reflects medical nationalism because extra doses are often unnecessary to prevent hospitalization for most individuals.⁸⁸ In addition, low contribution rates of excess vaccines and inadequate COVAX funding reflect medical nationalism because wealthy countries prioritize domestic vaccine needs even when there is ample supply.

Medical nationalism substantially impacts all countries during a global pandemic. Delayed vaccines cause unnecessary illness and death—

83. Aubrey Allegretti, *UK Set to 'Hoard' Up to 210 Million Doses of COVID Vaccine, Research Suggests*, GUARDIAN (Aug. 9, 2021, 1:00 AM), <https://www.theguardian.com/society/2021/aug/09/uk-set-to-hoard-up-to-210m-doses-of-covid-vaccine-research-suggests> (noting that only ninety-five million of the 306 million planned to be delivered to the UK in 2021 are needed for current vaccinations including booster doses for the most vulnerable); Goldhill, *supra* note 7; see also Denis Campbell & Nicola Davis, *COVID Booster Jabs in England to Be Thrown Away as Demand Falls*, GUARDIAN (Jan. 14, 2022, 1:09 PM), <https://www.theguardian.com/society/2022/jan/14/covid-booster-jabs-in-england-to-be-thrown-away-as-demand-falls> (noting that purchased doses are going to waste in wealthy countries where there is inadequate interest in boosters).

84. Weixel, *supra* note 52.

85. Weiland & Robbins, *supra* note 53.

86. *Id.* (noting AstraZeneca requested the U.S. government donate unused doses); Josh Wingrove & Bloomberg, *Biden to Distribute an Additional 20 Million COVID Vaccines Abroad*, FORTUNE (May 17, 2021, 11:19 AM), <https://fortune.com/2021/05/17/global-covid-vaccines-20-million-joe-biden-administration-vaccination-supply/>; see also *Coronavirus: EU 'Not Ready' to Share COVID Vaccines With Poorer Countries*, DEUTSCHE WELLE (Mar. 21, 2021), <https://www.dw.com/en/coronavirus-eu-not-ready-to-share-covid-vaccines-with-poorer-countries/a-56944274> (noting EU delayed planned donations to poor countries after reduction in anticipated supplies).

87. Wingrove & Bloomberg, *supra* note 86.

88. Kershner, *supra* note 54; Markham Heid, *Why Experts Can't Seem to Agree on Boosters*, N.Y. TIMES (Apr. 13, 2022), <https://www.nytimes.com/2022/04/13/opinion/covid-booster-shot.html>; Marty Makary, *FDA Shuts Out Its Own Experts in Authorizing Another Vaccine Booster*, WALL ST. J. (Apr. 3, 2022, 5:04 PM), <https://www.wsj.com/articles/fda-shuts-out-its-own-experts-in-authorizing-another-booster-covid-vaccine-pandemic-science-11649016728>.

potentially nearly twice as many as would occur if vaccines were proportionately distributed.⁸⁹ Vaccine inequity also leads to greater income inequity.⁹⁰ Moreover, the impact of inequitable distribution affects all nations.⁹¹ After all, if COVID cases are uncontrolled in some parts of the world, this increases the risk of mutation, which can create variants that may not be controlled by existing vaccines or treatments.⁹² Studies show that *all* countries, even wealthy ones, suffer economically if poorer countries have inadequate vaccine supplies because these shortages disrupt global supply chains, which can lead to inflation.⁹³ Astonishingly, one study estimates that for every dollar spent on vaccines for poor countries, high income countries would get back nearly five dollars.⁹⁴ In short, if medical nationalism continues to prevent the poorest countries from accessing vaccines, the entire world stands to suffer billions of dollars in losses.

89. Matteo Chinazzi, Jessica T. Davis, Natalie E. Dean, Kunpeng Mu, Ana Pastore y Piontti, Xinyue Xiong, M. Elizabeth Halloran, Ira M. Longini Jr., & Alessandro Vespignani, *Estimating the Effect of Cooperative Versus Uncooperative Strategies of COVID-19 Vaccine Allocation: A Modeling Study*, NE. U. NETWORK SCI. INST., 2020, at 5–6.

90. *UN Analysis Shows Link Between Lack of Vaccine Equity and Widening Poverty Gap*, U.N. NEWS (Mar. 28, 2022), <https://news.un.org/en/story/2022/03/1114762>; see also *Vaccine Equity and Speed*, UNDP: DATA FUTURES, <https://data.undp.org/vaccine-equity-archive/vaccine-equity-and-speed/> (last visited Oct. 22, 2022) (noting that if low-income countries had the same vaccination rate as high-income countries in September 2021, their GDP would have increased by over sixteen billion in 2021); *Impact of Vaccine Inequity on Economic Recovery*, UNDP: DATA FUTURES (Feb. 2022), <https://data.undp.org/vaccine-equity-archive/impact-of-vaccine-inequity-on-economic-recovery-2022/> (noting continued downward trend for poor countries, tied to inequitable vaccine rates).

91. Cem Çakmakli, Selva Demiralp, Şebnem Kalemlı-Özcan, Sevcan Yeşiltaş, & Muhammed A. Yildirm, *The Economic Case for Global Vaccinations: An Epidemiological Model with International Production Networks* 50–51 (Nat'l Bureau of Econ. Rsch., Working Paper No. 28395, 2021); Federico Suárez Ricaurte, *Understanding Supply Chain Disruption During the COVID-19 Pandemic*, MCGILL BUS. L. PLATFORM (Feb. 22, 2022), <https://www.mcgill.ca/business-law/article/understanding-supply-chain-disruptions-during-covid-19-pandemic>; Marco Hafner, Erez Yerushalmi, Clement Fays, Eliane Dufresne, & Christian van Stolk, *COVID-19 and the Cost of Vaccine Nationalism*, RAND EUR., 2020, at 27–30, 32.

92. Caroline E. Wagner, Chadi M. Saad-Roy, Sinead E. Morris, Rachel E. Baker, Michael J. Mina, Jeremy Farrar, Edward C. Holmes, Oliver G. Pybus, Andrea L. Graham, Ezekiel J. Emanuel, Simon A. Levin, C. Jessica E. Metcalf, & Bryan T. Grenfell, *Vaccine Nationalism and the Dynamics and Control of SARS-CoV-2*, SCI., Sept., 2021, at 9; William A. Haseltine, *Omicron Evades Most But Fortunately Not All Monoclonal Antibodies*, FORBES (Dec. 23, 2021, 10:39 AM), <https://www.forbes.com/sites/williamhaseltine/2021/12/23/omicron-evades-most-but-fortunately-not-all-monoclonal-antibodies/?sh=64c35ce582fe>.

93. Çakmakli et al., *supra* note 91, at 35 (estimating global economy could lose up to \$9 trillion in U.S. dollars if vaccinations do not happen for several years, with half the cost suffered by rich nations whose exports would be suppressed); Tina Fong, *How's Vaccine Inequality Driving Up Global Inflation?*, SCHRODERS (Sept. 30, 2021), <https://www.schroders.com/en/mt/professional-investor/insights/economics/hows-vaccine-inequality-driving-up-global-inflation/> (noting that unequal vaccine distribution can prompt global inflation); see also World Health Org., *Vaccine Inequity Undermining Global Economic Recovery*, WHO (Jul. 22, 2021), <https://www.who.int/news/item/22-07-2021-vaccine-inequity-undermining-global-economic-recovery> (noting that low-income countries could add nearly \$40 billion to their 2021 GDP if they had similar vaccination rates as high-income countries); Ana Maria Santacreu & Jesse LaBelle, *Global Supply Chain Disruptions and Inflation During the COVID-19 Pandemic*, FED. RSRV. BANK OF SAINT LOUIS REV., 2022, at 12; Ricaurte, *supra* note 91.

94. Hafner et al., *supra* note 91, at vi.

II. AN UNSPOKEN YET CRITICAL PROBLEM: IP NATIONALISM

This Part provides an overview of IP nationalism as a new and dangerous type of nationalism.⁹⁵ This Part begins by explaining IP nationalism, which is evidenced by the Global North's efforts to extract profits from IP-intensive exports, typically to the detriment of the Global South. Then, this Part provides examples of IP nationalism prior to COVID to contextualize how this nationalist behavior originated. It also discusses how IP nationalism has been unnecessarily harmful during the pandemic by undermining a global public goods approach that could have helped to combat vaccine nationalism.

A. IP Nationalism Primarily of the Global North

1. Basics of IP Nationalism

As noted above, although all countries may take a nationalistic approach to IP, this Article focuses on delineating the dangers of IP nationalism as exhibited by the wealthy countries of the Global North that, by promoting strong IP rights globally, price essential goods, such as vaccines, out of reach for many citizens of the Global South. For countries that have high exports of IP-protected products, such as drugs, technology, and entertainment (films and movies), this promotes overall domestic economic interests only if other countries also provide strong IP rights that maximize revenue. For example, overall gross domestic product (GDP) increases if a nation's exports of copyrighted films are protected in other countries by strong copyright laws as those copyright laws result in profits to domestic industries.⁹⁶ Given that the United States is a major exporter of IP-intensive goods, it is unsurprising that U.S. government officials often promote "strong" or "effective" IP rights.⁹⁷ Of course, such actions

95. Alex Capri, *Techno-Nationalism: What Is It and How Will It Change Global Commerce?*, FORBES (Dec. 20, 2019, 4:50 AM), <https://www.forbes.com/sites/alexcapri/2019/12/20/techno-nationalism-what-is-it-and-how-will-it-change-global-commerce/?sh=4d175770710f> (noting it may be somewhat related, yet distinct from the concept of techno-nationalism that emphasizes technology contributing to domestic economic growth, as well as social stability and national security); Amol Rajan, *Techno-Nationalism Could Determine the 21st Century*, BBC (Sept. 8, 2018), <https://www.bbc.com/news/technology-45370052> (noting that the focus on techno-nationalism is on technology, but does not require strong IP rights).

96. STEPHEN E. SIWEK, COPYRIGHT INDUSTRIES IN THE U.S. ECONOMY 3 (2018); Christian Handke, *Economic Effects of Copyright: The Empirical Evidence So Far*, NAT'L ACADEMIES, Apr. 2011, at 16.

97. See, e.g., *Intellectual Property*, OFF. U.S. TRADE REPRESENTATIVE, <https://ustr.gov/issue-areas/intellectual-property> (last visited Oct. 22, 2022) (noting that United States Trade Representative uses a variety of levers to promote "strong intellectual property rights"); *Intellectual Property Enforcement*, U.S. DEP'T STATE, <https://www.state.gov/intellectual-property-enforcement/> (last visited Oct. 22, 2022) (referring to IP as "the lifeblood of our economy"); *Remarks By Director Iancu at U.S. Chamber of Commerce Event "How Innovation and Creativity Drive American Competitiveness"*, USPTO (Jan. 19, 2021), <https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-us-chamber-commerce-event-how-innovation-and> (noting importance of strong IP); *Why Is IP Important?*, U.S. CHAMBER COM. GLOB. INNOVATION POL'Y CTR., <https://www.theglobalip-center.com/why-is-ip-important/> (last visited Oct. 22, 2022) (noting that U.S. IP is worth \$6.6 trillion and that IP-intensive industries account for over one third of U.S. GDP and more than half of U.S.

also impose substantial costs on the Global South that then struggles to pay an IP premium on needed medicines and other essential items such as books central to education.⁹⁸

IP nationalism can also include actions to protect domestic IP from being stolen. For example, visa limits on Chinese students and scholars were purportedly enacted to limit these individuals from stealing IP for China.⁹⁹ Additionally, the ban forbidding U.S. companies from working with the Chinese company Huawei to avoid IP theft is IP nationalism.¹⁰⁰ Laws and proposed laws that protect domestic IP are also included.¹⁰¹ Similarly, IP nationalism extends beyond simply protecting domestic IP to include negative characterizations of other nations. This is reflected in a statement by the Assistant Attorney General for National Security who said, in the context of hackers, that “the Chinese Communist party [has an] insatiable hunger for American and other non-Chinese companies’ hard earned intellectual property, including COVID-19 research.”¹⁰²

IP nationalism is a concept related to, yet distinct from, “innovation nationalism.” The term innovation nationalism was coined to explain how the United States embraces a national identity of innovation, which has

merchandise exports); *see also* Congressional Letter to Tai, *supra* note 62 (noting “respect for IP rights has been a cornerstone of US trade policy for decades and should not be set aside lightly”); *Intellectual Property Rights*, OFF. U.S. TRADE REPRESENTATIVE, <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-chapter-chapter-negotiating-9> (last visited Oct. 22, 2022) (“As the world’s most innovative economy, strong and effective protection and enforcement of IP rights is critical to U.S. economic growth and American jobs.”); Letter from Stephen J. Ubl, PhRMA President and CEO, to Joseph R. Biden, President of the United States (Mar. 5, 2021), <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/20210305-PhRMA-Letter-to-President-Biden.pdf> (asserting IP has been essential to development of COVID treatments).

98. Max Bearak & Emily Rauhala, *Hopes Surge for Boosted Vaccine Supply After U.S. Voices Support for Waiving Patents, Even as Uncertainty Remains*, WASH. POST (May 6, 2021, 5:02 PM), <https://www.washingtonpost.com/world/2021/05/06/vaccine-intellectual-property-world-reaction/>; Alexander Smith, *U.S. Reversal on Vaccine Patents Offers Countries in Crisis Hope, But Hurdles Persist*, NBC NEWS (May 6, 2021, 10:21 AM), <https://www.nbcnews.com/news/world/u-s-reversal-vaccine-patents-offers-countries-crisis-hope-hurdles-n1266520>.

99. Elizabeth Redden, *Trump Proclamation Bars Entry of Certain Chinese Students*, INSIDE HIGHER ED (June 1, 2020), <https://www.insidehighered.com/quicktakes/2020/06/01/trump-proclamation-bars-entry-certain-chinese-students>.

100. Damian Paletta, Ellen Nakashima, & David J. Lynch, *Trump Administration Cracks Down on Giant Chinese Tech Firm, Escalating Clash With Beijing*, WASH. POST (May 16, 2019, 2:09 PM), https://www.washingtonpost.com/world/national-security/trump-signs-order-to-protect-us-networks-from-foreign-espionage-a-move-that-appears-to-target-china/2019/05/15/d982ec50-7727-11e9-bd25-c989555e7766_story.html.

101. *See, e.g.*, Stop Online Piracy Act, H.R. 3261, 112th Cong. (2011); Combating Online Infringement and Counterfeits Act, S. 3804, 111th Cong. (2010); The Preventing Real Online Threats to Economic Creativity and Theft of Intellectual Property Act, S. 968, 112th Cong. (2011); 35 U.S.C. § 203 (2011). During COVID, some legislators proposed laws to prevent the United States from supporting change to global IP laws for similar reasons. *See infra* note 268.

102. Press Release, U.S. Dept. of Just., *Two Chinese Hackers Working with the Ministry of State Security Charged with Global Computer Intrusion Campaign Targeting Intellectual Property and Confidential Business Information, Including COVID-19 Research* (July 12, 2020), <https://www.justice.gov/opa/pr/two-chinese-hackers-working-ministry-state-security-charged-global-computer-intrusion>.

contributed to the exportation and forced adoption of U.S. IP norms globally.¹⁰³ However, IP nationalism is broader in that it focuses on a nation's interactions in the global arena that emphasize strong IP rights notwithstanding any domestic identity based on innovation.¹⁰⁴ Although the United States engages in both IP nationalism and innovation nationalism, such behavior is not true of all countries that embrace IP nationalism. Notably, a country could embrace IP nationalism not because it predominantly believes that the country is innovative—despite lobbying by self-interested companies that so proclaim—but rather because it believes that the approach yields (or will yield) financial benefits.¹⁰⁵

Based upon this definition, IP nationalism can be embraced by countries that do not have substantial exports of IP-intensive goods because these countries assume that the approach will yield financial benefits. A nation could embrace IP nationalism in the global context by agreeing to higher international IP norms with the belief that strong IP rights globally will ultimately promote domestic innovation resulting in greater direct economic benefits. Alternatively, a nation could embrace IP nationalism to indirectly lead to economic benefits. For example, a nation may embrace IP nationalism to curry favor with a country known to embrace IP nationalism in hopes that it would result in preferential trade associations bringing economic benefits. This scenario would explain why some countries without strong IP export industries, such as Colombia and Mexico, have opposed changing IP norms during COVID.¹⁰⁶ Further, some countries with limited IP exports may nonetheless support strong IP norms because of the economic benefits from trading non-IP goods under free trade agreements with countries that require strong IP rights like the United States. For example, although Canada and Australia have fewer IP exports than the United States,¹⁰⁷ both countries have free trade agreements with

103. Kumar, *supra* note 3, at 208–09 (arguing that the United States has historically embraced innovation to better understand U.S. patent policy, and how the Trump Administration's promotion of nativism was a departure).

104. *Id.*

105. Of course, it is also possible that corporate lobbying results in policy capture. *E.g.*, Jerome H. Reichman & Keith H. Maskus, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 J. INT'L ECON. L. 279, 286 (2004) (noting that countries that promote IP often seem subject to policy capture, rather than rational balancing of domestic needs).

106. Sidhartha, *Patent Waiver Talks Falter on Developed Nations' Hurdles*, TIMES INDIA (July 1, 2021, 4:10 PM), <https://timesofindia.indiatimes.com/business/india-business/patent-waiver-talks-falter-on-developed-nations-hurdles/articleshow/84017314.cms>.

107. CONG. RSCH. SERV., USMCA: INTELLECTUAL PROPERTY RIGHTS (IPR) 1 (2020). They have industries that benefit from IP, although not to the same extent as the United States. *See id.* (noting United States' comparative advantage); David Richardson, *Intellectual Property Rights and the Australia–US Free Trade Agreement*, ECON., COM. & INDUS. RELS. SECTION, May 2014 (noting that Australia is a net importer of IP); DANIEL SCHWANEN & AARON JACOBS, PATENTS, COPYRIGHT AND UNFAIR COMPETITION: ASSESSING THE IMPACT OF TRADE DEALS ON CANADA 1 (noting that Canada is a net importer of IP).

the United States that require stronger IP rights in exchange for non-IP export benefits.¹⁰⁸

2. The Relationship Between Medical Nationalism and IP Nationalism

Whereas medical nationalism is about the hoarding of physical supplies¹⁰⁹ (which creates or exacerbates scarcity), IP nationalism is about hoarding knowledge and IP to prevent physical supplies from being produced.¹¹⁰ Medical nationalism inherently involves a zero-sum game whereby one person's (or nation's) win necessarily means another's loss of a tangible good such as a drug or ventilator valve that is in limited supply.¹¹¹ On the other hand, IP nationalism is different than medical nationalism because if IP nationalism is rejected, there could be adequate quantities of needed goods.¹¹² IP owners can legally bar others from making IP-protected goods, creating an artificial scarcity of these products.¹¹³ Additionally, to the extent that IP nationalism focuses on maintaining the status quo IP rights during a pandemic when there are inadequate supplies, this exacerbates medical nationalism. However, if IP nationalism were rejected and the usual IP exclusivity lifted, artificial scarcity could be alleviated, thereby reducing the harms of medical nationalism.¹¹⁴ Indeed, the hoarding of limited medical supplies during a pandemic can be attributed at least in part to the existence of usual IP rights; after all, there would be no need to stockpile medical supplies during the pandemic if IP rights were waived and more manufacturers could freely make these supplies.¹¹⁵ Of course, even if IP rights are waived, supply issues are not immediately abated because companies need time to ramp up facilities, although this

108. *E.g.*, *USMCA is Good for Canada and Small Business, Minister Ng Tells Audience in Guelph*, GOV'T CAN. (Oct. 26, 2018), <https://www.canada.ca/en/innovation-science-economic-development/news/2018/10/usmca-is-good-for-canada-and-good-for-small-business-minister-ng-tells-audience-in-guelph.h> (noting that USMCA helps to stabilize Canada's economy, but not suggesting that IP norms are helpful). Indeed, some argued that stronger IP rights would harm citizens in Australia and in Canada. *See, e.g.*, James McLeod, *Canada 'Caved' on Intellectual Property Provisions in USMCA Trade Deal, Experts Say*, FIN. POST (Oct. 1, 2018), <https://financialpost.com/technology/canada-caved-on-intellectual-property-provisions-in-usmca-trade-deal-experts-say>; *see generally* Thomas Faunce, Evan Doran, David Henry, Peter Drahos, Andrew Searles, Brita Pekarsky, & Warwick Neville, *Assessing the Impact of the Australia–United States Free Trade Agreement on Australian and Global Medicines Policy*, GLOBALIZATION & HEALTH, Oct. 2005, at 1–2, 9.

109. Zhongyuan Wang, *From Crisis to Nationalism?*, 6 CHINESE POL. SCI. REV. 20, 25 (2021).

110. *Id.*

111. *E.g.*, 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 (July 17, 2020) [hereinafter *Beyond Access to Medicines*]; *The Netherlands Joins COVID-19 IP Pool Initiative; Kentucky Governor Requests 3M Release N95 Patent*, HEALTH POL'Y WATCH (Aug. 4, 2020), <https://healthpolicy-watch.news/the-netherlands-joins-covid-19-ip-pool-initiative-kentucky-governor-requests-3m-release-n95-patent/>.

112. *Beyond Access to Medicines*, *supra* note 111.

113. *E.g.*, 35 U.S.C. § 271(a)–(d).

114. *See id.*

115. This is true even though some aspects of medical nationalism are not directly attributable to typical IP rights, like contracts with vaccine manufacturers that limit the ability of nations to resell or donate.

can be done in a matter of months.¹¹⁶ Accordingly, some problems of medical nationalism can be mediated if typical IP rights are modified.

Although IP nationalism and medical nationalism are often interrelated, IP nationalism can exist separately from medical nationalism. The Bill and Melinda Gates Foundation (Gates Foundation) is an example of an entity that acts consistent with IP nationalism but not medical nationalism. Historically, it has provided global donations and funding to manufacturers in poor countries, which can help combat medical nationalism.¹¹⁷ Unsurprisingly, during the COVID pandemic, Bill Gates argued against nationalist approaches to vaccines and suggested that nations work together to increase vaccine capacity, illustrating an opposition to medical nationalism.¹¹⁸ Initially, however, the Gates Foundation was strongly critical of any modification of IP rights to promote COVID treatments,¹¹⁹ including allegedly pressuring one of the vaccine coinventors to not waive IP rights.¹²⁰ This opposition to waiving IP rights prevented the Gates Foundation from promoting its goal of countering medical nationalism.

3. Who Engages in IP Nationalism and to What Extent?

Wealthy countries in the Global North engage in IP nationalism but the extent to which they engage is not uniform. At the surface, this may seem unsurprising because not all wealthy countries have IP-intensive exports. However, the situation is more complex. For example, even though the United States' actions in recent decades reflect IP nationalism, the United States surprised many when it announced partial support of a

116. 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/#> (noting that it takes six months to ramp up production for vaccines).

117. *Ahead of EU–AU Summit, African Medicines Regulators Receive Boost of More Than 100 Million Euros from Team Europe and the Bill & Melinda Gates Foundation*, BILL & MELINDA GATES FOUND. (Feb. 15, 2022), <https://www.gatesfoundation.org/ideas/media-center/press-releases/2022/02/100-million-euros-donated-to-fund-african-medicines-agency>.

118. James Paton, *Bill Gates Best on Solution to Vaccine Nationalism: Mass Output*, BLOOMBERG (June 4, 2020, 9:30 AM), <https://www.bloomberg.com/news/articles/2020-06-04/gates-bets-on-solution-to-vaccine-nationalism-mass-output>.

119. Alexander Zaitchik, *How Bill Gates Impeded Global Access to COVID Vaccines*, NEW REPUBLIC (Apr. 12, 2021), <https://newrepublic.com/article/162000/bill-gates-impeded-global-access-covid-vaccines> (“As it happens, a novel use of one category of intellectual property—copyright, applied to computer code—made Gates the richest man in the world for most of two decades beginning in 1995.”); see also Sandi Doughton, *Have Gates Foundation Efforts to Vaccinate World Against COVID-19 Helped—or Hindered?*, SEATTLE TIMES (June 20, 2021, 6:00 am), <https://www.seattletimes.com/seattle-news/health/have-gates-foundation-efforts-to-vaccinate-the-world-against-covid-19-helped-or-hindered/> (arguing Gates' embrace of IP nationalism is likely due to the fact that IP helped create his current wealth).

120. Jay Hancock, *Oxford's COVID Vaccine Deal with AstraZeneca Raises Concerns About Access and Pricing*, FORTUNE (Aug. 24, 2020, 3:00 AM), <https://fortune.com/2020/08/24/oxford-astrazeneca-covid-vaccine-deal-pricing-profit-concerns/> (explaining that after the United States indicated support for a waiver of IP rights, he signaled support for that); but see *Statement from Gates Found. CEO Mark Suzman: No Barriers Should Stand in the Way of Equitable Vaccine Access*, BILL & MELINDA GATES FOUND., <https://www.gatesfoundation.org/ideas/media-center/press-releases/2021/05/covid-vaccine-access> (last visited Oct. 22, 2022).

waiver of international obligations for COVID IP.¹²¹ This support still reflected IP nationalism, however, because it was only for vaccines and excluded non-vaccine treatments despite their necessity for the many who could not obtain vaccines.¹²² Moreover, the United States also embraced IP nationalism by resisting pressure to persuade U.S. companies to share vaccine technology and trade secrets, which are necessary to make vaccines.¹²³

In addition, although the European Union (EU) as a whole generally embraces IP nationalism and lobbies for stronger IP rights alongside the United States, member states of the EU do not all share this view and have taken different approaches to IP sharing during COVID.¹²⁴ For example, the Netherlands and Portugal support the WHO COVID-19 Technology Access Pool (WHO Pool), a mechanism that facilitates companies to voluntarily share COVID IP,¹²⁵ but still opposed a broad waiver of international IP obligations.¹²⁶ These actions still reflect IP nationalism because the WHO Pool simply enables companies to elect to share IP, whereas a waiver of international obligations would permit all WTO member-countries to waive IP rights without the approval of the companies that own the IP.¹²⁷ Thus, support for the WHO Pool is consistent with strong IP rights because while it promotes sharing, it also permits companies to decline sharing just as they historically have done.

121. *E.g.*, Contreras, *supra* note 37.

122. *See id.*

123. *E.g.*, Zain Rizvi, Jishian Ravinthiran, & Amy Kapczynski, *Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide*, HEALTH AFF. (Aug. 6, 2021), <https://www.healthaffairs.org/doi/10.1377/forefront.20210804.101816/>; Matthew Kavanagh & Madhavi Sunder, *Biden Must Push Drug Firms to Share Science with the World*, BLOOMBERG (Apr. 23, 2021, 2:00 AM), <https://news.bloomberglaw.com/us-law-week/biden-must-push-drug-firms-to-share-science-with-the-world/>; Jake Johnson, *NIH Scientist Who Developed Key Vaccine Technology Says Patent Gives US Leverage Over Big Pharma*, COMMON DREAMS (Apr. 23, 2021), <https://www.commondreams.org/news/2021/04/23/nih-scientist-who-developed-key-vaccine-technology-says-patent-gives-us-leverage/>; Christopher J. Morten, Laurel Boman, Joe Rabinovitsj, & Celine Rohr, *US 10,960,070: The U.S. Government's Important New Coronavirus Vaccine Patent*, N.Y. UNIV., Apr. 2021, at 5; Christopher Rowland, *Advocates Want NIH to Use Its Moderna Vaccine Patent to Push for Global Access*, WASH. POST (Mar. 25, 2021, 7:00 AM), <https://www.washingtonpost.com/business/2021/03/25/moderna-vaccine-patent-nih/>.

124. *See infra* Section II.B (discussing how creation of TRIPS was due to efforts of United States and EU).

125. World Health Org., *Endorsements of the Solidarity Call to Action*, WHO, <https://www.who.int/initiatives/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action> (last visited Oct. 22, 2022); Ed Silverman, *The WHO Launched a Voluntary COVID-19 Product Pool. What Happens Next?*, STAT (May 29, 2020), <https://www.statnews.com/pharmalot/2020/05/29/who-covid19-coronavirus-patents/> [hereinafter *What Happens Next?*]; Ingeborg Eliassen, Harald Schumann, Maria Maggiore, Sigrid Melchior, & Wojciech Cieřla, *The Unexpected European Dilemma: Support the US—or Big Pharma?*, INVESTIGATE EUR. (May 7, 2021), <https://www.investigate-europe.eu/en/2021/vaccine-patent-waiver-usa-europe-covid-trips-wto/>.

126. Nuala Moran, *WHO Launches COVID-19 Patent Pool, Backed By 35+ Countries*, BIOWORLD (May 29, 2020), <https://www.bioworld.com/articles/435437-who-launches-covid-19-patent-pool-backed-by-35-countries?v=preview> (noting Norway, the Netherlands, Portugal, and Luxembourg as wealthy countries in favor of the pool); *EU Sceptical on Vaccine Waiver, But Ready to Discuss Proposal*, REUTERS (May 8, 2021), <https://www.reuters.com/world/europe/eu-sceptical-vaccine-waiver-ready-discuss-proposal-2021-05-08/> [hereinafter *EU Sceptical*].

127. *EU Sceptical, supra* note 126.

Even wealthy countries without IP-intensive exports may engage in IP nationalism. For example, although Canada historically has not supported strong IP rights before being required to by free trade agreements,¹²⁸ it has not endorsed the WHO Pool.¹²⁹ This could be based on a desire to maintain good trade relations with the United States, a country that certainly does embrace strong IP rights and originally objected to the WHO Pool.¹³⁰ Interestingly, two years after the WHO Pool was created, the United States signaled that it recognizes that IP can be a barrier during emergencies and contributed some COVID IP to the WHO Pool.¹³¹ However, Canada's position on the WHO Pool has not changed. Additionally, unlike the United States, Canada did not initially support a waiver of international IP obligations beyond being open to discussion.¹³²

Further, countries of the Global North only engage in IP nationalism when it is in their self-interest. For example, although the United States generally insists that other nations have strong IP rights and objected to South Africa's use of legitimate international exceptions to patents in the wake of a human immunodeficiency virus (HIV) epidemic, the United States did not hesitate to consider an exception to its own patent rights to permit the government to make a patented antibiotic after a few of its citizens died from anthrax.¹³³ More recently, although the United States and

128. CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY 162 (2011) (noting that Canada broadly granted compulsory licenses on drugs to increase access to medicine until a free trade agreement with the United States required it to change its laws).

129. Jordan Jarvis & Joel Lexchin, *WHO's COVID-19 Technology Access Pool Deserves Canada's Support*, POL'Y OPTIONS POLITIQUES (July 14, 2020), <https://policyoptions.irpp.org/magazines/july-2020/whos-covid-19-technology-access-pool-deserves-canadas-support/> (criticizing Canada's lack of support for WHO patent pool); Joel Lexchin, *Canada is Virtue Signaling While Waffling on Global Access to COVID-19 Vaccines*, CONVERSATION (May 11, 2021, 5:22 PM), <https://theconversation.com/canada-is-virtue-signalling-while-waffling-on-global-access-to-covid-19-vaccines-160685> (stating that although the WHO Pool is endorsed by forty countries, Canada is not one of them).

130. 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> [hereinafter *Voluntary Pool*] (noting United States rejecting involvement in the WHO Pool).

131. Ed Silverman, *National Institutes of Health Licenses Nearly a Dozen COVID-19 Technologies to WHO Program*, STAT (May 12, 2022), <https://www.statnews.com/pharmalot/2022/05/12/nih-covid19-vaccines-who-patents/>; see also Jon Cohen, *'A Pretty Big Deal': U.S. Makes COVID-19 Technologies Available for Use in Developing Countries*, SCIENCEINSIDER (May 13, 2022, 3:50 PM), <https://www.science.org/content/article/pretty-big-deal-u-s-makes-covid-19-technologies-available-use-developing-countries#> (noting that the United States' contribution could have an important signaling function).

132. E.g., Council of Canadians, *Over 100 Organizations and Experts Call on Canada to Publicly Support a Trips Waiver Now*, (Nov. 25, 2021), <https://canadians.org/media/over-100-organizations-and-experts-call-canada-publicly-support-trips-waiver-now/> (highlighting letter to Honorable Mary Ng); John Willinsky, *Time for Canadian Leadership on the TRIPS Waiver*, SLAW (Mar. 9, 2022), <http://www.slaw.ca/2022/03/09/time-for-canadian-leadership-on-the-trips-waiver/>.

133. HO, *supra* note 128, at 339.

the EU criticized countries for issuing permissible, internationally recognized, compulsory licenses in 2020,¹³⁴ that same year, certain wealthy nations such as Canada, France, and Germany amended compulsory license laws to make them easier to issue for COVID treatments.¹³⁵

B. Illustrations of IP Nationalism Prior to COVID

Although the COVID pandemic has revealed serious problems with IP nationalism, it is not a new phenomenon. In fact, IP nationalism is reflected in current global IP norms. Since 1995, most members of the WTO have been obligated to provide certain “minimum” levels of IP pursuant to the WTO IP agreement (commonly referred to as TRIPS).¹³⁶ However, the creation of TRIPS as part of the global trade system was orchestrated by a handful of powerful companies that persuaded the United States and the EU to seek these global IP rights.¹³⁷ In particular, pharmaceutical manufacturers, technology companies, and the film industry strongly advocated for global IP norms because such norms would permit them to profit more from exports of their IP-intensive products.¹³⁸ Although some developing countries, such as India, fought hard against the erosion of their domestic sovereignty by suggesting narrower international IP obligations, those suggestions did not prevail.¹³⁹ Indeed, scholars have repeatedly noted that the discussion was unbalanced and even that developing countries may have been coerced into accepting TRIPS.¹⁴⁰ The current infrastructure means that nations must largely comply with the IP goals of IP-exporting nations. As a result, today’s international rules concerning IP inherently reflect and arguably even endorse IP nationalism by the Global North.

Although TRIPS already reflects IP nationalism, it is simply a pivotal point in the global landscape—there are examples of IP nationalism from both before and after its requirements went into effect. Prior to TRIPS, the

134. OFF. OF THE U.S. TRADE REPRESENTATIVE, SPECIAL 301 REPORT 5, 14, 48, 50, 62, 75 (2020) [hereinafter Special 301 Report] (criticizing Indonesia, India, Chile, and Turkey for potential threat of compulsory licenses). The EU IP enforcement report 2020 criticized several developing countries for using compulsory licenses. Jan. 15, 2021, WTO Communication, *supra* note 24.

135. *E.g.*, Adam Houldsworth, *The Key COVID-19 Compulsory Licensing Developments So Far*, IAM (Apr. 7, 2020), <https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far>.

136. *See generally* World Trade Org., *Members and Observers*, WHO, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Oct. 22, 2022) (noting 169 members).

137. *See generally* SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* (2003); *see also* PETER DRAHOS & JOHN BRAITHWAITE, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?* 60–73 (2002) (discussing successful corporate framing of IP issues).

138. *E.g.*, SELL, *supra* note 137, at 96–101.

139. *E.g.*, *id.* at 108 (noting developing countries led by India and Brazil strongly objected to incorporating IP within the international trade structure); Communication from India, *Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, GATT Doc. MTN.GNG/NG11/W/7 (Sept. 12, 1989).

140. *E.g.*, Donald P. Harris, *Carrying a Good Joke Too Far: Treaty of Adhesion*, 27 UNIV. PA. J. INT’L. ECON. L. 681, 724–25 (2006).

United States applied unilateral trade pressure to individual countries to increase IP rights.¹⁴¹ Contrary to the expectations of the Global South, agreeing to TRIPS did not relieve the pressure. Rather, the United States and the EU continued to apply unilateral trade pressure to individual countries. These pressures included retaliatory trade sanctions against countries that did not adopt desired IP laws that benefited IP-intensive industries, even when those countries complied with TRIPS and other international IP agreements.¹⁴² Worse, the United States and the EU have enacted more international agreements that impose heightened IP requirements on developing countries.¹⁴³ These combined actions by the United States and the EU resulted in yet more profits to the Global North at the expense of the Global South.¹⁴⁴

The United States' actions against South Africa during an HIV pandemic provide a good example of IP nationalism. At that time, South Africa had recently enacted a law intended to provide affordable medicine to combat the HIV crisis because it was considered the epicenter of this pandemic; it permitted broad use of compulsory licenses and "parallel" imports of drugs, both of which are long-recognized exceptions to patent laws.¹⁴⁵ A compulsory license grants a manufacturer permission to make a patented invention during the patent term, subject to payment of a government-dictated, reasonable royalty to the patent owner.¹⁴⁶ The royalty is typically far lower than what the patent owner would willingly charge.¹⁴⁷ Compulsory licenses are historically issued for the public interest, which easily includes a national health crisis.¹⁴⁸ Parallel imports permit a country to import drugs first sold by a patent owner in another country at a cheaper rate than in the importing country.¹⁴⁹ Although South Africa's laws were in some ways broader than other countries' laws, TRIPS explicitly permits use of both methods.¹⁵⁰ Notably, despite no TRIPS challenge at the WTO, the United States imposed trade sanctions on South Africa and eliminated financial aid pending "progress" on IP in 1998.¹⁵¹ The United States' sanctions were contrary to a resolution from the UN Commission on Human

141. SELL, *supra* note 137, at 90–91 (discussing U.S. pressure against Korea, Brazil, and Mexico).

142. *Id.* at 75–95 (discussing U.S. 301 actions, as well as special 301); European Commission Staff Working Document, *Counterfeit and Piracy Watch List*, EUR. COMM'N, at 5, 38, 41.

143. *E.g.*, HO, *supra* note 128, at 225–26.

144. Rosa Balfour, Lizza Bomassi, & Marta Martinelli, *Coronavirus and the Widening Global North–South Gap*, (Carnegie Eur., Working Paper, Apr. 2022).

145. HO, *supra* note 128, at 327.

146. *E.g.*, *id.* at 127.

147. *E.g.*, *id.* at 138.

148. *E.g.*, *id.* at 132–33; *see also* World Trade Org., *Agreement on Trade-Related Aspects of Intellectual Property Rights* art. 31 (Apr. 15, 1994), https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm [hereinafter TRIPS] (providing international rules regarding compulsory licenses).

149. *E.g.*, HO, *supra* note 128, at 45.

150. *Id.* at 328.

151. *Id.* at 330–31.

Rights that recognized access to medicine to treat pandemics as fundamental to the human right to health.¹⁵² These actions by the United States demonstrate IP nationalism because they result from a focus on strong IP rights that economically benefit the United States without consideration of negative impacts on other countries. Moreover, these actions also illustrate how IP nationalism problematically results in one country prioritizing its economic self-interests above all other interests, including access to medicine, a recognized human right.

IP nationalist policies may be masked by rhetoric that claim global benefits, even if those global benefits are unlikely to transpire. For example, the United States has repeatedly claimed that stronger IP rights benefit not just its IP-intensive industries but all nations by promoting technology transfer and innovation.¹⁵³ However, nations that have increased IP rights have not realized these gains.¹⁵⁴ Some scholars suggest that benefits may take longer to manifest in developing countries that are not yet ready to take advantage of the rights, but even when stronger IP rights were introduced in developed countries like Canada and Italy, the benefits were elusive.¹⁵⁵

III. HOW IP NATIONALISM UNDERMINES A GLOBAL PUBLIC GOODS APPROACH TO IP ON ESSENTIAL DRUGS AS SEEN DURING THE COVID PANDEMIC

Although the COVID pandemic could have been curtailed with a global public goods approach, IP nationalism has undermined this approach and unnecessarily prolonged the COVID pandemic to the detriment of all. As will be explained, if COVID vaccine IP was treated as a global public good, IP essential to making vaccines would have been shared long ago and the entire world could have been vaccinated. Recognizing that a global public goods approach would have been highly beneficial in curtailing the pandemic, as well as why IP nationalism forestalled this approach, is essential to avoiding another vaccine apartheid.

152. U.N. Comm'n on Human Rights, *Access to Medication in the Context of Pandemics Such as HIV/AIDS*, Res. 2001/33 (Apr. 23, 2001).

153. E.g., *Trans-Pacific Partnership: Summary of Objectives*, OFF. U.S. TRADE REPRESENTATIVE, <https://ustr.gov/tpp/Summary-of-US-objectives> (last visited Oct. 22, 2022) (alleging IP rights will benefit all countries); see also *SETTING A NEW STANDARD: 21ST CENTURY IP PROTECTIONS FOR A MODERNIZED NAFTA*, GLOB. INNOVATION POL'Y CTR. 16–17 (2018) (suggesting benefits for all NAFTA countries from increased IP protection); *INTELLECTUAL PROPERTY: POWERHOUSE FOR INNOVATION AND ECONOMIC GROWTH*, ICC 5–8 (2011) (arguing that IP promotes growth).

154. Contrary to the advocacy of countries such as the United States, stronger IP rights do not necessarily prompt development, but in fact, are often only adopted *after* a nation has an adequately developed economy that can then promote innovative activity. E.g., Alexander Peukert, *Intellectual Property and Development—Narratives and Their Empirical Validity*, 20 J. WORLD INTELL. PROP. 2, 12 (2017); see also Keith E. Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 UNIV. ILL. L. REV. 457, 471–72 (2001) (noting that although intellectual property rights could be beneficial for developing countries, there are also challenges).

155. E.g., Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 472–74 (2014).

A. COVID IP Should Be a Global Public Good

1. Global Public Goods and the IP Nationalism Barrier

In a world free of IP nationalism, IP on certain essential drugs, including COVID vaccines, would be considered so important that the IP would be freely available to all. IP on agreed-upon essential treatments would be considered global public goods, from which no one in the world could be barred because the goods would be “non-excludable” (no one can be barred) and “non-rivalrous” (use by one does not diminish its existence).¹⁵⁶ An example of a global public good is knowledge because it is available to all and does not diminish with consumption.¹⁵⁷ Further, there is a societal benefit from knowledge. Similarly, global public goods include clean air and water, which are beneficial to all.¹⁵⁸ Notably, it often requires collective action to ensure the existence of a global public good because the inherent lack of exclusivity means there is no profit-based incentive to create the good.¹⁵⁹

In the context of health, a global public good would be something that all countries have access to even if not all countries equally contributed to its existence. For example, global eradication of a disease such as smallpox benefits all, as does international surveillance of infectious diseases that might result in a global pandemic.¹⁶⁰ However, because by definition no one is excluded from global public goods, private parties may lack incentive to create them. Governments can better finance domestically generated public goods to ensure their creation, whereas globally coordinating and supporting such efforts is more challenging.¹⁶¹

Although some have used the term “global public good” loosely to refer to the idea that COVID vaccines should be free for all,¹⁶² vaccines do

156. See, e.g., *Defining Global Public Goods*, in GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 3–4 (Inge Kaul, Isabelle Grunberg, & Marc Stern eds., 1999) (providing definition).

157. Joseph E. Stiglitz, *Knowledge as a Global Public Good*, in GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 308–310 (Inge Kaul, Isabelle Grunberg, & Marc Stern eds., 1999).

158. See, e.g., Gil Siegal, Neomi Siegal, & Richard J. Bonnie, *An Account of Collective Actions in Public Health*, 99 AM. J. PUB. HEALTH 1583, 1584 (2009).

159. *Id.*; see generally *Global Public Goods: Concepts, Policies and Strategies*, in GLOBAL PUBLIC GOODS: INTERNATIONAL COOPERATION IN THE 21ST CENTURY 450, 450–98 (Inge Kaul, Isabelle Grunberg, & Marc Stern eds., 1999) (discussing how to address factors that undermine collective action problems).

160. See Richard G.A. Feachem & Carol A. Medlin, *Health is Wealth*, 417 NATURE 695, 695 (2022); Richard D. Smith, *Global Public Goods and Health*, 81 BULL. WORLD HEALTH ORG. 475, 475 (2003).

161. E.g., *Defining Global Public Goods*, *supra* note 162, at 7–10 (suggesting mechanisms to promote global collective creation of global public goods); Shaffer, *supra* note 12, at 673–74.

162. *Uniting Behind a People’s Vaccine Against COVID-19*, UNAIDS (May 14, 2020), https://www.unaids.org/en/resources/presscentre/featurestories/2020/may/20200514_covid19-vaccine-openletter; U.N. Secretary-General, *COVID-19 Vaccines Must Be a Global Public Good*, Secretary-General Says, U.N. Doc. SG/SM/20620 (Mar. 11, 2021); Priti Patnaik, *A Strong Call for COVID-19 Treatments and Vaccines to be Global Public Goods—World Health Assembly*, INT’L HEALTH POL’YS (May 20, 2020), <https://www.internationalhealthpolicies.org/featured-article/a->

not fit the definition because use of a vaccine on one patient means that it is unavailable for use on another. In other words, individual vaccines are rivalrous, just like an apple that can be consumed. In contrast, *global vaccination* can be a global public good.¹⁶³ Additionally, the IP that covers vaccines do not diminish with use. So, COVID vaccine IP fits the definition of a global public good. If all IP rights on COVID vaccine IP were waived, any company with adequate technical capacity could use that IP to make more COVID vaccines.

Considering any type of IP to be a global public good is fundamentally contrary to both traditional IP rules and IP nationalism. After all, IP is generally associated with legal exclusion.¹⁶⁴ To consumers, this is usually reflected by higher prices because IP rights that exclude competitors from making the IP-protected item permit the IP owner to charge a premium given the lack of competition.¹⁶⁵ Of course, if IP rights on some goods were considered a global public good, this scarcity would likely not exist because there would be no laws perpetuating artificial scarcity. Admittedly, there could be additional practical issues beyond IP rights that cause scarcity, such as a shortage of raw materials. However, considering IP a global public good removes a significant legal barrier to increasing access.

Although many during COVID have suggested that a global pandemic is a reason to stray from typical defaults, including the usual IP norms, IP nationalism makes that challenging.¹⁶⁶ As noted earlier, IP nationalism focuses on strong IP rights globally.¹⁶⁷ Moreover, even though exceptions to IP rights and treating COVID IP as a global public good could arguably benefit all countries by ending the pandemic more quickly, IP nationalism still resists this reasoning.¹⁶⁸ This resistance is well illustrated in the next Section, which explores opposition to global public health proposals during COVID.

strong-call-for-covid-19-treatments-and-vaccines-to-be-global-public-goods-world-health-assembly/. Some suggest that it is common in global health discussions to refer to public goods as any goods that should be universally available even if not non-rivalrous. *E.g.*, Sharifah Sekalala, Lisa Forman, Timothy Hodgson, Moses Mulumba, Hadijah Namyalo-Ganafa, & Benjamin Mason Meier, *Decolonising Human Rights: How Intellectual Property Laws Result in Unequal Access to the COVID-19 Vaccine*, BRIT. MED. J. GLOB. HEALTH, June 2021, at 3; Lawrence O. Gostin, Safura Abdool Karim, & Benjamin Mason Meier, *Facilitating Access to a COVID-19 Vaccine Through Global Health Law*, 48 J. L. MED. & ETHICS 622, 623–24 (2020).

163. World Health Assembly, COVID-19 Response, 73rd World Health Assembly, Res. 73.1 (May 19, 2020) (recognizing “role of extensive immunization against COVID-19 as a global public good” that can help end the pandemic).

164. *E.g.*, 35 U.S.C. § 271(a) (2010).

165. *E.g.*, WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 299–300 (2003); *see also* F.T.C. v. Actavis, Inc., 570 U.S. 136, 147 (2013) (“[Patent rights] may permit the patent owner to charge a higher-than-competitive price for the patented product.”).

166. *E.g.*, Brink Lindsey, *Why Intellectual Property and Pandemics Don’t Mix*, BROOKINGS (June 3, 2021), <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>.

167. *Id.*

168. *Id.*

2. Recognition of the Benefit of a Global Public Goods Approach During COVID

A global pandemic like COVID illustrates how considering IP on COVID treatments, especially vaccines, as a global public good would be a benefit to all. As discussed earlier, the continued COVID pandemic impacts all countries. After all, even countries able to secure COVID vaccines are vulnerable to new variants that inevitably develop because of inadequate global vaccinations.¹⁶⁹ The WHO estimates that at least 70% of all global citizens must be fully vaccinated to reduce the risk of new variants and resume full socioeconomic activity.¹⁷⁰ However, in poor countries, vaccination rates are under 6% overall, and in some countries, less than 1% have been vaccinated.¹⁷¹ Moreover, a global pandemic has negative economic impacts on *all* countries, including those that generally benefit from IP nationalism through profits from IP exports.¹⁷² Obviously, large-scale containment, such as limiting access to public places to reduce infections, negatively impacts many businesses, including restaurants and tourism.¹⁷³ Beyond that, some estimate that inadequate worldwide inoculation reduces the global GDP annually by nearly 4% as compared to equitable access to vaccines and the entire global population sufficiently inoculated.¹⁷⁴

Recognizing all COVID IP as a global public good has been acknowledged and encouraged in statements by the UN Secretary General,¹⁷⁵ the WHO,¹⁷⁶ and certain individual countries.¹⁷⁷ In May 2020, just months after global recognition of the pandemic, the WHO proposed a pool to facilitate the sharing and transfer of all technology and IP concerning

169. E.g., Stephanie Desmon, *Without Global Vaccinations, Further Variants Ahead*, HUB (Dec. 21, 2021), <https://hub.jhu.edu/2021/12/21/global-vaccination-prevents-variants-durbin-moss/>.

170. E.g., WORLD HEALTH ORG., STRATEGY TO ACHIEVE GLOBAL COVID-19 VACCINATION BY MID-2022 3 (2021).

171. E.g., Chloe Taylor, *These Countries Have the Lowest COVID Vaccination Rates in the World*, CNBC (Feb. 2, 2022, 4:39 AM), <https://www.cnbc.com/2022/02/02/these-countries-have-the-lowest-covid-vaccination-rates-in-the-world.html>; *COVID Vaccines: Widening Inequality and Millions Vulnerable*, U.N. NEWS (Sept. 19, 2021), <https://news.un.org/en/story/2021/09/1100192>.

172. Hafner et al., *supra* note 91, at iii.

173. E.g., David Aharon, Arie Jacobi, Eli Cohen, Joseph Tzur, & Mahmoud Qadan, *COVID-19, Government Measures and Hospitality Industry Performance*, PLOS ONE, Aug. 2021, at 4–5.

174. Hafner et al., *supra* note 91, at 20–23. The report estimates that if “only” low-income countries lack adequate access to COVID vaccines, global GDP declines thirteen billion dollars a month, U.S. GDP declines sixteen billion dollars a year, and the EU’s GDP declines about forty billion dollars a year. *Id.* at 22.

175. U.N. Secretary-General, *COVID-19 Vaccines Must Be a Global Public Good, Secretary-General Says, Announcing “Only Together” Campaign to Encourage Sharing of Technology, Doses*, U.N. Doc. SG/SM/20620 (Mar. 11, 2021).

176. World Health Org., *Making the Response to COVID-19 a Public Common Good: Solidarity Call to Action*, WHO (May 29, 2020), <https://www.who.int/publications/m/item/solidarity-call-to-action> [hereinafter *WHO Call to Action*].

177. Patnaik, *supra* note 162.

COVID¹⁷⁸ as part of its call for global solidarity.¹⁷⁹ Although this proposal did not explicitly state that all COVID IP should be a global public good, the request to share COVID IP implicitly recognizes that it should be. The UN, as well as the United Nations Educational, Scientific and Cultural Organization (UNESCO), have also argued for companies to share IP related to COVID consistent with a global public goods approach.¹⁸⁰ Beyond the efforts of international groups, some world leaders have stated that COVID treatments should be a global public good, although they have typically done so without any corollary action.¹⁸¹ The Open COVID Pledge, started by a number of individuals to make it easier for companies to make IP freely available to manage the pandemic, is also consistent with considering COVID IP a global public good.¹⁸² Of course, the recognition by some that COVID IP should be a global public good has been met with serious resistance by both IP owners and nations embracing IP nationalism.¹⁸³

However, there are some glimmers of hope. Even before world leaders embraced a global public health approach, Oxford, which helped develop the COVID vaccine made by AstraZeneca, initially intended to make its IP either completely free or low cost¹⁸⁴ and only reversed course at the urging of the Gates Foundation.¹⁸⁵ More recently, academic researchers in Texas developed a new vaccine but did not patent it, instead

178. World Health Org., *WHO COVID-10 Technology Access Pool*, WHO, <https://www.who.int/initiatives/covid-19-technology-access-pool> (last visited Oct. 22, 2022).

179. *WHO Call to Action*, *supra* note 176; see also World Health Org., *What is the ACT-Accelerator*, WHO (Apr. 2020), <https://www.who.int/initiatives/act-accelerator/about> (emphasizing that the goal is not simply accelerating development but ensuring that any developed products are equally accessible to all).

180. UNESCO Int'l Bioethics Comm., UNESCO's Ethics Commissions' Call for Global Vaccines Equity and Solidarity, SHS/BIO/IBC-COMEST/COVID-19 Vaccines 4–5 (Feb. 24, 2021); *Statement by UN Human Rights Experts Universal Access to Vaccines Is Essential for Prevention and Containment of COVID-19 Around the World*, U.N. HUM. RIGHTS COUNCIL (Nov. 9, 2020), <https://www.ohchr.org/en/statements/2020/11/statement-un-human-rights-experts-universal-access-vaccines-essential-prevention> (calling on companies to not invoke IP rights in light of the fact that vaccines should be considered global public goods, alongside extensive immunization against COVID); *Vaccines Against COVID-19 Must Be Considered as a Global Public Good*, High Commissioner for Human Rights Tells Human Rights Council as It Opens Its Forty-Seventh Regular Session, U.N. HUM. RIGHTS COUNCIL (June 21, 2021), <https://www.ohchr.org/en/2021/06/vaccines-against-covid-19-must-be-considered-global-public-good-high-commissioner-human>.

181. *E.g.*, *WHO: Leaders Call COVID-19 Vaccines a "Global Public Good"*, TWN (May 20, 2020), <https://www.twn.my/title2/health.info/2020/hi200511.htm>.

182. *Open Covid Pledge*, OPEN COVID PLEDGE, <https://opencovidpledge.org/> (last visited Oct 22, 2022).

183. Nerina Boschiero, *COVID-19 Vaccines as Global Common Goods: An Integrated Approach of Ethical, Economic Policy and Intellectual Property Management*, 22 DE GRUYTER 177, 205–06 (2021).

184. *Expedited Access for COVID-19 Related IP*, UNIV. OF OXFORD INNOVATION, <https://innovation.ox.ac.uk/technologies-available/technology-licensing/expedited-access-covid-19-related-ip/> (last visited Oct. 22, 2022) (stating default approach is royalty-free licensing).

185. Jay Hancock, *They Pledged to Donate Rights to Their COVID Vaccine, Then Sold Them to Pharma*, KAISER HEALTH NEWS (Aug. 25, 2020), <https://khn.org/news/rather-than-give-away-its-covid-vaccine-oxford-makes-a-deal-with-drugmaker/>.

sharing its technology with an Indian company to promote vaccine equity.¹⁸⁶ Unique in the context of multinational companies that maintain most COVID IP, Pfizer recently agreed to license the IP for its newly approved antiviral drug Paxlovid to permit manufacture by generic companies in ninety-five countries (including the poorest countries and some middle-income countries) and waived royalties during the pandemic.¹⁸⁷ This covers just over 50% of the global population.¹⁸⁸ Although this gesture is not a complete global public goods approach, which would make the IP free to all, it is still a positive development considering that major COVID vaccine manufacturers have thus far resisted sharing their IP.¹⁸⁹ Also, although the United States was previously skeptical about the WHO Pool, the National Institute of Health (NIH) shared IP on some COVID vaccines in development with the pool.¹⁹⁰ However, critics argue that these efforts are inadequate.¹⁹¹ Further, many poor countries that lack adequate vaccines are not currently clamoring for them because of distribution problems and vaccine hesitancy.¹⁹² However, perhaps there are still some

186. E.g., Erum Salam, *Texas Scientists' New Covid-19 Vaccine is Cheaper, Easier to Make and Patent-Free*, GUARDIAN (Jan. 15, 2022, 5:00 PM), <https://www.theguardian.com/us-news/2022/jan/15/corbevax-covid-vaccine-texas-scientists>; Elaine Ruth Fletcher, 'Vaccine for World' Gets Emergency Use Authorization in India; Texas Children's Hospital Grants Non-Exclusive License to Biological E, HEALTH POL'Y WATCH (Dec. 28, 2021), <https://healthpolicy-watch.news/vaccine-for-world-gets-emergency-use-authorization-in-india-texas-childrens-hospital-grants-non-exclusive-license-to-biological-e/>.

187. E.g., Kerry Cullinan, *Pfizer and Medicines Patent Pool Reach 'Ground-Breaking' Voluntary Licensing Deal for New Covid-19 Treatment Pill*, HEALTH POL'Y WATCH (Nov. 16, 2021), <https://healthpolicy-watch.news/pfizer-and-medicines-patent-pool/>.

188. *Id.*

189. E.g., *MSF Responds to Pfizer and Medicines Patent Pool License for New COVID-19 Treatment*, DRS. WITHOUT BORDERS (Nov. 16, 2021), <https://www.doctorswithoutborders.org/latest/msf-responds-pfizer-and-medicines-patent-pool-license-new-covid-19>.

190. See *Voluntary Pool*, *supra* note 130.

191. E.g., Kevin Dunleavy, *WHO Gives a Thumbs-Up to Pfizer's Paxlovid While Scolding the Company for Its 'Lack of Price Transparency'*, FIERCE PHARMA (Apr. 22, 2022, 10:50 AM), <https://www.fiercepharma.com/pharma/who-gives-thumbs-pfizers-paxlovid-while-scolding-company-its-lack-price-transparency>. In addition, although Pfizer has shared IP on Paxlovid with some countries, the benefit of this sharing is unclear because Paxlovid treatment is only effective in the early days of COVID and requires efficient testing that is unlikely to exist in poor countries. E.g., Kenny Stancil, *Rollout of New Effective COVID Pill Mirrors the "Injustice of Vaccine Apartheid" in Poor Countries*, SALON (Apr. 26, 2022, 5:00 AM), https://www.salon.com/2022/04/26/rollout-of-new-effective-pill-mirrors-the-injustice-of-vaccine-apartheid-in-poor-countries_partner/; see also *SARS-COV-2 Test Tracker*, FIND, <https://www.finddx.org/covid-19/test-tracker/> (last visited Oct. 22, 2022) (noting that only 22.1% of COVID tests administered have been used in poor countries despite those countries comprising 50.8% of the global population). Also, some are critical of Pfizer's motivations. E.g., Melissa Barber, *Speaking of Medicine and Health: A Strategy that Gives Half of the World a Discount on COVID-19 Antivirals, but Keeps a Firm Grip on Power*, PLOS GLOB. PUB. HEALTH BLOG (May 25, 2022), <https://speakingofmedicine.plos.org/2022/05/25/a-strategy-that-gives-half-of-the-world-a-discount-on-covid-19-antivirals-but-keeps-a-firm-grip-on-power/>; *Pfizer is Building a 'Paxlovid Patent Wall,' New Research Reveals*, PUB. CITIZEN (Feb. 18, 2022), <https://www.citizen.org/news/pfizer-is-building-a-paxlovid-patent-wall-new-research-reveals/> (suggesting that Paxlovid IP sharing responds to prior criticism about lack of sharing of vaccine IP, but still limits affordable access in many countries not only excluded from the agreement, but due to patent protection); Robert Langreth, Madison Muller, & Riley Griffin, *Pfizer's Grip on Paxlovid Thwarts Research on COVID Treatment*, BLOOMBERG (May 18, 2022, 3:30 AM), <https://www.bloomberg.com/news/articles/2022-05-18/pfizer-s-tight-paxlovid-rein-stymies-drug-combination-research> (noting that Pfizer has resisted sharing its Paxlovid drug with researchers and thus stymied research on COVID treatments).

192. See *supra* notes 18–22 and accompanying text.

long-term lessons learned. For example, the United States is recommending that companies share IP in future health emergencies in the context of WHO-led discussions of a pandemic treaty.¹⁹³

Additionally, as detailed more thoroughly in the next Section, after IP nationalism forestalled consideration of any proposal to broadly share global IP, India and South Africa, supported by a number of other countries, proposed a broad waiver of international IP obligations regarding COVID health products so that nations that endorse a global public goods approach can create vaccines despite supply shortages caused by vaccine nationalism.¹⁹⁴ The proposed waiver of IP obligations, including all aspects of patents as well as trade secrets, is based on a policy of promoting equitable access similar to a global public goods approach to COVID IP in terms of recognizing the overall global benefits of modifying IP rights.¹⁹⁵ At the same time, it is admittedly less effective than declaring all COVID IP to be a global public good because the waiver would only reduce legal liability in countries that elect to implement it.¹⁹⁶ Notably, it still would not require companies to affirmatively share the trade secrets essential to making COVID vaccines.¹⁹⁷ Arguably, some countries could compel or at least encourage companies to share trade secrets if they considered COVID vaccines to be a global public good.

Nonetheless, if COVID IP continues to not be a global public good, the broad waiver is the closest next step even though it is less comprehensive and requires additional steps to be of any utility. For example, although a very limited waiver of patents on COVID vaccines has now been adopted, any waiver of WTO rules has no immediate impact on domestic laws.¹⁹⁸ Rather, nations still need to modify their own laws because the waiver only vacates their international patent obligations pursuant to the

193. Erin Banco, *U.S. Pushes for More Global Sharing of Health Tech in Next Pandemic*, POLITICO (Mar. 17, 2022, 4:30 AM), <https://www.politico.com/news/2022/03/17/u-s-global-health-tech-sharing-next-pandemic-00017977>.

194. Council for Trade-Related Aspects of Intell. Prop. Rts., *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) [hereinafter *Communication from India*]; Council for Trade-Related Aspects of Intell. Prop. Rights, *Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe: 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).

195. *WHO Call to Action*, *supra* note 176.

196. Marianne Meijer, Marieke Verschuuren, & Ella Weggen, *COVID-19 Vaccines a Global Public Good? Moving Past the Rhetoric and Making Work of Sharing Intellectual Property Rights, Know-How and Technology*, 31 EUR. J. PUB. HEALTH 925, 925 (2021).

197. Ian Lopez & Matthew Bultman, *COVID Vaccine Waiver Deal Threatens Investment for Future Crises*, HEALTH L. & BUS. (June 21, 2022, 3:15 AM), <https://ne.s.bloomberglaw.com/health-law-and-business/covid-vaccine-waiver-deal-threatens-investment-for-future-crises>.

198. Ministerial Conference Twelfth Session Geneva, *Draft Ministerial Declaration on the TRIPS Agreement*, WT/MIN(22)/W/15/Rev.2 (June 17, 2022) [hereinafter *WTO June 2022*]; *Inability of WTO Members to Agree on Original TRIPS Waiver is a Devastating Failure for People's Health Worldwide*, DRS. WITHOUT BORDERS (June 17, 2022), <https://www.doctorswithoutborders.org/latest/inability-wto-members-agree-original-trips-waiver-devastating-failure-peoples-health>.

WTO but not any domestic obligations.¹⁹⁹ Countries would need to suspend their own domestic IP laws to ensure that any capable manufacturer could utilize COVID IP. However, without the waiver, a country that suspends its IP laws risks international liability²⁰⁰ but notably, even violation of TRIPS does not result in any immediate penalty.²⁰¹ To illustrate, if one country challenges another country for noncompliance with TRIPS in a formal dispute proceeding *and* the dispute panel agrees that there is a violation, the result is simply that the noncomplying country is ordered to bring its laws into compliance.²⁰² In other words, there is no immediate monetary penalty. Given that, it may be surprising that countries proposed to waive rules that do not have immediate financial consequences for noncompliance. However, individual nations that embrace IP nationalism, such as the United States, have historically pressured countries unilaterally for alleged noncompliance of TRIPS, sometimes even when countries clearly comply.²⁰³ Accordingly, even for nations that recognize COVID IP as a global public good, they cannot correspondingly change their own domestic IP rules without changing international norms to avoid, or at least minimize, backlash from countries like the United States.²⁰⁴

199. Moreover, some countries may have international obligations under other agreements that would not necessarily be waived, although there could be other defenses in these agreements. Henning Gross Ruse-Khan & Federica Paddeu, *A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investment Agreements*, ECONSTOR (Jan. 27, 2022); Carlos M. Correa, Nirmalya Syam, & Daniel Uribe, *Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements*, S. CTR. 7 (Sept. 2021), https://www.southcentre.int/wp-content/uploads/2021/09/RP135_Implementation-of-a-TRIPS-Waiver-for-Health-Technologies-and-Products-for-COVID-19_EN.pdf (arguing that under the estoppel doctrine of international law if a state waives IP in the WTO, other countries should expect similar attitude to IP in other agreements).

200. However, domestic suspension of IP rules could trigger a claim for violating different international agreements that protect investments that include IP for nations that are party to agreements permitting so-called investor–state disputes. *E.g.*, Cynthia Ho, *Potential Claims Related to IP and Public Health in Investment Agreements: COVID-19, the Proposed TRIPS Waiver and Beyond*, INVEST. POL’Y BRIEF, Dec. 2021, at 2–4. Some have suggested that nations will be hesitant to bring such disputes for actions taken during the COVID pandemic, but not necessarily once endemic. *E.g.*, Rochelle Cooper Dreyfuss, *ISDS and Intellectual Property in 2020—Protecting Public Health in the Age of Pandemics*, in YEARBOOK ON INT’L INV. L. & POL’Y (2020). However, there is one non-IP dispute based on COVID and the financial repercussions of these disputes are substantial. Unlike the WTO/TRIPS context, there are financial penalties and defending a suit can cost millions. Cecilia Olivet & Bettina Müller, *Latin America’s Battle with COVID-19 Hampered by Investment Arbitration Cases*, TRANSNAT’L INST. (Sept. 1, 2020), <https://longreads.tni.org/jugglingcrises>.

201. See Uruguay Round Agreement, *Understanding on Rules and Procedures Governing the Settlement of Disputes*, art. 19 (Apr. 15, 1994); Uruguay Round Agreement, *Marrakesh Agreement Establishing the World Trade Organization*, 1869 U.N.T.S. 401; THE LEGAL AFFS. DIV. AND THE APP. BODY, THE WTO SECRETARIAT, A HANDBOOK ON THE WTO DISPUTE SETTLEMENT SYSTEM 88 (2nd ed. 2017).

202. See *supra* note 201.

203. The usual mode of pressure is through the annual U.S. Special 301 Report targeting countries with perceived inadequate or ineffective levels of IP protection, which can exist notwithstanding the fact that the country may be in compliance with international agreements. See Press Release, Off. of the U.S. Trade Representative, USTR Releases 2022 Special 301 Report on Intellectual Property Protection and Enforcement (Apr. 27, 2022); 19 U.S.C. § 2242(a), (d)(4) (2020).

204. Even if vaccines are currently not in high demand, more COVID treatments are still needed, as evidenced by pending compulsory license requests. *E.g.*, Luis Gil Abinader, *Amicus Brief of Pro-*

*B. IP Nationalism Undermines a Global Public Goods Approach:
COVID Examples*

This Section specifically illustrates how IP nationalism undermines efforts to take a global public goods approach to COVID. This Section first explains how initial proposals that would have effectively endorsed a global public goods approach to COVID IP were rejected because of IP nationalism. Then, this Section explains why the original proposed waiver of international obligations regarding COVID IP was the next best solution, yet nonetheless was thwarted due to IP nationalism. Although countries enacted a limited waiver of TRIPS obligations for COVID vaccines, this is mostly an empty solution that reflects IP nationalism, as will be explained.

1. IP Nationalism Undermined Proposals to Treat COVID IP as a
Global Public Good

Early in the pandemic, there were proposals to treat COVID IP as a global public good. The WHO requested that nations act in “global solidarity” and stated that the response to COVID should be a “public common good,” including sharing of IP to promote detection, prevention, and treatment.²⁰⁵ Notably, the WHO proposal requested all those in possession of relevant IP to share on a nonexclusive global basis through either the preexisting Medicines Patent Pool or the newly created WHO Pool.²⁰⁶ Although the WHO solidarity call did not explicitly state that the IP should be transferred for free, the statement did indicate that the shared IP should promote equitable and affordable access for all, and the WHO stated that its goals were in line with its general efforts to “promote global public health goods.”²⁰⁷ When the WHO launched this proposal, thirty-seven nations, primarily from the Global South, supported it.²⁰⁸ Wealthy countries home to major pharmaceutical companies (such as the United States, Germany, and Switzerland) did not support the WHO Pool.²⁰⁹ Additionally,

fessor Brook Baker on the Human Right Principles and TRIPS-Compliant Interpretation of the Compulsory License Petition Filed by KEI in the Dominican Republic, KEI (Apr. 21, 2022), <https://www.keionline.org/37688>; Ed Silverman, *Colombian Government Faces Calls to Issue Compulsory License for Pfizer COVID-19 Pill*, STAT (Apr. 5, 2022), <https://www.statnews.com/pharmalot/2022/04/05/covid19-colombia-pfizer-paxlovid-patents/>; Zoey Becker, ‘Betrayal of Public Trust’: Pfizer Under Fire for Resisting Paxlovid Compulsory License, FIERCE PHARMA (Apr. 12, 2022, 4:00 PM), <https://www.fiercepharma.com/pharma/stark-betrayal-public-trust-pfizer-rebuked-advocacy-groups-intellectual-property-human-right>.

205. *WHO Call to Action*, *supra* note 176; *C-TAP: A Concept Paper*, WHO (Oct. 27, 2020), https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9_36.

206. *WHO Call to Action*, *supra* note 176.

207. *Id.*

208. William Worley, *WHO and Costa Rica Launch COVID-19 Technology Access Pool*, DEVEX (May 29, 2020), <https://www.devex.com/news/who-and-costa-rica-launch-covid-19-technology-access-pool-97368>.

209. *Id.* Moreover, the CEO of Pfizer derided the pool as “nonsense.” Sarah Newey, *WHO Patent Pool for Potential COVID-19 Products is ‘Nonsense’*, *Pharma Leaders Claim*, TELEGRAPH (May 29,

the United States refused to support a broadly endorsed resolution by the World Health Assembly that called for equitable access to COVID treatments, arguing that modifying IP norms to promote access would stifle innovation.²¹⁰ This rejection is consistent with IP nationalism because sharing IP is fundamentally anathema to the interests of IP owners and the countries that benefit from exports by IP owners. Even some countries that typically are not strong advocates of IP, such as Canada and India, did not endorse the WHO Pool.²¹¹ Problematically, IP nationalism bars a global public goods approach to COVID IP that would permit any capable manufacturer to use IP to alleviate unnecessary scarcity. Since the WHO Pool's initiation in May 2020, no companies have donated IP.²¹² The first license to the WHO Pool was from the Spanish National Research Council, the largest public research organization in Spain, for technology to detect COVID antibodies.²¹³ Two years after creation, the NIH licensed IP related to COVID vaccines, although the donations were mostly research tools and vaccine candidates.²¹⁴

Most countries of the Global North also rejected the WHO recommendation to facilitate open sharing of IP as is consistent with a global public goods approach. In particular, the WHO requested that countries facilitate open sharing of IP; it reasoned that publicly funded COVID research should be made affordable and accessible globally by sharing IP.²¹⁵ Not only did nations reject the WHO recommendation, but some engaged in more IP nationalism than usual.

2020, 11:33 AM), <https://www.telegraph.co.uk/global-health/science-and-disease/patent-pool-potential-covid-19-products-nonsense-pharma-leaders/>; see also *C-TAP Has Not (Yet) Lived Up to High Expectations*, HEALTH ACTION INT'L (May 28, 2021), <https://haiweb.org/c-tap-has-not-yet-lived-up-to-high-expectations/> (noting governments share blame for failing to persuade the industry to share IP).

210. E.g., Press Release, U.S. Mission Geneva, U.S. Explanation of Position "COVID-19 Response" Resolution (May 19, 2020) (arguing that the proposal "send[s] the wrong message to innovators" who need IP incentives to develop new products that "the whole world needs.").

211. Rather, the initial support was only from a small group of developing countries, together with Norway, the Netherlands, Portugal, and Luxembourg. *What Happens Next?*, *supra* note 125.

212. E.g., Etienne Billete de Villemeur, Vianney Dequiedt, & Bruno Versaavel, *Pool Patents to Get COVID Vaccines and Drugs to All*, 591 NATURE 529, 529 (2021); *Experts Identify 100 Plus Firms to Make COVID-19 mRNA Vaccines*, HUM. RIGHTS WATCH (Dec. 15, 2021, 12:01 AM), <https://www.hrw.org/news/2021/12/15/experts-identify-100-plus-firms-make-covid-19-mrna-vaccines>. In fact, the only contributions are from government agencies. See *infra* note 213 and accompanying text (noting first contribution).

213. Press Release, The Joint United Nations Programme on HIV/AIDS [UNAIDS], UNAIDS Welcomes the First WHO COVID-19 Technology Access Pool Licensing Agreement (Nov. 24, 2021), https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2021/november/20211124_technology-access-pool; Press Release, World Health Org., WHO and MPP Announce the First Transparent, Global, Nonexclusive License for COVID-19 Technology (Nov. 23, 2021), <https://notifier.in/item/0qm7qm8ujt3xt78kltzmzbiiw342ykk3/3199121.html>.

214. *WHO and MPP Announce Agreement with NIH for COVID-19 Health Technologies*, WHO (May 12, 2022), <https://www.who.int/news/item/12-05-2022-who-and-mpp-announce-agreement-with-nih-for-covid-19-health-technologies>; Paul Schloesser, *NIH Offers to Share Covid-19 Technologies with WHO—Report*, ENDPOINTS NEWS (Mar. 3, 2022, 2:00 PM), <https://endpts.com/nih-offers-to-share-covid-19-technologies-with-who-report/> (noting that the license was not planned to include vaccines on the market).

215. *WHO Call to Action*, *supra* note 176.

U.S. actions were contrary to the WHO's suggestion that government-funded COVID treatments should be made globally affordable through contractual provisions.²¹⁶ Although U.S. contracts often have language that permits the government to make publicly funded inventions accessible, many U.S. contracts funding COVID were more restrictive than usual. In particular, U.S. contracts typically permit the government to "march in" and require licensing of federally funded inventions to someone besides the patent owner to "alleviate health or safety needs which are not reasonably satisfied."²¹⁷ In theory, the inadequacy of available COVID treatments could be a situation where the government marches in and makes treatments available for the United States and other countries. Although the United States has historically rejected all petitions to intervene when drugs were priced exorbitantly²¹⁸ (though some thought that this previously toothless provision would finally be used for COVID), even this possibility was nonexistent in most contracts.²¹⁹ For example, the Johnson & Johnson contract avoided the usual march-in rights because it was negotiated through a third party rather than the government and instead had march-in rights that only apply if there is a public health emergency declaration by the U.S. government or the WHO Director General.²²⁰ Further, although the contract that funded the Moderna vaccine included march-in rights, it lacked a clause that permitted the government to affirmatively own the vaccine patents—a provision recommended by public health advocates.²²¹ Similarly, a contract to purchase antibody treatments from Regeneron was also negotiated with a third party on behalf of the United States and thus avoided the usual rules that permit government

216. *Id.* Global Solidarity requested that governments ensure COVID-19 publicly funded research is "affordable, available and accessible to all on a global scale through appropriate provisions in funding agreements . . ." *Id.*

217. 35 U.S.C. § 203(a)(2) (2011).

218. *E.g.*, JOHN R. THOMAS, CONG. RSCH. SERV., MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 8 (2016). Most recently there was a proposed rule to ensure that cost can never be considered. Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 Fed. Reg. 35 (proposed Jan. 4, 2021) (to be codified at 37 C.F.R. pt. 401). Although the Biden Administration has paused implementation of this rule, that does not mean that the NIH will grant a pending petition on this basis given that no petitions on the basis of costs have ever been granted. *E.g.*, Peter Arno, Robert Sachs, & Kathryn Ardizzone, *Will the Biden Administration 'March-in' to Protect Prostate Cancer Patients From Excessive Drug Prices?*, STAT (Jan. 3, 2022), <https://www.statnews.com/2022/01/03/march-in-rights-protect-prostate-cancer-patients-from-excessive-drug-prices/>.

219. Ryan Davis, *How COVID-19 Could Spur the Gov't to Seize Patents*, LAW360 (Mar. 31, 2020, 10:36 PM), <https://www.law360.com/articles/1258140/how-covid-19-could-spur-the-gov-t-to-seize-patents> (noting that some thought that COVID might present the most compelling case for use of march-in rights to ensure affordable access).

220. Janssen Contract section IX.8(b), <https://www.hhs.gov/sites/default/files/janssen-corp-covid-19-vaccine-contract.pdf>. The contracts raised concern for many given the lack of usual protections for federally funded research. *E.g.*, Sydney Lupkin, *Novavax Posts Coronavirus Vaccine Contract that Government Didn't Disclose*, NPR (Nov. 11, 2020, 1:10 PM), <https://www.npr.org/sections/health-shots/2020/11/11/933864908/novavax-posts-coronavirus-vaccine-contract-that-government-didnt-disclose>.

221. Sydney Lupkin, *A Federal Coronavirus Vaccine Contract Released at Last, but Redactions Obscure Terms*, NPR (Oct. 24, 2020, 6:16 PM), <https://www.npr.org/sections/health-shots/2020/10/24/927474041/a-federal-coronavirus-vaccine-contract-released-at-last-but-redactions-obscure-t>.

access to data.²²² Although the contract does permit government rights to the data, such access only happens after ten years, which is contrary to the usual rule that permits immediate acquisition.²²³ It also affirmatively bars the government from disclosing the data, which is the complete opposite of the WHO suggestion that publicly funded research be shared.²²⁴

All these contracts reflect IP nationalism and are inconsistent with a global public goods approach to COVID IP because they prioritize IP rights, thus barring use of COVID IP to quickly alleviate the artificial scarcity of vaccines and other treatments. Notably, although nationalism is often assumed to protect domestic citizens, in the case of COVID, IP nationalism may still fail to protect the public health of domestic interests. This is exemplified by a statement by Alex Azar, then-Secretary of Health and Human Services, who made headlines for refusing to promise that a COVID vaccine would be made affordable despite government funding.²²⁵

IP nationalism can exist in conjunction with efforts that seem to suggest an approach consistent with an IP global public goods approach. Moderna's vaccine "sharing" perfectly exemplifies this. Moderna's assertion that it has a "special obligation under the current circumstances" to help with the pandemic by not enforcing its COVID patents seems consistent with global solidarity.²²⁶ Notably, however, this pledge is *only* for patent rights.²²⁷ Agreeing to not enforce patent rights does nothing to address the IP barrier of trade secrets, which are often crucial to effectively making vaccines. Moreover, whereas patents are published, trade secrets are by definition not publicly available, making it difficult to use the COVID vaccine patents because trade secret methods of making vaccines are generally hard to reverse engineer from the vaccine.²²⁸ Even beyond the trade secret hurdle, there is another undiscussed IP right that Moderna has not pledged to share that can expedite regulatory approval of a drug or vaccine. Many countries bar immediate reliance on earlier clinical data by

222. Sydney Lupkin, *Federal Supply Deal for COVID-19 Antibody Treatment Lacks Some Customary Protections*, NPR (Nov. 6, 2020, 1:35 PM), <https://www.npr.org/sections/health-shots/2020/11/06/931795256/federal-supply-deal-for-covid-19-antibody-treatment-lacks-some-customary-protect>.

223. Kathryn Ardizzone, *Regeneron COVID-19 Contract Weakens the Government's Rights in Data*, KEI (Nov. 5, 2020), <https://www.keionline.org/34402>.

224. *Id.*

225. Isabel Togoh, *Health Secretary Alex Azar Refuses to Guarantee Coronavirus Vaccine Would be Affordable for All*, FORBES (Feb. 27, 2020, 8:30 AM), <https://www.forbes.com/sites/isabel-togoh/2020/02/27/health-secretary-alex-azar-refuses-to-guarantee-coronavirus-vaccine-would-be-affordable-for-all/?sh=553db578490c>.

226. *Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic*, MODERNA (Oct. 8, 2020), <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19>.

227. *Id.*

228. *E.g.*, Allison Durkin, Patricia Anne Sta Maria, Brandon Willmore, & Amy Kapczynski, *Addressing the Risks that Trade Secret Protections Pose for Health and Rights*, 23 HEALTH & HUM. RTS. J. 129, 134 (2021); Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines Via Involuntary Technology Transfer*, 16 J. INTELL. PROP. L. & PRACT. 1242, 1248 (2021).

a second developer (this is called “data exclusivity”), which can delay regulatory approval for a duplicate version, typically for years, by barring a second company from relying on the primary clinical data to expedite the process.²²⁹ Importantly, whereas most countries have exceptions to patent rights, the opposite is true regarding data exclusivity despite suggestions from scholars that such exceptions are needed.²³⁰ At bottom, Moderna’s nonenforcement of *one* of three types of IP that it owns still reflects IP nationalism. If Moderna was fully committed to recognizing COVID IP as a global public good, it would share all of its relevant trade secrets and clinical data. Similarly, if the United States was to jettison an IP nationalism approach during the pandemic, it would recommend that Moderna share its trade secret methods.²³¹

2. Compulsory License of Vaccines in Lieu of Broad TRIPS Waiver Undermines a Global Public Goods Approach

Nations have also engaged in IP nationalism by rejecting and arguing against the broad waiver of TRIPS (proposed by South Africa and Brazil) to address the COVID pandemic. For more than a year and a half, wealthy countries that house IP-owning pharmaceutical companies have strongly objected to waiving multiple IP issues under TRIPS for all COVID diagnostics, treatments, and vaccines.²³² This approach is consistent with IP nationalism and bars nations from engaging in self-help to make supplies they need that are unavailable or unaffordable.²³³ IP nationalism is apparently unsurprising to many because the United States was lauded for supporting the original waiver²³⁴—even though it only did so for vaccines for which waiver of IP rights was least likely to be helpful because the waiver did not mandate disclosing trade secrets. IP nationalism is further represented in the EU’s objection to the broad waiver and its purported alternative solution based on compulsory licenses,²³⁵ as well as the very limited

229. *E.g.*, 21 U.S.C. § 355 (2018); Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, O.J. (L 136) 34–57 (EC). For a rare discussion of the value of data exclusivity in the popular press, see Alexander Zaitchik, *Moderna’s Pledge Not to Enforce the Patents on Their COVID-19 Vaccine Is Worthless*, JACOBIN (Apr. 22, 2021), <https://www.jacobin-mag.com/2021/04/moderna-patents-covid-19-vaccine>.

230. Ellen ‘t Hoen, *Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity*, in ACCESS TO MEDICINES AND VACCINES 183, 191 (Carlos M. Correa & Reto M. Hilty, eds. 2022); *see also* Ellen ‘t Hoen, Pascale Boulet, & Brook K. Baker, *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, J. PHARM. POL’Y & PRAC., June 2017, at 6–7 (arguing that the EU should have an exception from data exclusivity).

231. Sidhartha, *supra* note 106.

232. *Id.*

233. *Id.*

234. *Id.*

235. The industry has repeatedly made false statements concerning when such licenses are proper; for example, it was recently stated that granting compulsory licenses on the basis of national security and health protection would be in violation of international IP law when in fact the international rules place no restrictions on the proper scope of what can be licensed. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), SPECIAL 301 SUBMISSION 133 (2021)

modification of TRIPS compulsory licenses that was agreed to, as will be explained.

Even though countries that engage in IP nationalism typically strongly oppose compulsory licenses (i.e., use of a patented invention without the owner's express permission in exchange for a government-determined royalty),²³⁶ any approach to modifying IP issues for COVID that focuses on compulsory licenses should be considered IP nationalism.²³⁷ This is because a broader waiver of IP rights, like the original proposal, would be more consistent with a global public goods approach. In other words, because IP nationalism emphasizes the maximum global protection of IP, this includes not just increased global IP rights but also resistance to exceptions of existing rights during a global pandemic. A focus on compulsory licenses is more protective of IP-intensive industries than the original, broader COVID waiver.²³⁸ This means that the EU's approach is far less helpful than simply waiving the IP impediments that continue to create legal scarcity during the pandemic. A compulsory license approach involves a time-intensive process to waive every relevant patent, which permits the patent owner to object and appeal both the issuance of a license and the remuneration required.²³⁹ In contrast, the original waiver would permit nations to immediately repeal rights on *all* COVID-related patents, trade secrets, and copyrights, without any procedural hurdles.²⁴⁰ Additionally, the broad waiver would have permitted countries to decline to patent new COVID-related technologies to avoid the procedural hurdles associated with a compulsory license, as there would be no compulsory license if there was no patent.²⁴¹

The June 2022 agreement by WTO countries to minimally modify TRIPS similarly reflects IP nationalism.²⁴² To some extent, this is unsurprising because the adopted text emerged from an outcome document based on discussions of four WTO members, including the United States and EU, which have historically engaged in IP nationalism.²⁴³ The final

(criticizing draft Russian law that would permit licenses on “vague and unduly broad grounds of when-ever it is determined to be in the interests of national security and health protection” which is alleged to be “inconsistent with . . . TRIPS”).

236. See *supra* Section II.B. (discussing South Africa challenge).

237. Such approaches include the EU proposal in 2021, as well as the 2022 agreement by all WTO Parties. *E.g.*, General Council, Urgent Trade Policy Responses to the COVID-19 Crisis: Communication from the European Union to the WTO General Council, WT/GC/231 (June 4, 2021) [hereinafter EU, Urgent Trade Policy].

238. *Id.*

239. See TRIPS *supra* note 148, at art. 31(i)–(j).

240. See Communication from India, *supra* note 194.

241. See Contreras, *supra* note 37.

242. Ministerial Conference Twelfth Session Geneva, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30/WT/L/1141 (June 22, 2022) [hereinafter Ministerial Decision on TRIPS].

243. Council for Trade Related Aspects of Intellectual Property Rights, Communication from the Chairperson, IP/C/W/688 (May 3, 2022) [hereinafter May 2022 WTO Communication]; see also Ed Silverman, *A Compromise Is Reached on an Intellectual Property Waiver for COVID-19 Vaccines, but Does It Go Far Enough?*, STAT (Mar. 15, 2022), <https://www.statnews.com/pharmalot/2022/03/15/covid19-vaccine-patents-wto/> (discussing leaked draft in advance of draft circulated

agreement rejects the broad waiver originally proposed and recommended by many health advocates.²⁴⁴ In some ways it is even more limited than the prior EU suggestion to permit all members to use compulsory licenses. The agreement is currently limited to COVID vaccines, consistent with the United States' position.²⁴⁵ Although it contemplates potentially applying to needed diagnostics and treatments in six months, lack of inclusion of these from the outset, contrary to prior proposals reflects IP nationalism.²⁴⁶ Additionally, whereas the original proposed waiver and even the EU proposal to use compulsory licenses would have been relevant to all countries, the final agreement only permits use for certain WTO members.²⁴⁷

Although this agreement creates a new mechanism for avoiding the usual complex procedure to permit the compulsory license of drugs in predominantly wealthy countries for export to poor countries that lack adequate manufacturing capacity, it simultaneously introduces new requirements and limitations beyond the many that already exist in TRIPS.²⁴⁸ These new requirements include limiting the use of compulsory licenses to only when "necessary," notifying the WTO of issuance of a license, and a duty to prevent re-exportation of vaccines.²⁴⁹ All of these limitations reflect IP nationalism in that they reflect the interests of the United States and the EU to protect their IP industries.²⁵⁰ Because these restrictions are

by WTO). Original waiver proponents, India and South Africa, were part of the negotiations as well and although the small group negotiation was controversial, the WTO Directorate General took this approach in light of stalemate among the broader membership. *E.g.*, John Zarocostas, *Mixed Response to COVID-19 Intellectual Property Waiver*, 399 LANCET 1292, 1291 (2022); Kerry Cullinan, *WTO Head Welcomes Compromise for COVID Vaccines—But Activists and Pharma Express Dismay*, HEALTH POL'Y WATCH (Mar. 16, 2022), <https://healthpolicy-watch.news/wto-head-welcomes-ip-waiver-compromise/>.

244. See Ministerial Decision on TRIPS, *supra* note 242.

245. *Id.*

246. *Id.* at ¶ 8 n.1.

247. Ministerial Decision on TRIPS, *supra* note 242 (developing country members). It is not clear whether this includes countries generally considered poor enough to be developing countries but that might have given up that designation for other purposes. *E.g.*, MSF Comments on the Reported Draft Text of the TRIPS Waiver Negotiation, Briefing Document 5 (Mar. 15, 2022). However, even if these countries might arguably be included, the Declaration recommends that countries with capacity to manufacture vaccines make a binding commitment to not use the designation. Ministerial Decision on TRIPS, *supra* note 242, n.1. This exclusion is potentially broader in scope than a prior proposal, although not binding. See May 2022 WTO Communication, *supra* note 243, at 1 (suggesting that developing countries that exported more than 10% of global COVID vaccine doses in 2021 be barred from inclusion).

248. Ministerial Decision on TRIPS, *supra* note 242, ¶ 1.

249. TRIPS does not require that compulsory licenses only be used when necessary. TRIPS *supra* note 148, art. 31. In addition, contrary to the usual TRIPS rules granting countries complete discretion to decide when to issue compulsory licenses, the proposed text suggests that the TRIPS Council be notified of every compulsory license on COVID vaccines. Ministerial Decision on TRIPS, *supra* note 242, ¶ 5. In addition, where there are no rules preventing countries from exporting drugs under a compulsory license, this text imposes such an obligation. *Id.* at ¶ 3(d).

250. Priti Patnaik, *The Compromise Text on the TRIPS Waiver Will Undermine Vaccine Donations*, GENEVA HEALTH FILES (Mar. 31, 2022), <https://genevahealthfiles.substack.com/p/current-compromise-text-on-the-trips> (noting provision was favored by the United States and EU). Even though these countries act to promote the interests of their respective pharmaceutical industry, the industry itself may prefer even more protection of IP rights, as reflected by the fact that they have suggested

contrary to the originally proposed broad TRIPS waiver, it underscores the power of IP nationalism.²⁵¹

The suggestion that compulsory licenses of COVID vaccines (June agreement) or any treatment (EU proposal) alone is adequate to address the COVID pandemic is inaccurate. Compulsory licenses have always been an option under TRIPS.²⁵² However, the United States and the EU have criticized other countries for considering compulsory licenses during COVID.²⁵³ Even if there was no political pressure to avoid using compulsory licenses, they are not an effective solution during the pandemic because of serious logistical issues. A major issue is that the poor countries most in need of help generally cannot effectively use a compulsory license for domestic use due to lack of manufacturing capacity. Although the June 2022 agreement eases the international rules to permit compulsory licenses for export, it does nothing to address domestic laws that continue to be barriers.²⁵⁴ For example, although Bolivia has been fortunate enough to find a Canadian company willing to seek a compulsory license for export to Bolivia,²⁵⁵ until Canada amends its current laws to permit COVID treatments to be subject to compulsory license for export,²⁵⁶ this process cannot begin.²⁵⁷ And, even if this process does begin, there are still additional hurdles. After all, a single COVID treatment may involve multiple

that no change at all is required. *E.g.*, IFPMA Statement on Quad's Outcome Document on TRIPS, IFPMA (May 10, 2022), <https://www.ifpma.org/resource-centre/ifpma-statement-on-quads-outcome-document-on-trips/>; *see infra* note 24.

251. *E.g.*, Estelle Ellis, *Ramaphosa Urged Not to Endorse 'Sham of a Waiver' for COVID-19 Patents*, DAILY MAVERICK (Mar. 22, 2022), <https://www.dailymaverick.co.za/article/2022-03-22-ramaphosa-urged-not-to-endorse-sham-of-a-waiver-for-covid-19-patents/> (quoting letter from South African academics and Doctors Without Borders that the proposed compromise outcome of quadrilateral (quad) discussions between the EU, United States, South Africa, and India reflects “an admission of capitulation to unreasonable demands from the United States and European Union . . .”); *see also* Civil Society Letter to European Commissioners, Member State Ambassadors to the WTO and Members of the European Parliament (Mar. 30, 2022), https://haiweb.org/wp-content/uploads/2022/03/CS-Letter-on_Leaked-Waiver-Text.pdf (expressing concern that adoption of the quad proposal would terminate discussion without providing a comprehensive response to IP issues related to COVID).

252. *Compulsory Licensing of Pharmaceuticals and TRIPS*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_faqs_e.htm (last visited Oct. 22, 2022).

253. SPECIAL 301 REPORT, *supra* note 134. And pharmaceutical companies have been even more vehement in their criticisms of compulsory licenses. *E.g.*, PhRMA Special 301 Submission 2022, *supra* note 241 (referring to the original proposal as “extreme and unnecessary”).

254. Ministerial Decision on TRIPS, *supra* note 242.

255. Luis Gil Abinader, *Bolivia Seeks to Import COVID-19 Vaccines from Biolyse, if Canada Grants Them a Compulsory License*, KEI (May 11, 2021), <https://www.keionline.org/36119>.

256. Canada does show some recognition of the need to modify its laws during COVID because it amended the law to streamline the process for export. Ed Silverman, *A Canadian Bill Would Make It Easy to Issue Compulsory Licenses for COVID-19 Products*, STAT (Mar. 25, 2020), <https://www.statnews.com/pharmalot/2020/03/25/canada-compulsory-license-coronavirus-covid19/>.

257. Zachary Brennan, *How to Manufacture COVID-19 Vaccines Without the Help of J&J, Pfizer or Moderna? Biolyse Sees the Difficulties Up Close*, ENDPOINTS NEWS (May 17, 2021, 10:41 AM), <https://endpts.com/how-to-manufacture-covid-19-vaccines-without-the-help-of-jj-pfizer-or-moderna-biolyse-sees-the-difficulties-up-close/> (noting that the Canadian law only permits export of drugs on Schedule 1, which currently does not include any COVID-19 drugs or vaccines). Thus far, Canada does not seem to be taking steps to amend its laws although many experts have requested action. *E.g.*, Arianna Schouten, *41 Canadian Experts Request Amendment to Schedule 1 of the Patent Act to Include COVID-19 Vaccines*, KEI (Apr. 30, 2021), <https://www.keionline.org/36017>. In the

patents for which the patent owner has the right to contest the license and determine the amount of remuneration, which could lead to months of delay from initiation of the compulsory license proceeding to issuance.²⁵⁸ Moreover, because the agreement only refers to the compulsory license of issued patents, there could be even more delays after new patents issue. In contrast, a broader waiver of all COVID-related patents would have avoided the issuance of new patents that would further bar a country from making COVID treatments.

Although compulsory licenses permit patented inventions to be used at a lower cost than the patent owner's preferred rate, the emphasis on using compulsory licenses is completely anathema to a global public goods approach for COVID IP because these licenses only waive patents.²⁵⁹ As many have noted, patents alone are likely inadequate to help any country make vaccines so long as trade secret methods are involved.²⁶⁰ Therefore, the alleged solution of using compulsory licenses to solely address patent issues both reflects IP nationalism and undermines the global public goods approach towards COVID IP that is necessary to alleviate the artificial scarcity of vaccines.

IV. THE BENEFIT OF A GLOBAL PUBLIC GOODS APPROACH FOR ALL

As previously noted, IP nationalism has unnecessarily prolonged the pandemic and resulted in unnecessary deaths as well as economic loss to all. This Part explains why considering essential medicine IP, such as COVID vaccine IP, as a global public good can be consistent with international IP agreements and is supported by historical IP policy. Moreover, a global public goods approach is consistent with international human rights policies that emphasize IP as a tool to foster innovation while still recognizing other societal interests. Although IP nationalism has prioritized innovation above all other interests and has been a strong lens that has blinded some nations to other arguments during COVID, this Part illustrates how innovation can be promoted while also promoting other societal values in both domestic and international law.

past, it has taken from seven to fifteen months to amend the law to add a new drug from when first proposed, which is a long process. *E.g.*, Arianna Schouten, *Canadian Experience with Compulsory Licensing Under the Canadian Access to Medicines Regime*, KEI BRIEFING NOTE 2021:2, Mar. 31, 2021, at 7–8.

258. TRIPS, *supra* note 148, art. 31.

259. *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 252.

260. *E.g.*, Mark Eccleston-Turner & Michelle Rourke, *The TRIPS Waiver Is Necessary, but It Alone Is Not Enough to Solve Equitable Access to COVID-19 Vaccines*, 25 INSIGHTS 2 (2021); *Watch Out for a Vaccine Patent Heist*, WALL. ST. J. (Mar. 28, 2021, 3:29 PM), <https://www.wsj.com/articles/watch-out-for-a-vaccine-patent-heist-11616959785>.

A. A Global Public Goods Approach Can Be Consistent with International Norms and Policy

1. Addressing International Norms for a Global Public Goods Approach

Considering COVID IP as a global public good is consistent with international IP standards under the WTO. The WTO rules require nations to have laws that guarantee the existence and enforcement of IP rights.²⁶¹ However, the WTO does not bar IP owners themselves from electing to not enforce any WTO-consistent rights.²⁶² So, if companies could be persuaded to consider COVID IP a global public good that would not violate the TRIPS agreement.²⁶³ Similarly, it would not violate domestic laws because all IP laws permit IP owners to voluntarily share—IP laws only prevent use unauthorized by IP owners.²⁶⁴ Additionally, although there are international laws that allow private companies to challenge domestic actions that negatively impact the value of their IP rights, these laws would not bar voluntary action by companies.²⁶⁵ Moreover, if companies voluntarily share, there is no domestic action by countries that gives rise to a claim.²⁶⁶

The original broad proposal to waive COVID IP rights is also consistent with the WTO framework and would have been more consistent with a global public goods approach. However, as discussed earlier, even if members had agreed to this, it would only remove liability under the WTO/TRIPS system but would not immediately change domestic laws.²⁶⁷ Admittedly, modifying domestic laws could take time and face domestic opposition. For example, although the United States has endorsed international waiver of COVID vaccine IP rights, some members of Congress oppose the action, as reflected by proposed legislation to bar the United States from supporting the TRIPS waiver without congressional action.²⁶⁸

261. *Intellectual Property: Protection and Enforcement*, WTO, https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Oct. 22, 2022).

262. See TRIPS, *supra* note 148, art 41.

263. Although voluntarily sharing IP seems anathema to most drug companies, other companies have shared IP during COVID such as through the Open COVID pledge. Open Covid Pledge, *supra* note 182. Moreover, some companies share beyond pandemic contexts. *E.g.*, Elon Musk, *All Our Patent Are Belong to You*, TESLA (June 12, 2014), <https://www.tesla.com/blog/all-our-patent-are-belong-you>.

264. See, *eg.*, 35 U.S.C. § 271 (barring only uses “without authority” of right owner).

265. This is because the agreements create liability for countries that fail to provide adequate protection of investments, including IP, but do not address IP owners voluntarily sharing their IP. See generally *Primer on International Investment Treaties and Investor-State Dispute Settlement*, COLUMB. CTR. ON SUSTAINABLE INV. (Jan. 2022), <https://ccsi.columbia.edu/content/primer-international-investment-treaties-and-investor-state-dispute-settlement> (discussing mechanism permitting companies to challenge actions taken by countries pursuant to certain international agreements).

266. See, *eg.*, 35 U.S.C. § 271.

267. See WTO June 2022, *supra* note 198.

268. No Free TRIPS Act, S. 4063, 117th Cong. (2022); Protecting American Innovation Act, HR 7430, 117th Cong. (2022); see also Letter from the U.S. Chamber of Commerce to the U.S. Congress (April 11, 2022), <https://www.uschamber.com/intellectual-property/u-s-chamber-letter-on-the-no-free-trips-act> (supporting No Free TRIPS Act).

On the other hand, although the EU has strongly resisted the original waiver, the EU Parliament has been supportive.²⁶⁹ Moreover, even if domestic efforts were successful, there could still be international liability under agreements that protect corporate investments unless nations also agree to suspend liability under the agreements regarding COVID, as some have suggested.²⁷⁰

Considering essential medicine IP a global public good is also consistent with international human rights norms. Although creators and their respective nations may assert that they have an international human right to benefit from their creations,²⁷¹ international norms declare that *all* should benefit from scientific progress, including progress that is protected by IP rights.²⁷² UN committees have repeatedly reiterated that creations should benefit all.²⁷³ It is difficult to balance competing human rights obligations because there is no hierarchy among these rights, as all human rights are inalienable, indivisible, and interdependent.²⁷⁴ Nonetheless, there are additional human rights that suggest that IP rights should be limited. In particular, the human right to enjoy the “highest attainable standard” of health is relevant because IP rights can negatively impact attainment of this right when IP enables drugs to be priced beyond the reach of many.²⁷⁵ Further, the UN has specifically asserted that nations have a core obligation to make “essential medicines” available and accessible.²⁷⁶ The UN Commissioner stated that when IP and public health conflict, IP rights should yield to the right to public health—a sentiment reaffirmed by other

269. E.g., David Meyer, *Pressure Grows to Drop COVID-19 Vaccine Patent Protections as Europe Lawmakers Back Waiver*, FORTUNE (June 11, 2021, 3:20 AM), <https://fortune.com/2021/06/10/covid-vaccine-patent-waiver-european-parliament-commission-wto/>; Inbar Preiss, *MEPs Renew Demand for COVID-19 Vaccine Patents to Be Lifted*, PARLIAMENT MAG., <https://www.theparliamentmagazine.eu/news/article/meps-renew-demand-for-covid19-vaccine-patents-to-be-lifted> (last visited Oct. 22, 2022).

270. Ho, *supra* note 200, at 3.

271. International Covenant on Economic, Social and Cultural Rights, art. 15(1)(c), Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR] (providing “the right of everyone . . . to benefit from the protection of . . . interests resulting from any scientific, literary or artistic production of which [they are] the author.”); G.A. Res. 217 (III) A, Universal Declaration of Human Rights art. 17, U.N. Doc. A/RES/217(III) (Dec. 10, 1948) [hereinafter UDHR] (providing similar language).

272. ICESCR, *supra* note 271, art. 15(1)(b).

273. UNESCO, *Venice Statement on the Right to the Benefits of Scientific Progress and Its Applications*, ¶ 16, SHS/RSP/HRS (July 17, 2009) [hereinafter *Venice Statement*]; Committee on Economic, Social and Cultural Rights, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*, ¶ 4, U.N. Doc. E/C.12/2001/15 (Dec. 14, 2001) (noting IP rights must be balanced with the right to enjoy benefits of scientific rights).

274. See *Venice Statement*, *supra* note 273, at ¶ 12 (noting all human rights are universal, indivisible, and interdependent and interrelated); UDHR, *supra* note 271, at art. 1 (noting all human beings are born equal). As other scholars have noted, it can be difficult to resolve conflicts among rights. E.g., Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039, 1094–95 (2007).

275. ICESCR, *supra* note 271, at art. 12(1).

276. Office of the High Commissioner for Human Rights, *CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health*, ¶ 43(d), U.N. Doc. E/C.12/2000/4 (adopted Aug. 11, 2000) (noting core obligation to fulfill right to health includes providing essential drugs); Commission on Human Rights, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, UN Doc. E/CN.4/2004/49/Add.1, ¶¶ 43–44 (Mar. 1, 2004).

UN subcommittees.²⁷⁷ Accordingly, considering essential medicine IP a global public good is also consistent with the human rights to health and to benefit from science.

2. Current IP Exceptions

Although default patent rules make patents on drugs the opposite of global public goods, international laws governing patents have historically recognized exceptions to override the usual right of exclusivity, such as a compulsory license.²⁷⁸ Recognizing the necessity of exceptions opens the door to treating some IP as a global public good because it is already understood that usual IP rights need modification in certain situations. Compulsory licenses are not identical to a global public good because they are granted by individual nations and require remuneration to a patent owner, whereas global public goods are provided at zero cost. Still, the cost imposed by the government is typically far lower than the patent owner's usual rate, and the existence of domestic and international laws permitting compulsory licenses underscore that typical IP exclusivity needs to be re-adjusted. Countries have granted compulsory licenses to make patented drugs more affordable, although countries that embrace IP nationalism have strongly opposed their use.²⁷⁹ Nonetheless, this well-recognized exception shows that long-standing patent rules acknowledge that some goods should be more accessible. As such, considering patents on some IP goods to be a global public good need not be considered radical.

Additionally, although trade secrets do not typically have a compulsory license right, some have suggested that they should, which aligns somewhat with the idea of modifying usual exclusivity of private goods, which in turn aligns with the idea of public goods.²⁸⁰ Although not ultimately adopted, Brazil considered a proposal to modify its compulsory licenses of patents to also require sharing of trade secrets (and clinical data

277. See Office of the High Commissioner for Human Rights, Intellectual Property Rights and Human Rights: Sub-Commission on Human Rights Res. 2000/7, U.N. Doc.E/CN.4/Sub.2/Res/2000/7, ¶ 3 (Nov. 23, 2000); Commission on Human Rights: Sub-Commission on Promotion and Protection of Human Rights, The Realization of Economic, Social and Cultural Rights, U.N. Doc. E/CN.4/Sub.2/2000/13 (June 15, 2000) (referring to actual or potential conflict); Commission on Human Rights, Sub-Commission on Promotion and Protection of Human Rights, Economic, Social and Cultural Rights: Globalization and Its Impact on the Full Enjoyment of Human Rights, U.N. Doc. E/CN.Sub.2/2001/10 (Aug. 2, 2001) (noting that IP undermines human rights objectives).

278. *Questionnaire on Exceptions and Limitations to Patent Rights*, WIPO, <https://www.wipo.int/scp/en/exceptions/> (last visited Oct. 23, 2022).

279. E.g., *Timeline for US–Thailand Compulsory License Dispute*, PROGRAM ON INFO. JUST. & INTELL. PROP. (Apr. 2009), <http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf>; Special 301 Report, *supra* note 134 (noting United States and EU criticism of compulsory licenses during COVID).

280. E.g., Gurgula & Hull, *supra* note 228, at 1249–52.

of drugs).²⁸¹ Sharing trade secrets is tricky because a trade secret is terminated if publicly disclosed.²⁸² Nonetheless, there are existing laws, such as the U.S. Defense Protection Act, that can compel companies to disclose trade secrets as “technical information” ancillary to promoting national defense needs.²⁸³ Also, even when not legally mandated, there is sometimes recognition that trade secrets should be shared. For example, Pfizer agreed to transfer relevant technology from its partner BioNTech as part of its contract with the U.S. government.²⁸⁴ Moreover, scholars have noted that methods of making biologic drugs that are typically protected by trade secrets should nonetheless be publicly disclosed for public health and safety.²⁸⁵

3. The Historical Genesis of IP Focuses on Societal Interests Rather than IP Owners

Although all IP rights are arguably contrary to a global public goods approach (which requires sharing), the historical policy underlying IP strongly focused on IP as a benefit to society rather than for maximizing IP owners’ wealth with IP nationalism. It is important to consider the historical basis of IP policy when evaluating whether IP nationalism is inappropriate and whether, in some cases, usual IP exclusivity should give way to a global public goods approach.

Historically, IP was a policy lever that each nation could independently decide whether to use and tailor to its domestic conditions.²⁸⁶ Prior to the TRIPS agreement, which resulted from IP nationalism, a country that prioritized access to medicine could legitimately decline to patent medical products to ensure more affordable drugs—even wealthier countries such as Portugal and Spain pursued this approach until the late 1980s.²⁸⁷ Additionally, because developing countries often find it helpful to copy information as part of their development process, those countries

281. *E.g.*, Montauray Pimenta Machado & Vieira de Mello, *New Bill About Compulsory License Sanctioned in Brazil*, LEXOLOGY (Sept. 3, 2021), <https://www.lexology.com/library/detail.aspx?g=ed4922e6-357f-47de-bff5-9e1463eac28>.

282. 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.”).

283. *See* 50 U.S.C. § 4511(a) (2014) (noting President has authorization to allocation materials); 50 U.S.C. § 4552(13) (2009) (noting “materials” can include technical information).

284. Letter from Army Contracting Command, U.S. Department of the Army, to Advanced Technology International (July 21, 2020), <https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf>.

285. *E.g.*, Yaniv Heled, *The Case for Disclosure of Biologics Manufacturing Information*, 47 J.L. MED. & ETHICS 54, 55 (2021); *see also* David S. Levine, *The People’s Trade Secrets*, 18 MI TELECOMM. & TECH. L. REV. 61, 62–63 (2011) (arguing that infrastructure more broadly should not be protected by trade secrets).

286. Donald P. Harris, *TRIPS’ Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet Back Against the United States*, 25 NW. J. INT’L L. & BUS. 99, 99, 104 (2004).

287. JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 109 (2001). Moreover, even countries now associated with pharmaceutical companies such as Switzerland and Japan did not grant patents on drug compositions until the middle to late 1970s. *Id.*

often adopt weak IP rights.²⁸⁸ In recent decades the United States has claimed that strong IP rights are essential but that has not always been its stance; historically, while still developing, the United States itself commonly copied from other countries.²⁸⁹

Patents, the most exclusive type of IP, were historically granted to promote sharing of technology—not to ensure profits to investors. Patents were originally granted only to inventors that would make the patented invention in the patent-granting nation to ensure the invention benefited domestic citizens.²⁹⁰ Countries considered the transfer of technology through patents so important that they would revoke the patent if the inventor failed to use the invention domestically.²⁹¹ Additionally, a nation that granted patents did not affirmatively harm other countries because no country pressured others to have certain IP rights.²⁹² That pressure only began in the late 1980s after countries with strong IP-exporting industries lobbied for creation of global laws that would increase their global revenues.²⁹³ So, although patents have always involved exclusivity, those exclusive rights were tied to ensuring overall societal benefits and were revoked in the absence of those benefits.

B. Debunking Arguments Against a Global Public Goods Approach

1. The Overstated Innovation Argument

A major concern for countries considering whether any IP is a global public good is the extent to which the recognition would negatively impact innovation. Some argue that it would harm innovation for vaccines against new COVID variants and hamper treatments for future pandemics.²⁹⁴ As

288. E.g., Christopher Klein, *The Spies Who Launched America's Industrial Revolution*, HIST. (Jan. 10, 2019), <https://www.history.com/news/industrial-revolution-spies-europe>.

289. CHRISTOPHER MAY & SUSAN K. SELL, *INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY* 114 (2006) (discussing widespread piracy of British books in the mid-1800s); Carla Hesse, *The Rise of Intellectual Property, 700 B.C.–A.D. 2000: An Idea in the Balance*, in DAEDALUS 40 (James Miller, ed. 2002).

290. E.g., Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.–Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 370–71 (2002).

291. Forfeiture or cancellation of a patent for lack of working existed in patent laws dating back to the Venetian Patent Act of 1474. *Id.* at 371.

292. *See id.*

293. *See id.*

294. E.g., Arne Delfs & Eric Martin, *Merkel Pushes Back on Vaccine Patent Waiver in Row with U.S.*, BLOOMBERG (May 6, 2021, 10:23 AM), <https://www.bloomberg.com/news/articles/2021-05-06/merkel-pushes-back-on-vaccine-patent-waiver-in-clash-with-biden> (noting Germany's position that "intellectual property is a source of innovation and this has to remain so in the future" and also suggesting that COVID vaccines require high-quality standards that waiving patents would not address); Rithika Sangameshwaran, *Understanding Germany's Trenchant Opposition to the TRIPS Waiver*, GENEVA HEALTH FILES (Aug. 13, 2021), <https://genevahealthfiles.substack.com/p/understanding-germanys-trenchant> (noting "strong belief that IP is . . . an important incentive" for Angela Merkel's party that some consider a case of nationalism); Letter from Tom Cotton, Joni Ernst, Todd Young, & Mike Lee, U.S. Senators, to President Biden (Mar. 4, 2021), <https://www.cotton.senate.gov/imo/media/doc/Biden%20WTO%20IP%20letter.pdf> (alleging that waiver "would end the innovation pipeline and stop the development of new vaccines or boosters to address variants."); *see also* Special 301 Report, *supra* note 134, at 28 (asserting "adequate" IP is necessary to fight current

will be explained, such claims are overstated. This is especially true regarding innovation for vaccines against new COVID variants. After all, it is known that existing vaccines are highly effective and that the inadequacy of global vaccinations prompts more variants. Given this, it is unclear if maintaining the incentive to develop *potential* treatments is better than foregoing a waiver that could provide *known* treatments that effectively prevent COVID infections and forestall more variants.

Before considering whether the waiver will harm future innovation, it is first important to consider the related claim that existing COVID vaccines and treatments are due to IP rights such that IP rights should remain inviolate. In particular, some attribute the plethora of effective COVID vaccines in record time to IP.²⁹⁵ However, it is questionable whether IP is primarily responsible for these developments. For example, as part of Operation Warp Speed, the U.S. government funded late-stage human clinical trials in addition to more basic research.²⁹⁶ The U.S. government also made advance commitments to purchase effective vaccines.²⁹⁷ Estimates of direct U.S. government spending on COVID vaccine development and manufacturing range from \$18 billion to \$23 billion without counting decades of financing for the key innovations central to COVID vaccines, such as the mRNA platforms used in the Pfizer and Moderna vaccines.²⁹⁸ One report asserts that over 98% of COVID research funding came from public sources.²⁹⁹ In other words, as innovation scholars have suggested for years, relying on the patent system alone is inefficient when other measures used during COVID, such as advance commitments, can be effective.³⁰⁰ Additionally, as noted above, countries have produced and approved new COVID treatments in the shadow of discussions to waive IP rights.³⁰¹ Accordingly, the claim that innovation will not happen if IP rights are potentially subject to modification is questionable.

and future pandemics); BIOTECHNOLOGY INNOVATION ORGANIZATION: 2021 SPECIAL 301 SUBMISSION, BIOTECHNOLOGY INNOVATION ORGANIZATION 5 (Jan. 29, 2021) (suggesting limits to IP during the pandemic could negatively impact future innovation); *AIPLA Statement on the US Administration's Decision on Waiver of IP Protections*, AM. INTELL. PROP. L. ASS'N (May 6, 2021), <https://www.aipla.org/detail/news/2021/05/06/aipla-statement-on-the-us-administration-s-decision-on-waiver-of-ip-protections> (arguing that waiver would have “a chilling effect on research and development to address future health threats, including COVID-19 variants.”).

295. E.g., EU, Urgent Trade Policy, *supra* note 237, at ¶ 6 (asserting that “rapid development of several safe and effective COVID-19 vaccines has shown the value of intellectual property”); Van Etten, *supra* note 25 (attributing COVID vaccines to IP).

296. E.g., Richard G. Frank, Leslie Dach, & Nicole Lurie, *It Was the Government that Produced COVID-19 Vaccine Success*, HEALTH AFFS. FOREFRONT (May 14, 2021), <https://www.healthaffairs.org/doi/10.1377/forefront.20210512.191448/>; Bhaven Sampat & Kenneth C. Shadlen, *The COVID-19 Innovation System*, 40 HEALTH AFF. 400, 401 (2021).

297. E.g., Callaway, *supra* note 69, at 506–07 (discussing global pre-purchasing of vaccines); Ingrid Torjesen, *COVID-19: Pre-Purchasing Vaccine—Sensible or Selfish?*, BRIT. MED. J., Aug. 2020, at 1; Anthony D. So & Joshua Woo, *Reserving Coronavirus Disease 2019 Vaccines For Global Access: Cross Sectional Analysis*, BRIT. MED. J., Dec. 2020, at 1–2.

298. Frank et al., *supra* note 296.

299. E.g., Niall McCarthy, *The Top Recipients of COVID-19 R&D Funding*, STATISTA (May 6, 2021), <https://www.statista.com/chart/24806/main-recipients-of-covid-19-investments/>.

300. E.g., Hemel & Oulette, *supra* note 30, at 92, 304–05.

301. See *supra* Section III.A.

A tougher question to address is the potential negative impact on non-COVID treatments if a global public goods approach is adopted and thus sets a precedent that IP rights are not immutable. This may seem a powerful argument, but it overstates the impact. Although companies generally fund the last step before market that involves expensive human clinical tests, there are many others that contribute to innovation, such as university and government scientists.³⁰² Also, the federal government often provides financing for research with grants from the NIH.³⁰³ Moreover, scholars and policy makers have repeatedly noted that IP *imperfectly* incentivizes innovation because it encourages companies to invest in what is most profitable.³⁰⁴ Therefore, companies do not often invest in antibiotics, vaccines, or conditions that primarily impact the poor, who lack the resources to pay premium prices.³⁰⁵ So, decreasing innovation—that is already imperfect—is not compelling.

Claims that inadequate IP protection will be a death knell to innovation is a specious argument because that would only be true if current pharmaceutical companies decide to completely exit the business rather than earn lower profits. In other contexts where industry has made similar arguments, such as against disclosure of data submitted to regulatory authorities that would allegedly compromise innovation, after countries ignored these arguments, the companies did not exit the business and instead operated under circumstances that they previously claimed were unworkable.³⁰⁶ That is likely because what is considered unworkable is simply less profitable, as pharmaceutical companies are one of the most profitable businesses.³⁰⁷ Nonetheless, protecting existing profit margins globally is consistent with IP nationalism and thus explains these claims.

302. E.g., Emily H. Jung, Alfred Engelberg, & Aaron S. Kesselheim, *Do Large Companies Provide Drug Development Innovation? Our Analysis Says No*, STAT (Dec. 10, 2019), <https://www.statnews.com/2019/12/10/large-pharma-companies-provide-little-new-drug-development-innovation/>.

303. E.g., Katie Gallogly-Swan, Rachel Thrasher, & Özlem Ömer, *Vaccinating the World: Waiving Intellectual Property Rules on COVID-19 Products*, GLOB. ECON. GOV. INITIATIVE POL'Y BRIEF, Mar. 2021, at 4–5 (noting decades of public research).

304. E.g., UN HIGH LEVEL PANEL, *supra* note 33, at 29; Joseph E. Stiglitz & Arjun Jayadev, *Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals*, 7 J. GENERIC MED. 217, 218–19, (2010); Luke Hawksbee, Martin McKee, & Lawrence King, *Don't Worry About Drug Industry's Profits When Considering a Waiver on Intellectual Property Rights*, BRIT. MED. J., Jan. 2022, at 3; Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 UNIV. CHI. L. REV. 999, 1029–33 (2014).

305. E.g., Kevin Outterson, Unni Gopinathan, Carles Clift, Anthony D. So, Chantal M. Morel, & John-Arne Rottingen, *Delinking Investment in Antibiotic Research and Development from Sales Revenues: The Challenges of Transforming a Promising Idea into Reality*, PLOS MED., June 2016, at 3–4 (2016); *see also infra* note 360 and accompanying text (noting issue with inadequate antibiotic development).

306. See Cynthia Ho, *Avoiding the TRIPS Trap: A Path to Domestic Disclosure of Drug Data Consistent with International Norms*, 54 CORNELL J. INT'L L. (forthcoming), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3667995.

307. Fred D. Ledley, Sarah Shonka McCoy, Gregory Vaughan, & Ekaterina Galkina Cleary, *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323 J. AM. MED. ASS'N. 834, 839–40 (2020).

2. Recognizing the Power of IP Nationalism: Opposition to a Broad TRIPS Waiver

Although there are cogent reasons to ignore the overstated claim that innovation will be harmed by a broad waiver of TRIPS requirements (and by extension, a global public health approach to COVID IP), it must nonetheless be acknowledged that IP nationalism is powerful. This Subsection shows the strength of IP nationalism by showcasing factually incorrect, or at least misleading, claims that are likely a function of the tenacity of IP nationalism. Additionally, this Subsection provides some reason for optimism that it is possible to mitigate the harms of IP nationalism globally, even if disabusing nations of this general sentiment may prove challenging.

Countries embracing IP nationalism have raised the following unfounded statements that should be viewed as reflecting the power of IP nationalism as a lens through which facts may be ignored or distorted. Although many examples exist, this Subsection focuses on highlighting the recurring misleading statements made by countries (rather than companies) that are especially baseless:

- That there is no evidence IP has ever been a barrier during COVID;
- That the waiver would undermine public health by causing an increase of dangerous vaccines;
- That the waiver is unnecessary because of the existence and effectiveness of voluntary licenses; and
- That IP has helped and not hindered COVID treatments.³⁰⁸

The allegation that there is no evidence that IP has ever been a barrier must be seriously questioned.³⁰⁹ Despite claims that vaccine shortages are due to production capacity rather than IP issues, IP was a legal issue that barred an increase in production capacity.³¹⁰ For example, although 3D

308. There are some other misleading statements such as that the waiver of patent rights would be ineffectual because trade secrets are necessary, overlooking the fact that the waiver also applies to trade secrets and that some domestic trade secret laws could permit exceptions. *E.g.*, Jan. 15, 2021, WTO Communication, *supra* note 24, at ¶ 127.

309. Council for Trade-Related Aspects of Intellectual Property Rights, *Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19*, WTO Doc. IP/C/W/671 (Nov. 27, 2020) (requesting clarification to what extent IP has “impeded or prevented the timely procurement of COVID-19 diagnostics, equipment, therapeutics or vaccines”); Letter to Ambassador Katherine C. Tai, from AIPLA, IPO, LES, & NYIPLA (Mar. 30, 2021), <https://patentlyo.com/media/2021/03/Joint-IP-Association-Letter-Regarding-TRIPS-Waiver-Proposal-March-30-20201.pdf> [hereinafter AIPLA Letter to Tai]; David J. Kappos & Paul R. Michel, *Waiving COVID-19 Vaccine Patents Won’t Get Shots in Arms Faster. It Slows Down New Vaccines*, NBC NEWS (May 25, 2021, 6:24 AM), <https://www.nbcnews.com/think/opinion/waiving-covid-19-vaccine-patents-won-t-get-shots-arms-ncna1268099>.

310. Philip Blenkinsop & Carl O’Donnell, *EU Supports COVID Vaccine Patent Waiver Talks, but Critics Say Won’t Solve Scarcity*, REUTERS (May 6, 2021, 1:32 AM), <https://www.reuters.com/world/europe/eu-willing-discuss-covid-19-vaccine-patent-waiver-eus-von-der-leyen-2021->

printing could have helped to address the inadequacy of supplies like ventilator valves, there was inadequate sharing for fear of IP liability.³¹¹ Patents and trade secrets on COVID vaccines were also a barrier to the creation of more vaccines.³¹² Although by mid-2022 there was an adequate supply of vaccines given less interest from the Global South, this was untrue for most of the prior two years; poor countries suffered both unnecessary deaths and economic harm as a result.³¹³ IP has been an affirmative barrier even when companies voluntarily licensed some of their COVID treatment patents, such as Remdesivir and Paxlovid, because roughly half the world's population (including many in middle-income countries) was excluded from this licensing.³¹⁴ Accordingly, the claim that IP has never been a barrier is false and instead underscores the power of IP nationalism to distort reality.

Not only does the allegation that IP has never been a barrier have no basis, but the related argument that there are non-IP issues that are true barriers is overstated. For example, it has been argued that poor countries lack technical capacity or raw materials such that waiving IP rights would have no impact. These are red herrings, however, that reflect the ability of IP nationalism to detract from the reality that strong IP rights can have negative consequences. Experts have identified over 100 firms, some in developing countries, that can make COVID mRNA vaccines.³¹⁵ And, one firm in South Africa has already done so.³¹⁶ Additionally, there are companies with untapped technical capacity in countries like Canada and Israel.³¹⁷ Although the lack of raw materials is a plausible concern, the issue is not only hard to prove but also diverts serious consideration away from the clear impact that existing IP laws have by unnecessarily constraining

05-06/ (noting Germany claims vaccine shortages are due to production capacity and quality standards, rather than patent issues); Press Release, Innovative Medicines Canada, Innovative Medicines Canada Cautions Against COVID-19 TRIPS IP Waiver (May 6, 2021), <http://innovativemedicines.ca/innovative-medicines-canada-cautions-covid-19-trips-ip-waiver/> (arguing that the waiver “will not address the real issues of trade barriers, global supply chain bottlenecks, and scarcity of raw materials . . .”).

311. *Beyond Access to Medicines*, *supra* note 111.

312. Council for Trade-Related Aspects of Intellectual Property Rights, Examples of IP Issues and Barriers in COVID-19 Pandemic, WTO Doc. IP/C/W/670 (Nov. 23, 2020) [hereinafter Nov. 23, 2020, WTO Communication].

313. See Fahad Kaizer, *UN Analysis Shows Link Between Lack of Vaccine Equity and Widening Poverty Gap*, UN NEWS (Mar. 28, 2022), <https://news.un.org/en/story/2022/03/1114762>.

314. See Nov. 23, 2020, WTO Communication, *supra* note 312. Excluded countries are pursuing other avenues to obtain necessary treatments such as compulsory licenses. *E.g.*, Barber, *supra* note 191.

315. *Experts Identify 100 Plus Firms to Make COVID-19 mRNA Vaccines*, HUM. RTS. WATCH (Dec. 15, 2021, 12:01AM), <https://www.hrw.org/news/2021/12/15/experts-identify-100-plus-firms-make-covid-19-mrna-vaccines>.

316. David Meyer, *Moderna Wouldn't Share Its Technology, So South Africa and the WHO Made a COVID Jab Based on It Anyway*, FORTUNE (Feb. 4, 2022, 6:59 AM), <https://fortune.com/2022/02/04/south-africa-afri-gen-moderna-covid-vaccine-mrna-who-hotez-corbevax/amp/>.

317. Furlong, *supra* note 116 (noting rejection of requests to help from Biolyse Pharma in Canada, Incepta in Bangladesh, Teva Pharmaceuticals in Israel, and Bavarian Nordic in Denmark).

adequate supplies.³¹⁸ Admittedly, there are logistical barriers to distributing vaccines in poor countries given weak infrastructure and limited health care workers.³¹⁹ Nevertheless, IP has still been a barrier to timely providing adequate supplies of not only vaccines but also treatments and diagnostics. This is important because, whereas some of the most effective vaccines require special cold storage, effective and nonperishable pill treatments are easy to make and distribute—if there was not an IP barrier for many countries to do so.

Allegations that the waiver should be resisted to best protect public health similarly show the power of IP nationalism to focus on groundless red herrings. For example, the U.S. Chamber of Commerce asserted that the originally proposed waiver would undermine the belief that “individuals can be confident [vaccines] are safe and effective.”³²⁰ Similarly, in discussions at the WTO, the United Kingdom asked how a waiver of TRIPS requirements would ensure the safety and quality of COVID treatments.³²¹ However, IP rights are not intended to protect public health and safety; rather, that is the goal of non-IP health laws.³²² Rather, countries generally have regulatory authorities to ensure new drugs and vaccines are

318. However, there is some evidence that raw material shortages are overstated. For example, although Merck’s 2020 annual financial report suggests risks with supply chain, the first quarter financial report does not indicate that the risks have materialized. Compare Merck & Co., Inc., *Annual Report 2020*, SEC FORM 10-K (Feb. 25, 2021), https://s21.q4cdn.com/488056881/files/doc_financials/2020/q4/4df43d8f-8b85-45da-92ef-7ad82f343c3b.pdf, with Press Release, Merck & Co., Inc., Merck Announces First-Quarter 2021 Financial Results (2021) (noting expansion of raw material production). Similarly, BioNTech, which partners to make the Pfizer vaccine, indicated in 2021 that it would scale up next year, which suggests no problems with obtaining raw materials. Frank Jordans, *Vaccine Maker BioNTech Says No Need to Waive Patents*, AP NEWS (May 10, 2021), <https://apnews.com/article/europe-coronavirus-vaccine-coronavirus-pandemic-health-business-2a03ff6d794f6e6b92a58c1403683e7b>.

319. Eunice Twumwaa Tagoe, Nurnabi Sheikh, Alec Morton, Justice Nonvignon, Abdur Razzaque Sarker, Lynn Williams, & Itamar Megiddo, *COVID-19 Vaccination in Lower-Middle Income Countries: National Stakeholder Views on Challenges, Barriers, and Potential Solutions*, FRONTIERS PUB. HEALTH, Aug. 2021, at 4–5.

320. *U.S. Chamber Opposes Administration Decision on IP Waiver for Vaccines: “Move Will Undermine the Global Fight Against COVID”*, U.S. CHAMBER COM. (May 5, 2021), <https://www.uschamber.com/security/pandemic/us-chamber-opposes-administration-decision-ip-waiver-vaccines-move-will-undermine-the>; see also Philip Thompson, *Stop Tripping Over TRIPS*, IPWATCHDOG (May 6, 2021, 4:15 PM), <https://www.ipwatchdog.com/2021/05/06/stop-tripping-trips/id=133245/> (noting former USPTO Director Iancu alleging that the waiver posed “an immediate danger to the widespread distribution of quality vaccines”).

321. See Jan. 15, 2021, WTO Communication, *supra* note 24, at § 2.17; see also Letter from Senator Cotton, Ernst, Young, & Lee, *supra* note 301 (alleging that the waiver would result in major quality control problems that would then cause people to lose faith in safety and efficacy of the vaccines); Stephen Ezell, *TRIPS Waiver on COVID-19 IP Rights Wouldn’t Help Vaccine Access; It Would Just Harm Innovation*, INFO. TECH & INNOV. FOUND. (Mar. 9, 2021), <https://itif.org/publications/2021/03/09/trips-waiver-covid-19-ip-rights-wouldnt-help-vaccine-access> (arguing that IP-owning companies should have the right to evaluate potential license partners to ensure that they can safely and reliably produce COVID treatments).

322. For example, trade secrets are provided for economically valuable information and patents are provided to new and useful inventions. See *What Are Intellectual Property Rights?*, WTO, https://www.wto.org/english/tratop_e/trips_e/intell_e.htm#:~:text=Intellectual%20property%20rights%20are%20the,a%20certain%20period%20of%20time. (last visited Oct. 23, 2022). So, these criteria have nothing to do with health.

safe and effective before sold—even if they are patented.³²³ So, ignoring this fundamental principle reflects not a lack of knowledge but instead the fact that IP nationalism has the power to cause gross distortion.

Similarly, allegations that voluntary approaches, such as voluntary licensing and donations, are adequate and effective are contradicted by reality. The fact that IP owners rejected license requests from capable manufacturers undermines the supposed effectiveness of voluntary licensing.³²⁴ This stands in contrast to the repeated claims of nations that voluntary licensing is being used or will be used to provide adequate capacity.³²⁵ Moreover, even when voluntary licenses are issued, they are generally limited in scope, such as with the previously mentioned Remdesivir and Paxlovid licenses that exclude half the world.³²⁶

A related claim is that IP has helped rather than hindered the development of COVID treatments. For example, the EU claims that IP rights resulted in the record-fast creation of several highly effective COVID vaccines.³²⁷ However, even if the prospect of IP rights helped provide an incentive, this statement is misleading in suggesting that IP is the key reason the vaccines exist and fails to acknowledge the massive amount of public

323. Jayshree D. Patel & Gregorio Kahn, *Drug Approval Regulation: The Global Impacts*, 4 J. BACTERIOLOGY & MYCOLOGY 191, 191 (2017); see also Douglas Ball, Susann Roth, & Jane Parry, *Better Regulation of Medicines Means Stronger Regional Health Security*, ADB BRIEFS, Apr. 2016, at 2–3 (noting that although domestic drug regulation should ensure safety and efficacy, inadequate resources can hamper this effort); Drita Dhami, *List of Countries Without Formal Regulatory Approval Process*, REGDESK (Jan. 25, 2017), <https://www.regdesk.co/countries-no-medical-device-regulations/> (noting that there are forty-nine countries without formal drug approval processes).

324. E.g., Maria Cheng & Lori Hinnant, *Countries Urge Drug Companies to Share Vaccine Know-How*, AP NEWS (Mar. 1, 2021), <https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92afbc3ea9ed519be007f8887bcf6> (noting factories in Bangladesh, South Africa, and Denmark that could quickly start producing vaccines on short notice if provided technical know-how); Christopher Rowland, Emily Rauhala, & Miriam Berger, *Drug Companies Defend Vaccine Monopolies in Face of Global Outcry*, WASH. POST (Mar. 20, 2021, 9:49 PM), <https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/> (noting Bangladeshi manufacturer Incepta rebuffed in its attempt to help make 600–800 million doses a year).

325. E.g., Jan 15, 2021, WTO Communication, *supra* note 24, at ¶ 35.

326. See *supra* note 191 and accompanying text.

327. EU, Urgent Trade Policy, *supra* note 237, ¶ 6 (attributing vaccine development to IP); see also *Intellectual Property is the Key Driver of Medical Innovation. Without IP, We Wouldn't Have Any Tools to Fight COVID-19*, EFPIA, <https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/> (last visited Oct. 22, 2022) (noting that “it is only because of intellectual property protection that we have over 300 treatments and more than 200 vaccines currently being explored for use against COVID-19.”).

funding provided.³²⁸ Indeed, over 90% of the cost of AstraZeneca's vaccine was publicly funded.³²⁹ Nonetheless, because those that embrace IP nationalism want to avoid modifying IP rights for fear of diminishing future profits, that motivation results in the overemphasis of IP rights.³³⁰ Similarly, some claim that IP has been essential in promoting the licensure of IP rights to effectively counter the pandemic, but as discussed above, the voluntary licensing to date has been limited.³³¹

As shown above, IP nationalism can be a powerful lens that resists acknowledging facts that are inconsistent with IP nationalism tenets, like the assumption that IP rights are only ever beneficial. Research on individuals shows that it can be difficult to change beliefs, especially those that are tied to political beliefs or group identity, both of which are inherently connected to IP nationalism.³³² At the same time, there is other research showing that even without changes in beliefs, it is possible to structure laws and systems to influence desired actions.³³³ For example, people who reject the existence of global warming despite scientific evidence could nonetheless be financially incentivized to purchase and use an electric car, which helps address global warming, even if their views do not change. This Article assumes that just as individual beliefs are hard to change, so too are national beliefs, or at least the policies embraced by

328. The U.S. government spent between \$18 billion and \$23 billion on vaccine development. Lancet Comm'n on COVID-19 Vaccines and Therapeutics Task Force Members, *Operation Warp Speed: Implications for Global Vaccine Security*, 9 LANCET GLOB. HEALTH e1017, e1017 (2021) (noting that the United States spent \$18 billion, mostly for late-stage clinical development and early manufacturing of vaccines, as well as to buy 455 million doses); see also Chad P. Bown & Thomas J. Bollyky, *Here's How to Get Billions of COVID-19 Vaccine Doses to the World*, PETERSON INST. INT'L ECON. (Mar. 18, 2021, 12:00 PM), <https://www.piie.com/blogs/trade-and-investment-policy-watch/heres-how-get-billions-covid-19-vaccine-doses-world> (providing breakdown of U.S. payment to vaccine manufacturers and equipment and other input suppliers).

329. Michael Safi, *Oxford/AstraZeneca COVID Vaccine Research 'Was 97% Publicly Funded'*, GUARDIAN (Apr. 15, 2021), <https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded>; see also Jonathan Saltzman, *The US Government Has Now Paid Moderna \$6b for Vaccine Effort*, BOS. GLOBE (Apr. 29, 2021, 9:47 AM), <https://www.bostonglobe.com/2021/04/29/nation/us-government-has-now-given-moderna-6b-vaccine-effort/> (noting that Moderna will receive another \$236 million for a clinical trial on top of nearly \$6 billion the government previously paid to develop, test, manufacture, and provide doses, and that Johnson & Johnson received \$2 billion for its COVID vaccine development and orders).

330. In fact, some suggest that even though companies like Moderna received funding, private investment before COVID laid the groundwork. E.g., John Stanford, *Thank Private Risk-Taking, Not Public Funding, for COVID-19 Vaccines, Therapies*, STAT (Apr. 5, 2021), <https://www.statnews.com/2021/04/05/thank-private-risk-taking-not-public-funding-for-covid-19-vaccines-therapies/>.

331. E.g., Kappos & Michel, *supra* note 309 (arguing that IP rights ensure competitors are comfortable licensing technology); PhRMA Letter to President Joseph R. Biden, *supra* note 97 (noting that IP has been "essential" to sharing); AIPLA Letter to Tai, *supra* note 309 (noting IP has enabled innovators to collaborate to counter the pandemic); Ashleigh Furlong & Sarah Anne Aarup, *Why Waiving Patents Might Not Boost Global Access to Coronavirus Vaccines*, POLITICO (Apr. 21, 2021, 4:33 PM), <https://www.politico.eu/article/waiving-patents-coronavirus-vaccine/> (noting that Director of International Federation of Pharmaceutical Manufacturers & Associations suggests waiver of IP rights would "remove trust").

332. Nathan Walter & Sheila T. Murphy, *How to Unring the Bell: A Meta-Analytic Approach to Correction of Misinformation*, 85 COMM'N MONOGRAPHS 423, 436 (2018).

333. E.g., Cynthia M. Ho, *Biosimilar Bias: A Barrier to Addressing American Drug Costs*, 99 DENV. L. REV. 517 (2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3908625.

nations premised on these beliefs. Nevertheless, there may be some reason for optimism.

History has shown that even countries that repeatedly exhibit IP nationalism will sometimes take actions contrary to IP nationalism—if there is adequate public and especially global pressure. For example, the United States, Japan, and the EU, consistent with their IP nationalist tendencies, negotiated the Anti-Counterfeiting Trade Agreement, an international treaty primarily designed to increase copyright standards.³³⁴ However, even after these countries signed the Agreement in 2011, it never took effect due to significant public protests in Europe and prominent websites blacking out their websites in protest.³³⁵ Additionally, the United States ultimately stopped pressuring South Africa from using legitimate, internationally supported exceptions to patent rights to address its HIV epidemic with the adoption of an Executive Order.³³⁶ Moreover, during the COVID pandemic, the United States’ position evolved. To illustrate, the United States originally opposed the WHO Pool but two years later contributed patents related to COVID vaccines.³³⁷

3. International Law and Policy: Pandemic Treaty and Other Norms

Now is an ideal time to consider IP for essential pandemic treatments as a global public good because global leaders recognize that to prepare for future pandemics, it is necessary to develop a pandemic treaty involving a robust global, rather than nationalistic, response.³³⁸ The stated objective is to “save lives and protect livelihoods” by addressing a wide range of issues including prevention, preparedness, and response.³³⁹ Early proposals on the need for such a treaty typically did not single out the need to address IP issues despite the fact that IP has been a major barrier in accessing COVID treatments.³⁴⁰ However, the industry highlighted the need

334. Brussels & Wellington, *Joint Statement on Anti-Counterfeiting Trade Agreement (ACTA)*, at 1–2, IP/10/437 (Apr. 16, 2010) (noting ACTA first developed by Japan and the United States in 2006).

335. Charles Arthur, *ACTA Criticised After Thousands Protest in Europe*, GUARDIAN (Feb. 13, 2012), <https://www.theguardian.com/technology/2012/feb/13/acta-protests-europe>; Ben Rooney, *Thousands Protest Against ACTA*, WALL ST. J. (Feb 13, 2012, 1:18 PM), <https://www.wsj.com/articles/BL-TEB-3855>.

336. Access to HIV/AIDS Pharmaceutical and Medical Technologies, Exec. Order No. 13,155, 65 Fed. Reg. 30,521 (May 12, 2000).

337. Silverman, *supra* note 130.

338. *COVID-19 Shows Why United Action Is Needed for More Robust International Health Architecture*, WHO (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> (noting twenty-five heads of state recommending that WHO develop a pandemic treaty); Catherine Thonlinson, *The Politics and Promise of a Pandemic Treaty*, NEW FRAME (Apr. 16, 2021), <https://www.newframe.com/the-politics-and-promise-of-a-pandemic-treaty/> (noting support by developed and developing countries such as Germany, the UK, and South Africa).

339. WHO Draft Outline, *supra* note 39.

340. E.g., *International Treaty on Pandemic Prevention and Preparedness*, EUR. COUNCIL, <https://www.consilium.europa.eu/en/policies/coronavirus/pandemic-treaty/> (last visited Oct. 23, 2022) (noting a number of issues but not specifically mentioning IP as something to be overcome); see also Luke Taylor, *World Health Organization to Begin Negotiating International Pandemic*

to directly address IP issues because it believes the contributions of IP must be recognized in discussion of any treaty.³⁴¹ Those concerned about the interests of the Global South have also noted the need to address IP barriers.³⁴² Some countries specifically noted time-bound waivers of intellectual property should be considered to promote needed transfer of technology.³⁴³ Some members of the public even suggested that companies should provide medicines regardless of patent rights.³⁴⁴

To accomplish the proposed goals of universal and equitable access to needed treatments, countries should consider IP related to a pandemic a global public good. There are, however, some serious hurdles to achieving this goal. First, not all agree that it should be a binding agreement.³⁴⁵ Although countries recently agreed for the pandemic treaty to be binding, that may result in a narrower scope.³⁴⁶ After all, some countries negotiating the treaty objected to a broad TRIPS waiver in favor of the more limited use of compulsory licensing for only COVID vaccines.³⁴⁷ Even if countries agree in a binding pandemic treaty to include a declaration that IP on certain issues is a global public good, this would not immediately waive existing international norms in other agreements because no single treaty preempts others. However, such an acknowledgement would at least promote the recognition of this need so that countries that are members to other agreements could create needed exceptions. For example, if the pandemic treaty made this statement, member states to the WTO could then amend TRIPS to create exceptions for a pandemic. This would avoid replicating the COVID scenario where precious time was wasted while member states debated whether to waive usual TRIPS requirements.

Treaty, 375 BRIT. MED. J. 2991, 2991 (2021) (noting that Global North has emphasized non-IP issues such as information sharing).

341. *COVID-19 Vaccine and Treatment Innovators Response to Global Leaders Urgent Call for International Pandemic Treaty*, IFPMA (Mar. 30, 2021), <https://www.ifpma.org/resource-centre/covid-19-vaccine-and-treatment-innovators-response-to-global-leaders-urgent-call-for-international-pandemic-treaty/> (noting that negotiators should consider “importance of incentives for future innovation” and arguing for recognition of “the critical role played by the incentive system,” which seems to be the term used in lieu of IP for developing tests, drugs, and vaccines against COVID).

342. *E.g.*, Paul Ogendi, *Addressing IP Barriers in the Context of a Pandemic Treaty*, HARV. L. BILL OF HEALTH (Dec. 22, 2021); *see also* Velásquez & Syam, *supra* note 38, at 4, 6 (recognizing that the treaty needs to consider relationship with the WTO).

343. First Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response, Outcomes of the First Round of Public Meetings, WHO Doc. A/INB/1/10 (June 1, 2022).

344. *Id.*

345. Taylor, *supra* note 340 (noting that the United States and Brazil prefer a non-binding obligation). Moreover, even if it were binding, that may not have the desired result considering that binding agreements during COVID were ignored. *E.g.*, David P. Fidler, *The Case Against a Pandemic Treaty*, THINK GLOB. HEALTH (Nov. 26, 2021), <https://www.thinkglobalhealth.org/article/case-against-pandemic-treaty>.

346. *Pandemic Instrument Should Be Legally Binding, INB Meeting Concludes*, WHO (July 21, 2022), <https://www.who.int/news/item/21-07-2022-pandemic-instrument-should-be-legally-binding-inb-meeting-concludes>.

347. *E.g.*, Velásquez & Syam, *supra* note 38, at 6.

Of course, even if this principle were recognized, countries must provide adequate incentives to ensure that companies will invest in developing needed treatments for a pandemic. History shows that companies generally have no incentive to develop treatments such as vaccines until a pandemic strikes, which then causes deadly delay.³⁴⁸ If a pandemic treaty also required IP for such treatment to be shared, countries would also have to put other mechanisms in place to incentivize pharmaceutical companies in lieu of profits from IP-protected products. Although this seems challenging, there is already recognition for the need to publicly fund this research as part of broader proposals to respond to emerging pandemics more rapidly.³⁴⁹ Moreover, either the pandemic treaty or a separate international treaty could focus on ensuring adequate incentives. Countries could consider incentives to promote research beyond treating pandemics and build upon prior suggestions to correct the flawed current system where private companies are incentivized only by profits from patents and thus focus on only the most profitable treatments. However, countries could correct this not only by domestic actions but also with globally binding agreements, such as the previously proposed global research and development treaty, to ensure the development of essential drugs.³⁵⁰

4. Domestic IP Laws Should Be Reformed and Non-IP Innovation Levers Maximized

Countries should also revise domestic laws to create exceptions for IP related to essential drugs including, but not limited to, drugs and vaccines needed for a pandemic. Such an approach would be consistent with those that advocate that essential drugs should be affordably available to all.³⁵¹ To some extent, existing domestic laws do exist to create exceptions, such as compulsory licenses to patent laws. However, as previously mentioned, not only are nations often pressured to not use these exceptions but

348. See, e.g., Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, 7 TEX. A&M J. PROP. L. 110, 111, 117–18 (2019) (noting that vaccines are generally unprofitable and thus chronically underfunded).

349. Shira Stein, *Biden Looks to Invest \$30 Billion in Preventing Future Pandemics*, BLOOMBERG L. (Mar. 31, 2021, 1:37 PM), <https://news.bloomberglaw.com/health-law-and-business/biden-looks-to-invest-30-billion-in-preventing-future-pandemics>; Ann Danaiya Usher, *New Funds Proposed to Prevent Pandemics*, 396 LANCET 155, 155 (2020).

350. Kaitlin Mara, *World Health Assembly Creates New Initiative for R&D Financing*, INTELL. PROP. WATCH (May 21, 2010), <https://www.ip-watch.org/2010/05/21/world-health-assembly-creates-new-initiative-for-rd-financing/> (noting that some countries proposed that WHO consider an R&D Treaty).

351. E.g., *Improving Access to Essential Medicines*, WHO, <https://www.who.int/westernpacific/activities/improving-access-to-essential-medicines> (last visited Oct. 22, 2022); Ellen 't Hoen, Salomé Meyer, Patrick Durisch, Wilbert Bannenberg, Katrina Perehudoff, Tim Reed, & Melissa J. Barber, *Improving Affordability of New Essential Cancer Medicines*, 20 LANCET ONCOLOGY 1052, 1052–53 (2019); Lukas Roth, Daniel Bempong, Joseph B. Babigumira, Shabir Banoo, Emer Cooke, David Jefferys, Lombe Kasonde, Hubert G.M. Leufkens, John C.W. Lim, Murray Lumpkin, Gugu Mahlangu, Rosanna W. Pelling, Helen Rees, Margareth Ndomondo-Sigonda, Andy Stergachis, Mike Ward, & Jude Nwokike, *Expanding Global Access to Essential Medicines: Investment Priorities for Sustainably Strengthening Medical Product Regulatory Systems*, 14 GLOB & HEALTH 102, 103 (Nov. 1, 2018); *Access to Medicines and Human Rights*, HARV. HEALTH AND HUM. RTS. RES. GUIDE (June 9, 2017), <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>.

the exceptions are often inadequate because other barriers like trade secrets and data exclusivity are not addressed.³⁵² Although an exception to data exclusivity could and should be created in domestic laws, trade secrets are more complex because a trade secret exception is likely not enough on its own for companies to access the trade secret.³⁵³ However, given that some scholars have previously recognized that trade secret law may inadequately balance needs of the public versus its owner, especially in cases of public health and infrastructure, a new global public goods approach to trade secret law might be appropriate.³⁵⁴ In particular, nations should consider mandating compulsory transfer of trade secret rights similar to the compulsory licenses of patents.³⁵⁵ Moreover, even if IP laws are not changed, governments could require that receipt of government funding is conditioned upon transfer of related technology, at least for IP related to essential goods.

Considering IP on essential drugs to be a global public good could also have implications beyond the IP realm. For example, as COVID has shown, there are levers beyond patents, such as advance purchase commitments, that stimulate innovation and speed the development of drugs to market.³⁵⁶ Accordingly, it would be wise to learn from COVID what some innovation scholars and some policy makers have long recognized—that we *can* and *should* use alternatives to IP more often to promote innovation. There are a variety of possibilities that could include not just advance purchase agreements but also other financial support methods to promote development. One possibility is a prize system to encourage development of essential drugs rather than solely patent protection.³⁵⁷ Another possibility is to provide public funding of clinical trials for essential drugs rather than to have self-interested drug companies cover the cost of clinical trials and then later claim that high prices are necessary to cover these costs.³⁵⁸ These

352. E.g., Ana Santos Rutschmann & Julia Barnes-Weise, *The COVID-19 Patent Waiver: The Wrong Tool for the Right Goal*, HARV. BILL OF HEALTH (May 5, 2021), <https://blog.petrief-lom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/>.

353. *Id.*

354. Some suggest trade secret protection is not appropriate if it involves health and safety data, environmental concerns, or public infrastructure. Durkin et al., *supra* note 228, at 130–31; Levine, *supra* note 285, at 80.

355. See Viviana Muñoz Tellez, *The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines*, S. CTR. POL'Y BRIEF, Apr. 2020, at 5 (suggesting governments could require trade secrets disclosed in the case of a public health emergency). Indeed, although it did not become law, Brazil proposed that compulsory license of patents include sharing relevant technology. E.g., Machado & Mello, *supra* note 281.

356. James C. Robinson, *Funding of Pharmaceutical Innovation During and After the COVID-19 Pandemic*, 325 J. AM. MED. ASS'N. 825, 825–826 (2021).

357. E.g., Thomas Pogge, *The Health Impact Fund: How to Make New Medicines Accessible for All*, in GLOBAL HEALTH AND GLOBAL HEALTH ETHICS 241 (Solomon Benatar & Gillian Brock, eds. 2011).

358. E.g., Tracy R. Lewis, Jerome H. Reichman, & Anthony D. So, *The Case for Public Funding and Public Oversight of Clinical Trials*, in ECONOMISTS' VOICE 1–3 (2007). Of course, even corporate claims of the high cost of drug development are suspect because companies seem to spend more on buybacks and dividends and increase prices for existing drugs. See, e.g., U.S. HOUSE OF REPRESENTATIVES STAFF REPORT COMMITTEE ON OVERSIGHT AND REFORM, DRUG PRICING

are not brand-new ideas. Indeed, a UN commission tasked with evaluating the intersection of health and IP specifically suggested “delinking” the price of drugs from research by having the government pay for things like these clinical trials so that drug development is directly funded rather than indirectly through prices inflated by patents.³⁵⁹ However, the travesties of COVID may hopefully finally inspire countries to put into practice what scholars have previously suggested.

Of course, all these ideas require addressing some challenging issues. First, there must be commitment to a global public goods approach to essential medicine IP. Commitment to this view could be challenging because there may be differing views on what is essential. Additionally, even if that hurdle could be overcome, there are serious practicalities to consider, like how the system would be funded. It would likely require a massive infusion of capital to involve the government in funding expensive human clinical trials. However, governments have recently shown during COVID that they can provide substantial capital to promote research. So, it is possible. The key is to start with small areas where there is agreement and once success is shown, expand the scope. For example, governments could address the market failure in terms of lack of private incentive to develop unprofitable but needed treatments like antibiotics; although governments already recognize that this is an issue that creates a looming crisis, solutions thus far have been inadequate.³⁶⁰

CONCLUSION

The COVID crisis has highlighted the existence of IP nationalism and its problems. Historically, IP nationalism has resulted in global laws and policies that have led to inadequate supplies of affordable drugs but not a

INVESTIGATION: INDUSTRY SPENDING ON BUYBACKS DIVIDENDS AND EXECUTIVE COMPENSATION 1 (2021) (noting that companies spend more on buybacks and dividends than research and increase prices for existing drugs); U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON OVERSIGHT AND REFORM, DRUG PRICING INVESTIGATION: MAJORITY STAFF REPORT xvii (2021) (finding claims of research costs are not supported given that drug prices are frequently increased to meet revenue targets). At a minimum, mandating companies to report the actual costs pursuant to current proposed legislation is a positive step. *E.g.*, Ava Alkon, Christopher Morten, & Reshma Ramachandran, *Are High-Cost Prescription Drugs the Price of Innovation? Disclose the Costs of Clinical Trials*, HILL (Apr. 21, 2022, 4:30 PM); *see also* Pharmaceutical Research Transparency Act of 2022, H.R. 7474, 117th Cong., 2d Session (2022), S. 4037, 117th Cong., 2d Sess. (2022).

359. UN HIGH LEVEL PANEL, *supra* note 33.

360. *E.g.*, Christine Ardal, Yohann Lacotte, Suzanne Edwards, & Marie-Cécile Ploy, *National Facilitators and Barriers to the Implementation of Incentives for Antibiotic Access and Innovation*, J. ANTIBIOTICS, June 2021, at 5; Chantal M. Morel, Olof Lindahl, Stephan Harbarth, Marlieke E. A. de Kraker, Suzanne Edwards, & Aidan Hollis, *Industry Incentives and Antibiotic Resistance: An Introduction to the Antibiotic Susceptibility Bonus*, 73 J. ANTIBIOTICS 421, 427 (2020); Meghana Keshavan, *Fixing a ‘Market Failure’: To Develop Antibiotics, Upend the Incentive Structure, Experts Urge*, STAT (May 2, 2019), <https://www.statnews.com/2019/05/02/fixing-a-market-failure-to-develop-new-antibiotics-upend-the-incentive-structure-experts-urge/>; Kevin Outterson, *Time To Pull Out All the Stops in the Fight Against Superbugs*, REVIVE (Feb. 13, 2019), <https://revive.gardp.org/time-to-pull-out-all-the-stops-in-the-fight-against-superbugs/>; *see also* Michael Kremer & Christopher Snyder, *Strengthening Incentives for Vaccine Development*, NBER (Dec. 2020), <https://www.nber.org/reporter/2020number4/strengthening-incentives-vaccine-development> (discussing need to incentivize vaccines, as opposed to drugs, because vaccines are considered less profitable).

complete scarcity. COVID underscores that IP nationalism can also result in actual scarcity of needed treatments during a global pandemic, creating a new reason why IP nationalism is problematic as a matter of public policy.

Although many have long questioned the overvaluation of IP rights in all countries, identifying IP nationalism as a phenomenon helps to better understand its repercussions. The basis for IP nationalism is debatable as a matter of economic policy and yet has had fatal repercussions during the COVID pandemic. If nations were to abandon IP nationalism and instead consider IP for essential treatments like COVID vaccines to be a global public good, this could expedite solutions to the current crisis and hopefully abate unnecessary crises in the future.