ESSAY

WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review

BRYAN MERCURIO*

In view of the increasing concern over global efforts to ensure equitable access to affordable COVID-19 vaccines, India and South Africa presented a proposal to the World Trade Organization (WTO) in October 2020 seeking a waiver of intellectual property rights (IPRs) in order to increase access to vaccines or other COVID-19 related technologies. The original proposal sought to waive IPRs that could relate to and impact the prevention, containment or treatment of COVID-19 prior to the availability of widespread vaccination and herd immunity. While the proposal has attracted support from some WTO Members and non-governmental organizations (NGOs), it has proven to be contentious and has not been endorsed by all WTO Members.

This essay reviews the justifications put forward by proponents of the waiver, namely that it would improve access to affordable vaccines and that alternatives available in the WTO's agreement on IPRs are too complex for use by many developing countries. In response, this essay argues that the waiver is unnecessary, would not alleviate the burden of access to effective and affordable medicines and vaccines, and could potentially hamper research, development, and innovation in the pharmaceutical sector.

* Simon F.S. Li Professor of Law at The Chinese University of Hong Kong. The author thanks Kaidrian Yu for research assistance and the editors of VJIL Online for their diligence.

I. INTRODUCTION

The debate over whether and to what extent intellectual property rights (IPRs) lead to increased innovation and life-saving medical technologies or unfairly restrict access to those technologies has raged for nearly three decades.[1] There is general consensus among public health scholars and advocates that the current system – which allows innovator companies to control research and development (R&D), manufacturing, and distribution – is suboptimal, and when facilitated by the monopoly power granted by patent rights, can lead to excess pricing. Several legitimate proposals have been put forward that attempt to unwind the current system to provide less costly medical treatments while still adequately rewarding and encouraging further investment in innovation.[2] These proposals, however, have failed to gain traction among domestic policymakers in key jurisdictions or at the international level. Thus, treatments and vaccines developed to combat and prevent COVID-19 are subject to patent protection, as set out in the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and distributed by the innovator companies to governments around the globe.[3] Under Articles 28 and 33 of the TRIPS Agreement, countries must grant patent holders the exclusive rights to make, use, and sell the treatments and vaccines for a minimum term of twenty years from the date of the patent filing.[4] Thus, it is possible that IPRs can restrict supply, exacerbate shortfalls in production capacity, and lead to excessive pricing. However, the system contains built-in safeguards against anti-competitive abuse, most notably in the form of government-issued compulsory licenses, which allow someone other than the patent owner to produce and/or use a patented product or process without the consent of the patent owner under certain conditions.[5]

Notwithstanding, in light of the increasing concern over global efforts to ensure equitable access to affordable COVID-19 vaccines, India and

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1. *See generally* Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, http://www.unsgaccessmeds.org/final-report (2016) (discussing various positions and arguments).

2. *See, e.g.*, THE HEALTH IMPACT FUND, https://healthimpactfund.org/en/ (last visited Feb. 7, 2021); Knowledge Ecology International, et al., *The Need for Global Negotiations on Agreements to Fund R&D within the Context of a Progressive De-linking of R&D Costs from Product Prices*, Submission to U.N. High Level Panel, http://www.unsgaccessmeds.org/inbox/2016/2/29/james-love (Feb. 29, 2016).

3. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

4. *Id.* at art. 28, 33.

5. *See Compulsory licensing of pharmaceuticals and TRIPS,* WTO, *available at* https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited July 25, 2021).

South Africa presented a proposal to the WTO asking for a waiver of the IPRs in order to increase access to vaccines or other COVID-19 related technologies.[6] The proposal, tabled at a meeting of the TRIPS Council in October 2020, called on WTO Members to waive patent and other IPRs which could relate to and impact the "prevention, containment or treatment of COVID-19."[7]

The proposal attracted the support of the majority of developing country Members and co-sponsorship from Kenya, Eswatini, Mozambique, Bolivia and Pakistan.[8] However a handful of Members including the United States, United Kingdom, Canada, and the European Union opposed it.[9] Given that consensus could not be reached within the deadline of ninety days as set out in Article IX:3 of the Agreement Establishing the WTO, Members agreed to keep the COVID-19 waiver proposal on the agenda of the TRIPS Council for 2021.[10] While the U.S. has since announced it would support a waiver,[11] several other Members remain unconvinced and negotiations remain ongoing.[12]

This article reviews the justifications put forward by the sponsors of the proposal before presenting counterarguments that the waiver is unnecessary, would not alleviate the burden of access to effective and

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6. WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, *Communication from India and South Africa*, WTO Doc. IP/C/W/669, ¶ 12 (Oct. 2, 2020), [hereinafter WTO Waiver Proposal]; *see generally supra* note 3, ¶ IX:3 ("In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the Members unless otherwise provided for in this paragraph.").

7. WTO Waiver Proposal, *supra* note 6.

8. *Members to continue discussion on proposal for temporary IP waiver in response to COVID-19,* WTO News Item, (Dec. 10, 2020), https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm.

9. Amiti Sen, *WTO members divided over India-South Africa proposal for TRIPS waiver during Covid-19,* THE HINDU BUSINESS LINE (Oct. 17, 2020), https://www.thehindubusinessline.com/economy/wto-members-divided-over-india-south-proposal-for-trips-waiver-during-covid-19/article32878713.ece. Under what is referred to as "consensus decision-making," every Member of the WTO essentially has a veto over all organizational decisions. *See generally* SIMON LESTER, BRYAN MERCURIO, & ARWEL DAVIES, WORLD TRADE LAW 74-77 (Bloomsbury ed., 2018).

10. Importantly, while the WTO rules would allow for Members to vote on the proposal (on the basis of one value, one vote), with a three-fourths majority needed in order for the waiver to be adopted, in practice the WTO has never abandoned "consensus decision-making" in favor of a vote. *See id.* at 82-83.

11. *See* Office of the United States Trade Representative, Statement from Ambassador Katherine Tai on the COVID-19 Trips Waiver (May 5, 2021), https://ustr.gov/node/10649.

12. *See, e.g.*, *Covid: Germany rejects US-backed proposal to waive vaccine patents*, BBC NEWS (May 6, 2021), https://www.bbc.com/news/world-europe-57013096. *See also* European Commission, Opening statement by Executive Vice-President Valdis Dombrovskis at the European Parliament plenary debate on the Global Covid-19 challenge (May 21, 2021), https://ec.europa.eu/commission/commissioners/2019-2024/dombrovskis/announcements/opening-statement-executive-vice-president-valdis-dombrovskis-european-parliament-plenary-debate_en; Bryan Mercurio, *The IP Waiver for COVID-19: Bad Policy, Bad Precedent*, INT'L REV INTELL. PROP. COMPET. L. (forthcoming, 2021).

affordable medicines and vaccines, and could potentially hamper R&D and innovation in the pharmaceutical sector.

II. JUSTIFICATIONS FOR A WAIVER OF INTELLECTUAL PROPERTY RIGHTS TO COMBAT COVID-19

The waiver proposal is broad in scope as it seeks a waiver from the implementation, application and enforcement of Sections 1, 4, 5 and 7 (covering copyrights, industrial designs, patents and undisclosed trade information)[13] related to the "prevention, containment or treatment of COVID-19.[14] While the original proposal called for the waiver to remain in place "until widespread vaccination is in place globally, and the majority of the world's population has developed immunity," a revised proposal tabled in May 2021 calls for the waiver to remain in place until the Membership agrees by consensus that it is no longer required – meaning even a single Member's objection to ending the waiver would mean the waiver continues to remain in force.[15] Justifying their proposal by claiming that a waiver would be an effective response to a pandemic, the two sponsors expressed concern whether the supply of new vaccines developed for COVID-19 would be made available in sufficient quantities and at affordable prices.[16]

The sponsors make several arguments in support of their proposal for a waiver. First, the sponsors argue that limitations within the TRIPS Agreement hamper and may even prohibit many smaller, poorer developing countries from taking advantage of the existing flexibilities.[17] For instance, while the TRIPS Agreement allows countries to issue compulsory licenses to generic producers for the manufacture and distribution of patented medicines or vaccines, in countries with no or insufficient manufacturing capabilities, such licenses are needed both in the country which requires the supply and the exporting country which is supplying the product under the

13. With the exception of the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement. *See* WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Revised Decision Text, 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*, WTO Doc. P/C/W/669/Rev.1 ¶ 3 (May 21, 2021) [hereinafter Revised Waiver Proposal].

14. WTO Waiver Proposal, *supra* note 6, ¶ 12.

15. *See* WTO Waiver Proposal, *supra* note 6, ¶ 13; Revised Waiver Proposal, *supra* note 13, ¶ 2 ("This waiver shall be in force for at least 3 years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver.").

16. WTO Waiver Proposal, *supra* note 6, ¶¶ 5, 7.

17. *See id.* ¶ 10.

compulsory license.[18] India claims many smaller countries were not able to fulfill the formalities required to initiate the process.[19] In a communication co-sponsored with several Members, South Africa concurs, arguing that the case-by-case or product-by-product approach required when using flexibilities could be limiting during the pandemic.[20] The communication also reiterates concern that the nuances involved with the issuance of compulsory licenses as well as the complex procedural requirements needed to make use of this provision within the TRIPs Agreement limit its value and usability.[21] Relatedly, several countries – including Chile, Indonesia, Colombia, Egypt, India, Malaysia, Russia, Turkey, Ukraine and El Salvador – experienced intense pressure from the pharmaceutical industry and developed country governments for attempting to make provisions in their law for the importation of medicines under a compulsory license or for even contemplating making use of the flexibility.[22] The waiver would allow Members to act in their best interest free from external pressure.

The second point raised by the sponsors is lack of access to affordable vaccines. The argument is that IPRs over COVID-19 health technologies threaten scale-up of manufacturing, lock out diversified suppliers, and undermine competition that would result in lower prices.[23] Critics refer to Gilead Sciences' licensing agreements for Remdesivir (a medicine developed with substantial public funding[24]) as an illustrative example, claiming the agreements restrict manufacturing and prevent low-cost supply to nearly half of the world's population.[25] Critics have also noted that despite wealthy nations representing 13 percent of the global population, these countries pre-purchased at least half the doses of the world's five leading potential

18. *See* TRIPS Agreement, Article 31bis (making clear that the exporting Member must also issue a compulsory license). *See generally* Bryan Mercurio, *TRIPS, Patents and Access to Life-Saving Drugs in the Developing World,* 8 MARQ. INTELL. PROP. REV. 211, 234 (2004).

19. *See* Sen, *supra* note 9.

20. WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Responses to Questions, Communication from The Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, The Bolivarian Republic of Venezuela and Zimbabwe,* WTO Doc. IP/C/W/672, ¶ 1.1.3 (Jan. 14, 2021)[hereinafter WTO Responses to Questions].

21. *Id.*

22. WTO, *Council for Trade-Related Aspects of Intellectual Property Rights: Examples of IP Issues and Barriers in COVID-19 Pandemic, Communication from South Africa*, WTO Doc. IP/C/W/670 (Nov. 23 2020); WTO, *Council for Trade-Related Aspects of Intellectual Property Rights: Response to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19,* WTO Doc. IP/C/W/671; *Communication from The Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, The Bolivarian Republic of Venezuela and Zimbabwe,* WTO Doc. IP/C/W/673, ¶¶ 37-40 (Jan. 15, 2021).

23. WTO Responses to Questions, *supra* note 20, ¶ 2.9.59.

24. *See* Kathryn Ardizzone, *Role of the Federal Government in the Development of Remdesivir,* KEI Briefing Note 2020:1 (updated May 28, 2020).

25. WTO Responses to Questions, *supra* note 20, ¶ 1.2.7.

vaccines.[26] With such exclusive licensing agreements in place, the sponsors argue that other generic manufacturers cannot acquire the technology and put themselves in a position to manufacture supplies to meet global demand.

Third, the sponsors claim that despite efforts from many in industry and government, the current voluntary sharing mechanisms are not working as designed.[27] The vaccines and biologic medicines being developed for COVID-19 are complex products. They are more difficult to replicate than small molecules medicines (such as those used to combat HIV/AIDS) if technology transfer does not take place.[28] The scale-up of vaccines and other biologics requires more than the transfer of patents alone. It also involves the transfer of technology, data, know-how and cell-lines. But, the sponsors argue, "no pharmaceutical company has committed to sharing its IP and technologies in the Covid-19 Technology Access Pool (C-TAP) since its launch more than five months ago."[29]

Finally, the sponsors argue that with so much public funding involved in inventing treatments and vaccines for COVID-19, the benefits should not merely flow to the pharmaceutical industry.[30] In this context, they believe that the common justification of the necessity of monopoly rights to recoup investment costs does not fully apply.[31]

III. THE CASE AGAINST A WAIVER FOR INTELLECTUAL PROPERTY RIGHTS

While waiving certain IPRs might in theory bring about immediate benefits for developing countries and increase access to COVID-19 technologies, in practice, achieving such a result is far from certain. Other major factors – such as infrastructure, supply chains, production capabilities and capacity – may prove to be a major stumbling block in distributing

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26. *Small group of rich nations have bought up more than half the future supply of leading COVID-19 vaccine contenders*, OXFAM INT'L (Sept. 17, 2020), https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19.

27. WTO, *Council for Trade-Related Aspects of Intellectual Property Rights*, WTO Doc. IP/C/M/669 (Oct. 16, 2020), *Item 15 Proposal for a Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa*, https://pmindiaun.gov.in/public_files/assets/pdf/TRIPS_Agreement.pdf [hereinafter Correspondence Communication from India and South Africa].

28. *See, e.g.*, Thomas Morrow & Linda Hull Felcone, *Defining the difference: What Makes Biologics Unique* (Biotechnology Healthcare, 2004), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/; *Small molecule versus biological drugs* (Generics and Biosimilar Initiative, 2012), https://www.gabionline.net/Biosimilars/Research/Small-molecule-versus-biological-drugs.

29. *Id. See also* WTO, *Council for Trade-Related Aspects of Intellectual Property Rights: Intellectual Property and Public Interest: Beyond Access to Medicines and Medical Technologies Towards a More Holistic Approach to TRIPS Flexibilities, Communication from South Africa*, WTO Doc. IP/C/W/666, ¶ 8 (July 17, 2020).

30. WTO Responses to Questions, *supra* note 20, ¶ 1.3.12.

31. WTO Correspondence Communication from India and South Africa, *supra* note 27.

medicines and vaccines.[32] Moreover, legal determinants such as the efficacy of existing mechanisms in the international rules and the role that stable IPRs play in facilitating investment and innovation in medical development should not be discounted in the rush to alleviate the health, economic, and social devastation and uncertainty brought about by COVID-19. Thus, having reviewed the arguments put forward in favor of granting the waiver, this section argues that the IP waiver is unnecessary, would not alleviate the burden of access to effective and affordable medicines and vaccines and has the potential to significantly hamper R&D and innovation in the pharmaceutical sector.

A. An IP Waiver Would Undermine R&D and Innovation

The IP system is designed to encourage and reward creativity and innovation while benefiting society. The idea is that IPRs stimulate innovation by "enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks."[33] While in the short term, waiving IPRs may arguably accelerate the distribution of goods and services – i.e., access to COVID-19 vaccines – in the long term, undermining IPRs would eliminate the incentives that spark innovation.

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32. *See* Jonathan Dakin, *Supply Chain Challenges Creating Hurdles to COVID-19 Vaccine Production,* PHARMTECH (Apr. 2, 2021), https://www.pharmtech.com/view/supply-chain-challenges-creating-hurdles-to-covid-19-vaccine-production; Costas Paris, *Supply-Chain Obstacles Led to Last Month's Cut to Pfizer's Covid-19 Vaccine-Rollout Target*, WALL ST. J. (Dec. 3, 2020), https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787; Edward Segal, *New Vaccine Supply And Distribution Problems Slow Fight Against Covid –And Provide More Crisis Management Lessons*, FORBES (Jan. 26, 2021), https://www.forbes.com/sites/edwardsegal/2021/01/26/new-vaccine-supply-and-distribution-problems-slow-fight-against-covid---and-provide-more-crisis-management-lessons/; Charles Clift, *Scaling up covid-19 vaccine production: What are the problems and implications?* THE BMJ OPINION BLOG (Mar. 17, 2021), https://blogs.bmj.com/bmj/2021/03/17/scaling-up-covid-19-vaccine-production-what-are-the-problems-and-implications/; Prashant Yadav & Rebecca Weintraub, *4 Strategies to Boost the Global Supply of Covid-19 Vaccine*, HARV. BUS. REV. (May 6, 2021), https://hbr.org/2021/05/4-strategies-to-boost-the-global-supply-of-covid-19-vaccines; Divya Kottadiel & Benson Kibiti, *Vaccine cold chain is the beginning, not the end, for rural healthcare*, POWER FOR ALL (Jan. 21, 2021), https://www.powerforall.org/insights/impact/vaccine-cold-chain-beginning-not-end-rural-healthcare; Margi Van Gogh, Ludwig Hausmann, Detlev Mohr, & Christoph Wolff, *Is the world up to the challenge of mass COVID-19 vaccination?*, MCKINSEY & CO. (Feb. 8, 2021) https://www.mckinsey.com/industries/travel-logistics-and-infrastructure/our-insights/is-the-world-up-to-the-challenge-of-mass-covid-19-vaccination.

33. Stephen Ezell & Nigel Cory, *The Way Forward for Intellectual Property Internationally,* INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION (Apr. 25, 2019), https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally. *See also* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MANAGEMENT SCIENCE 173 (1986) (surveying 100 U.S. manufacturing firms to ascertain the extent to which patent protection impacts innovation and inventions).

This would hinder the discovery and development of knowledge necessary for new products or technologies that the world needs.[34]

Synthetic mRNA, the genetic technology behind the COVID-19 vaccines of both Pfizer and Moderna, is illustrative of the significance of IP protection. Synthetic mRNA is a genetic technology that has long held tremendous promise but has so far run into biological roadblocks. The concept of tweaking specific strands in synthetic mRNA to deliver desired results was first introduced in the 1990s. But at that time, while it made sense in theory, it often failed in the real world as synthetic RNA was notoriously vulnerable to the body's natural defenses and the synthetic RNA was often destroyed before reaching its target cells. In some situations, the foreign materials even elicited an immune response that posed health risks for some patients. The solution, substituting one of the nucleosides (building blocks of mRNA) for a slightly tweaked version to bypass the body's defense, was not discovered until 2005 and did not reach the commercialization stage for another 15 years.[35]

Without the prospect of IP protection, it is simply unimaginable that scientists would devote the human and monetary resources into such R&D, as there would have been no incentive to spend the time and effort on a promising but extremely challenging technology. Similarly, venture capitalists would refuse to invest billions of dollars into research if any company could simply take the successful result and produce a medicine without paying for the R&D costs; in such a scenario, it would be virtually impossible to recoup the initial investment. Thus, without the promise of IP protection the technology underpinning the most advanced and promising COVID-19 vaccines would likely never have been developed.

IPRs have played a major role in the response to COVID-19;[36] a response which led to an incredible feat of humanity – the identification of

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34. James Bacchus, *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines*, CATO INSTITUTE (Dec. 16 2020), https://www.cato.org/publications/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid; "Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021" 5, https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_07_Position_statement_Covid_IP_waiver.pdf (last visited June 20, 2021) [hereinafter Max Planck Position Statement].

35. *See generally* Damian Garde & Jonathan Saltzman, *The story of mRNA: How a once-dismissed idea became a leading technology in the Covid vaccine race*, STAT (Nov. 10, 2020), https://www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/; Norbert Pardi, Michael J. Hogan, Frederick W. Porter & Drew Weissman, *mRNA vaccines — a new era in vaccinology,* 17 NATURE REVIEWS DRUG DISCOVERY 261-279 (2018).

36. *See* Philip Stevens & Mark Schultz, *Why Intellectual Property Rights Matter for COVID-19*, GENEVA NETWORK (Jan. 2021), https://geneva-network.com/wp-content/uploads/2021/01/Why-IP-matters-for-Covid-19.pdf (last visited June 20, 2021). *See also* Max Planck Position

the genome of a new pathogen and development of several treatments and promising vaccines within a year. Without the promise of financial gain, the amount of R&D invested into the novel coronavirus would have been greatly reduced and innovation hampered and delayed. In short, the IP system encouraged a robust response to the threat by innovator companies and worked as designed. It would be unwise, if not reckless, to jeopardize the innovation system, which has delivered results in record time, for what are at best short-term benefits.

B. Intellectual Property Rights Have Not Hampered Access to COVID-19 Vaccines

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licensing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement.[37] This was also the case with the Kimberley Process, which attempted to eliminate trade in "conflict diamonds."[38]

Although the IP waiver proposal states that "there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients,"[39] the sponsors did not provide further elaboration or evidence to support their declaration that "many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]."[40] Instead, many of the examples used by the sponsors point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory license in 2003, yet many developing countries failed to put in place any framework to allow their country to make

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Statement, *supra* note 34, ¶ 1 (arguing that "IP rights might so far have played an enabling and facilitating rather than hindering role in overcoming COVID-19, and that the global community might not be better off by waiving IP rights, neither during nor after the pandemic").

37. Under Article 3(f) of the TRIPS Agreement, Members are limited in the issuance of a compulsory license "predominantly for the supply of the domestic market." TRIPS Agreement, *supra* note 3 at art. 3(f). The waiver, granted in 2003, remained in force until ratification of an amendment to the TRIPS Agreement in the form of Article 31*bis*, which occurred in 2017. *See Amendment of the TRIPS Agreement*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Aug. 8, 2021).

38. *Agreement reached on WTO waiver for "conflict diamonds,"* WTO News Item (Feb. 26, 2003), https://www.wto.org/english/news_e/news03_e/goods_council_26fev03_e.htm.

39. WTO Waiver Proposal, *supra* note 6, ¶ 9.

40. *Id.* ¶ 10.

use of the flexibility.[41] This is not an institutional problem of the international IP system but rather a problem at the domestic level.

Two additional factors render the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at reasonable rates, and several announced plans for extensive not-for-profit sales.[42] Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. De Bleeker's tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: ($2.16), Johnson & Johnson ($8.50), Sanofi/GSK ($9.16), CureVac ($12.12), BioNTech/Pfizer ($14.55) and Moderna ($18).[43] While South Africa's agreement to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of $5.26 per dose has attracted negative attention,[44] criticism is directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs.

Moreover, while the disparity in pricing pertains to the overall per dosage rate South Africa is paying, it nevertheless captures the value of the expected health and economic returns on investment. Despite the disparity in pricing between nations, the industry has not only rapidly produced

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41. Sisule F. Musungu & Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?*, SOUTH CENTRE AND WORLD HEALTH ORGANIZATION 119-120 (2006); *see generally* Brin Anderson, *Better Access to Medicines: Why Countries Are Getting "Tripped" Up and Not Ratifying Article 31-Bis,* 1 CASE W. RES. J.L. TECH. & INTERNET 166 (2010).

42. *See, e.g.*, *Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use*, Johnson & Johnson Press Release (Mar. 30, 2020), https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use. *See also* Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic (Oct. 8, 2020), https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19.

43. Jillian Deutsch & Camille Gijs, *Belgian secretary of state accidentally reveals EU vaccine prices*, POLITICO (Dec. 17, 2020), https://www.politico.eu/article/belgian-secretary-of-state-accidentally-reveals-eu-vaccine-prices/.

44. Helen Sullivan, *South Africa paying more than double EU price for Oxford vaccine,* THE GUARDIAN (Jan. 22, 2021), https://www.theguardian.com/world/2021/jan/22/south-africa-paying-more-than-double-eu-price-for-oxford-astrazeneca-vaccine. In the article, South Africa's deputy director general of health, Anban Pillay, stated that the reason for the price disparity is that countries which have "invested in the [research and development, receive], the discount on the price." This point directly counters criticism that the public in developed countries funded the vaccine efforts but only the pharmaceutical industry was benefiting with monopoly pricing power.

vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices.

Second, the proposed waiver will do nothing to address the issue of a lack of capacity and the necessity of transferring technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries; in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.[45] Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability. While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistical expertise exist in only a handful of countries.[46] Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced access and will remain reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the license fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary license from the patent holder because such licenses include provisions for the transfer of know-how and ongoing quality assurance support.

C. Voluntary Licensing and Other Initiatives are Supporting Access to COVID-19 Vaccines

Contrary to the TRIPS Council sponsors' assertions, pharmaceutical companies have been actively signing voluntary licensing agreements with various generic drug manufacturers to scale up the production of COVID-

45. *See generally* Reed F. Beall, Rosanne Blanchet & Amir Attaran, *In which developing countries are patents on essential medicines being filed?*, 13 GLOBALIZATION AND HEALTH 38 (2017) (discussing patenting pharmaceutical patents in the developing world). *See also COVID-19 Datasets*, https://about.lens.org/covid-19/.

46. *Using trade to fight COVID-19: Manufacturing and distributing vaccines,* OECD (Feb. 11, 2021). One interesting proposal is the creation of a fund to purchase know-how as a means of facilitating mass production of vaccines. *E.g.*, James Love, *Buying Know-How to Scale Vaccine Manufacturing* (Mar. 21, 2021), https://jamie-love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36.

19 medication. For instance, Gilead's antiviral drug Remdesivir was approved for emergency use for COVID-19 treatment by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency in May 2020.[47] As demand surged following the approvals for use against COVID-19, Gilead issued non-exclusive voluntary licenses to generic producers based in India, Egypt, and Pakistan to meet the growing demand for the product.[48] Under the voluntary licensing agreements, these manufacturers receive the technology necessary to manufacture Remdesivir and set their own prices for the generic drugs they produce.[49] The arrangement allows drug distribution in 127 countries, covering nearly all low-income and lower-middle-income countries.[50]

The COVID-19 vaccine co-developed by AstraZeneca and University of Oxford is yet another example of industry cooperation. AstraZeneca has committed to granting voluntary licensing in developing countries and signed sublicense agreements with several generic drugs producers to increase the supply of future vaccines, including with the Serum Institute of India (one of the world's largest vaccine producers),[51] Fiocruz in Brazil,[52] BioKangtai in China[53] and R-Pharm in Russia,[54] enabling the massive production of cheap generic vaccines and supply of over two billion doses to lower-middle-income countries once the vaccine is approved for sale in those countries.

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47. *Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment*, U.S. Food and Drug Administration (May 1, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment; *First COVID-19 treatment recommended for EU authorisation*, EUROPEAN MEDICINES AGENCY (June 25, 2020), https://www.ema.europa.eu/en/news/first-covid-19-treatment-recommended-eu-authorisation.

48. Gilead, *Voluntary Licensing Agreements for Remdesivir*, https://www.gilead.com /purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir (last visited May 7, 2021).

49. *Id.*

50. *Id. See also* Sara Jerving, *Gilead's closed-door deal sets precedent for COVID-19 drug access*, DEVEX (June 16, 2020), https://www.devex.com/news/gilead-s-closed-door-deal-sets-precedent-for-covid-19-drug-access-97214.

51. *AstraZeneca takes next steps towards broad and equitable access to Oxford University's potential COVID-19 vaccine*, ASTRAZENECA (June 4, 2020), https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html; *About Us*, SERUM INST. OF INDIA PRIV. LTD., https://www.seruminstitute.com/about_us.php (last visited May 8, 2021).

52. Marcelo Rochabrun, *Brazil signs agreement to produce AstraZeneca's experimental COVID-19 vaccine*, REUTERS (June 27, 2020), https://www.reuters.com/article/us-health-coronavirus-brazil-vaccine-idUSKBN23Y0NB.

53. Roxanne Liu & Ludwig Burger, *AstraZeneca in first COVID-19 vaccine deal with Chinese company*, REUTERS (Aug. 6, 2020), https://www.reuters.com/article/us-health-coronavirus-astrazeneca-kangta-idUSKCN2520Y1.

54. *Russia's R-Pharm signs deal to make UK-developed COVID-19 vaccine*, REUTERS (July 17, 2020), https://www.reuters.com/article/us-health-coronavirus-cyber-russia-vacci-idUSKCN24I1XF.

Other initiatives set up in response to IP issues related to COVID-19 treatments and vaccines include the World Health Organization's (WHO) COVID-19 Technology Access Pool (C-TAP), launched to gather COVID-19 technology related patents and other kinds of intellectual properties, such as data, know-how and software.[55] C-TAP aims to accelerate the scale-up of the production of medical inventions to fight against COVID-19 and ensure they are available globally and equitably.[56] It is similar to Medicines Patent Pool (MPP), which was established to pool and distribute generic licenses for HIV/AIDS-related treatments.[57] To date, forty-three WHO member states and four intergovernmental bodies have indicated their support for C-TAP.[58] Moreover, a coalition of eighteen generic drugs manufacturers located in India, China, Bangladesh and South Africa have pledged to work together via the non-profit non-governmental organization Medicines Patent Pool (MPP) to accelerate access to millions of doses of new interventions for COVID-19 for low- and middle-income countries.[59]

The Access to Covid-19 Tools (ACT) Accelerator is yet another initiative that has raised $5.8 billion from nearly forty countries and over forty private and non-governmental sources for the deployment tests, treatments and vaccines.[60] COVAX, convened by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, is the vaccine pillar of the ACT and acts as a global initiative to pool procurement of safe and effective COVID-19 vaccines. The objective of this accelerator collaboration is to guarantee rapid and fair access to COVID-19 vaccines for every country in the world. As early as January 2021, COVAX had agreements in place to access 2 billion doses of promising COVID-19 vaccine candidates, implying that all 190 participating economies are eligible

55. This initiative was first proposed by Costa Rica in March 2020. *See generally COVID-19 response: Draft resolution*, WORLD HEALTH ASSEMBLY [WHA], A73/CONF./1 Rev. 1 (2020); *WHO COVID-19 technology access pool*, WORLD HEALTH ORGANIZATION (2021), https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool (last visited Feb. 7, 2021).

56. In March, UNITAID also made the decision to expand the scope of MPP for COVID-19 treatments and technologies. *See The Medicines Patent Pool and UNITAID respond to access efforts for COVID-19 treatments and technologies* (Mar. 27, 2020), https://unitaid.org/news-blog/with-special-investment-unitaid-bolsters-covid-19-response/#en.

57. *See generally* MEDICINES PATENT POOL, https://medicinespatentpool.org/ (last visited Jun. 16, 2021).

58. *Endorsements of the Solidarity Call to Action*, WORLD HEALTH ORGANIZATION, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action (last visited Feb. 7, 2021).

59. *Leading Generic Drug Makers Unite to Pledge Capacity for Developing and Delivering Affordable COVID-19 Interventions as Pandemic Intensifies*, MEDICINES PATENT POOL (Nov. 12, 2020), https://medicinespatentpool.org/news-publications-post/covid-19-generic-pledge-press-release/.

60. *The Access to COVID-19 Tools (ACT) Accelerator*, WORLD HEALTH ORGANIZATION (2021), https://www.who.int/initiatives/act-accelerator.

to access effective and approved vaccines in the first half of 2021.[61] At least 1.3 billion donor-funded doses will be made available to 92 low- and middle-income economies,[62] with 88 million vaccines to be distributed to 131 participants by June 2021.[63]

With the advance of reasonably priced patented treatments and vaccines, as well as the widespread and growing use of non-exclusive voluntary license agreements and several newly established global initiatives, it is unnecessary to waive IPRs to ensure access to affordable medicines for all populations around the world during the pandemic. It is also unwise as a waiver would stifle cooperative efforts and may potentially lead to less availability of needed treatments and vaccines.

D. Existing Mechanisms Can Effectively Safeguard Public Health

The international system was designed to deal with all circumstances – including global pandemics like COVID-19 – by providing both incentives to industry to spend large amounts of time and money on research and development and tools for developing countries to leverage in their fight against COVID-19.

The rights and protections granted by the TRIPS Agreement must be read in the context of the objectives and principles of the agreement as set out in Article 7 and 8: Article 7 of the TRIPS Agreement provides that the "protection and enforcement of intellectual property rights [shall be] in a manner conducive to social and economic welfare" while Article 8 states that WTO Members "may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement."[64] Read together, these two provisions should allow for a wide range of policy choices and health measures taken during a health crisis or emergency, such as the COVID-19 pandemic.[65]

Moreover, in the wake of the HIV/AIDS crisis, developing countries secured a significant victory when WTO Members agreed to adopt the Doha

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61. *COVAX Announces additional deals to access promising COVID-19 vaccine candidates; plans global rollout starting Q1 2021*, WORLD HEALTH ORGANIZATION (2020), https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021 (last visited Feb. 7, 2021).

62. *Id.*

63. *See* GAVI, https://www.gavi.org/covax-vaccine-roll-out (last visited June 20, 2021).

64. TRIPS Agreement, *supra* note 3.

65. The exact role Articles 7 and 8 play has, however, been the subject of dispute settlement. *See generally* Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R, ¶¶ 7.23-7.26 (adopted 7 Apr. 2000); Appellate Body Report, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS435 - 441/AB/R ¶¶ 6.625-6.626, 6.658 (adopted on 29 June 2020).

Declaration on TRIPS and Public Health as part of the Doha Ministerial Declaration in November 2001.[66] The Doha Declaration, *inter alia*, reiterated that every WTO Member "has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[67] However, Members could not agree on how to resolve the issue of how Members with insufficient or no manufacturing capability could make use of the compulsory licensing provision set out in Article 31 of the TRIPS Agreement.[68] This issue was resolved in August 2003, when Members adopted a waiver allowing such Members to import generic drugs under a compulsory license from another country even if the required drugs are protected by patent in that third country.[69] In such a case, licenses have to be issued in both the importing and exporting countries. In 2017, the waiver became the first (and to date only) amendment to any WTO Agreement in the form of Article 31bis of the TRIPS Agreement.[70]

Despite repeated assertions by leading NGOs that the TRIPS flexibilities such as the aforementioned compulsory license regime are too complicated to use or that threats from developed countries restrict their use, a study by leading public health advocates found that the flexibilities have "been used more frequently than commonly assumed and proven effective for procuring generic versions of essential medicines."[71] Specifically, the study found extensive use of TRIPS flexibilities between 2001 and 2016, with the four leading flexibilities being (i) compulsory licensing (including public non-commercial use licensing); (ii) least-developed countries (LDCs) making use of the pharmaceutical transition

66. WTO, Doha Declaration on the TRIPS agreement and public health of 20 November 2001, WTO Doc. WT/MIN(01)/DEC/2 (2001).

67. *Id.* ¶ 5(b).

68. *See generally* Bryan Mercurio, *TRIPs, Patents and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L.R. 211, 211-253 (2004).

69. *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30 August 2003*, WTO Doc. WT/L/540 (2003); *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30 August 2003*, Corrigendum, WTO Doc. WT/L/540/Corr.1 (2005). *See also TRIPS and public health: notifications*, https://www.wto.org/english/tratop_e/trips_e/public_health_e.html.

70. *See generally TRIPS and public health*, WTO, https://www.wto .org/english/tratop_e/trips_e/pharmpatent_e.htm.

71. ELLEN FM'T HOEN, ET AL., MEDICINE PROCUREMENT AND THE USE OF FLEXIBILITIES IN THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, 2001-2016, 96 BULLETIN OF THE WORLD HEALTH ORGANIZATION 185, 193 (2018).

measure;[72] (iii) parallel importation;[73] and (iv) the research exception.[74] In total, the study identified 176 occurrences of possible use of TRIPS flexibilities by 89 countries, of which around 60 percent engaged in the use of compulsory or government use licenses and over one-fifth involved the LDC pharmaceutical transition measure.[75]

The flexibilities described above have been proven effective in reducing the price of medicines by promoting generic competition and effectively ensuring equitable access to medical products for all.[76] This is especially the case with regards to compulsory licensing. For example, Malaysia's use of compulsory licenses in 2002 reduced the price of antiretrovirals to treat HIV/AIDS by up to 83 percent, while Thailand's granting of compulsory licenses on five medicines (including antiretrovirals and medicines to treat cancer and coronary disease) between 2006 and 2008 contributed to a reduction in prices of up to 98 percent.[77]

Thus, while the sponsors to the proposal may argue a waiver is urgently needed given that the TRIPS flexibilities are not being fully utilized, the reality is that several developing countries and LDCs have made good use of the flexibilities, and those that have not done so lack explicit provisions in their domestic legislation.[78]

Where available flexibilities have not been utilized, it is often the complicated and unworkable domestic framework which proves to be the stumbling block rather than the existing international system. This point is perhaps best illustrated by compulsory licensing. In Zimbabwe, for example, the institutional framework and capacity to effectively implement and take advantage of the TRIPS flexibility is overly-complicated. A compulsory license decision requires the approval of two government agencies with

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72. The WTO has provided an extended transition period for LDCs to comply with the patent provisions contained in the TRIPS Agreement. *See generally* Arno Hold & Bryan Mercurio, *A Second Extension of the Transition Period: Can the WTO Better Integrate LDCs into TRIPS*, *in* SCIENCE AND TECHNOLOGY IN INTERNATIONAL ECONOMIC LAW: BALANCING COMPETING INTERESTS (Routledge ed., 2014).

73. Parallel importation is the importation and resale of a product from another country (where the same product is legitimately on sale at a lower price) without the consent of the patent holder. *See generally* Clause E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185 (1999) (providing analysis in relation to the pharmaceutical industry).

74. The research exception refers to the use of a patented product or process for research or experimentation without the consent of the patent holder. *See generally* BRYAN MERCURIO, DRUGS, PATENTS AND POLICY: A CONTEXTUAL STUDY OF HONG KONG, 114-40 (Cambridge Univ. Press ed., 2018) (discussing the research exception).

75. HOEN ET AL., *supra* note 71, at 188.

76. *Id.*

77. *See* Martin Khor, *Patents, compulsory licenses, and access to medicines: some recent experiences,* WORLD HEALTH ORGANIZATION (2010), https://apps.who.int/iris/bitstream/handle/10665/205351/B4552.pdf#page=96.

78. *See* Musungu & Oh, *supra* note 41, at Annexes I and II.

"overlapping roles and responsibilities": the Ministry of Health for medicines procurement and the Patent Office for enquiry on the patent status of medicines.[79] The lack of a clear, workable framework is not only a problem for developing countries. In the wake of the COVID-19 pandemic in 2020, several developed countries including Australia, Germany, Canada and Hungary "amended their national laws to simplify and/or facilitate the use of compulsory licensing for public health purposes (without any specific instance of IP barriers necessitating the actual use of such a measure) demonstrating that even developed country Members found shortcomings in their national legislations to address pandemic-related challenges."[80]

Another flexibility available to Members is Article 73 of the TRIPS Agreement, which allows a Member to take "any action which it considers necessary for the protection of its essential security interests . . . taken in time of war or other emergency in international relations." Following precedent established in the *Russia – Transit* dispute,[81] the WTO panel in *Saudi Arabia–IPRs* found that Article 73 is not self-judging.[82] More specifically, the panel held that the mere invocation of Article 73 is justiciable and that it could proceed to assess:

> a. whether the existence of a "war or other emergency in international relations" has been established . . .;
> b. whether the relevant actions were "taken in time of" that war or other emergency in international relations;
> c. whether the invoking member has articulated its relevant "essential security interests" sufficiently to enable an assessment of whether there is any link between those actions and the protection of its essential security interests; and
> d. whether the relevant actions are so remote from, or unrelated to, the "emergency in international relations" as to make it implausible that the invoking member considers those actions to be necessary for the protection of its essential security interests arising out of the emergency.[83]

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79. *Id.* ¶¶ 33, 41.

80. WTO TRIPS Council, Response to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19 in Document IP/C/W/671, 42 WTO Doc. Communication from The Plurinational State Of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, The Bolivarian Republic of Venezuela and Zimbabwe, IP/C/W/673 (Jan. 15, 2021).

81. *See* Report of the Panel, *Russia – Measures Concerning Traffic in Transit*, WTO Doc. WT/DS512/R, ¶¶ 7.64-7.103 (Apr. 26, 2019).

82. Report of the Panel, *Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights*, WTO Doc. WT/DS567/R, ¶¶ 7.241-7.294 & 8.1(b) (June 16, 2020).

83. *Id.* ¶ 7.242.

While it is not certain whether the COVID-19 pandemic constitutes an emergency in international relations, whether measures taken by WTO members to override IPRs may be considered necessary to protect their essential security interests, or whether the presence of other provisions in the TRIPS Agreement addressing emergencies preclude Members from invoking Article 73, there is scholarly support that this provision could be used to justifiably override IPRs during the current pandemic.[84] The debate may indeed be academic as it is extremely unlikely that any Member would file a WTO complaint and initiate dispute settlement against a developing country Member invoking Article 73.

Instead of calling for an IP waiver, a better way to ensure equitable distribution of vaccines during the pandemic and a more lasting, sustainable, and pro-development solution would be for developing countries to revise their domestic laws to allow for better use of the flexibilities existing within the TRIPS Agreement.

E. A Waiver Assumes Institutional Capacity and Good Governance

The waiver proposal not only seeks to suspend patent rights, but also rights to "copyrights, industrial designs and undisclosed information."[85] This may cover information such as the combination and doses of raw materials, test data, medical formulas, and other genomic information. However, the operationalization of a trade secret waiver has not been well thought-out. Even a representative of South Africa admitted minimal experience in how government measures could apply to force disclosure of certain types of confidential and proprietary information. [86] More specifically, how could a government force the transfer of a "secret" without being aware of the presence or content of the "secret"? What would be the procedure and mechanism of enforcement? Who would be responsible for resolving matters when disputes arise?

Before making use of a waiver, countries must quickly amend their own legal frameworks. Considering that many of these countries have not put in place pathways to take advantage of existing flexibilities within the

84. Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, SOUTH CENTRE (Aug. 2020), https://www.southcentre.int/wp-content/uploads/2020/08/RP-116.pdf.

85. WTO Waiver Proposal, *supra* note 6.

86. Kerry Cullinan & Elaine Ruth Fletcher, *Philanthropy Alone Will Not Ensure Global Access To COVID-19 Vaccines – South Africa's Take*, HEALTH POLICY WATCH (Nov. 11, 2020), https://healthpolicy-watch.news/mustaqeem-de-gama-qa-philanthropy-will-not-fix-lack-of-vaccine-access/.

international IP system despite having more than seventeen years to do so,[87] it seems fanciful that these same countries would rush to implement the necessary framework needed to operationalize and enforce the waiver. While a waiver may allow Members to escape WTO obligations, it will not change the nature of domestic IP rules and regulations. Accordingly, the waiver will only be in force in jurisdictions that elect to amend their own legislation while IPRs pertaining to COVID-19 vaccines and treatments would remain in force elsewhere.[88]

Moreover, countries importing generic drugs should be concerned about issues of far greater importance than patent rights. Most notably, governments must ensure the safety and efficacy of imported drugs or manufactured locally and offered for sale within their territory. With so much uncertainty in the implementation procedures and mechanisms of enforcement, waiving rights for undisclosed information could open a floodgate to undesirable consequences such as abuse, fraud, and unsafe treatments and vaccines. To further their calls for a waiver, proponents point to a lack of legal and regulatory capacity in some developing countries with respect to issuance of compulsory licenses and for taking advantage of other TRIPS-flexibilities. However, they remain silent as to how these same countries would be able to safely and efficiently legislate for and operate under an open system.

F. IP Enforcement Is of Vital Importance to Maintaining Safety Standards

The protection of IP incentivizes innovators to create. It plays a crucial role in ensuring vaccine safety and helping to prevent the importation of fraudulent and dangerous goods. Unlike the pharmaceutical industry in general, the vaccine market is not a free and open market.[89]

Vaccines contain biological products made from living organisms, and the risk of failure in vaccine development and production is high. [90]

87. *See generally*, Musungu and Oh, *supra* note 41; Moses Nkomo, WIPO-WTO Colloquium Papers, Volume 1, The under-utilization of TRIPS flexibilities by developing countries: the case of Africa WIPO-WTO Colloquium Papers, Volume 1 (2010) 1 U.N. Doc. 135, https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2010/2010_complete_file_e.pdf (calling on African countries to "engage in a deliberate and systemic review of their legislation, so they can take full advantage of the public health safeguards and regulatory flexibilities permitted by the TRIPS Agreement").

88. It should be noted that in a handful of jurisdictions, the WTO Agreements have direct effect and therefore a waiver from TRIPS would automatically become a waiver of domestic obligations. *See* Hélène Ruiz Fabri, *Is There a Case – Legally and Politically – for Direct Effect of WTO Obligations?*, 25 EUR. J. INT. LAW 151, 155 (2014).

89. UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION, ET AL., VMPA STUDY: VACCINE MANUFACTURING AND PROCUREMENT IN AFRICA, 15-16 (2017), https://www.avmi-africa.org/wp-content/uploads/2017/09/VMPA-Study-e-book.pdf.

90. *Id.* at 16, 43, 53.

Moreover, the manufacturing process for vaccines is much more complex as it requires facilities and equipment with a high degree of specialization.[91] The complexity of vaccine products implies that more time and regulatory requirements are needed to make or "copy" the vaccine production process. Therefore, the innovator should be expected to make conscious and meticulous decisions as to when and to whom to issue licenses to in order to responsibly bring their technologies to the world and safeguard global health.

In addition, as the COVID-19 pandemic continues, there has been a noticeable increase in the circulation of fake medicines around the world. According to the International Criminal Police Organization (Interpol), organized crime groups have produced counterfeit drugs and medical products and sold them for lucrative profits in developing countries.[92] With the development of COVID-19 vaccines on the market, a rapid rise in the illegal sale of fake items is expected, according to the United Nations Office on Drugs and Crime (UNODC).[93] Counterfeits of the legitimate products provide false promises of protection and could lead to disastrous consequences, including worsened illness, death, and the retardation of herd immunity for the population at large.

Effective and proactive IP procurement is essential and useful in mitigating the risks of counterfeit and substandard medicines. IP enforcement measures play a significant role in preventing these fake and illicit medicines from circulating in the market. IP enforcement can take on an enhanced role of safeguarding the public during this critical period of time. Waiving all COVID-19 related IPRs raises the risk of unsafe or fake vaccines circulating in supply channels and being sold to unsuspecting governments, putting millions of human lives at risk and jeopardizing public trust in vaccines.[94]

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91. *Id.* at 5, 45, 47, 54.

92. *COVID-19-The Global Threat of Fake Medicines*, INTERNATIONAL CRIMINAL POLICE ORGANIZATION (INTERPOL) (May 2020), https://www.interpol.int/content/download/15305/file/20COM0356%20-%20IGGH_COVID-19%20threats%20to%20medicines_2020-05_EN.pdf?inLanguage=eng-GB.

93. *COVID-19-related Trafficking of Medical Products as a Threat to Public Health* (July 6, 2020), https://www.unodc.org/documents/data-and-analysis/covid/COVID-19_research_brief_trafficking_medical_products.pdf.

94. *See* Gareth Iacobucci, *Covid-19: How will a waiver on vaccine patents affect global supply?* 373 (2021) (quoting Nathalie Moll, director general of the European Federation of Pharmaceutical Industries and Associations who noted, "You simply cannot achieve this kind of capacity expansion by waiving patents and hoping that hitherto unknown factories around the world will turn their hand to the complex process of vaccine manufacture…A waiver risks diverting raw materials and supplies away from well established, effective supply chains to less efficient manufacturing sites where productivity and quality may be an issue. It opens the door to counterfeit vaccines entering the supply chain around the world.").

IV. CONCLUSION

The world was unprepared for COVID-19. This result was not unexpected, as preparation for a severe but unlikely event is not a priority for governments and budgets are inevitably tailored for addressing more pressing issues. Likewise, the private sector does not spend large amounts of R&D on treatments or vaccines which may never be utilized. In fact, the pharmaceutical industry has recently been "burned" by quickly reacting to and directing R&D towards emerging pandemics only for the pandemic to quickly pass, without the R&D efforts commercializing. This happened both with SARS in 2001 and Ebola from 2014-16. Unfortunately, COVID-19 did not pass quickly, and pharmaceutical companies have spent copious amounts of monetary and human resources in developing treatments and vaccines. Several governments have played their part in ensuring that R&D is conducted by subsidizing companies and pre-purchasing yet to be tested medicines and vaccines.[95] For various reasons, there is a shortage of companies researching and producing vaccines.[96] Under these circumstances, it is unlikely that demand can easily be met by waiving IPRs.

If the proposal for a waiver is approved, India and South Africa will have accomplished their long-standing goal of rolling back IPRs and changing the bargain struck during the Uruguay Round, but at a devastating cost. Access to COVID-19 treatments and vaccines would not significantly improve and companies would hesitate to devote R&D to combatting the next pandemic.

Vaccine manufacturing is a complicated process that involves complex raw materials and components along the value chain.[97] There are several challenges involved with vaccine manufacturing, from sourcing active pharmaceutical ingredients and machinery, to testing, packaging, and storage. It is estimated that a typical vaccine manufacturing plant needs to source 9,000 different raw materials from 300 suppliers across 30

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95. *See, e.g.,* Lev Facher, *NIH Partners with 16 Drug Companies in Hopes of Accelerating Covid-19 Treatments and Vaccines*, STAT NEWS (April 19, 2020), https://www.statnews.com/2020/04/17/nih-partners-with-16-drug-companies-in-hopes-of-accelerating-covid-19-treatments-and-vaccines/.

96. Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24(3) HEALTH AFFAIRS (2005); Roxanne Khamsi, *If a Coronavirus Vaccine Arrives, Can the World Make Enough?*, 580 NATURE 578-580 (Apr. 9, 2020); Julie Steenhuysen and Kate Kelland, *Vaccine Makers Face Biggest Medical Manufacturing Challenge in History*, REUTERS (June 25, 2020), https://www.reuters.com/article/us-health-coronavirus-vaccines-manufactu idUKKBN23W1ND.

97. *The Complex Journey of a Vaccine – The Manufacturing Chain, Regulatory Requirements and Vaccine Availability*, INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS & ASSOCIATIONS (IFPMA) (2016), https://www.ifpma.org/wp-content/uploads/2016/01/TheComplexJourneyofaVaccinePRINT-EN.pdf. *See also*, *Manufacturing vaccines is a complex journey*, SANOFI (Feb. 7, 2021), https://www.sanofi.com/en/your-health/vaccines/production.

countries.[98] Several trade and regulatory issues also affect the sourcing of imported raw materials and scale-up operations, namely export controls and border clearance. Even WHO Director-General Tedros Adhanom Ghebreyesus pointed not to supply-based issues for vaccine access but to barriers in increasing the speed and volume of production as a result of export bans and shortages of raw materials, among other things.[99]

Each stage of the vaccine manufacturing process requires significant investment and know-how, requiring deep expertise in the subject matter and years of experience. While it may be tempting to simply attribute all vaccine accessibility problems to IP protection, such a view diverts attention and resources away from real on-the-ground obstacles standing in the way of equal access to vaccines, such as manufacturing, approvals, distribution networks and risk control. In short, IPRs will not be the obstacle to access COVID-19 vaccines, related medicines and technologies; instead, the real access issues will be production, logistics, and distribution capacity.[100] At the same time, concerns that companies will withhold or limit supply in some jurisdictions seem unrealistic given that most jurisdictions have approved or will soon approve multiple vaccines for sale. Failing to offer a vaccine to sell in one market will simply mean the government in that market will purchase a vaccine from a different supplier.

There is little to no evidence that IPRs are preventing the manufacturing and distribution of vaccines and treatments for COVID-19. Until such evidence is established, it seems unnecessary and potentially harmful to waive all IPRs associated with COVID-19. Instead, efforts should be made to reinforce supply chains, upgrade infrastructure and ensure distribution can provide the level of access needed to combat the global pandemic.

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98. *See id.*

99. *WHO calls for urgent action to ramp up production of COVID-19 vaccines for all* (Mar. 5, 2021), https://news.un.org/en/story/2021/03/1086512.

100. Andrew Green, *At WTO, a battle for access to COVID-19 vaccine*, DEVEX (Dec. 15, 2020), https://www.devex.com/news/at-wto-a-battle-for-access-to-covid-19-vaccines-98787; Anne Moore, *COVID vaccines: why waiving patents won't fix global shortage – scientist explains*, THE CONVERSATION (May 4, 2021), https://theconversation.com/covid-vaccines-why-waiving-patents-wont-fix-global-shortage-scientist-explains-158643 ("Little (if any) evidence has been presented that suggests IP protection is blocking COVID-19 vaccine manufacture. Rather, technical and logistic issues are the biggest barriers currently standing in the way of increasing vaccine production and deployment. To boost vaccine availability right now, it would be better to address these.")

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