

Deferring Intellectual Property Rights in Pandemic Times

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This Article examines an unprecedented proposal that India and South Africa submitted to the World Trade Organization (WTO) in October 2020, which called for a waiver of more than thirty provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights to help combat COVID-19. It begins by recounting the proposal's strengths and weaknesses. The Article then identifies the challenges surrounding the negotiation and implementation of the proposed waiver. It shows why these two sets of challenges were neither separate nor sequential, but deeply entangled at the time of the international negotiations. To respond to these challenges and the negotiation impasse at the WTO, this Article advances an alternative proposal that calls for the deferral of select intellectual property rights in pandemic times. Aiming to "split the difference" between the proponents and opponents of the waiver, the proposal draws support from precedents involving temporal adjustments to intellectual property rights at both the international and domestic levels. The Article concludes by exploring the proposal's scope, strengths, and limitations.

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INTRODUCTION

Since the emergence of the SARS-CoV-2 virus in winter 2019, the COVID-19 pandemic has wreaked havoc around the world, costing millions of human lives¹ and tens of trillions of dollars in damages.² In the intellectual property arena, policymakers and commentators have advanced different proposals to combat the coronavirus. These proposals include efforts to maximize the limitations, safeguards, and flexibilities in the intellectual property system;³ dramatic adjustments to extant domestic and international intellectual property standards;⁴ and creative solutions that lie outside of, but complement, the intellectual property system.⁵

One pathbreaking proposal that has become highly controversial calls for a waiver of more than thirty provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights⁶ (“TRIPS Agreement”) of the World Trade Organization (WTO) to help combat COVID-19.⁷ In October 2020, India

1. See *WHO Coronavirus (COVID-19) Dashboard*, WORLD HEALTH ORG., <https://covid19.who.int> (last visited Jan. 28, 2023) (stating that COVID-19 has taken more than six million human lives).

2. See David M. Cutler & Lawrence H. Summers, *The COVID-19 Pandemic and the \$16 Trillion Virus*, 324 JAMA 1495, 1495 (2020) (estimating the total cumulative financial costs of the COVID-19 pandemic relating to lost output and health reduction at more than \$16 trillion); Australian Nat’l Univ., *Economic Pain: COVID-19 Pandemic Will Cost Global Economy \$21 Trillion*, SCITECHDAILY (July 5, 2020), <https://scitechdaily.com/economic-pain-covid-19-pandemic-will-cost-global-economy-21-trillion/> (providing a July 2020 estimate that the pandemic’s global economic toll could reach \$21 trillion); Shahar Ziv, *Coronavirus Pandemic Will Cost U.S. Economy \$8 Trillion*, FORBES (June 2, 2020), <https://www.forbes.com/sites/shaharziv/2020/06/02/coronavirus-pandemic-will-cost-us-economy-8-trillion/#5ce83d7c15e4> (estimating that “the pandemic would cost \$7.9 trillion in real economic output, or a staggering \$16 trillion over the next 10 years without adjusting for inflation”).

3. See, e.g., Letter from Carlos Correa, Exec. Dir., S. Centre, to Tedros Adhanom Ghebreyesus, Dir.-Gen. of the World Health Org., Francis Gurry, Dir.-Gen. of the World Intell. Prop. Org., & Roberto Azevêdo, Dir.-Gen. of the World Trade Org. (Apr. 4, 2020) [hereinafter Article 73 Letter] (“The use of [article 73] will be fully justified to procure medical products and devices or to use the technologies to manufacture them as necessary to address the current health emergency.”). See generally Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic* (S. Centre, Research Paper No. 116, 2020) (discussing the use of article 73 in the COVID-19 context).

4. See, e.g., Council for Trade-Related Aspects of Intellectual Property Rights, *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 (Oct. 2, 2020) [hereinafter *TRIPS Waiver Proposal*]; Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text*, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021) [hereinafter *Revised TRIPS Waiver Proposal*].

5. Among the more notable efforts developed outside the WTO and the World Intellectual Property Organization were the COVID-19 Technology Access Pool (C-TAP), the Open COVID Pledge, the Access to COVID-19 Tools Accelerator, and its COVID-19 Vaccines Global Access Initiative. See Peter K. Yu, *Modalities, Challenges, and Possibilities: An Introduction to the Pharmaceutical Innovation Symposium*, 7 TEX. A&M J. PROP. L. 1, 32–40 (2021) (discussing these efforts).

6. 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 [hereinafter *TRIPS Agreement*].

7. *TRIPS Waiver Proposal*, *supra* note 4; *Revised TRIPS Waiver Proposal*, *supra* note 4. For discussions of this proposal, see generally Peter K. Yu, *A Critical Appraisal of the COVID-19 TRIPS Waiver, in INTELLECTUAL PROPERTY RIGHTS IN THE POST PANDEMIC WORLD: AN INTEGRATED FRAMEWORK OF SUSTAINABILITY, INNOVATION AND GLOBAL JUSTICE* (Taina E. Pihljarinne et al. eds., forthcoming 2023); Bryan

and South Africa submitted this unprecedented proposal to the Council for Trade-Related Aspects of Intellectual Property Rights (“TRIPS Council”), urging the suspension of “Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement . . . [and related enforcement obligations] under Part III . . . in relation to [the] prevention, containment or treatment of COVID-19.”⁸

Policymakers and commentators were deeply divided on this proposal. For instance, James Bacchus, a former U.S. Congressman and a past Chair of the WTO Appellate Body, called the proposal “unnecessary.”⁹ The *Wall Street Journal* also released a strongly worded editorial entitled *Biden’s Vaccine Patent Theft*, asking whether future innovators would still invest in research and development for therapeutics if intellectual property rights were waived.¹⁰ By contrast, the waiver received endorsement from the World Health Organization (WHO),¹¹ the Committee on Economic, Social and Cultural Rights,¹² the South

Mercurio, *WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review*, 62 VA. J. INT’L L. ONLINE 9 (2021); Andrew D. Mitchell, Antony Taubman & Theodore Samlidis, *The Legal Character and Practical Implementation of a TRIPS Waiver for COVID-19 Vaccines*, 33 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 100 (2022); Franziska Sucker & Kholofelo Kugler, *The Proposed COVID-19 TRIPS Waiver: Not a Silver Bullet but Part of a Solution for Africa’s COVID-19 Health*, 19 MANCHESTER J. INT’L ECON. L. 37 (2022); Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang & Graham Dufield, *Addressing Vaccine Inequity During the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond*, 81 CAMBRIDGE L.J. 384 (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. Centre, Research Paper No. 135, 2021); Henning Grosse Ruse-Khan & Federica Paddeu, *A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investment Agreements* (S. Centre, Research Paper No. 144, 2022); Reto M. Hilty, Pedro Henrique D. Batista, Suelen Carls, Daria Kim, Matthias Lamping & Peter R. Slowinski, *Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021* (Max Planck Inst. for Innovation & Competition, Research Paper No. 21-13, 2021); Srividhya Ragavan, *Waive IP Rights & Save Lives* (S. Centre, Southviews No. 231, 2021); Yousuf Vawda, *The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonizing Intellectual Property* (S. Centre, Policy Brief No. 99, 2021); Sven J.R. Bostyn, *Why a COVID IP Waiver Is Not a Good Strategy 6* (May 10, 2021) (unpublished manuscript), <https://ssrn.com/abstract=3843327>.

8. *TRIPS Waiver Proposal*, *supra* note 4, annex, ¶ 1.

9. James Bacchus, *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines*, CATO INST. (Dec. 16, 2020), <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>.

10. Editorial, *Biden’s Vaccine Patent Theft*, WALL ST. J., <https://www.wsj.com/articles/bidens-vaccine-patent-theft-11620255362> (May 5, 2021, 7:46 PM); *see also* Adam Mossoff, *The COVID-19 Intellectual Property Waiver: Threats to U.S. Innovation, Economic Growth, and National Security* (Heritage Found., Legal Memorandum No. 290, 2021), <https://www.heritage.org/sites/default/files/2021-09/LM290.pdf> (“The IP [intellectual property] waiver raises broad concerns about innovation policy, economic policy, and even national security. The U.S. should oppose the IP waiver.”).

11. *See Director-General’s Opening Remarks for Panel “Is Africa Ready to Finance Its Own Vaccine?”*, WORLD HEALTH ORG. (Mar. 23, 2021), <https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-for-panel-is-africa-ready-to-finance-its-own-vaccine> (urging African ministers to “support the proposal by South Africa and India for intellectual property waivers at the World Trade Organization”).

12. *See* Comm. on Econ., Soc. & Cultural Rts., *Statement on Universal Affordable Vaccination for COVID-19, International Cooperation and Intellectual Property*, ¶ 13, U.N. Doc. E/C.12/2021/1 (Mar. 12, 2021) (“[T]he Committee strongly recommends that States support the proposals of this temporary waiver, including by using their voting rights within WTO.”).

Centre (an intergovernmental think tank for developing countries),¹³ hundreds of civil society organizations, and academic and policy experts around the world.¹⁴

Following the arrival of the Biden Administration, the United States changed its negotiating position on May 7, 2021, shifting from outright opposition to the waiver to limited support for text-based negotiations in relation to vaccines.¹⁵ Two weeks later, India and South Africa, along with over sixty cosponsors, took advantage of the United States' changed negotiating position and submitted a revised proposal.¹⁶ Drawing on feedback received from WTO members and other stakeholders, this revised proposal attracted support from over 100 countries.¹⁷

Although the WTO membership agreed in June 2021 to conduct text-based negotiations based on this new proposal,¹⁸ those negotiations were stalled by contentious issues such as the scope of the waiver (in relation to both the products and intellectual property rights covered), the waiver's duration, implementation issues, and the protection of undisclosed information (including regulatory data).¹⁹ By December, it was unclear if the waiver proposal would ever be adopted, causing the European Union, India, South Africa, and the United States, with the support of the WTO Secretariat, to launch their own consultations to find a compromise.²⁰ These consultations, which this Article will refer to as the "Quad consultations," eventually produced an outcome

13. See *Proposal by India and South Africa to Waive Certain Provisions of the WTO TRIPS Agreement to Support the Global COVID-19 Pandemic Response*, S. CENTRE (Oct. 6, 2020), <https://www.southcentre.int/wp-content/uploads/2020/11/Note-on-India-SA-proposal-waiver-TRIPS.pdf> ("The South Centre strongly supports the [waiver] proposal and strongly urges other G77 countries that are WTO members to extend their support and co-sponsorship in the upcoming TRIPS Council meeting on 15–16 October 2020 to forward a request to the General Council for the adoption of the proposed decision.").

14. See, e.g., *Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal* (London Sch. of Econ. & Pol. Sci., Policy Briefing No. 46, 2021) [hereinafter *Academic Open Letter*]; *Statement on Copyright and Proposal of a Waiver from Certain Provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the Prevention, Containment and Treatment of COVID-19 (IP/C/W/669)*, INFOJUSTICE (Mar. 22, 2021), infojustice.org/wp-content/uploads/2021/03/Civil-Society-Statement-on-Copyright-and-Proposed-TRIPS-Waiver-FINAL.pdf.

15. See Press Release, Off. of the U.S. Trade Representative, Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> [hereinafter USTR Statement] ("The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines. We will actively participate in text-based negotiations at the World Trade Organization . . . needed to make that happen.").

16. *Revised TRIPS Waiver Proposal*, *supra* note 4.

17. See Correa et al., *supra* note 7, at 1 (noting "the support of more than 100 countries as well as over 300 civil society organizations" and the cosponsorship of "64 countries from Asia, Africa and Latin America, including the African Group and the least developed countries (LDC) group").

18. D. Ravi Kanth, *WTO Members Agree to Text-Based Negotiations on Revised TRIPS Waiver*, THIRD WORLD NETWORK (June 11, 2021), <https://www.twn.my/title2/wto.info/2021/ti210606.htm>.

19. Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting: Held in the Centre William Rappard on 20 July 2021*, ¶ 4, WTO Doc. IP/C/M/101 (July 23, 2021).

20. D. Ravi Kanth, *US, EU, India, South Africa Hold Talks on TRIPS Waiver Compromise*, THIRD WORLD NETWORK (Dec. 14, 2021), <https://www.twn.my/title2/wto.info/2021/ti211210.htm>.

document that provided the basis for negotiating the Ministerial Decision on the TRIPS Agreement (“Ministerial Decision”) at the Twelfth WTO Ministerial Conference in Geneva in June 2022 (“MC12”).²¹ Instead of covering four types of intellectual property rights and a wide array of health products and technologies, the Ministerial Decision focuses primarily on the patents in COVID-19 vaccines.

Although the WTO membership ultimately did not adopt the proposed waiver to combat the pandemic, the debate surrounding this unprecedented proposal remains important for four reasons. First, this debate captured an effort on the part of developing countries, along with allies in the developed world, to push for temporary but very significant changes to the TRIPS-based international intellectual property norms to address a global crisis. Should we have the unfortunate need to revisit this debate in response to a future pandemic or another major global crisis, the debate on the COVID-19 TRIPS waiver will be highly relevant. Indeed, it is not farfetched to assume that similar proposals will resurface in the future. Many medical and public health experts have already predicted that another global pandemic will happen in the next decade or two.²²

Second, the arguments advanced by those supporting and opposing the waiver illustrate the complexities involved in policy debates at the intersection of intellectual property and public health. Considering that all delegations at the TRIPS Council shared the common objective of quickly ending the global pandemic,²³ their struggle to reach an international consensus on the waiver is indeed revealing.

21. World Trade Organization, Ministerial Decision on the TRIPS Agreement, WTO Doc. WT/MIN(22)/30 (June 22, 2022) [hereinafter Ministerial Decision]. For discussions of this Ministerial Decision, see generally Peter K. Yu, *The COVID-19 TRIPS Waiver and the WTO Ministerial Decision*, in IPR IN TIMES OF CRISIS: LESSONS LEARNED FROM THE COVID-19 PANDEMIC (Jens Schovsbo ed., forthcoming 2023); Bryan Mercurio & Pratyush Nath Upreti, *From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments*, 21 WORLD TRADE REV. 633 (2022); Carlos M. Correa & Nirmalya Syam, *The WTO TRIPS Decision on COVID-19 Vaccines: What Is Needed to Implement It?* 14–15 (S. Centre, Research Paper No. 169, 2022); Reto Hilty, Daria Kim, Juan I. Correa, Pedro Henrique D. Batista & Matthias Lamping, *Position Statement of 5 July 2022 on the Decision of the WTO Ministerial Conference on the TRIPS Agreement Adopted on 17 June 2022* (Max Planck Inst. for Innovation & Competition, Research Paper No. 22-14, 2022).

22. See, e.g., STEFAN ELBE, PANDEMICS, PILLS, AND POLITICS: GOVERNING GLOBAL HEALTH SECURITY 34 (2018) (“The episodic recurrence of . . . influenza pandemics leads many experts to believe that new flu pandemics occur roughly once every couple of decades.”); SONIA SHAH, PANDEMIC: TRACKING CONTAGIONS, FROM CHOLERA TO EBOLA AND BEYOND 8 (2016) (noting a survey by epidemiologist Larry Brilliant that “90 percent of epidemiologists said that a pandemic that will sicken 1 billion, kill up to 165 million, and trigger a global recession that could cost up to \$3 trillion would occur sometime in the next two generations”).

23. See G.A. Res. 74/270, Global Solidarity to Fight the Coronavirus Disease 2019 (COVID-19), U.N. Doc. A/RES/74/270, ¶ 1 (Apr. 2, 2020) (reaffirming “its commitment to international cooperation and multilateralism and its strong support for the central role of the United Nations system in the global response to the [COVID-19] pandemic”); G.A. Res. 74/274, International Cooperation to Ensure Global Access to Medicines, Vaccines and Medical Equipment to Face COVID-19, U.N. Doc. A/RES/74/274, recital 8 (Apr. 20, 2020) (recognizing that “the COVID-19 global pandemic requires a global response based on unity, solidarity and multilateral cooperation”).

Third, because the recently adopted Ministerial Decision has gone only slightly beyond the provisions laid down in articles 31 and 31*bis* of the TRIPS Agreement, anyone searching for new ideas to reform international intellectual property law and policy will likely find the waiver debate highly instructive. A deeper understanding of this debate will also inform the difficult choices involved in developing the newly adopted Ministerial Decision.

Finally, the difficulty in resolving the disagreements between the waiver's supporters and opponents suggests the need to find compromises, including the creation of new mechanisms. Recognizing that it will not be easier to make significant adjustments to the international intellectual property system the next time a global crisis emerges, it is high time we start exploring how best to address this type of difficult situation. In doing so, we will greatly improve our emergency preparedness in the intellectual property arena.

To provide the context needed to better understand the proposal for the COVID-19 TRIPS waiver, Part I recounts the proposal's strengths and weaknesses. This Part draws on the negotiating records at the TRIPS Council²⁴ and commentaries from both academic and policy circles.²⁵

Part II turns to the challenges surrounding the negotiation and implementation of the proposed waiver. Drawing from the literature on international treaty negotiations, including those in the intellectual property area, this Part shows why the international negotiation and domestic implementation challenges were neither separate nor sequential. Rather, these two sets of challenges were deeply entangled at the time of the international negotiations. Appreciating this entanglement provides insights into not only why the WTO membership ultimately adopted the Ministerial Decision, but also the low likelihood of quickly implementing the waiver worldwide to combat COVID-19 despite the support of more than 100 countries.

To respond to these challenges and the negotiation impasse at the WTO, Part III offers an alternative proposal that calls for the deferral of select intellectual property rights in pandemic times. This Part first outlines the proposal, detailing its suspension, extension, and dispute settlement mechanisms. This Part further discusses precedents involving past temporal adjustments to intellectual property rights at both the international and domestic levels. It concludes by exploring the strengths and limitations of the deferral proposal.

Although this alternative proposal was developed with COVID-19 in mind, this Article takes the position that such a proposal will also be needed to combat future pandemics. Instead of having an ad hoc waiver every time a pandemic breaks out, society will be better off learning from the present pandemic and

24. See, e.g., Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting: Held in the Centre William Rappard on 15–16 October and 10 December 2020*, WTO Doc. IP/C/M/96/Add.1 (Feb. 16, 2021).

25. See sources cited *supra* note 7.

instituting a new mechanism that will help address similar public health exigencies in the future. Such a proposal could also provide a meaningful response to other major global crises.

I. THE WAIVER PROPOSAL

Since India and South Africa submitted their waiver proposal to the TRIPS Council in October 2020, the proposal has sparked a heated debate over its necessity, expediency, effectiveness, and likelihood of successful implementation.²⁶ To help fully understand this proposal,²⁷ Subpart A briefly describes the waiver's original language, revised texts, and key objectives. Subparts B and C then identify the arguments for and against the waiver, respectively. Like many policy choices during the global pandemic, the waiver proposal has both benefits and drawbacks.²⁸

A. PROPOSAL

Proposed in October 2020, the waiver was time-limited and purpose-specific, with its application narrowly tailored to the “prevention, containment or treatment of COVID-19.”²⁹ Although the original text did not lay down the different products and technologies covered, recital 6 underscored the need to promote the “unimpeded and timely access to affordable medical products including diagnostic kits, vaccines, medicines, personal protective equipment and ventilators for a rapid and effective response to the COVID-19 pandemic.”³⁰ At the time of the proposal, developing countries were not only concerned about the lack of affordable access to the needed diagnostics, vaccines, treatments, medical devices, and other health products and technologies, but also feared that they would have difficulty competing with developed countries to acquire these products and technologies. Their fears were not unfounded, considering their past negative experiences with vaccine accessibility during the H5N1 avian influenza outbreak and the H1N1 pandemic, as well as the well-documented concerns about vaccine nationalism during the COVID-19 pandemic.³¹ Adding

26. See *infra* Part II.A.

27. The discussion of the waiver proposal in this Article was adapted and expanded from Yu, *supra* note 7.

28. See Peter K. Yu, *Intellectual Property Paradoxes in Pandemic Times*, 71 GRUR INT'L 293, 294 (2022) (noting the difficult policy choices during the pandemic that came with both major benefits and significant drawbacks).

29. *TRIPS Waiver Proposal*, *supra* note 4, annex, ¶ 1.

30. *Id.* annex, recital 6.

31. See David P. Fidler, *Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1*, PLOS MED., May 2010, at 1 (“Developed countries placed large advance orders for 2009-H1N1 vaccine and bought virtually all the vaccine companies could manufacture.”); Kai Kupferschmidt, “Vaccine Nationalism” Threatens Global Plan to Distribute COVID-19 Shots Fairly, SCI. INSIDER (July 28, 2020), <https://www.sciencemag.org/news/2020/07/vaccine-nationalism-threatens-global-plan-distribute-covid-19-shots-fairly> (“The United States and Europe are placing advance orders for hundreds of millions of doses of successful vaccines, potentially leaving little for poorer parts of the world.”); see also PEOPLE’S HEALTH MOVEMENT, MEDACT & GLOBAL

insult to injury, reports emerged shortly after the submission of the original waiver proposal that developing countries had been charged higher prices than developed countries for COVID-19 vaccines, due perhaps to the former's inability to purchase large quantities.³² Taken together, all of these inequities explain why developing countries actively demanded significant adjustments to the TRIPS-based intellectual property system to combat the global pandemic.

Out of the eight forms of intellectual property rights explicitly listed in the TRIPS Agreement,³³ the waiver covered only copyrights, industrial designs, patents, and the protection of undisclosed information (such as test or other data for pharmaceutical products).³⁴ As India explained at the TRIPS Council, these four types of intellectual property rights were included because they were implicated in “health products and technologies like test kits, masks, medicines, vaccines, components of ventilators like valves, control mechanisms and the algorithms and CAD files used in their manufacturing.”³⁵ If adopted, the waiver would further suspend the enforcement of these rights as required by part III of the TRIPS Agreement.³⁶ The proposed instrument, however, would not directly affect trademarks, geographical indications, plant variety protection, layout designs of integrated circuits, and the neighboring rights of performers, phonogram producers, and broadcasting organizations.³⁷

To provide the greatest flexibility, the original proposal left the waiver's duration open-ended, opting for the language “for [X] years.”³⁸ As paragraph 13 of the proposal stated, “[t]he waiver should continue until widespread

EQUITY GAUGE ALLIANCE, GLOBAL HEALTH WATCH 2: AN ALTERNATIVE WORLD HEALTH REPORT 233 (2008) (“As drug companies can produce only a limited amount of vaccines in a given year, many developed countries have made advance purchase orders for vaccines, limiting even further the prospects of countries like Indonesia benefiting from vaccine development.” (internal citation omitted)); Peter K. Yu, *Virotech Patents, Viropiracy, and Viral Sovereignty*, 45 ARIZ. ST. L.J. 1563, 1608 (2013) (“Because both developed and less developed countries have an equally strong demand for vaccines, those vaccines are likely to be priced according to the economic ability of developed countries, not their less developed counterparts.”). See generally ANA SANTOS RUTSCHMAN, VACCINES AS TECHNOLOGY: INNOVATION, BARRIERS, AND THE PUBLIC HEALTH 99–105 (2022) (discussing vaccine nationalism in the H1N1 and COVID-19 contexts).

32. See Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting: Held in the Centre William Rappard on 10–11 March 2021*, ¶ 284, WTO Doc. IP/C/M/98/Add.1 (July 30, 2021) (“It is well reported that South Africa has paid USD 5.25 a dose for a version of the vaccine manufactured in India while it seems that the European Commission paying only USD 3.50 per shot. Uganda seems to have paid USD 8.50 a dose.”); Behrang Kianzad & Jakob Wested, “No-One Is Safe Until Everyone Is Safe”—Patent Waiver, Compulsory Licensing and COVID-19, 5 EUR. PHARM. L. REV. 71, 73 (2021) (“[H]ealth officials in countries such as South Africa and Uganda could confirm that they are . . . paying more per vaccine dose than European counterparts.”).

33. See TRIPS Agreement, *supra* note 6, arts. 9–39 (stipulating standards in the area of copyrights and related rights, trademarks, geographical indications, industrial designs, patents, plant variety protection, layout designs of integrated circuits, and the protection for undisclosed information).

34. *TRIPS Waiver Proposal*, *supra* note 4, annex, ¶ 1.

35. Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 24, ¶ 871.

36. *TRIPS Waiver Proposal*, *supra* note 4, annex, ¶ 1; see also TRIPS Agreement, *supra* note 6, arts. 41–61 (stipulating standards for intellectual property enforcement).

37. *TRIPS Waiver Proposal*, *supra* note 4, annex, ¶¶ 1–2.

38. *Id.* annex, ¶ 1.

vaccination is in place globally, and the majority of the world's population has developed immunity.”³⁹ In reading this language, it is important to keep in mind that “there [wa]s no vaccine or medicine to effectively prevent or treat COVID-19” when this proposal was submitted in October 2020.⁴⁰ COVID-19 vaccines did not become available until a few months later.⁴¹

Paragraph 4 of the original waiver text included the usual language in article IX.4 of the Marrakesh Agreement Establishing the World Trade Organization (“WTO Agreement”),⁴² which states that “[a]ny waiver granted for a period of more than one year shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates.”⁴³ Paragraph 5 further created a moratorium on WTO challenges to measures implementing the waiver.⁴⁴ The provision stated specifically that “Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO’s Dispute Settlement Mechanism.”⁴⁵

In May 2021, India and South Africa, along with over sixty cosponsors, took advantage of the United States’ changed negotiating position and submitted a revised proposal.⁴⁶ Drawing on feedback received from WTO members and other stakeholders,⁴⁷ the revised text updated the original proposal in three ways. First, it provided more specificity to the range of products and technologies covered—namely, “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture.”⁴⁸ Second, although the original proposal included an open-ended duration that the General Council was to determine, the revised proposal stated that the waiver “shall be in force for at least 3 years.”⁴⁹ After this initial period, the General Council would review the circumstances to determine whether the waiver should continue or terminate—an arrangement consistent with article IX.4 of the WTO Agreement.⁵⁰ Third, the revised proposal updated the language in the waiver’s preamble, noting “the continuous mutations and emergence of new variants of

39. *Id.* ¶ 13.

40. *Id.* ¶ 4.

41. See *A Timeline of COVID-19 Developments in 2020*, AM. J. MANAGED CARE, <https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020> (Jan. 1, 2021) (providing a timeline that includes COVID-19 vaccine developments).

42. *TRIPS Waiver Proposal*, *supra* note 4, annex, ¶ 4.

43. Marrakesh Agreement Establishing the World Trade Organization art. IX.4, Apr. 15, 1994, 1867 U.N.T.S. 154 [hereinafter *WTO Agreement*].

44. *TRIPS Waiver Proposal*, *supra* note 4, annex, ¶ 5.

45. *Id.*

46. *Revised TRIPS Waiver Proposal*, *supra* note 4.

47. See USTR Statement, *supra* note 15 (announcing the change of the United States’ negotiation position).

48. *Revised TRIPS Waiver Proposal*, *supra* note 4, annex, ¶ 1.

49. *Id.* annex, ¶ 2.

50. *WTO Agreement*, *supra* note 43, art. IX.4.

SARS-COV-2,” “the significant uncertainties and complexities of controlling [the virus],” “the urgent need to diversify and scale-up production to meet global needs and promote economic recovery,” and “the importance of preserving incentives for research and innovation . . . [and of balancing these incentives] with the public health interest.”⁵¹ Although the preambular language would not be operative, it highlighted the many challenges posed by the global pandemic and would provide contextual guidance to the waiver’s future interpretation.

B. SUPPORT

To facilitate the adoption of the proposed COVID-19 TRIPS waiver, supporters advanced several arguments. First, the TRIPS Agreement does not provide adequate accommodation to address the global pandemic.⁵² Although article 31 allows for the issuance of compulsory licenses⁵³ and article 31*bis* extends those licenses to countries with insufficient or no capacity to manufacture generic drugs,⁵⁴ any license issued under the TRIPS Agreement requires a determination on a country-by-country, product-by-product, and case-by-case basis.⁵⁵ Even if the arrangements are less complex than the compulsory licensing regimes found in some WTO members,⁵⁶ developing countries face

51. *Revised TRIPS Waiver Proposal*, *supra* note 4, annex, recitals 6–7, 9.

52. See Council for Trade-Related Aspects of Intellectual Property Rights, *Response to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19 in Document 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*, ¶¶ 28–53, WTO Doc. IP/C/W/673 (Jan. 15, 2021) (discussing the challenge of relying on articles 31 and 31*bis* to contain COVID-19 globally and the pressure tactics deployed by trading partners and patent holding corporations); Thambisetty et al., *supra* note 7, at 407–09 (explaining why compulsory licenses do not provide a good alternative to the proposed waiver); Carlos M. Correa, *Expanding the Production of COVID-19 Vaccines to Reach Developing Countries Lift the Barriers to Fight the Pandemic in the Global South* 3 (S. Centre, Policy Brief No. 92, 2021) (discussing the difficulty in relying on the use of compulsory licenses to combat COVID-19); Médecins Sans Frontières, *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies* 6–9 (2021), <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies> (discussing the limitations of compulsory licenses during a pandemic). Although the discussion of the TRIPS Agreement’s lack of accommodation to address the global pandemic tends to focus on articles 31 and 31*bis*, it is worth keeping in mind that the Agreement contains other flexibilities, including notably the underutilized article 73. See *supra* note 3 and *infra* text accompanying notes 78–79.

53. TRIPS Agreement, *supra* note 6, art. 31.

54. *Id.* art. 31*bis*.

55. See Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 24, ¶ 1416 (“Article 31 compulsory licences are issued on a case-by-case, country-by-country basis according to national patent law procedures and practices.”).

56. See Hilty et al., *supra* note 7, at 4 (“[T]he efficiency of the compulsory licensing mechanism ultimately depends on how it is implemented under the national laws.”). Immediately coming to mind are the criticisms of Canada’s Access to Medicine Regime (“CAMR”) in relation to the challenges confronting generic manufacturer Apotex in the late 2000s when it undertook efforts to export the HIV/AIDS drug TriAvis to Rwanda under a compulsory license. See Richard Elliott, *Managing the Market for Medicines Access: Realizing the Right to Health by Facilitating Compulsory Licensing of Pharmaceuticals—a Case Study of Legislation and the Need for Reform*, in ACCESS TO MEDICINES AS A HUMAN RIGHT: IMPLICATIONS FOR PHARMACEUTICAL INDUSTRY RESPONSIBILITY 151, 157 (Lisa Forman & Jillian Clare Kohler eds., 2012) (“As enacted, CAMR embodies the basic mechanism for obtaining a compulsory licence authorizing export of generics that was agreed into the WTO Decision in 2003, but in unnecessarily restricted form.”); Yu, *supra* note 31, at 1585–86 (discussing the

considerable challenges when they make plans to issue these licenses. To complicate matters, many products and technologies involve the exploitation of multiple forms of intellectual property rights. Except in the patent area and for specific copyright-related situations covered by the appendix to the Berne Convention for the Protection of Literary and Artistic Works,⁵⁷ the TRIPS Agreement does not provide for compulsory licensing. It is therefore no surprise that during the COVID-19 pandemic policymakers and commentators repeatedly called for greater adjustments to the TRIPS Agreement to ensure that product and technology developers had the needed “freedom to operate without the risk of litigation or the fear that exported [products and] technologies could be seized in transit and impounded for alleged infringement.”⁵⁸

Second, and relatedly, the products and technologies needed to combat COVID-19 involve intellectual property rights belonging to multiple rights holders, of which the developers of these products and technologies may not be aware without undertaking prior art searches or other due diligence.⁵⁹ The development of COVID-19 vaccines, for example, implicates not only the patents in relevant vaccines, but also a wide variety of intellectual property rights in the underlying platform technologies—whether mRNA, adenovirus, or more conventional ones.⁶⁰ The challenges in clearing these rights have precipitated what Michael Heller and Rebecca Eisenberg have referred to as the “tragedy of the anticommons,”⁶¹ in which “multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use.”⁶² To

CAMR). During the COVID-19 pandemic, Bolivia expressed interest in purchasing Ad26.COV2.S vaccines from Biolyse Pharma in Canada. See Council for Trade-Related Aspects of Intellectual Property Rights, *Notification Under the Amended TRIPS Agreement*, WTO Doc. IP/N/8/BOL/1 (Feb. 19, 2021); Muhammad Zaheer Abbas, *Canada’s Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case 10* (S. Centre, Research Paper No. 136, 2021). Unfortunately, Bolivia faced considerable challenges similar to those confronting Apotex, and no shipment has yet been made at the time of writing. In May 2021, Antigua and Barbuda also notified the WTO about its intention to issue an article 31bis compulsory license as an importing member. Council for Trade-Related Aspects of Intellectual Property Rights, *Notification Under the Amended TRIPS Agreement*, WTO Doc. IP/N/8/ATG/1 (May 17, 2021).

57. Berne Convention for the Protection of Literary and Artistic Works app., Sept. 9, 1886, 1161 U.N.T.S. 3 (revised at Paris July 24, 1971) [hereinafter Berne Convention]; see also TRIPS Agreement, *supra* note 6, art. 9.1 (“Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto.”).

58. Thambisetty et al., *supra* note 7, at 399.

59. See Correa, *supra* note 52, at 3 (“[I]t is often difficult to identify all the patents or other intellectual property rights covering a product or process, and patent applications are not published for 18 months after their filing.”); Vawda, *supra* note 7, at 3 (noting that “it is usually difficult to track the multiple patents on a single product that may not be publicly known, increasing the risk of infringement claims”).

60. See Bostyn, *supra* note 7, at 6 (“[T]here are . . . hundreds of patents on the underlying platform technology, such as the mRNA technology and the adenovirus technology These platform technologies, which have been developed and patented years before the present COVID-19 pandemic, will . . . need to be navigated to produce the present vaccines” (citation omitted)).

61. For discussions of the tragedy of the anticommons in the biomedical research area, see generally MICHAEL HELLER, *THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES* 49–78 (2010); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

62. Heller & Eisenberg, *supra* note 61, at 698.

a large extent, this thicket of intellectual property rights has made it difficult for governments, businesses, and nongovernmental organizations to quickly offer products and technologies to combat COVID-19. The issue of patent thickets is nothing new in the public health arena. During the Severe Acute Respiratory Syndrome (SARS) epidemic, researchers at Erasmus University in the Netherlands registered a similar concern:

[Without the creation of the proposed SARS Patent Pool, i]t is likely that patent rights incorporating the SARS genomic sequence will be fragmented across several groups. Sorting out these rights will be complex and may require intervention of the law court. . . . [For firms considering whether to develop a SARS vaccine], uncertainty over patent rights makes this decision even more difficult, because it is neither possible to determine the future cost of licensing the patent rights, nor whether all necessary patents will be available for licensing. . . . The incentive for vaccine manufacturers is therefore to delay the decision to invest.⁶³

Third, the mandatory nature and high costs of WTO dispute settlement⁶⁴ have made many governments and their officials compliance-oriented.⁶⁵ Fearing

63. James H.M. Simon, Eric Claassen, Carmen E. Correa & Albert D.M.E. Osterhaus, *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling*, 83 BULL. WORLD HEALTH ORG. 707, 708 (2005).

64. As Håkan Nordström and Gregory Shaffer observe:

Under . . . back-of-the-envelope calculations, a case of average complexity would cost \$100,000 if it ends after the initial consultations because the parties have settled or the complaint is otherwise withdrawn. If the case advanced to the panel stage, it would cost another \$320,000. And if the panel decision were appealed, the bill would rise by another \$135,000. The total cost would then top one-half of \$1 million.

Håkan Nordström & Gregory Shaffer, *Access to Justice in the WTO: A Case for a Small-Claims Procedure?*, in DEVELOPING COUNTRIES IN THE WTO LEGAL SYSTEM 191, 205–06 (Chantal Thomas & Joel P. Trachtman eds., 2009); see also Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 884, 899 (Keith E. Maskus & Jerome H. Reichman eds., 2005) [hereinafter INTERNATIONAL PUBLIC GOODS] (noting that “an average WTO claim costs in the range of U.S.\$300,000–400,000 in attorneys’ fees (although they possibly can be much more)”; Peter K. Yu, *The Comparative Economics of International Intellectual Property Agreements*, in COMPARATIVE LAW AND ECONOMICS 282, 302 (Theodore Eisenberg & Giovanni B. Ramello eds., 2016) (explaining why “it may not be worthwhile for a small or poor country with limited exports to file a WTO complaint even when their economic interests were at stake”); Anna Joubin-Bret, *Establishing an International Advisory Centre on Investment Disputes?* 8 (E15 Task Force on Inv. Pol’y, Think Piece, 2015), <https://e15initiative.org/wp-content/uploads/2015/09/E15-Investment-Joubin-Bret-Final.pdf> (“Minimum free-market rates for litigating a relatively simple WTO dispute through to the basic panel report stage may range from US\$250,000 to US\$750,000.”).

65. See CAROLYN DEERE, THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES 242 (2009) (“TRIPS implementation in the OAPI [African Intellectual Property Organization] countries was shaped by a pro-IP and ‘compliance-plus’-oriented political environment.”); Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in INTERNATIONAL PUBLIC GOODS, *supra* note 64, at 3, 18 (expressing concern that many developing countries are “compliance oriented”); Antony Taubman, *Australia’s Interests Under TRIPS Dispute Settlement: Trade Negotiations by Other Means, Multilateral Defence of Domestic Policy Choice, or Safeguarding Market Access?*, 9 MELB. J. INT’L L. 217, 228 (2008) (“[T]he assertion that legislation is ‘TRIPS compliant’ . . . served as a metonym—a

that their countries will be dragged into the WTO dispute settlement process and thereby suffer economic and reputational harms, they have actively avoided efforts that would reach or push the limits of TRIPS flexibilities, even if those efforts could help protect public health.⁶⁶ To a large extent, the waiver, if adopted, would enable policymakers to maximize their policy space at the intersection of intellectual property and public health.

Fourth, and relatedly, the concerns about noncompliance with intellectual property standards are not limited to the TRIPS Agreement. Governments and their officials are equally concerned about deviations from the high TRIPS-plus standards found in developed countries—the United States, in particular. After all, the U.S. Trade Act empowers the United States Trade Representative (“USTR”) to take section 301 actions⁶⁷ against countries that have failed to provide “adequate and effective protection of intellectual property rights notwithstanding the fact that [they] may be in compliance with the specific obligations of the [TRIPS] Agreement.”⁶⁸ In the past two decades, the USTR has taken action against South Africa, Thailand, and other countries issuing WTO-permissible compulsory licenses.⁶⁹ By preempting such action, the waiver would serve a similar function as Executive Order 13,155, which the Clinton Administration issued in May 2000.⁷⁰ Adopted after the global pharmaceutical industry’s ill-advised lawsuit against President Nelson Mandela’s government in South Africa, that order enabled countries in sub-Saharan Africa to enhance

brand, even—of a country’s willingness and capacity to provide a regulatory regime that is receptive to the trade interests that defined ‘new economy’ or innovation-based models of growth and prosperity.”); Peter K. Yu, *Six Secret (and Now Open) Fears of ACTA*, 64 SMU L. REV. 975, 1042–43 (2011) (lamenting that policymakers in developing countries may “have developed a maximalist mindset” and “be blinded by their concern about compliance with international obligations”).

66. See *infra* text accompanying notes 152–53, 186–87.

67. Section 301 permits the U.S. President to investigate and impose sanctions on countries engaging in unfair trade practices that threaten the United States’ economic interests. See 19 U.S.C. §§ 2411–2420. For discussions of the section 301 process, see generally PETER DRAHOS WITH JOHN BRAITHWAITE, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?* 88–107 (2002); Joe Karaganis & Sean Flynn, *Networked Governance and the USTR*, in *MEDIA PIRACY IN EMERGING ECONOMIES* 75 (Joe Karaganis ed., 2011); Paul C.B. Liu, *U.S. Industry’s Influence on Intellectual Property Negotiations and Special 301 Actions*, 13 UCLA PAC. BASIN L.J. 87 (1994).

68. 19 U.S.C. § 2411(d)(3)(B)(i)(II).

69. See Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 24, ¶ 1157 (“USTR 2020 Special 301 report, issued right in the middle of the COVID-19 pandemic, continue to condemn countries who improve their laws on compulsory license or make use of compulsory license—countries specifically pressured for their law or their use of compulsory license include Chile, Indonesia, Colombia, Egypt, India, Malaysia, [the] Russian Federation, Turkey, Ukraine, [and] El Salvador.”); Jonathan Burton-MacLeod, *Tipping Point: Thai Compulsory Licences Redefine Essential Medicines Debate*, in *INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES* 406, 406–07 (Thomas Pogge et al. eds., 2010) (recounting Thailand’s issuance of the compulsory licenses, its dispute with the developers of the compulsorily licensed drugs, and the United States Trade Representative’s section 301 response).

70. See Exec. Order No. 13,155, 65 Fed. Reg. 30,521 (May 10, 2000) (enabling countries in sub-Saharan Africa to enhance access to HIV/AIDS medicines and related medical technologies without fear of trade retaliation).

access to HIV/AIDS medicines and related medical technologies without the fear of trade retaliation.⁷¹

Fifth, the adoption of the waiver could induce pharmaceutical companies and other private enterprises to become more proactive in issuing voluntary licenses, including those that would be open or heavily discounted. In the early days of the COVID-19 pandemic, commentators and the mass media noted AbbVie's pledge to forgo enforcement of its patents in Kaletra, Moderna's promise to do the same for COVID-19 vaccines, Gilead's issuance of nonexclusive voluntary licenses to remdesivir, and AstraZeneca's active engagement with Brazil, India, and other developing countries to increase global access to vaccines.⁷² To be sure, all of these voluntary activities took place without the waiver. Nevertheless, they involved decisions made at a time when rights holders were apprehensive of imminent government intervention.⁷³ It is therefore not farfetched to assume that these rights holders would have behaved similarly had the waiver been adopted.⁷⁴ As Jayashree Watal, a former WTO official and TRIPS negotiator for India, observed, the waiver would serve as an "indirect attempt to put pressure on the original manufacturers to cooperate."⁷⁵

Finally, considering the scale of the COVID-19 pandemic and its massive challenges to countries around the world, adjustments to the TRIPS Agreement

71. See SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* 151–55 (2003) (discussing the pharmaceutical industry's legal challenge and the executive order); Yu, *supra* note 31, at 1620 (discussing the enactment of the Medicines and Related Substances Control Amendment Act 1997 under President Nelson Mandela's administration in South Africa and the United States' response); see also Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J.L. & MED. 345, 355 n.58 (2008) [hereinafter Yu, *Access to Medicines*] (collecting sources that discuss the United States' response).

72. See Mercurio, *supra* note 7, at 20–23 (discussing the use of voluntary licensing and other initiatives to support access to COVID-19 vaccines); Thambisetty et al., *supra* note 7, at 389 (discussing voluntary industry cooperation to boost vaccine production); Phil Taylor, *AbbVie Won't Enforce Patents for COVID-19 Drug Candidate Kaletra*, PHARMAPHORUM (Mar. 25, 2020), <https://pharmaphorum.com/news/abbvie-wont-enforce-patents-for-covid-19-drug-candidate-kaletra/> (reporting that AbbVie "agreed to drop enforcement of Kaletra patents worldwide" following Israel's issuance of the compulsory license).

73. See Carie Steele, *The Biden Administration Supports Waiving Patents on Coronavirus Vaccines. Big Pharma Won't Be Happy*, WASH. POST (May 5, 2021, 5:51 PM), https://www.washingtonpost.com/politics/2021/05/05/biden-administration-supports-waiving-patents-coronavirus-vaccines-big-pharma-wont-be-happy ("[Pharmaceutical companies] might try to forestall state action by licensing their products to other pharmaceutical companies. For example, Gilead, the maker of remdesivir, a pharmaceutical drug used to treat covid-19, extended voluntary licenses to several European pharmaceutical companies in 2020 to prevent countries from issuing compulsory licenses.").

74. See Bryan Mercurio, *The IP Waiver for COVID-19: Bad Policy, Bad Precedent*, 52 INT'L REV. INTELL. PROP. & COMPETITION L. 983, 986 (2021) (stating that the United States' support for the waiver can be viewed as "a threat to encourage vaccine innovators to increase production"); Bostyn, *supra* note 7, at 17 ("The mere idea that an IP waiver could become a reality will probably have sent shockwaves through the headquarters of both the pharmaceutical companies and their major shareholders. That might make them perhaps more willing to license out the manufacturing of the COVID-19 vaccines to third parties, which they have hitherto done only to a very limited extent."); Maximilian Steinbeis & Evin Dalkilic, *Three Crises and One Waiver*, VERFASSUNGSBLOG (May 7, 2021), <https://verfassungsblog.de/three-crises-and-one-waiver> (discussing the ability of the proposed waiver to put pressure on pharmaceutical developers).

75. Steinbeis & Dalkilic, *supra* note 74.

are both logical and understandable. Just as a country's constitution should not be "a suicide pact"—a memorable observation made by Justice Arthur Goldberg in *Kennedy v. Mendoza-Martinez*⁷⁶—the TRIPS Agreement should not prevent WTO members from addressing those public health exigencies that threaten their well-being, such as COVID-19. Moreover, given the transborder nature of global pandemics⁷⁷ and the emergence of the delta, omicron, and other variants in different parts of the world, the benefits of implementing the waiver would inure to the entire global community. It is therefore no surprise that the South Centre and other commentators have championed the use of the national security exception under article 73 of the TRIPS Agreement to combat the pandemic.⁷⁸ If adopted, the waiver would have built on this recommendation while preempting any potential challenge before the WTO Dispute Settlement Body to the provision's requirements concerning "essential security interests," necessity, and the existence of an "emergency in international relations."⁷⁹

C. OPPOSITION

Despite the strong case for the proposed waiver, those opposing the instrument or questioning its necessity, expediency, or effectiveness have advanced some convincing counterarguments. First, many of the problems relating to the inadequate supply of vaccines and other needed medical products and technologies during the COVID-19 pandemic were caused by the lack of manufacturing capacity and know-how, the shortage of raw materials, delivery and logistical challenges, and deficiencies in public health infrastructure.⁸⁰ As

76. 372 U.S. 144, 160 (1963).

77. See DAVID P. FIDLER, SARS, GOVERNANCE AND THE GLOBALIZATION OF DISEASE 13–16 (2004) (discussing the "germs do not recognize borders" mantra of public health); Colin McInnes, *National Security and Global Health Governance*, in GLOBAL HEALTH GOVERNANCE: CRISIS, INSTITUTIONS AND POLITICAL ECONOMY 42, 44 (Adrian Kay & Owain David Williams eds., 2009) ("Health threats, the provision of healthcare services and the market for pharmaceuticals are increasingly transborder in nature. In terms of health security, this makes defence 'at the border' a near impossibility despite efforts by states to do just that."); MARK W. ZACHER & TANIA J. KEEFE, THE POLITICS OF GLOBAL HEALTH GOVERNANCE: UNITED BY CONTAGION 1 (2008) ("The world is becoming an ever smaller place, and microbes that cause devastating diseases do not stop for border guards.")

78. See Article 73 Letter, *supra* note 3; Abbott, *supra* note 3, at 20–21.

79. TRIPS Agreement, *supra* note 6, art. 73.

80. See Mercurio, *supra* note 7, at 15–16 ("Other major factors—such as infrastructure, supply chains, production capabilities and capacity—may prove to be a major stumbling block in distributing medicines and vaccines."); Hilty et al., *supra* note 7, at 1 ("The holdups in vaccine manufacturing and distribution have been caused mainly by the shortage in raw materials, insufficient production capacity and highly complex manufacturing process[es] (in the case of mRNA and vector vaccines)." (citation omitted)); Justin Hughes, *Biden Decision on COVID Vaccine Patent Waivers Is More About Global Leadership Than IP*, USA TODAY (May 6, 2021, 7:04 PM), <https://www.usatoday.com/story/opinion/2021/05/06/covid-vaccine-patents-biden-boosts-american-leadership-column/4932766001> ("Practically everyone agrees that the issue in production of these drugs—whether conventional vaccines or the new mRNA vaccines—is not the patented technology, but (a) proper manufacturing facilities, (b) raw materials, (c) production know-how, and (d) logistical hurdles in administering the shots."); Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, HARV. L. SCH. PETRIE-FLOM CTR. (May 5, 2021), <https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver> ("[E]ven if all types of legal

Francis Gurry, the former Director General of the World Intellectual Property Organization (WIPO), observed in the early days of the pandemic, “there are many other policy challenges in the management of the COVID-19 crisis that are not directly related to IP [intellectual property] and innovation” and that do not involve the “question of IP blocking access to vital medical vaccines, treatments or cures.”⁸¹ Even with the waiver’s adoption, it is unclear whether countries would have quickly addressed many of these preexisting problems. To be sure, arguments emphasizing problems unrelated to intellectual property⁸² are as unpopular as the pharmaceutical industry’s longstanding attribution of the lack of access to HIV/AIDS medicines to drug delivery problems and deficient public health infrastructure.⁸³ Nevertheless, it is not unreasonable to question the wisdom of taking such a drastic measure as suspending intellectual property rights when lingering doubts exist over whether such suspension would have effectively addressed the problem. Indeed, the waiver’s critics repeatedly demanded concrete evidence of how intellectual property rights had erected barriers to accessing pandemic-related vaccines, treatments, and technologies.⁸⁴

restrictions on the use of vaccine technology were lifted—or had never existed in the first place—there is simply not enough infrastructure (manufacturing facilities and equipment) nor raw materials (the components needed to manufacture and deliver vaccines) to produce and distribute COVID-19 vaccines as predicted under current waiver proposals.”)

81. Francis Gurry, *Some Considerations on Intellectual Property, Innovation, Access and COVID-19*, ¶ 10, WORLD INTELL. PROP. ORG. (Apr. 24, 2020), https://www.wipo.int/about-wipo/en/dg_gurry/news/2020/news_0025.html.

82. See Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 853 (2007) (noting the need “to distinguish among the IP-relevant, IP-related, and IP-irrelevant factors and develop solutions that are tailored to each type of factor”).

83. See Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886, 1891 (2001) (“[T]he extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa.”); see also Yu, *supra* note 82, at 850 (discussing the claims made by the pharmaceutical industry and their supporters about the impediments within local healthcare systems).

84. See, e.g., Mercurio, *supra* note 74, at 986 (“[T]he proponents (and their supporters) have not even pointed to one credible instance where [intellectual property rights] have blocked the production of a COVID-19 vaccine.”); Adam Mossoff & Amesh Adalja, *Patents as a Driver of the Unprecedented Biomedical Response to COVID-19*, INQUIRY (Sept. 21, 2022), <https://journals.sagepub.com/doi/full/10.1177/00469580221124819> (“There is no evidence that patents have blocked the research, development, or distribution of any vaccines for the treatment of COVID-19.”); Alden Abbott, Adam Mossoff, Kristen Osenga & Zvi Rosen, *COVID Vaccine IP Waiver: A Pathway to Fewer, Not More, Vaccines* (2021), <https://regproject.org/paper/covid-vaccine-ip-waiver-a-pathway-to-fewer-not-more-vaccines> (“There is zero evidence that patents have blockaded the research, development, or distribution of any drugs or vaccines for the treatment of COVID-19.”). In defense of the waiver’s supporters, governments and their supportive non-governmental organizations have provided considerable evidence documenting the many challenges intellectual property rights have posed to the development of COVID-19 products and technologies. See, e.g., 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); Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 52; Médecins Sans Frontières, *WTO COVID-19 TRIPS Waiver Proposal: Myths, Realities and an Opportunity for Governments to Protect Access to Lifesaving Medical Tools in a Pandemic* (Dec. 3, 2020), <https://msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access>. Moreover, access barriers generated by intellectual property rights tend to exacerbate those access barriers that are unrelated to these rights. See Thambisetty et al., *supra* note 7, at 405 (“IP barriers have been a factor in shortages of raw materials and consumables, preventing workarounds. For

Second, the development of different products and technologies requires a range of incentive frameworks, some of which the waiver could have undermined. The incentives needed for the development of COVID-19 vaccines are quite different from those needed for the creation of new therapeutic treatments or medical equipment.⁸⁵ Moreover, interventions to incentive frameworks can both stimulate and impede innovation, depending on the situation at hand. As Jorge Contreras observes:

In some cases, allocative interventions may promote innovation, as when the government subsidizes individual purchases of a patented drug, thereby ensuring patient access to the drug while at the same time rewarding its developer and funding future research. Yet, in other cases, allocative interventions such as compulsory licensing of patents . . . may depress an innovator's financial returns and thus reduce its incentive to innovate further.⁸⁶

Thus, even if we acknowledge that the intellectual property system has erected some barriers to accessing the needed medical products and technologies—a position actively challenged by the waiver's opponents⁸⁷—it remains unclear empirically whether the waiver would, on balance, have undermined the incentive frameworks for developing the different medical products and technologies needed to combat COVID-19. The answer to this question will likely vary from country to country and from product to product.

It is even more difficult to determine in advance whether the waiver would, on balance, strengthen or weaken our ability to prepare for the next global pandemic. It is worth keeping in mind that many of those pre-pandemic products and technologies used to accelerate our effort to combat COVID-19, including those relating to SARS, were developed in an environment supported by strong

example, plastic single-use bioreactor bags have been scarce due to the global dependency on a few suppliers for these materials; indeed, there are currently more than 2,000 patents covering them, making entering the market as a new supplier onerous.”).

85. See Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, 7 TEX. A&M J. PROP. L. 110, 111 (2021) (“Vaccines are often described as one of the most unprofitable types of biopharmaceutical goods, under-incentivized from a research and development . . . perspective, and routinely failing to attract sufficient investment from traditional funders in biopharma.”); Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 731 (2019) (“[I]n spite of the increasing burden posed by infectious diseases in the United States and abroad, the market for vaccines targeting emerging pathogens is often considered unprofitable.”); Xue Qiwei Claire & Lisa Larrimore Ouellette, *Innovation Policy and the Market for Vaccines*, 7 J.L. & BIOSCIENCES 1, 7 (2020) (“[A]bsent significant government intervention in healthcare markets—such as mandatory or free vaccination—the prospect of monopoly profits will under-incentivize the development of vaccines relative to treatments. In particular, traditional market-based IP incentives may be specifically insufficient for promoting vaccine development, despite the outsized social benefits of vaccines.” (citation omitted)); see also Yu, *supra* note 5, at 11 (noting “the incentive framework needed to promote pharmaceutical innovation tends to vary according to medical needs, market conditions, and technological advances”).

86. Jorge L. Contreras, *Expanding Access to Patents for COVID-19*, in ASSESSING LEGAL RESPONSES TO COVID-19 158–59 (Scott Burris et al. eds., 2020).

87. See sources cited *supra* note 80.

intellectual property rights.⁸⁸ We will never know how much research for those products and technologies would have been undertaken, if at all, without intellectual property protection—the massive outpouring of public funding and private donations notwithstanding.⁸⁹ Moreover, “[t]hose platform technologies [that are now being deployed to combat COVID-19] have a potential to yield numerous therapeutic applications in other medical areas, including cancer treatment.”⁹⁰ It is therefore unsurprising that the Max Planck Institute for Innovation and Competition declared in a position paper that “[a] waiver of IP protection would not serve the interest of . . . society, as it would create a disincentive for companies to pursue research in those areas.”⁹¹

Third, although the pandemic is a rare occurrence that involves “extraordinary circumstances . . . call[ing] for extraordinary measures,”⁹² those opposing the waiver understandably feared that its potential adoption would set an undesirable precedent for further adjustments to intellectual property rights in the event of a future global crisis. Indeed, during the deliberations on the draft Ministerial Decision at MC12, some WTO members pushed for language that would automatically extend the Decision to future pandemics, reportedly causing the U.S. delegation to storm out of the negotiations.⁹³ To those who firmly believe in the need for a strong intellectual property system to promote innovation in the health and other sectors, crisis-induced adjustments could undermine the system’s stability and predictability.

Fourth, because of the consensus-based process used in WTO negotiations, it would have taken quite some time to get a compromise version of the waiver adopted had negotiations continued. A good point of comparison is article 31*bis* of the TRIPS Agreement, which allows countries with insufficient or no manufacturing capacity to import generic versions of patented pharmaceuticals.⁹⁴ Although WTO members adopted the Doha Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”) in November

88. See WORLD INTELL. PROP. ORG., COVID-19-RELATED VACCINES AND THERAPEUTICS: PRELIMINARY INSIGHTS ON RELATED PATENTING ACTIVITY DURING THE PANDEMIC 7 (2022), <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-1075-en-covid-19-related-vaccines-and-therapeutics.pdf> (stating that “[m]ost COVID-19 drug candidates are repurposed”); *id.* at 20 (“Companies including Moderna, BioNTech and Curvac designed their first generation of COVID vaccines using 2P S protein as antigen, based on the data from other betacoronavirus, SARS and MERS, which resulted in higher protein (antigen) expression and elicited potent immune responses”); Mercurio, *supra* note 7, at 17 (discussing the incentives needed to support the development of synthetic mRNA technology, which dates back to more than a decade before the COVID-19 pandemic).

89. Commentators continue to debate whether intellectual property rights provide an ex-ante incentive or an ex-post reward, or even a windfall, especially in cases where the inventive activities involve a considerable amount of public funding.

90. Hilty et al., *supra* note 7, at 5.

91. *Id.*

92. USTR Statement, *supra* note 15.

93. D. Ravi Kanth, *WTO: US Storms Out from Discussions on WTO Response to Pandemic*, THIRD WORLD NETWORK (June 8, 2022), <https://www.twon.my/title2/wto.info/2022/ti220607.htm>.

94. TRIPS Agreement, *supra* note 6, art. 31*bis*.

2001⁹⁵ and a protocol to amend the Agreement four years later,⁹⁶ the proposed TRIPS amendment did not enter into effect until January 2017, upon ratification by two-thirds of the WTO membership.⁹⁷ If this past track record provides any guide, the proposed waiver, even if it were adopted, might not have arrived in time to address the current pandemic.

Fifth, many of the concerns and problems in developing countries relate to implementation, which Part II.B discusses in greater depth. Even if the waiver were quickly adopted, countries would still need to enact or amend laws and regulations to implement it. What could have taken place in the implementation process would also depend on other preexisting intellectual property obligations in bilateral, regional, and plurilateral trade and investment agreements.⁹⁸ It is therefore no surprise that Carlos Correa and his South Centre colleagues called on countries to negotiate “complementary waivers from [these agreements] where there [might] be conflict with the implementation of the waiver.”⁹⁹ As they explained:

While a TRIPS waiver would apply to IP rights covered under the Agreement and waive the related obligations thereunder, it will not in itself waive TRIPS-plus obligations that are not arising from TRIPS but assumed under [free trade agreements], such as the obligations on the part of the drug regulatory authorities to deny grant of marketing approval to generic versions of drugs that are under patent protection, or to grant data exclusivity for a specified period over clinical trial data submitted by an originator. Hence, it may be necessary to execute complementary waivers under [these agreements], including for TRIPS-plus provisions.¹⁰⁰

Sixth, because WTO negotiations are always filled with concessions and compromises, it is highly unlikely that many developed countries that opposed the waiver would have turned around to support it without getting anything in return¹⁰¹—assuming they do not consider significant improvements in global

95. World Trade Organization, Declaration on the TRIPS Agreement and Public Health of 14 November 2001, ¶ 6, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration] (recognizing that “WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement”).

96. World Trade Organization, *Amendment of the TRIPS Agreement: Decision of 6 December 2005*, WTO Doc. WT/L/641 (2005).

97. Press Release, World Trade Org., WTO IP Rules Amended to Ease Poor Countries’ Access to Affordable Medicines (Jan. 23, 2017), https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm.

98. See Correa et al., *supra* note 7 (discussing the interplay of the proposed waiver and the preexisting international obligations under free trade and investment agreements); Prabhash Ranjan, *Trade-Related Aspects of Intellectual Property Rights Waiver at the World Trade Organization: A BIT of a Challenge*, 56 J. WORLD TRADE 523 (2022) (discussing how multinational pharmaceutical companies can use the investor-state dispute settlement mechanism under bilateral investment treaties to challenge waiver-related intellectual property measures).

99. Correa et al., *supra* note 7, at 20.

100. *Id.* at 5.

101. See D. Ravi Kanth, *Developing Countries Call for Text-Based Negotiations on TRIPS Waiver*, THIRD WORLD NETWORK (Feb. 8, 2021), <https://www.twn.my/title2/wto.info/2021/ti210204.htm> (reporting that “those opposed to the TRIPS waiver proposal, particularly Canada, the EU, Japan, and Switzerland, who are part of the

health security something worth bargaining for.¹⁰² In view of the potential need for a quid pro quo, one cannot help but wonder whether and how the adoption of the waiver would have affected negotiations on other limitations and exceptions to intellectual property rights at the WTO and WIPO. Given the tradeoffs in the intellectual property domain and in other trade or trade-related areas, it is worth holistically evaluating whether the waiver's purported benefits would outweigh its costs, especially after a significant segment of the global population had been fully vaccinated.

Seventh, we have long criticized the ill-advised one-size-fits-all approach enshrined in the TRIPS Agreement and TRIPS-plus bilateral, regional, and plurilateral agreements.¹⁰³ Sadly, the waiver embraced this oft-criticized approach—except that it proceeded in the opposite direction. It is possible that, even with the waiver's adoption, many WTO members might not have implemented it, or might have used different implementation models, similar to the cross-country variations we have already seen in the TRIPS context.¹⁰⁴ Nevertheless, not all countries have the legal and technical expertise to customize the waiver language for domestic implementation.¹⁰⁵ Without appropriate customization, the waiver could have created similar mismatch problems at the local level, like the one-size-fits-all approach enshrined in the TRIPS Agreement. After all, few countries shared the same pandemic experience on the same scale at the same time, due in part to geographical and seasonal differences.¹⁰⁶ The vaccine rate and availability, the need for

Ottawa Group, want WTO members to consider their trade and health initiative that calls for further trade liberalization and removal of export-related restrictions”).

102. See Yu, *supra* note 5, at 31 (“[P]olicymakers and governments seem to be struck with a national pandemic response paradox: while policymakers and governments know full well that global pandemics will necessitate cross-border solutions, the national public health crises steer their time, efforts, and energies toward developing policies to protect domestic constituents.” (citation omitted)).

103. See James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 3 DUKE L. & TECH. REV. no. 9, 2004, at 4 (“Th[e] ‘one size fits all’ attitude has been widely condemned, in both the developed and developing world.”); Peter K. Yu, *The Strategic and Discursive Contributions of the Max Planck Principles for Intellectual Property Provisions in Bilateral and Regional Agreements*, 62 DRAKE L. REV. DISCOURSE 20, 28 (2014) (“[T]he intellectual property system cannot be designed with the belief that one size will always fit all. More importantly, if there is only one size, that size cannot be extra-large.”).

104. See *infra* Part III.D.

105. See Rochelle Cooper Dreyfuss, *TRIPS-Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21, 25 (2004) (noting that many developing countries lack “experience with intellectual property protection [and] sufficient human capital (in the form of legal talent) to codify wiggles into law”); Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 388 (2006) (“[M]any less developed countries still lack experience with intellectual property protection and the needed human capital to develop laws that are tailored to their interests and local conditions.”).

106. See Alex Broadbent & Benjamin T.H. Smart, *Why a One-Size-Fits-All Approach to COVID-19 Could Have Lethal Consequences*, THE CONVERSATION (Mar. 24, 2020, 1:29 AM), <https://theconversation.com/why-a-one-size-fits-all-approach-to-covid-19-could-have-lethal-consequences-134252> (suggesting that COVID-19 may have very different impacts in Africa considering that “only 6.09% of the population is over 65”); A. Odysseus Patrick & Max Bearak, *Dropping Temperatures Raise Coronavirus Concerns*, WASH. POST, June 7, 2020, at A25 (“As countries in the Northern Hemisphere tilt into summer and emerge from months-long coronavirus shutdowns, winter arrives this month in subtropical parts of the Southern Hemisphere—and with it increased concern for the virus’s spread.”).

incentives, and the availability of public funding and alternative support also varied significantly from country to country.

Finally, although least developed countries, the world's poorest nations,¹⁰⁷ were often mentioned in relation to the waiver—and although many of them cosponsored the instrument—they had limited domestic needs for the waiver unless the pandemic were to last for a long period of time. In June 2021, amid the pandemic, the WTO extended the transition period for these countries to July 1, 2034.¹⁰⁸ Before this extension, and at the time of submission of both the original and revised waiver proposals, the WTO already allowed least developed countries to delay protections for pharmaceutical patents and undisclosed test data until January 1, 2033.¹⁰⁹ Paragraph 4 of the revised waiver proposal took account of these arrangements and explicitly stated that the instrument would not “prejudice . . . the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.”¹¹⁰ Thus, to properly assess the waiver's benefits, we cannot lump all WTO members together as if they were similarly situated. To the extent that the waiver would benefit least developed countries, those benefits would have come primarily in the form of an improved ability to import health products and technologies from other WTO members, including developing countries with manufacturing capacity.

D. SUMMARY

Subparts B and C have shown that good arguments exist both for and against the waiver and that the debate has not produced a clear winner. Which side one takes will likely depend on one's values, preferences, and perspectives. Indeed, as with many contentious debates in the intellectual property area, the side that bears the burden of proof will have greater difficulty prevailing.¹¹¹ As David McGowan observed in relation to the equally polarized digital copyright debate two decades ago: “[T]he legal endgame is to place the burden of proof on the other side. Whoever has to prove the unprovable facts is likely to lose.”¹¹²

107. See *About Least Developed Countries*, UNITED NATIONS, <https://www.un.org/ohrlls/content/about-least-developed-countries> (last visited Jan. 28, 2023) (providing an overview of least developed countries).

108. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 for Least Developed Country Members: Decision of the Council for TRIPS of 29 June 2021*, WTO Doc. IP/C/88 (June 29, 2021).

109. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products: Decision of the Council for TRIPS of 6 November 2015*, WTO Doc. IP/C/73 (Nov. 6, 2015).

110. *Revised TRIPS Waiver Proposal*, *supra* note 4, annex, ¶ 4.

111. See David McGowan, *Copyright Nonconsequentialism*, 69 MO. L. REV. 1, 2 (2004) (“It is easy for each side to poke holes in the other side's positions. It is hard for either side to make an affirmative, instrumental case for their views.”); Peter K. Yu, *Anticircumvention and Anti-Anticircumvention*, 84 DENV. U. L. REV. 13, 15 (2006) (noting that, in the debate on digital rights management, “neither side has sufficient empirical evidence to either support its position nor disprove its rivals”).

112. McGowan, *supra* note 111, at 2.

While this Author argues in a forthcoming work that the wide devastation and disruption, heavy health and human toll, and considerable socioeconomic fallout caused by the COVID-19 pandemic have tipped the balance toward text-based negotiations at the WTO,¹¹³ whether one should support the ultimate adoption of this waiver remains a fair question. If the waiver debate were still ongoing, the answer would likely depend on factors such as “timing, the actual parameters delineated in the final text and whether side deals have emerged in the intellectual property or other trade-related areas that would allow countries to strike more creative compromises.”¹¹⁴ The more the COVID-19 pandemic evolved into an endemic,¹¹⁵ the less support the waiver would have received.

II. NEGOTIATION AND IMPLEMENTATION CHALLENGES

The previous Part has identified the most widely cited arguments for and against the COVID-19 TRIPS waiver. To show the complexities in the waiver negotiations and to explain why the debate was not simply about whether to adopt the waiver, this Part turns to some key negotiation and implementation challenges.

When the waiver proposal was first advanced, the scholarly and policy debates understandably were fixated on its merits and challenges—and, of course, the urgent need to combat COVID-19.¹¹⁶ As the debates dragged on, however, people began to pay greater attention to the negotiation and implementation challenges confronting efforts to adopt and eventually operationalize the waiver.¹¹⁷ These multifaceted challenges existed regardless of whether one supported or opposed the waiver.

Subpart A identifies the challenges of reaching international consensus on the waiver proposal at the TRIPS Council—a disturbing yet intriguing development considering that all WTO members shared the common objective of quickly ending the global pandemic.¹¹⁸ Subpart B explores the challenges confronting efforts to implement the waiver in individual countries had the instrument been adopted. Drawing from the literature on international treaty

113. See Yu, *supra* note 7.

114. *Id.*

115. With increased vaccination, the arrival of less fatal variants, and greater willingness that the SARS-CoV-2 virus is here to stay, this process has already begun. See Lara Herrero & Eugene Madzokere, *COVID Will Likely Shift from Pandemic to Endemic—but What Does That Mean?*, THE CONVERSATION (Sept. 20, 2021, 2:45 AM), <https://theconversation.com/covid-will-likely-shift-from-pandemic-to-endemic-but-what-does-that-mean-167782> (discussing the shift of COVID-19 from a pandemic to an endemic); Nicky Phillips, *The Coronavirus Is Here to Stay—Here’s What That Means*, NATURE (Feb. 16, 2021), <https://www.nature.com/articles/d41586-021-00396-2>.

116. See, e.g., Mercurio, *supra* note 7; Thambisetty et al., *supra* note 7; Hilty et al., *supra* note 7; Ragavan, *supra* note 7; Vawda, *supra* note 7; Henrique Zeferino de Menezes, *The TRIPS Waiver Proposal: An Urgent Measure to Expand Access to the COVID-19 Vaccines* (S. Centre, Research Paper No. 129, 2021).

117. See, e.g., Antony Taubman, *Solidarity as a Practical Craft: Cohesion and Cooperation in Leveraging Access to Medical Technologies Within and Beyond the TRIPS Agreement*, ASIA-PAC. SUSTAINABLE DEV. J., Nov. 2022, at 19; Correa et al., *supra* note 7; Grosse Ruse-Khan & Paddeu, *supra* note 7.

118. See sources cited *supra* note 23.

negotiations, including those in the intellectual property area, Subpart C shows why these two sets of challenges were neither separate nor sequential, but deeply entangled at the time of the international negotiations. To a large extent, this entanglement explains the negotiation impasse at the TRIPS Council and why the WTO membership ultimately adopted the Ministerial Decision in lieu of the proposed waiver. This Subpart also explains the low likelihood of quickly implementing the waiver worldwide to combat COVID-19 despite the support of more than 100 countries—about two-thirds of the WTO membership.¹¹⁹

A. INTERNATIONAL NEGOTIATION CHALLENGES

In view of the many arguments supporting and opposing the COVID-19 TRIPS waiver, one can easily anticipate the considerable challenges in the international negotiation process. To capture some of these challenges, this Subpart recounts the negotiations and related developments from India and South Africa's submission of a revised proposal in May 2021 to the end of the Quad consultations between the European Union, India, South Africa, and the United States.¹²⁰ These consultations eventually led to the development of the draft Ministerial Decision.¹²¹

Although more than 100 WTO members in both the developed and developing worlds endorsed the waiver proposal,¹²² a few developed countries strongly opposed it.¹²³ Meanwhile, some countries provided only limited support. For instance, despite its eventual support of text-based negotiations, the United States limited its support to only the narrow area of vaccines, and not diagnostics, therapeutics, or other health products and technologies.¹²⁴ Even more disappointing to the waiver's supporters, the press release accompanying the USTR's high-profile announcement of its support of text-based negotiations underscored the many challenges in a consensus-based WTO negotiation

119. See Correa et al., *supra* note 7, at 1 (noting “the support of more than 100 countries”); *Members and Observers*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Jan. 28, 2023) (listing the 164 members of the WTO).

120. Kanth, *supra* note 20.

121. Ministerial Decision, *supra* note 21.

122. Correa et al., *supra* note 7, at 1.

123. Those WTO members that had strongly opposed the initial version of the waiver proposal were Australia, Brazil, Canada, the European Union, Japan, Norway, Switzerland, the United Kingdom, and the United States. See *Academic Open Letter*, *supra* note 14. Some, like the United States, shifted their negotiating positions in the middle of the negotiations. Among the remaining major holdouts that the press frequently mentioned were the European Union, Switzerland, and the United Kingdom. See D. Ravi Kanth, *EU, Switzerland, UK Continue Opposition, amid Support for TRIPS Waiver*, THIRD WORLD NETWORK (Sept. 16, 2021), <https://www.twn.my/title2/wto.info/2021/ti210913.htm> (reporting that “the European Union led by Germany, Switzerland, and the United Kingdom . . . seem determined to undermine an expeditious decision on the temporary waiver for combating the COVID-19 pandemic”); see also Ashleigh Furlong, Sarah Anne Aarup & Samuel Horti, *Who Killed the COVID Vaccine Waiver?*, POLITICO (Nov. 10, 2022), <https://www.politico.eu/article/covid-vaccine-poor-countries-waiver-killed/> (providing an investigative report on the lobbying against the COVID-19 TRIPS waiver).

124. See USTR Statement, *supra* note 15 (limiting support to “the waiver of those protections for COVID-19 vaccines”).

process.¹²⁵ As the USTR observed, “[t]hose [waiver-related] negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved.”¹²⁶ This language, to some extent, has raised questions about the sincerity and extent of the United States’ support of the waiver.

The approach taken by the USTR was unsurprising, the difficult circumstances surrounding the COVID-19 pandemic notwithstanding. Indeed, it is not uncommon for the United States to actively participate in international negotiations to foster compromises that accommodate its preferences, only to reject the negotiated instruments at the very end. An illustrative precedent was the United States’ effort in negotiating the Convention on the Protection and Promotion of the Diversity of Cultural Expressions under the auspices of the United Nations Educational, Scientific and Cultural Organization (UNESCO) in the early 2000s.¹²⁷ Despite the many concessions made by other countries to accommodate the United States’ position, the United States and its close ally, Israel, became the only two countries voting against the adoption of this declaration.¹²⁸

Similarly, when WTO members sought to help members with insufficient or no capacity to manufacture generic drugs, the United States pushed hard on its positions, including the rejection of a modification to article 30 of the TRIPS Agreement¹²⁹ and the creation of an opt-out mechanism that would curtail the use of the negotiated instrument.¹³⁰ While the United States’ willingness to support the negotiations led to the adoption of a protocol to amend the TRIPS Agreement—which eventually became article 31*bis*¹³¹—its push for limited applicability has taken away the opportunity for pharmaceutical developers to create a sufficiently large market for drugs that can benefit the developing world, especially during a global pandemic. As Frederick Abbott and Jerome Reichman explain:

125. *See id.*

126. *Id.*

127. Convention on the Protection and Promotion of the Diversity of Cultural Expressions, Oct. 20, 2005, U.N. Doc. CLT-2005/CONVENTION DIVERSITE-CULT REV.2.

128. *See* Eireann Brooks, Note, *Cultural Imperialism vs. Cultural Protectionism: Hollywood’s Response to UNESCO Efforts to Promote Cultural Diversity*, 5 J. INT’L BUS. & L. 112, 112 (2006) (“The adoption of the [UNESCO Convention] in October 2005 was opposed only by the United States and its sole ally, Israel.”); *see also* Peter K. Yu, *Cultural Relics, Intellectual Property, and Intangible Heritage*, 81 TEMP. L. REV. 433, 434 (2008) (discussing the UNESCO Convention on the Protection and Promotion of the Diversity of Cultural Expressions).

129. *See* Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317, 340 (2005) (“European Commission officials have suggested that they opted for an Article 31–based approach because they concluded that the United States would never accept an Article 30–based solution.”).

130. *See* TRIPS Agreement, *supra* note 6, annex, art. 1(b) (“It is noted that some Members will not use the system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency” (citation omitted)).

131. *Id.* art. 31*bis*.

When the USA, European Union, Japan, Canada, Australia, Switzerland, among others, took themselves out of the equation as eligible importing countries under Article 31*bis*, they eliminated a large part of the potential global demand for pharmaceutical products originating from countries exporting under compulsory licenses. As a result, for example, if India were asked by countries in Africa and Latin America to manufacture drugs under compulsory license and export to them, the Indian producers might not be able to supply the [high-income countries] with the same products. The efficiencies in production that might otherwise be achieved by Indian manufacturing facilities when addressing a global market would be reduced. Giving effect to requested compulsory licenses would thus become less cost-efficient and might result in higher selling prices for purchasers everywhere.¹³²

It is therefore no surprise that, in the early days of the pandemic, a consortium of nongovernmental organizations and individual experts called on those countries that had previously opted out of the use of article 31*bis* to reconsider their earlier positions.¹³³

With the momentum generated by the United States' shift of negotiating position under the Biden Administration in May 2021 and the submission of a slightly revised proposal by India, South Africa, and over sixty cosponsors two weeks later, WTO members quickly agreed to launch the text-based negotiations on the waiver in mid-June.¹³⁴ Notwithstanding this agreement, some highly vocal developed countries continued to oppose substantive textual engagement by repeatedly calling into question the waiver's necessity, expediency, and effectiveness, while also noting concerns about implementation challenges.¹³⁵ Some of these opponents also emphasized the need to retain protections for regulatory data, such as for clinical trial data submitted by pharmaceutical companies to governments to secure marketing approval.¹³⁶

132. Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT'L ECON. L. 535, 559 (2020).

133. See James Love, *Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured Under Compulsory License in Another Country, Under 31bis of TRIPS Agreement*, KNOWLEDGE ECOLOGY INT'L (Apr. 7, 2020), <https://www.keionline.org/32707> (reproducing an open letter that asked thirty-seven WTO members to "notify the WTO that they have changed their policy and now considers itself an eligible importing country, and in addition, to also use whatever legal means are available to revoke the opt-out as importing members, for goods manufactured under a compulsory license"); see also Abbott & Reichman, *supra* note 132, at 559–60 (outlining the different approaches that would enable those WTO members that had previously opted out of the use of article 31*bis* to opt back in or otherwise make use of the provision).

134. Kanth, *supra* note 18.

135. See *TRIPS Members Continue Discussions on IP COVID-19 Response as High-Level Engagement Intensifies*, WORLD TRADE ORG. (Dec. 16, 2021), https://www.wto.org/english/news_e/news21_e/trip_16dec21_e.htm [hereinafter *TRIPS Members Continue Discussions*] ("Co-sponsors stressed the need to urgently initiate text-based negotiations, but several delegations saw little promise in any textual engagement as long as fundamental disagreements persist.").

136. See *TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19*, WORLD TRADE ORG. (July 20, 2021), https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm (identifying the protection of undisclosed information among the four key topics of discussions, along with scope, duration, and implementation); see also Bostyn, *supra* note 7, at 7 (noting that such disclosure could go beyond the loss of intellectual property protection to affect the rights holders' competitive positions and commercial strategies).

In view of such opposition and the slow progress in the TRIPS Council negotiations, the waiver's proponents and their supportive nongovernmental organizations and commentators became deeply frustrated with the state of negotiations.¹³⁷ The longer the negotiations dragged on, the less likely the negotiated instrument would become operationalized in time to effectively combat COVID-19. One only has to recall the protracted negotiations and ratifications involved in developing article 31*bis* of the TRIPS Agreement, discussed in Part I.C.¹³⁸ By the time that provision entered into effect in January 2017, more than a decade and a half had passed since WTO members had adopted the language in the Doha Declaration to help countries with insufficient or no capacity to manufacture generic drugs.¹³⁹

By June 2021, countries were busy finding “landing zones” to accommodate WTO members' different positions.¹⁴⁰ There were high hopes that consensus would be reached in time for consideration at MC12, which was then scheduled for November 2021¹⁴¹ but postponed due to the emergence of the omicron variant of the SARS-CoV-2 virus.¹⁴² While the discussions on the proposed waiver continued at the TRIPS Council, most WTO members began to realize that achieving consensus on this proposal would be unlikely.¹⁴³

Around December 2021, the European Union, India, South Africa, and the United States, with the support of the WTO Secretariat, launched their own consultations.¹⁴⁴ Conducted in secret, these high-level consultations aimed to reduce differences between the key proponents and opponents of the waiver while facilitating compromises that would advance the negotiations.¹⁴⁵ As one Geneva observer stated: “It is understood that the US and the EU

137. See D. Ravi Kanth, *EU & Allies Adopt “Diversionsary” Tactics on TRIPS Waiver at WTO*, THIRD WORLD NETWORK (Nov. 9, 2021), <https://www.twn.my/title2/wto.info/2021/ti211112.htm> (criticizing the diversionary tactics deployed by those developed countries opposing the waiver).

138. See *supra* text accompanying notes 94–97.

139. Doha Declaration, *supra* note 95, ¶ 6.

140. *TRIPS Members Continue Discussions*, *supra* note 135.

141. See *TRIPS Members Pursue Convergence for an IP COVID-19 Response*, WORLD TRADE ORG. (Oct. 14, 2021), https://www.wto.org/english/news_e/news21_e/trip_14oct21_e.htm (noting the effort to “explore possible common ground to come to a substantive agreement in time for” the Twelfth WTO Ministerial Conference).

142. *General Council Decides to Postpone MC12 Indefinitely*, WORLD TRADE ORG. (Nov. 26, 2021), https://www.wto.org/english/news_e/news21_e/mc12_26nov21_e.htm.

143. See *supra* text accompanying notes 19–20.

144. *TRIPS Members Updated on High-Level Talks Aimed at Finding Convergence on IP COVID-19 Response*, WORLD TRADE ORG. (Mar. 10, 2022), https://www.wto.org/english/news_e/news22_e/trip_10mar22_e.htm.

145. For reports on the quadrilateral consultations, see *id.*; Roshan John, *The Quad Discussion Group's Compromise Falls Short of a Comprehensive TRIPS Waiver*, SPICYIP (Mar. 17, 2022), <https://spicyip.com/2022/03/the-quad-discussion-groups-compromise-falls-short-of-a-comprehensive-trips-waiver.html>; D. Ravi Kanth, *WTO: Dangers of “Take-It-or-Leave-It” Compromise Outcome on TRIPS Waiver*, THIRD WORLD NETWORK (Feb. 24, 2022), <https://www.twn.my/title2/wto.info/2022/ti220222.htm>; Ed Silverman, *A Compromise Is Reached on an Intellectual Property Waiver for Covid-19 Vaccines, but Does It Go Far Enough?*, STAT NEWS (Mar. 15, 2022), <https://www.statnews.com/pharmalot/2022/03/15/covid19-vaccine-patents-wto/>.

have . . . favoured a limited application of such a waiver. Some suggestions include restricting the waiver only to African countries . . . [and] exclud[ing] India and China [from the waiver].”¹⁴⁶ Even though the outcome document from the Quad consultations that the WTO released did not adopt these reported suggestions,¹⁴⁷ it is instructive to study the different choices concerning the eligibility requirements. These choices shed light on the complexity of the waiver negotiations at the TRIPS Council, including the ambivalent or conflicting policy positions taken by some WTO members. A close examination of these choices also deepens our understanding of the eligibility requirements now incorporated into the Ministerial Decision.¹⁴⁸

At first glance, the exclusion of China and India from the waiver’s eligibility seems problematic, considering the leverage of these two emerging trade powers, as well as India’s critical role in crafting both the original and revised waiver proposals.¹⁴⁹ In reality, however, such an exclusion might not have been a deal breaker. While India staunchly supported the waiver at the international level, its domestic landscape was much more complicated than South Africa, especially after its foreign ministry changed its policy direction.¹⁵⁰ Because many pharmaceutical companies in India opposed the waiver,¹⁵¹ the

146. Priti Patnaik, *Efforts to Limit the Implementation of the TRIPS Waiver, Proposals to Exclude India & China*, GENEVA HEALTH FILES (Feb. 4, 2022), <https://genevahealthfiles.substack.com/p/exclusive-efforts-to-limit-the-implementation>.

147. See Priti Patnaik, *The Lowest Common Denominator: The Quad Text on the TRIPS Waiver*, GENEVA HEALTH FILES (Mar. 18, 2022), <https://genevahealthfiles.substack.com/p/the-lowest-common-denominator-the?s=r>. A leaked text of this outcome document, published by *Stat News*, showed that those participating in the Quad consultations chose not to mention countries by name but instead opted for an eligibility requirement that would limit the waiver to “any developing country Member that exported less than 10 percent of world exports of COVID-19 vaccine doses in 2021.” *TRIPS COVID-19 Solution*, ¶ 1 n.1, <https://freepdfhosting.com/4d79fc6e70.pdf> (last visited Jan. 28, 2023); see also Silverman, *supra* note 145 (providing the leaked text). Because China had slightly over a third of these exports in December 2021, according to the WTO-IMF COVID-19 Vaccine Trade Tracker, the country was de facto the only developing economy that would have been disqualified for the proposed arrangement. *WTO-IMF COVID-19 Vaccine Trade Tracker*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm (Jan. 17, 2022) [https://web.archive.org/web/20220202185936/https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm]. By the time the WTO officially released the outcome document on May 3, that document had slightly evolved. Added to footnote 1 was new bracketed language stating that “[d]eveloping country Members with capacity to export vaccines are encouraged to opt out from this Decision.” Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the Chairperson*, WTO Doc. IP/C/W/688 (May 3, 2022); see also Yu, *supra* note 21 (discussing the outcome document); Carlos M. Correa & Nirmalya Syam, *Analysis of the Outcome Text of the Informal Quadrilateral Discussions on the TRIPS COVID-19 Waiver* (S. Centre, Policy Brief No. 110, 2022) (same).

148. See Ministerial Decision, *supra* note 21, ¶ 1 n.1 (providing the eligibility requirement).

149. See *TRIPS Waiver Proposal*, *supra* note 4; *Revised TRIPS Waiver Proposal*, *supra* note 4.

150. See Priti Patnaik, *What the TRIPS Waiver Discussions at the WTO Tell Us About Indian Diplomacy*, WIRE (June 23, 2022), <https://thewire.in/diplomacy/trips-waiver-indian-diplomacy> (“India’s visible lack of effective leadership [on the TRIPS waiver discussions] in Geneva might also be explained by the overall change in the direction of India’s foreign ministry.”).

151. See Patnaik, *supra* note 146 (“India’s pharmaceutical industry . . . has not favoured the waiver approach in order to address the supply challenges for COVID-19 medical products.”); Priti Patnaik, *Where Does India Truly Stand on the TRIPS Waiver: Q&A with Murali Neelakantan*, GENEVA HEALTH FILES (Aug. 6, 2021), <https://genevahealthfiles.substack.com/p/where-does-india-truly-stand-on-the> (providing an interview

country did not issue any compulsory licenses to increase access to pharmaceuticals during the COVID-19 pandemic,¹⁵² even though article 31 of the TRIPS Agreement expressly permits the issuance of such licenses.¹⁵³ As Arul George Scaria lamented: “When NITI Aayog [a government policy think tank in India] [said] IP [was] hardly a hurdle in the production of COVID-19 vaccines, it [was] echoing the pharma lobby and leaving the country a laughing stock in front of international negotiators on the subject.”¹⁵⁴

Compared with the exclusion of India, the exclusion of China was even less problematic. Although the U.S. pharmaceutical industry and its supportive politicians made arguably self-serving accusations about how the waiver would benefit countries like China and Russia,¹⁵⁵ China had mixed reactions to the waiver proposal from the very beginning and took a middle-of-the-road position as a result.¹⁵⁶ When the original proposal was submitted to the TRIPS Council in October 2020, the Chinese delegation made the following declaration:

China is willing to discuss access to commodities in relation to the prevention and control of COVID-19, including medicines and vaccines under the framework of the TRIPS Agreement, and supports the discussions on possible waiver or other emergency measures to respond to the pandemic, which are “targeted, proportional, transparent and temporary”, and which do not create unnecessary barriers to trade or disruption to global supply chains.¹⁵⁷

Even though China continued to support the waiver negotiations at the TRIPS Council, it was neither a proponent nor a cosponsor of the proposal.¹⁵⁸

with the former global general counsel of pharmaceutical manufacturer Cipla about the waiver and other pharmaceutical policies in India); Arul George Scaria, *NITI Aayog’s Position on Compulsory Licensing Fails Both Niti and Nyaya*, WIRE (May 29, 2021), <https://science.thewire.in/health/niti-aayog-position-compulsory-licensing-covid-19-vaccines-ip-waiver/> (“[T]he pharma lobby has been vehemently opposed to the waiver, primarily on the arguments that it would affect their incentives to engage in research in emerging challenges and that a waiver won’t help increase vaccine production.”).

152. See Patnaik, *supra* note 151 (“[T]he [Indian] government has consistently discouraged compulsory licenses and dissuaded everybody from applying for compulsory licenses.”); see also Scaria, *supra* note 151 (criticizing NITI Aayog’s stance on compulsory licensing).

153. TRIPS Agreement, *supra* note 6, art. 31.

154. Scaria, *supra* note 151.

155. See Hannah Kuchler & Aime Williams, *Vaccine Makers Say IP Waiver Could Hand Technology to China and Russia*, FIN. TIMES (Apr. 25, 2021), <https://www.ft.com/content/fa1e0d22-71f2-401f-9971-fa27313570ab> (“As industry lobbying has escalated in Washington, companies have warned in private meetings with US trade and White House officials that giving up the intellectual property rights could allow China and Russia to exploit platforms such as mRNA, which could be used for other vaccines or even therapeutics for conditions such as cancer and heart problems in the future.”); D. Ravi Kanth, *Big Pharma to Block TRIPS Waiver at WTO, Citing China & Russia*, THIRD WORLD NETWORK (Apr. 27, 2021), <https://www.twn.my/title2/wto.info/2021/ti210415.htm> (“Their latest bogey is that the temporary TRIPS waiver for suspending [intellectual property rights] in combating the COVID-19 pandemic ‘would risk handing novel technology to China and Russia’” (quoting Kuchler & Williams, *supra*)).

156. See Peter K. Yu, *China, the TRIPS Waiver and the Global Pandemic Response*, in INTELLECTUAL PROPERTY, COVID-19, AND THE NEXT PANDEMIC: DIAGNOSING PROBLEMS, DEVELOPING CURES (Madhavi Sunder & Sun Haochen eds., forthcoming 2023) [hereinafter INTELLECTUAL PROPERTY AND NEXT PANDEMIC] (discussing China’s position in the waiver debate).

157. Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 24, ¶ 977.

158. See *TRIPS Waiver Proposal*, *supra* note 4; *Revised TRIPS Waiver Proposal*, *supra* note 4.

Moreover, in the past decade, the positions taken by China in international intellectual property negotiations have become increasingly aligned with those of developed countries.¹⁵⁹ During the global pandemic, China-based Sinopharm and Sinovac derived substantial financial benefits from the international sale of COVID-19 vaccines.¹⁶⁰ In July 2021, the COVID-19 Vaccines Global Access Initiative (COVAX) entered into an agreement to purchase 550 million doses of COVID-19 vaccines from China, earning the ire of U.S. politicians, commentators, and the mass media.¹⁶¹ If adopted, the waiver would have undermined these commercial activities. It would also have complicated China's use of vaccine production and donation to engage in global pandemic diplomacy.¹⁶²

Notwithstanding the limited complications caused by the potential exclusion of China and India from the waiver, adding geographical limitations to the instrument could pose significant problems. Consider, for instance, the restriction of the waiver to African countries, the other suggested option reported by observers of the Quad consultations.¹⁶³ First, such a restriction would greatly weaken the benefits provided by the waiver. Many African countries, especially those in the least developed world, needed the waiver not just to foster adjustments to the domestic intellectual property system, but also to facilitate the export of COVID-19 products and technologies, due in large part to the lack of technical expertise and dependence on external support and assistance in those countries.¹⁶⁴ To some extent, an Africa-based restriction would repeat the

159. See Peter K. Yu, *Five Oft-Repeated Questions About China's Recent Rise as a Patent Power*, 2013 CARDOZO L. REV. DE NOVO 78, 113 ("It will . . . be no surprise if China is aligned with the developing world with respect to certain issues, but with the developed world with respect to others."); see also Peter K. Yu, *The RCEP and Trans-Pacific Intellectual Property Norms*, 50 VAND. J. TRANSNAT'L L. 673, 722 (2017) [hereinafter Yu, *RCEP and Trans-Pacific Norms*] ("Although [China, India, and other emerging countries] have yet to embrace the very high protection and enforcement standards found in the European Union, Japan, or the United States, they now welcome standards that are higher than what is currently available in the Asia-Pacific region.").

160. Julia Hollingsworth, *COVAX Signs Deal for 550 Million Chinese Covid-19 Vaccines amid Questions over Efficacy*, CNN (July 13, 2021, 4:07 AM), <https://www.cnn.com/2021/07/13/asia/covax-china-vaccines-intl-hnk/index.html>; see also China Power Team, *Is China's Covid-19 Diplomacy Succeeding?*, CTR. FOR STRATEGIC & INT'L STUD. (Oct. 26, 2021), <https://chinapower.csis.org/china-covid-medical-vaccine-diplomacy/> ("About 96 percent of Chinese vaccines were sold rather than donated, and 84 percent of Chinese vaccines were provided bilaterally, rather than through multilateral groupings such as COVAX.").

161. Hollingsworth, *supra* note 160.

162. Countries undertake pandemic diplomacy to gain soft power and goodwill through the donation or delivery of medical products and technologies to other countries or the support of these countries' policy positions. For discussions of China's pandemic diplomacy, see generally MARÍA EUGENIA BRIZUELA DE ÁVILA, RIYAD INSANALLY, CLAUDIA TREVISAN & BOSCO MARTI, *US-CHINA VACCINE DIPLOMACY: LESSONS FROM LATIN AMERICA AND THE CARIBBEAN* (Wazim Mowla ed., 2022); MARGARET MYERS, *CHINA'S COVID-19 DIPLOMACY IN LATIN AMERICA AND THE CARIBBEAN: MOTIVATIONS AND METHODS* (2021); Yu, *supra* note 156; China Power Team, *supra* note 160; Denny Roy, *China's Pandemic Diplomacy* (E.-W. Ctr., Analysis No. 144, 2020).

163. See Patnaik, *supra* note 146.

164. See Yu, *supra* note 82, at 887–91 (discussing the public health challenges for countries with insufficient or no capacity to manufacture generic drugs).

problem with the much criticized opt-out mechanism under article 31*bis*.¹⁶⁵ The more countries opted out or became ineligible, the fewer benefits the negotiated instrument would provide to the remaining WTO members, including those in Africa.

Second, the divide-and-conquer approach would greatly reduce the developing countries' collective leverage in pushing for the waiver, or for similar or complementary measures.¹⁶⁶ This bargaining approach has been widely used in international negotiations, especially by developed countries. For example, during the article 31*bis* negotiations, it is likely that the drafters had Africa in mind when developing an exception that would allow a country using article 31*bis* to harness economies of scale by exporting some of the licensed products to fellow members of a regional trade agreement.¹⁶⁷ Even though article 31*bis*.3 does not mention Africa by name, it provides a limited exception only to members of a regional trade agreement that has been notified under article XXIV of the General Agreement on Tariffs and Trade and that has "at least half of [its] current membership . . . made up of countries presently on the United Nations list of least developed countries."¹⁶⁸ Except in Africa, in which over thirty least developed countries are present, how likely will one be able to find a regional trade agreement in another continent that would fit the stipulated criteria?¹⁶⁹

Third, the geographical restriction in the waiver—whether for Africa or another continent—would be highly problematic from a public health

165. See *supra* text accompanying notes 130–33.

166. See generally Peter K. Yu, *Building Intellectual Property Coalitions for Development, in IMPLEMENTING THE WORLD INTELLECTUAL PROPERTY ORGANIZATION'S DEVELOPMENT AGENDA 79* (Jeremy de Beer ed., 2009) (discussing how the development of "intellectual property coalitions for development" can help developing countries strengthen their collective bargaining position, influence negotiation outcomes, and promote effective and democratic decision-making in the international intellectual property regime); Yu, *Access to Medicines*, *supra* note 71, at 384–87 (discussing the use of regional or pro-development fora to coordinate developing countries' efforts in the areas of public health, intellectual property, and international trade).

167. TRIPS Agreement, *supra* note 6, art. 31*bis*.3.

168. *Id.*

169. For comparison, Europe has no least developed country, North and South America has only one (Haiti), and Oceania has only three (Kiribati, the Solomon Islands, and Tuvalu), with the Solomon Islands graduating soon. See *Profiles of LDCs*, UNITED NATIONS, <https://www.un.org/ohrlls/content/profiles-ldcs> (last visited Jan. 28, 2023). With nine least developed countries, Asia is a possibility. *Id.* However, four of them (Bangladesh, Bhutan, Laos, and Nepal) will graduate soon, while the others are spread out from Southern Asia (Afghanistan, Cambodia, East Timor, and Myanmar) to Western Asia (Yemen), making the negotiation of a regional trade agreement highly unlikely. *Graduation from the LDC Category*, UNITED NATIONS, <https://www.un.org/development/desa/dpad/least-developed-country-category/ldc-graduation.html> (last visited Jan. 28, 2023). The strongest argument one could make in the provision's defense is that "regional trade agreement" can be loosely defined, as we have seen in recent plurilateral agreements—such as the Trans-Pacific Partnership Agreement and, to a lesser extent, the Regional Comprehensive Economic Partnership Agreement. Trans-Pacific Partnership Agreement, Feb. 4, 2016, <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>; Regional Comprehensive Economic Partnership Agreement, Nov. 15, 2020, <https://rcepsec.org/legal-text/>. Although both agreements included members from more than one continent, there is currently no similar agreement involving least developed countries. It is also very unlikely that the drafters of article 31*bis*.3 had loosely defined regional trade agreements in mind, considering that the negotiation of these plurilateral trade agreements did not emerge until the late 2000s.

standpoint. Viruses such as SAR-CoV-2 do not respect territorial borders,¹⁷⁰ and many countries in Asia and Latin America have faced similar COVID-19 challenges as those in Africa.¹⁷¹ To the extent that WTO members wanted to limit the waiver to only countries with a low level of economic development, one could not overlook the many low-income and lower-middle-income countries outside Africa.¹⁷² Indeed, many of these countries were the waiver's cosponsors.¹⁷³ Moreover, as we have painfully learned from SARS, H1N1, Ebola, and Zika, the easiest way to combat a virus is to target the place of outbreak.¹⁷⁴ By the time the virus has spread globally, it is just too late. With the continuous emergence of new variants of the SARS-CoV-2 virus, it would have been ill-advised to introduce arbitrary geographical restrictions while knowing full well that global coordination remains the key to ending the global pandemic and that "no-one is safe until everyone is safe."¹⁷⁵

Finally, and surprising to some, reports suggested that African countries had suffered fewer fatalities and infections during the initial wave of COVID-19 than countries in other continents.¹⁷⁶ Because of the younger age profile of the African population,¹⁷⁷ the earlier variants of the virus did not seem to have affected the continent as much, although experts suggested that the fatalities and infections were likely many times higher than reported, due to undercounting and weak health surveillance.¹⁷⁸ Regardless of the pandemic's health impact in Africa, there is no denying that the continent has been devastated by the global

170. See sources cited *supra* note 77.

171. See WHO *Coronavirus (COVID-19) Dashboard*, *supra* note 1 (providing regional comparisons on confirmed cases and deaths).

172. See *Low Income*, WORLD BANK, <https://data.worldbank.org/country/XM> (last visited Jan. 28, 2023) (listing low-income countries); *Lower Middle Income*, WORLD BANK, <https://data.worldbank.org/country/XN> (last visited Jan. 28, 2023) (listing lower middle-income countries).

173. See *Revised TRIPS Waiver Proposal*, *supra* note 4.

174. See SARA E. DAVIES, GLOBAL POLITICS OF HEALTH 140 (2012) ("The first line of defence is prevention, treatment and control programs before the disease reached US shores." (internal quotation marks omitted)); Kathryn White & Maria Banda, *The Role of Civil Society in Pandemic Preparedness*, in INNOVATION IN GLOBAL HEALTH GOVERNANCE 105, 118 (Andrew F. Cooper & John J. Kirton eds., 2009) ("Instead of hoarding the vaccine, the West ought to release it to the most vulnerable, because the regions the first to be hit would also be the first line of defence."); see also John D. Kraemer & Mark J. Siedner, *The Effect of Ebola Virus Disease on Health Outcomes and Systems in Guinea, Liberia, and Sierra Leone*, in GLOBAL MANAGEMENT OF INFECTIOUS DISEASE AFTER EBOLA 55, 67 (Sam F. Halabi et al. eds., 2017) (noting that resources "would likely be more cost-effectively deployed" to prevent epidemics than to control them).

175. E.g., *The Access to COVID-19 Tools (ACT) Accelerator*, WORLD HEALTH ORG., <https://www.who.int/initiatives/act-accelerator> (last visited Jan. 28, 2023).

176. See Broadbent & Smart, *supra* note 106 (noting the different impacts of COVID-19 in Africa).

177. See Peter Beaumont, *Africa Transitioning Out of Pandemic Phase of Covid*, WHO SAYS, GUARDIAN (Feb. 10, 2022, 8:39 AM), <https://www.theguardian.com/world/2022/feb/10/africa-transitioning-out-of-pandemic-phase-of-covid-who-says> ("Some have suggested that the much younger age profile across countries on the continent may have contributed, but a consensus is coalescing around significant undercounting in countries with weak health surveillance systems that have failed to pick up both infections and deaths over the past two years.")

178. See *id.* (reporting the observation of a WHO Regional Director for Africa that "the number of Covid infections in Africa could be seven times higher than official data suggests, and deaths from the virus two to three times higher").

economic fallout caused by COVID-19, whether in terms of lost trade or tourism receipts.¹⁷⁹ As a result, developing an effective global solution is crucial, even if we focus only on post-pandemic recovery in Africa.

In sum, there are many challenges in the international negotiation process. The complications around the early reported suggestions of excluding China and India from the waiver or introducing an Africa-based geographical restriction illustrate some of these challenges well. These complications show that the debate was not simply about whether the waiver should be adopted—the focus of Part I—but how the instrument, upon adoption, was to be operationalized and whether the chosen modalities could address the prevailing trade concerns of some powerful WTO members.¹⁸⁰ Until WTO members can come to a consensus on how to move forward, some members will oppose or resist negotiations, while others will deploy divide-and-conquer strategies to weaken the position of the *demandeur* countries or look for arguments or mechanisms to reduce the scope and applicability of the proposed waiver.¹⁸¹ The negotiated outcome will therefore become a much weaker instrument for combatting COVID-19 than the one originally conceived.

B. DOMESTIC IMPLEMENTATION CHALLENGES

Subpart A has identified various international negotiation challenges. This Subpart turns to domestic implementation challenges. Specifically, this Subpart discusses three sets of challenges: (1) incoherent policy positions taken at the WTO and in national capitals; (2) domestic legal constraints, including those relating to regulatory takings or expropriation of property; and (3) compliance with international treaty obligations outside the WTO, such as international investment agreements.

1. *Incoherent Policy Positions*

Commentators have noted the divide between positions asserted in national capitals and those taken in international treaty negotiations, such as those at the

179. See Broadbent & Smart, *supra* note 106 (“In Africa, millions will starve if the global economy enters a protracted downturn. We must ask whether the number will be more than COVID-19 will kill in a region where only 6.09% of the population is over 65.”); Davina Stanford & Adama Bah, *African Tourism Has Been Put on Ice by Coronavirus—Here’s How Some Countries Are Reviving It*, THE CONVERSATION (June 15, 2020, 4:21 AM), <https://theconversation.com/african-tourism-has-been-put-on-ice-by-coronavirus-heres-how-some-countries-are-reviving-it-140508> (“Tourism accounts for 9% of Kenya’s GDP and 20% in the Gambia. It provides a living to around 10% of Kenyans and nearly a fifth of Gambians, while acting as an important source of foreign exchange.”).

180. See Bryan Mercurio, *Sharpening the Tools in the Pandemic-Ending Toolbox*, THINK GLOB. HEALTH (June 23, 2022), <https://www.thinkglobalhealth.org/article/sharpening-tools-pandemic-ending-toolbox> (asking whether industrial policy or global public health was a key determinant for the negotiations on the Ministerial Decision).

181. See D. Ravi Kanth, *TRIPS Waiver Gains More Support Despite Efforts to Stall Its Passage*, THIRD WORLD NETWORK (Dec. 11, 2020), <https://www.twn.my/title2/health.info/2020/hi201208.htm> (noting “the relentless efforts by the US, the EU, Japan, Switzerland, Canada and other developed countries to stall the passage of the waiver”).

WTO and WIPO.¹⁸² For many countries, what is discussed in Geneva outposts does not always resonate with the policies and politics in national capitals. Even though more than sixty countries endorsed the proposal for the COVID-19 TRIPS waiver as either proponents or cosponsors, it remains unclear how many of these countries would be ready to implement the waiver domestically upon the instrument's adoption. It is one thing to support the international negotiations for the waiver, but quite another to support domestic legislative changes needed to implement that waiver.

The previous Subpart has already noted the internal opposition to the waiver proposal within India that would have created domestic implementation challenges.¹⁸³ Unlike Israel, Hungary, and Russia—the three countries that issued compulsory licenses to increase access to pharmaceuticals during the pandemic¹⁸⁴—India did not do so, due in large part to strong domestic opposition.¹⁸⁵ India, however, was not the only country that declined to maximize the use of flexibilities under the TRIPS Agreement to combat COVID-19. None of the sixty-plus proponents or cosponsors of the waiver proposal issued a compulsory license during the pandemic.¹⁸⁶ Nor did these countries introduce legislation to take advantage of the national security exception under article 73 of the TRIPS Agreement.¹⁸⁷ If those WTO members strongly backing the waiver were reluctant to embrace progressive measures at home to combat the global pandemic, one has to wonder how likely they would be to introduce legislation to suspend close to half of the provisions in the TRIPS Agreement. One might also query whether these countries would decline to introduce waiver-related legislation in exchange for a reliable supply of reasonably priced vaccines from multinational pharmaceutical companies or for their ability to enter into cooperative agreements with these companies.¹⁸⁸

It is possible that some of these countries would become more willing to introduce waiver-related legislation once the WTO had adopted the instrument and its developed country members turned around to extend enthusiastic support. Such support would alleviate their concerns about political repercussions from these powerful trading partners, such as the USTR's retaliatory measures following the issuance of compulsory licenses to meet

182. See DEERE, *supra* note 65, at 214 (noting the weak coordination between delegates in Geneva and their counterparts in national capitals and the incoherent policy positions taken by these two groups); Peter K. Yu, *ACTA and Its Complex Politics*, 3 WIPO J. 1, 14 (2011) (“[T]he positions taken by national leaders can be heavily skewed by political payoffs—or, worse, nepotism and corruption. Due to a lack of coordination and other reasons, the positions taken by policymakers in the capitals can be quite different from those residing in diplomatic outposts.” (citation omitted)).

183. See *supra* text accompanying notes 151–54.

184. Kianzad & Wested, *supra* note 32, at 74; Médecins Sans Frontières, *supra* note 52, at 5–6.

185. See *supra* text accompanying notes 151–54.

186. Israel, Hungary, and Russia were neither proponents nor cosponsors of the waiver proposal. See *TRIPS Waiver Proposal*, *supra* note 4; *Revised TRIPS Waiver Proposal*, *supra* note 4.

187. TRIPS Agreement, *supra* note 6, art. 73.

188. See Bostyn, *supra* note 7, at 12 (advancing the scenario in which countries would decline to invoke the waiver in exchange for the supply of attractively priced vaccines).

public health needs.¹⁸⁹ Nevertheless, as Parts I and II.A have shown, the waiver proposal was quite controversial at the TRIPS Council, and the countries eventually abandoned that proposal in the run-up to MC12.¹⁹⁰ Given the controversial nature of this proposal, it would not be misguided to assume that some developed countries might never enthusiastically support waiver-related legislation. Without strong support from these powerful countries, many WTO members, including the waiver's proponents and cosponsors, would likely have second thoughts about adopting legislation to implement the instrument.

2. Domestic Legal Constraints

Another set of challenges concerns the legal constraints that would have affected the waiver's domestic implementation. Before the waiver could take effect on domestic soil, countries would need to modify existing intellectual property laws. Consider the United States, for instance. The WTO's adoption of the waiver alone would have affected only its members' TRIPS obligations. Because the United States is a non-self-executing jurisdiction in relation to these obligations,¹⁹¹ the waiver would have no legal effect within the country, other than perhaps some influence on the interpretation of preexisting laws.¹⁹² If the waiver were to take effect, Congress would have to enact laws to allow for the limited suspension of intellectual property rights in the area of copyrights, industrial designs (and trade dresses), patents, and trade secrets for the purposes of combating COVID-19.

Moreover, some countries might consider the introduction of waiver-related legislation as a regulatory taking or an expropriation of property. In the United States, it remains unclear whether legislation suspending intellectual property rights for public health purposes would amount to such a taking.¹⁹³ For those COVID-19 inventions that are publicly funded, the march-in rights under

189. See sources cited *supra* note 69.

190. See discussion *supra* Parts I–II.A.

191. The Berne Convention, for example, does not have legal effect on U.S. soil except through the Berne Convention Implementation Act of 1988. See, e.g., *Itar-Tass Russian News Agency v. Russian Kurier, Inc.*, 153 F.3d 82, 90 (2d Cir. 1998) (noting that the authoritative Nimmer treatise “moves too quickly past the Berne Convention Implementation Act of 1988”); *Bridgeman Art Libr., Ltd. v. Corel Corp.*, 36 F. Supp. 2d 191, 195 (S.D.N.Y. 1999) (explaining the importance that the “Berne Convention is not self-executing”).

192. See *Murray v. The Schooner Charming Betsy*, 6 U.S. (2 Cranch) 64, 118 (1804) (“An act of Congress ought never to be construed to violate the law of nations, if any other possible construction remains.”). See generally Justin Hughes, *The Charming Betsy Canon, American Legal Doctrine, and the Global Rule of Law*, 53 *VAND. J. TRANSNAT'L L.* 1147, 1151–63 (2020) (discussing the *Charming Betsy* doctrine).

193. For discussions of government takings in the intellectual property context under U.S. law, see generally Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro®: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 *AM. BUS. L.J.* 125 (2002); Thomas F. Cotter, *Do Federal Uses of Intellectual Property Implicate the Fifth Amendment?*, 50 *FLA. L. REV.* 529 (1998); Shubha Ghosh, *Toward a Theory of Regulatory Takings for Intellectual Property: The Path Left Open After College Savings v. Florida Prepaid*, 37 *SAN DIEGO L. REV.* 637 (2000).

the Bayh-Dole Act could help the government avoid a taking claim.¹⁹⁴ As John Thomas describes:

The Bayh-Dole Act provides the government with the ability to “march in” and grant licenses for patents that resulted from publicly funded [research and development]. In particular, march-in rights allow the federal government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. The terms of the license must be “reasonable under the circumstances.”¹⁹⁵

In addition, to the extent that the federal government and its contractors have used patented products and technologies without authorization, § 1498(a) of Title 28 provides rights holders with a means to seek “reasonable and entire compensation.”¹⁹⁶ Notwithstanding these arguments against potential taking claims, legislators who believed that the waiver-induced suspension would amount to a regulatory taking would be reluctant to introduce or support implementing legislation. Such legislation, if enacted, could also invite protracted litigation that would delay, if not derail, the waiver’s implementation.

Moreover, some countries might have constitutional or fundamental right provisions that would prevent intellectual property rights from being suspended without due compensation. The European Union, for example, protects certain aspects of intellectual property rights as fundamental rights. The right to property provision in article 17(2) of the Charter of Fundamental Rights of the

194. See 35 U.S.C. § 203 (providing for march-in rights). Notwithstanding this possibility, the government has never exercised march-in rights. See JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT I (2016) (“[M]arch-in rights have never been exercised during the 35-year history of the Bayh-Dole Act. In particular, the National Institutes of Health . . . has received six march-in petitions and has denied each one.” (citation omitted)).

195. THOMAS, *supra* note 194, at 7.

196. See 28 U.S.C. § 1498(a) (providing for “the recovery of . . . reasonable and entire compensation for such use and manufacture, . . . including reasonable fees for expert witnesses and attorneys”); see also Mary Ellen Coster Williams & Diane E. Ghrist, *Intellectual Property Suits in the United States Court of Federal Claims*, 10 LANDSLIDE 30, 34–35 (2017) (discussing the remedies available under 28 U.S.C. § 1498). See generally Christopher J. Morten & Charles Duan, *Who’s Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1 (2020) (discussing the role of § 1498 in the context of national crises and emergencies like COVID-19). It is important to recognize that § 1498 provides compensation for the government’s use or manufacture of patented products and technologies, but not for the suspension of patent rights. See *id.* Thus far, the global pharmaceutical industry and its supporters have heavily criticized § 1498. *Id.* at 29. Nevertheless, a recent review by Knowledge Ecology International of sixty-two COVID 19-related research-and-development or procurement contracts involving the U.S. government shows that fifty-four “included the broadest authorization for non-voluntary use of patented inventions, and five included a more limited authorization.” James Love, *KEI Review of 62 COVID 19 Contracts Reveals 59 Authorizations for Non-Voluntary Use of Third Party Patents Under 28 USC 1498*, KNOWLEDGE ECOLOGY INT’L (July 20, 2022), <https://www.keionline.org/37987>; see also *166 Contracts Disclosed in SEC Filings Include Authorizations to Use U.S. Patents Without Consent from Patent Holders*, KNOWLEDGE ECOLOGY INT’L (Oct. 12, 2022) (noting that “166 contracts disclosed to the U.S. Securities and Exchange Commission . . . permit companies to use patented inventions without the consent of patent holders”).

European Union explicitly covers intellectual property.¹⁹⁷ Article 1 of the Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms further provides: “Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.”¹⁹⁸ These fundamental rights would therefore create complications for the domestic implementation of the waiver.

3. *Compliance with International Treaty Obligations*

A third set of implementation challenges pertains to the tensions and conflicts the waiver might pose to a country’s international treaty obligations. Because the waiver would have only affected obligations under the TRIPS Agreement, it would not have affected other international obligations, such as those in WIPO-administered agreements or bilateral, regional, or plurilateral trade and investment agreements. To ensure that countries do not breach their obligations under TRIPS-plus free trade agreements and international investment agreements, the South Centre called for the negotiation of complementary waivers to preempt conflicts.¹⁹⁹ Meanwhile, Henning Grosse Ruse-Khan and Federica Paddeu argue that internal and general defenses under public international law and within international trade and investment agreements would have supported the waiver’s domestic implementation.²⁰⁰

For many countries, especially in the developing world, noncompliance with multilateral and regional trade agreements would not be their only concern. They would also worry about potential conflicts with their international investment agreements.²⁰¹ While the TRIPS Agreement provides for state-to-state dispute settlement,²⁰² international investment agreements support investor-state dispute settlement, which enables private companies to sue host states without the involvement of their home governments.²⁰³ In recent years,

197. See Charter of Fundamental Rights of the European Union art. 17(2), Dec. 7, 2000, 2000 O.J. (C 364) 1 (“Intellectual property shall be protected.”). See generally OLE-ANDREAS ROGNSTAD, PROPERTY ASPECTS OF INTELLECTUAL PROPERTY (2018) (discussing the property aspects of intellectual property rights).

198. Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms art. 1, Mar. 20, 1952, 213 U.N.T.S. 262.

199. See Correa et al., *supra* note 7, at 20.

200. See generally Grosse Ruse-Khan & Paddeu, *supra* note 7.

201. For discussions of these potential conflicts, see generally Bryan Mercurio & Pratyush Nath Upreti, *The Legality of a TRIPS Waiver for Covid-19 Vaccines Under International Investment Law*, 71 INT’L & COMPAR. L.Q. 323 (2022); Correa et al., *supra* note 7; Grosse Ruse-Khan & Paddeu, *supra* note 7.

202. See TRIPS Agreement, *supra* note 6, art. 64 (providing for state-to-state dispute settlement through the WTO Dispute Settlement Body).

203. For comparison between state-to-state and investor-state dispute settlement, see generally Peter K. Yu, *State-to-State and Investor-State Copyright Dispute Settlement*, in LE DROIT D’AUTEUR EN ACTION: PERSPECTIVES INTERNATIONALES SUR LES RECOURS 421 (Ysolde Gendreau ed., 2019); Peter K. Yu, *The Pathways of Multinational Intellectual Property Dispute Settlement*, in INTELLECTUAL PROPERTY AND

investor-state disputes have begun to emerge in the intellectual property context.²⁰⁴ Notable disputes include cases brought by Philip Morris against Australia and Uruguay,²⁰⁵ Eli Lilly against Canada,²⁰⁶ Bridgestone against Panama,²⁰⁷ and the Einarssons and Geophysical Service Inc. against Canada.²⁰⁸ Since the beginning of the COVID-19 pandemic, some transnational firms have also filed, or threatened to file, investor-state complaints against developing countries to challenge pandemic-related emergency relief measures.²⁰⁹

To be sure, countries may remain reluctant to file state-to-state complaints during and shortly after the global pandemic, in view of the tremendous public health challenges confronting national governments and to avoid bad publicity and international relations. Nevertheless, private companies, such as developers of pharmaceuticals and medical technologies, can use investor-state dispute settlement mechanisms to sue host states.²¹⁰ Indeed, as we have learned from the disputes involving Eli Lilly and Philip Morris, the home government's refusal

INTERNATIONAL DISPUTE RESOLUTION 123 (Christopher Heath & Anselm Kamperman Sanders eds., 2019) [hereinafter Yu, *Pathways*].

204. For book-length treatment of investor-state disputes in the intellectual property context, see generally SIMON KLOPSCHINSKI, CHRISTOPHER S. GIBSON & HENNING GROSSE RUSE-KHAN, *THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS UNDER INTERNATIONAL INVESTMENT LAW* (2021); EMMANUEL K. OKE, *THE INTERFACE BETWEEN INTELLECTUAL PROPERTY AND INVESTMENT LAW: AN INTERTEXTUAL ANALYSIS* (2021); RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND INVESTMENT LAW (Christophe Geiger ed., 2020); LUKAS VANHONNAEKER, *INTELLECTUAL PROPERTY RIGHTS AS FOREIGN DIRECT INVESTMENTS: FROM COLLISION TO COLLABORATION 200–20* (2015). For the Author's discussions in this area, see generally Peter K. Yu, *Investor-State Dispute Settlement and the Trans-Pacific Partnership*, in *INTELLECTUAL PROPERTY AND THE JUDICIARY* 463 (Christophe Geiger et al. eds., 2018); Yu, *Pathways*, *supra* note 203; Peter K. Yu, *The Second Transformation of the International Intellectual Property Regime*, in *GLOBAL INTELLECTUAL PROPERTY PROTECTION AND NEW CONSTITUTIONALISM: HEDGING EXCLUSIVE RIGHTS* 176 (Jonathan Griffiths & Tuomas Mylly eds., 2021); Peter K. Yu, *Crossfertilizing ISDS with TRIPS*, 49 *LOY. U. CHI. L.J.* 321 (2017) [hereinafter Yu, *Crossfertilizing ISDS with TRIPS*]; Peter K. Yu, *The Investment-Related Aspects of Intellectual Property Rights*, 66 *AM. U. L. REV.* 829 (2017) [hereinafter Yu, *Investment-Related Aspects*].

205. Philip Morris Asia Ltd. v. Commonwealth of Austl., UNCITRAL, PCA Case No. 2012-12, Award on Jurisdiction and Admissibility (Dec. 17, 2015); Philip Morris Brands Sàrl v. Oriental Republic of Uru., ICSID Case No. ARB/10/7, Award (July 8, 2016).

206. Eli Lilly & Co. v. Gov't of Can., ICSID Case No. UNCT/14/2, Final Award (Mar. 16, 2017).

207. Bridgestone Licensing Servs., Inc. v. Republic of Panama, ICSID Case No. ARB/16/34, Award (Aug. 14, 2020).

208. Einarsson v. Gov't of Can., Notice of Arbitration (Apr. 18, 2019), https://www.italaw.com/sites/default/files/case-documents/italaw11478_0.pdf.

209. For discussions of these complaints, see generally Jason Haynes & Antonius R. Hippolyte, *The Covid-19 Pandemic and the Potential for Investor-State Claims: A Caribbean Perspective*, 21 *OXFORD U. COMMONWEALTH L.J.* 212 (2021); Valentina Vadi, *Crisis, Continuity, and Change in International Law and Arbitration*, 42 *MICH. J. INT'L L.* 321 (2021); Cecilia Olivet & Bettina Müller, *Juggling Crises: Latin America's Battle with COVID-19 Hampered by Investment Arbitration Cases*, *TRANSNAT'L INST.* (Aug. 25, 2020), <https://longreads.tni.org/jugglingcrises>. See generally Rochelle Cooper Dreyfuss, *ISDS and Intellectual Property in 2020: Protecting Public Health in the Age of Pandemics*, in *YEARBOOK ON INTERNATIONAL INVESTMENT LAW & POLICY* 2020, at 206 (Lisa E. Sachs et al. eds., 2022) (discussing intellectual property-related investor-state disputes in the pandemic context).

210. Cf. Mercurio, *supra* note 7, at 27 (“[I]t is extremely unlikely that any Member would file a WTO complaint and initiate dispute settlement against a developing country Member invoking Article 73.”).

to initiate state-to-state disputes may pave the way for intellectual property rights holders in that country to take matters into their own hands.²¹¹

C. THE ENTANGLEMENT OF INTERNATIONAL AND DOMESTIC CHALLENGES

The previous two Subparts have identified two different sets of challenges confronting efforts to operationalize the waiver: international negotiations and domestic implementation. Drawing from the literature on international treaty negotiations, including those in the intellectual property area, this Part shows why these two sets of challenges were neither separate nor sequential. Instead, they were deeply entangled at the time of the international negotiations. This entanglement helps explain the difficult choices confronting WTO members during the waiver negotiations at the TRIPS Council, including why these members ultimately adopted the Ministerial Decision in lieu of the proposed waiver.

Issues relating to the interplay between international negotiations and domestic politics are not new. They arise quite frequently in the negotiation of free trade and economic partnership agreements, virtually all of which contain a detailed intellectual property chapter.²¹² In relation to these agreements, commentators have expressed concern that powerful countries succumbing to pressure from domestic interest groups may introduce provisions that are considered unpopular at home.²¹³ They also fear that domestic political payoffs will create perverse incentives that undermine the integrity and health of the multilateral trading system.²¹⁴ As Chad Damro laments:

The domestic demand for reciprocity may lead governments to pursue [a regional trade agreement] for narrow domestic political gain. They will pursue [these agreements] based on their own political horizons—i.e., when is the next election? These domestic political calculations are not consistently tied to the potential long-term benefits of the liberal, multilateral trading system.²¹⁵

211. See Yu, *Pathways*, *supra* note 203, at 131 (“[D]espite the wish of Philip Morris and other relevant intellectual property right holders, the United States declined to use [state-to-state dispute settlement] to challenge the tobacco plain packaging regulations in Australia and Uruguay. Likewise, the United States refused to file a WTO complaint against Canada over its use of the so-called ‘promise doctrine’ in patent law to invalidate Eli Lilly’s patents on the hyperactivity drug Strattera (atomoxetine) and the anti-psychotic drug Zyprexa (olanzapine).”).

212. See, e.g., Dominican Republic–Central America Free Trade Agreement, ch. 15, Aug. 5, 2004, <http://www.ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text>; United States–Australia Free Trade Agreement, Austl.-U.S., ch. 17, May 18, 2004, <https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text>; United States–Singapore Free Trade Agreement, Sing.-U.S., ch. 16, May 6, 2003, <https://ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text>.

213. See Peter K. Yu, *Sinic Trade Agreements*, 44 U.C. DAVIS L. REV. 953, 983–86 (2011) (discussing these concerns).

214. See Chad Damro, *The Political Economy of Regional Trade Agreements*, in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM 23, 37 (Lorand Bartels & Federico Ortino eds., 2006).

215. *Id.*; see also Helen Milner, *Regional Economic Co-Operation, Global Markets and Domestic Politics: A Comparison of NAFTA and the Maastricht Treaty*, in REGIONALISM AND GLOBAL ECONOMIC INTEGRATION:

While domestic pressure has undoubtedly influenced international negotiations, governments have also utilized these negotiations to push through domestic policies to which they have encountered resistance at home. For many developing countries, international pressure and multilateral treaty negotiations can provide the needed impetus to push through local intellectual property reform.²¹⁶ In this scenario, foreign pressure helps counter entrenched, and often short-sighted, local interests. As I have noted in the Chinese context, as eager as the United States and other developed countries have been in pushing for intellectual property reforms in China, reformist leaders in the country have also taken advantage of this external pressure to push for their preferred reforms and to ward off resistance from their conservative counterparts.²¹⁷

The use of international negotiations to drive domestic intellectual property reforms is not limited to developing countries, however. When used by developed countries, such negotiation tactics have led to what commentators have criticized as “policy laundering”²¹⁸—efforts “to have policy initiatives seen

EUROPE, ASIA AND THE AMERICAS 19, 30 (William D. Coleman & Geoffrey R.D. Underhill eds., 1998) (“The [U.S.] administration was counting on [the North American Free Trade Agreement] as ‘a vote-winner for President Bush.’ The prospect of increased growth, competitiveness and jobs motivated political leaders. Domestic politics also shaped the Canadian government’s attitudes: ‘Like President Bush, Mr Mulroney is expected to use positive features of the trade agreement in his own bid for reelection.’” (citation omitted)).

216. See Peter K. Yu, *Intellectual Property, Economic Development, and the China Puzzle*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA 173, 185–88 (Daniel J. Gervais ed., 1st ed. 2007) (discussing the use of external pressure to push for intellectual property reforms in China).

217. See Peter K. Yu, *The Copyright Divide*, 25 CARDOZO L. REV. 331, 440 (2003) (noting that external pressure has “provid[ed] the reformist leaders with the needed push that helped reduce resistance from their conservative counterparts”); Yu, *RCEP and Trans-Pacific Norms*, *supra* note 159, at 726 (“To many reformist leaders, having their hands tied by international treaties can sometimes be used as an effective weapon against hardline leaders and conservative critics at home.”); Peter K. Yu, *The TRIPS Enforcement Dispute*, 89 NEB. L. REV. 1046, 1107 (2011) (“In China, the reformists are constantly challenged by their more conservative counterparts, who are uncomfortable with the country’s rapid socio-economic changes and the resulting social ills. By providing the much-needed external push that helps reduce resistance from conservative leaders, the panel report [in *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*] has helped accelerate reforms in the area of intellectual property protection and enforcement.” (citation omitted)); see also MARK A. GROOMBRIDGE & CLAUDE E. BARFIELD, *TIGER BY THE TAIL: CHINA AND THE WORLD TRADE ORGANIZATION* 41 (1999) (“An international institution such as the WTO can help bolster China’s reform leadership against powerful hard-liners. International institutions can tie the hands of leaders in ways that the ineffectual bilateral relationship is not able to do so.”); Michael E. DeGolyer, *Western Exposure, China Orientation: The Effects of Foreign Ties and Experience on Hong Kong*, in THE OUTLOOK FOR U.S.-CHINA RELATIONS FOLLOWING THE 1997–1998 SUMMITS: CHINESE AND AMERICAN PERSPECTIVES ON SECURITY, TRADE AND CULTURAL EXCHANGE 299, 300 (Peter Koehn & Joseph Y.S. Cheng eds., 1999) (“[Economic integration] would help the reformers tilt the internal Chinese debate in directions that would minimize, if not avoid, future economic conflicts. It would encourage and perhaps accelerate the inevitable transformation of China’s political regime.” (internal quotation marks omitted)); ZHANG ZHENQING, INTELLECTUAL PROPERTY RIGHTS IN CHINA 172 (2019) (“While the development of Chinese trademark works constituted the internal driving force for further progress of the Chinese trademark regime, negotiations with the United States provided a window of opportunity for Chinese trademark professionals to ‘lock in’ their legislative agenda.”).

218. For discussions of “policy laundering,” see generally David Banisar, *Stopping Science: The Case of Cryptography*, 9 HEALTH MATRIX 253, 282–86 (1999); Ian Hosein, *The Sources of Laws: Policy Dynamics in a Digital and Terrorized World*, 20 INFO. SOC’Y 187, 188–89 (2004); Yu, *supra* note 65, at 1024–28; Peter K. Yu, *The Political Economy of Data Protection*, 84 CHI.-KENT L. REV. 777, 786–91 (2010).

as exogenously determined, or even seen as requirements imposed by powerful others.”²¹⁹ A textbook example of policy laundering in the intellectual property context is the introduction of anti-circumvention protection through section 1201 of the U.S. Copyright Act.²²⁰ Noting the lack of traction in Congress to enact new laws to offer such protection, the Clinton Administration sought to make “an end run around Congress” by establishing new internet treaties at the 1996 WIPO Diplomatic Conference in Geneva.²²¹ Once the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty had been adopted, with provisions requiring anti-circumvention protection,²²² the lawmaking efforts returned to U.S. soil. In addition to domestic policymaking, the new legislative debates considered the need to implement newfound international obligations, which would not have existed without the policy-laundering tactics in the first place.²²³

In the TRIPS context, Ruth Okediji has shown how the interplay between international diplomacy and domestic politics in the negotiation process and the resulting compromises can continue to impact the domestic implementation process in a “two-stage game.”²²⁴ With the first stage focusing on international negotiations and the second stage targeting domestic implementation or treaty compliance, this game recognizes “the competing functions of the state in its

219. Bill D. Herman & Oscar H. Gandy, Jr., *Catch 1201: A Legislative History and Content Analysis of the DMCA Exemption Proceedings*, 24 *CARDOZO ARTS & ENT. L.J.* 121, 128 (2006).

220. 17 U.S.C. § 1201.

221. Pamela Samuelson, *The U.S. Digital Agenda at WIPO*, 37 *VA. J. INT'L L.* 369, 374 (1997); *see also id.* at 375–439 (discussing the 1996 WIPO diplomatic conference); Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 *LOY. L.A. L. REV.* 323, 369–74 (2004) (same).

222. WIPO Copyright Treaty art. 11, Dec. 20, 1996, 2186 U.N.T.S. 121; WIPO Performances and Phonograms Treaty art. 18, Dec. 20, 1996, 2186 U.N.T.S. 203.

223. *See* Samuelson, *supra* note 221, at 374 (noting that, had the Clinton Administration succeeded in pushing for the adoption of a new WIPO database treaty, “officials would almost certainly have . . . argued to Congress that ratification of the treaties was necessary to confirm U.S. leadership in the world intellectual property community and to promote the interests of U.S. copyright industries in the world market for information products and services”); Yu, *supra* note 218, at 787 (“When Congress deliberates treaty-implementing legislation, the main focus of the policy debate may no longer be whether the policy would benefit the American economy—or, better, the American people. Instead, the focus may become whether the failure to adopt such a policy would isolate the country from the international community.”).

224. As she observes:

The first stage of the game is the negotiation of TRIPS. This stage was characterized by coordination of developed country standards in order to facilitate a common bargaining position. As with coordination games, developed countries, notwithstanding their own policy differences, recognized that they were each better off with an agreement than with none. This resulted in coalitions between developed countries that made negotiation of a global set of standards a feasible objective.

The stage two game is the . . . process [for enforcing the TRIPS Agreement through the WTO dispute settlement process]. Having accomplished the primary goal of binding developing countries to high standards of intellectual property protection, developed countries must now deal with the costs of “winning” the first stage game. These include constraints on sovereign discretion in the area of policy development, and battles over extant policy differences between the member states.

Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 *EMORY INT'L L. REV.* 819, 823 (2003).

capacity as domestic social welfare planner, international negotiator, and enforcer of negotiated rules.”²²⁵ As she explains, “the players are able to anticipate the moves at the second stage of the game” in international negotiations.²²⁶ As a result, when they play the first-stage game, they try to avoid reaching negotiated outcomes that would make it difficult for their government to play the second-stage game.

As far as the mindsets of international negotiators are concerned, there is no more influential framework than the one advanced by political scientist Robert Putnam in the late 1980s.²²⁷ That model seeks to account for the interplay between international diplomacy and domestic politics in the development of international treaties:²²⁸

The politics of many international negotiations can usefully be conceived as a two-level game. At the national level, domestic groups pursue their interests by pressuring the government to adopt favorable policies, and politicians seek power by constructing coalitions among those groups. At the international level, national governments seek to maximize their own ability to satisfy domestic pressures, while minimizing the adverse consequences of foreign developments. Neither of the two games can be ignored by central decision-makers, so long as their countries remain interdependent, yet sovereign.

Each national political leader appears at both game boards. Across the international table sit his foreign counterparts, and at his elbows sit diplomats and other international advisors. Around the domestic table behind him sit party and parliamentary figures, spokespersons for domestic agencies, representatives of key interest groups, and the leader’s own political advisors. The unusual complexity of this two-level game is that moves that are rational for a player at one board . . . may be impolitic for that same player at the other board. Nevertheless, there are powerful incentives for consistency between the two games.²²⁹

Thus, if policymakers are to succeed in international negotiations—such as those on the COVID-19 TRIPS waiver—they will need to get buy-in at both the international and domestic levels. In Professor Putnam’s game-theory terms, policymakers will need to develop an overlapping win-set that will accommodate the preferences of two rather different audiences.²³⁰ After all, “[a]ny key player at the international table who is dissatisfied with the outcome

225. *Id.* at 863.

226. *Id.* at 866.

227. See generally Robert D. Putnam, *Diplomacy and Domestic Politics: The Logic of Two-Level Games*, 42 INT’L ORG. 427 (1988) (discussing the two-level game involved in international treaty negotiations); DOUBLE-EDGED DIPLOMACY: INTERNATIONAL BARGAINING AND DOMESTIC POLITICS (Peter B. Evans et al. eds., 1993) [hereinafter DOUBLE-EDGED DIPLOMACY] (providing a collection of essays inspired by this highly influential article).

228. See Putnam, *supra* note 227, at 430.

229. *Id.* at 434.

230. See *id.* at 435–53 (discussing the importance of win-sets).

may upset the game board, and conversely, any leader who fails to satisfy his fellow players at the domestic table risks being evicted from his seat.”²³¹

Even more complicated are the constraints a state has in the domestic game that could ultimately affect its negotiators’ leverage in the international game. As Thomas Schelling observes, “the power of a negotiator often rests on a manifest inability to make concessions and meet demands.”²³² Likewise, Professor Putnam notes:

The larger the perceived win-set of a negotiator, the more he can be “pushed around” by the other . . . negotiators. Conversely, a small domestic win-set can be a bargaining advantage: “I’d like to accept your proposal, but I could never get it accepted at home.” Lamenting the domestic constraints under which one must operate is (in the words of one experienced British diplomat) “the natural thing to say at the beginning of a tough negotiation.”²³³

To maximize negotiation space, negotiators thus have strong incentives to emphasize the implementation challenges at home—whether candidly or as a negotiation tactic.²³⁴ Meanwhile, negotiators in other countries will try hard to achieve better negotiated outcomes by evaluating the domestic constraints of their counterparts²³⁵ while making informed predictions of the likelihood that their negotiating partners will deliver the negotiated outcomes.²³⁶ In both the mindsets and strategies of the negotiators, there is significant entanglement of the international negotiation and domestic implementation processes.

The waiver negotiations vividly illustrate this entanglement. At the TRIPS Council, the waiver’s opponents registered their concerns about implementation challenges and repeatedly asked the instrument’s proponents and cosponsors to detail how the waiver was to be implemented.²³⁷ Meanwhile, the waiver’s supporters hesitated to adjust their intellectual property systems, fearing that the WTO membership would ultimately reject the instrument and that they would end up facing WTO challenges, external pressure, or other political repercussions.²³⁸ Given these complications, it is unsurprising that the WTO

231. *Id.* at 434.

232. THOMAS C. SCHELLING, *THE STRATEGY OF CONFLICT* 19 (1960).

233. Putnam, *supra* note 227, at 440.

234. *See id.* at 452 (“[N]egotiators have an incentive to understate their own win-sets.”).

235. *See* HELEN V. MILNER, *INTERESTS, INSTITUTIONS AND INFORMATION: DOMESTIC POLITICS AND INTERNATIONAL RELATIONS* 259 (1997) (“When assessing other countries’ behavior, policy makers should make sure they understand the domestic situation their foreign counterparts face.”). *But see* Putnam, *supra* note 227, at 452 (“[N]egotiators are often badly misinformed about [the politics in the ratification phase], particularly on the opposing side.”).

236. *See* Putnam, *supra* note 227, at 436 (discussing the importance of expectational effects); *see also id.* at 453 (“Deals can only be struck if each negotiator is convinced that the proposed deal lies within his opposite number’s win-set and thus will be ratified. Uncertainty about party A’s ratification lowers the expected value of the agreement to party B, and thus party B will demand more generous side-payments from party A than would be needed under conditions of certainty.”).

237. *See* Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 19, ¶ 4 (including implementation among the contentious issues that impeded the progress of the waiver negotiations).

238. *See supra* text accompanying notes 64–69.

membership ultimately adopted the Ministerial Declaration in lieu of the proposed waiver.²³⁹

D. SUMMARY

This Part has shown the international negotiation and domestic implementation challenges WTO members faced simultaneously—not separately or sequentially—when negotiating the COVID-19 TRIPS waiver at the WTO. Even for countries eager to adopt the waiver, anticipating these challenges would have created second thoughts about the likelihood of their success in pushing for the waiver’s adoption at the TRIPS Council. These reservations in turn would undermine the instrument’s support at the international level.

Domestic implementation challenges would also have made governments hesitant to implement the waiver—or implement it quickly enough to provide a meaningful response to COVID-19. To some extent, these challenges and the resulting variations in domestic implementation across the world would have divided the world into at least three distinct groups: (1) countries viewing the adoption of the waiver as a green light to quickly introduce waiver-related legislation at home; (2) countries declining to introduce waiver-related legislation at home due to their continuous opposition, ineligibility, or opting out; and (3) countries making limited progress in implementation, in varying degrees, due to their reluctance to enact waiver-related legislation or their preference for a wait-and-see approach to minimize international confrontation. In such a divided world, one cannot help but wonder how effective the waiver would have been had it been adopted at the WTO.

III. THE DEFERRAL PROPOSAL

The previous Part has explored several key challenges that countries faced in getting the waiver adopted at the WTO and implemented at the domestic level. While the waiver’s proponents were correct that these challenges would not have been insurmountable, it is worthwhile to explore whether better options exist to allow these countries to achieve the waiver’s intended goals while also addressing the concerns of the instrument’s opponents.

In addition, with the recent adoption of the Ministerial Decision—whose scope is narrower than that of the waiver—and the resulting dissatisfaction with the Decision, finding a better compromise has never been more important. To provide such an alternative, this Part calls for the deferral of select intellectual property rights during a pandemic. This proposal aims to “split the difference” between the proponents and opponents of the waiver.²⁴⁰ It also seeks to address

239. Ministerial Decision, *supra* note 21.

240. “Splitting the difference” is an approach commonly deployed in domestic and international negotiations. See Peter K. Yu, *Traditional Knowledge, Intellectual Property, and Indigenous Culture: An Introduction*, 11 CARDOZO J. INT’L & COMPAR. L. 239, 243 (2003) (noting that “negotiators having a zero-sum

implementation challenges while enlarging the negotiation options available at the WTO. In Professor Putnam's terms, the addition of the new deferral option will enlarge the "win-sets" of both sides, thereby increasing the chance of the proposal's adoption.²⁴¹

FIGURE 1: WIN-SET SIZE BEFORE THE PROPOSAL²⁴²

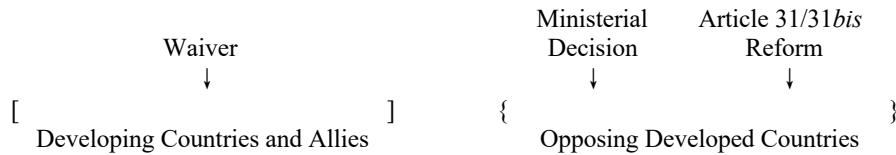
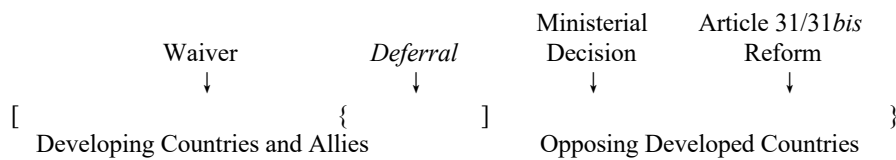


FIGURE 2: WIN-SET SIZE AFTER THE PROPOSAL



Subpart A outlines the deferral proposal, detailing its suspension, extension, and dispute settlement mechanisms. Subpart B discusses precedents involving past temporal adjustments to intellectual property rights at both the international and domestic levels. Subparts C and D explore the strengths and limitations of the deferral proposal, respectively.

A. PROPOSAL

The deferral proposal advanced in this Part is a simple combination of suspension and extension. It utilizes the intellectual property system's ability to make temporal adjustments to intellectual property rights. This Subpart further addresses the need for dispute settlement arrangements at both the domestic and international levels.

1. Suspension

Under this proposal, the deferral of intellectual property rights would begin when a triggering event occurs. This event could be a Phase 6 pandemic under the WHO's old warning system—or, in the current case, the COVID-19

mindset will be more likely to split the difference through accommodation and compromises"); Peter K. Yu, *TRIPS and Its Contents*, 60 IDEA 149, 209 (2020) (discussing the preference for WTO negotiators and dispute panelists to "splitting the difference").

241. See Putnam, *supra* note 227, at 447 (discussing the possibility of a strategy that "works not by changing the preferences of any domestic constituents, but rather by creating a policy option . . . that was previously beyond domestic control").

242. Figures 1 and 2 are inspired by *id.* at 441.

pandemic.²⁴³ Although the WHO opted not to use this multi-phase warning system during the present pandemic,²⁴⁴ this system illustrates the operation of this deferral proposal.²⁴⁵

This Article selects a Phase 6 pandemic as a triggering event, because a pandemic at this level involves “sustained community level outbreaks in two or more countries in one WHO region . . . and in at least one other country in another WHO region.”²⁴⁶ During such a major public health exigency, rights holders will not be in a good position to exploit their intellectual property rights on the open market, similar to what we saw in the first few months of the COVID-19 pandemic when the domestic and global economies completely shut down. Because a Phase 6 pandemic involves sustained community-level outbreaks in multiple geographical regions and multiple countries in at least one region, the massive public health challenges can easily justify deferral.

2. *Extension*

As the global pandemic subsides, and as economies around the world reopen, rights holders regain their ability to exploit intellectual property rights. Thus, once the pandemic has been downgraded or disappears—providing the second triggering event—the suspension would be lifted, intellectual property protection would resume, and the suspended rights would be extended, with additional years tacked on to the end of the original term of protection.²⁴⁷ While rights holders could not file lawsuits against the use of the intellectual property rights covered during the suspension period, they could seek resolution of disputes involving usage during the pandemic.²⁴⁸ To provide transition, the extension mechanism could also add a limited grace period—a year, perhaps.

243. See generally WORLD HEALTH ORG., PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE: WHO GUIDANCE DOCUMENT 31–44 (2009), https://www.ncbi.nlm.nih.gov/books/NBK143062/pdf/Bookshelf_NBK143062.pdf (discussing the six phases of a pandemic).

244. See Stephanie Nebehay, *WHO Says It No Longer Uses “Pandemic” Category, but Virus Still Emergency*, REUTERS (Feb. 24, 2020, 12:26 AM), <https://www.reuters.com/article/uk-china-health-who-idUKKCN20I0PD> (quoting WHO spokesperson saying that “WHO does not use the old system of 6 phases—that ranged from phase 1 (no reports of animal influenza causing human infections) to phase 6 (a pandemic)—that some people may be familiar with from H1N1 in 2009”).

245. It is not inconceivable that the WHO will revive this system in the future or replace it with a similar multi-phase warning system.

246. WORLD HEALTH ORG., *supra* note 243.

247. The extension portion of this proposal differs significantly from measures that would extend the patent term of COVID-19 inventions without any prior suspension of the targeted rights. A case in point is the Facilitating Innovation to Fight Coronavirus Act, S. 3630, 116th Congress (2020). Proposed by Senator Ben Sasse (R–Neb.), this bill provided an extended patent term of ten years to “a new or existing pharmaceutical, medical device, or other process, machine, manufacture, or composition of matter, or any new and useful improvement thereof used or intended for use in the treatment of [COVID-19],” on the condition that the protection would not begin until the termination of “the national emergency declared by the President under the National Emergencies Act . . . with respect to that disease.” *Id.* The bill was heavily criticized as an inappropriate “patent rights grab” in pandemic times. Joe Mullin, *Lengthening Patent Terms by 10 Years Is Exactly the Wrong Response to COVID-19*, ELEC. FRONTIER FOUND. (Apr. 8, 2020), <https://www EFF.ORG/deeplinks/2020/04/lengthening-patent-terms-10-years-exactly-wrong-response-covid-19>.

248. For further discussion of these disputes, see *infra* Part III.A.3–4.

As Professor Abbott observed in relation to the COVID-19 TRIPS waiver, there is a need for “an extended period of continuing requirement for medicines and vaccines to prevent re-emergence once the virus has been brought under control.”²⁴⁹ A limited grace period could therefore be easily justified.

The mechanics of the extension portion of this proposal could resemble the extension provided by the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), which compensates the patent holder’s lost marketing life due to delay in regulatory review.²⁵⁰ Taking a cue from this statute, the proposed extension could further limit the extension of the term of intellectual property rights to no more than the total term of protection allowable at the domestic level. For instance, for a patent expiring in two years, the proposal would not extend the term for more than two years, even if the pandemic were to last longer.

While an extension similar to the one provided by the Hatch-Waxman Act provides one of the easiest and most straightforward arrangements for the deferral proposal—thereby minimizing post-suspension disputes—this proposal can be further modified to allow countries to experiment with creative arrangements.²⁵¹ For example, countries eager to increase more access to health products and technologies could extend the term of protection for only some, but not all, of the claims in the patents. A case in point is the extension of the patent term in a vaccine but not the process for making that vaccine.²⁵² By contrast, countries seeking legislative proposals to enlist greater industry support could consider an extension for all patent claims. These countries could even extend those claims for longer time than the suspension period, if sufficient evidence justifies further extension.

One proposal that could be quite attractive to the pharmaceutical industry, but would also be highly controversial from a public health standpoint, is the proposal for a transferrable (or “wild card”) extension, similar to legislative proposals rejected by past U.S. Congresses.²⁵³ As Margo Bagley summarizes:

249. Abbott, *supra* note 3, at 9.

250. See 35 U.S.C. § 156 (providing a limited extension of the patent term based on the period during which a pharmaceutical product undergoes regulatory review).

251. See STEPHEN P. LADAS, PATENTS, TRADEMARKS, AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION 9–16 (1975) (discussing the “laboratory effects” of legal innovation); Sungjoon Cho, *A Bridge Too Far: The Fall of the Fifth WTO Ministerial Conference in Cancun and the Future of Trade Constitution*, 7 J. INT’L ECON. L. 219, 238 (2004) (discussing the “laboratory effect” of regionalism, which allows countries to experience trial and error and learning by doing at the regional level); John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 707–08 (2002) (discussing how countries can develop legal systems by experimenting with new regulatory and economic policies through interjurisdictional competition).

252. Thanks to Rochelle Dreyfuss for this suggestion.

253. See Project BioShield II Act of 2005, S. 975, 109th Congress, § 331 (2005) (providing for patent term restoration and extension and exclusive marketing); see also Margo A. Bagley, *Patent Term Restoration and Non-Patent Exclusivity in the US*, in PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW: A TRILATERAL PERSPECTIVE 111, 126 (Josef Drexler & Nari Lee eds., 2013) [hereinafter PHARMACEUTICAL INNOVATION] (discussing “wild card” patent term extensions); John R. Thomas, *The End of Patent Medicines*:

Designed to incentivize drug research in a targeted area, the provision [for a transferable or “wild card” patent term extension] is aptly named as it would, in theory, allow a patent holder to extend the term of any patent of its choosing, contingent on the patent holder complying with some requirement, such as developing a new antibiotic or counter-terrorism treatment.²⁵⁴

If years of protection, based on the duration of suspension, were added to the patent term for a high revenue-generating invention at the end of the pandemic, the pharmaceutical industry and its supportive legislators might become more willing to endorse the deferral proposal.²⁵⁵ A transferrable extension could also be attractive to developers of time-sensitive products and technologies who will lose significant economic value upon deferral due to technological obsolescence. Notwithstanding these benefits, such an extension “could seriously imperil competitor plans to introduce generic products after patent expiration.”²⁵⁶ That extension could also raise significant equity and policy concerns. For instance, why should a select group of future patients subsidize pandemic-time access to health products and technologies by the public at large? In addition, from a public health standpoint, it might be unwise to extend the patent terms of some highly profitable, and likely very expensive, products and technologies in exchange for access to potentially cheaper vaccines, treatments, and technologies during the pandemic.²⁵⁷

Whether one proposal should be chosen over another is a decision left for policymakers. Such a decision will likely vary from country to country. To maximize policy space, this proposal intentionally leaves out the specific details of how to extend the term of intellectual property rights. Nor does it state what intellectual property rights are covered and whether all forms of intellectual property rights should be extended the same way. Nevertheless, this proposal

Thoughts on the Rise of Regulatory Exclusivities, 70 FOOD & DRUG L.J. 39, 46 (2015) (“The draft 21st Century Cures Act would . . . amend the GAIN Act by allowing the owner of an approved application on a qualified infectious disease product to transfer up to twelve months of the five-year extension of exclusivity to another product.”).

254. Bagley, *supra* note 253, at 126.

255. *See id.* (“The fact that the extension would not have to relate to a patent obtained in complying with the requirement, but could instead be used to extend exclusivity for, perhaps, a different blockbuster drug, would make such an extension extremely desirable for innovator firms.”); Brad Spellberg, Robert Guidos, David Gilbert, John Bradley, Helen W. Boucher, W. Michael Scheld, John G. Bartlett & John Edwards Jr., *The Epidemic of Antibiotic-Resistant Infections: A Call to Action for the Medical Community from the Infectious Diseases Society of America*, 46 CLINICAL INFECTIOUS DISEASES 155, 161 (2008) (“[O]f all of the potential solutions, transferable patent extensions are generally acknowledged by pharmaceutical companies to be, by far, the incentives most likely to successfully stimulate new antibiotic development.”).

256. Bagley, *supra* note 253, at 126.

257. *But see* B. Spellberg, L.G. Miller, M.N. Kuo, J. Bradley, W.M. Scheld & J.E. Edwards Jr., *Societal Costs Versus Savings from Wild-Card Patent Extension Legislation to Spur Critically Needed Antibiotic Development*, 35 INFECTION 167, 167 (2007) (“[E]ven if the new antibiotic abrogated only 50% of the annual societal cost of multidrug-resistant *P. aeruginosa* (estimated \$2.7 billion), wild-card patent extension would be cost neutral by 10 years after approval of the new antibiotic, and would save society approximately \$4.6 billion by 20 years after approval.”).

recognizes the need to extend the term fairly to compensate those rights holders whose rights have been suspended during the pandemic.

3. *Domestic Dispute Settlement*

As noted earlier, disputes may arise, just like in any other arrangement involving temporal adjustments to intellectual property rights. To resolve such disputes, it will be useful to institute a settlement mechanism. At the domestic level, national courts can provide this mechanism. As long as the pandemic-related legislation has clearly spelled out the arrangements for suspension and extension, courts will be able to make appropriate determinations, similar to other adjustments under intellectual property laws. For example, courts may be asked to determine whether the exploitation permissible during the suspension period can continue after the pandemic has been downgraded or disappears—and if so, for how long and under what conditions.²⁵⁸

Making such determinations can be difficult at first glance. Because intellectual property rights holders have strong incentives to prevent arrangements that would facilitate such determinations, they may lobby against the deferral proposal. In reality, however, courts have made challenging determinations in the past. There is sufficient case law to provide certainty and predictability to rights holders.²⁵⁹ The relevant government agencies can also provide online tools to help improve information about extensions. A case in point is the new public webpage that the United States Patent and Trademark Office recently launched to “provid[e] information on applications for patent term extension . . . that have been filed within the past five years.”²⁶⁰

To be sure, keeping the status quo would provide, from the rights holders’ standpoint, even more certainty and predictability. However, the price of such certainty and predictability during a global pandemic could be very high, such as the substantial loss of human lives. As we learned during the COVID-19 pandemic, there may be no easy solutions to the problems we experience during a major public health exigency.²⁶¹ There will be tradeoffs no matter which policy option we choose, and governments often have to pick the lesser of two or more evils.

In the event that extension alone does not fully compensate rights holders whose rights have been suspended during the pandemic, the dispute settlement mechanism could award reasonable royalties, similar to the arrangement

258. See Federica Paddeu & Michael Waibel, *The Final Act: Exploring the End of Pandemics*, 114 AM. J. INT’L L. 698, 698 (2020) (“For adjudicators, it is . . . crucial to be able to identify a precise moment in time when an emergency . . . finished.”).

259. See *infra* text accompanying note 320.

260. *USPTO Launches New Public Webpage to Enhance Accessibility to Patent Term Extension Information*, U.S. PAT. & TRADEMARK OFF. (Sept. 2, 2022), <https://www.uspto.gov/subscription-center/2022/uspto-launches-new-public-webpage-enhance-accessibility-patent-term>.

261. See Yu, *supra* note 28, at 294.

provided by the United States Court of Federal Claims.²⁶² Section 1498(a) of Title 28 provides patent holders with a forum to seek “reasonable and entire compensation” when the federal government and its contractors use patented items without authorization.²⁶³ As Jorge Contreras reminds us:

[Section] 1498 has been used to bolster the U.S. supply of drugs and biomedical technologies at prices lower than those charged by patent holders. During a three-year period in the 1960s, the Department of Defense’s Military Medical Supply Agency . . . utilized § 1498 to obtain supplies of approximately 50 drugs including the antibiotic tetracycline.²⁶⁴

Even though the provision of monetary compensation is attractive, this proposal intends such compensation to be offered only when rights holders can demonstrate that extension alone cannot adequately compensate their losses during the pandemic. If monetary compensation is offered regardless, there is no need for extension in the first place. Moreover, many developing countries will simply not be in a good position to offer monetary compensation shortly after a pandemic. Although the provision of compensation in the dispute settlement portion of this proposal is modeled after § 1498, such an arrangement will likely require the introduction of new legislation. Unlike § 1498, the deferral proposal covers more than patents and copyrights, and the suspension would go beyond usage by the government or its contractors in some cases.

Apart from monetary compensation, the dispute settlement mechanism could provide additional alternative remedies to help reduce the negative impacts on intellectual property rights holders. For instance, the mechanism could consider the issuance of FRAND licenses—licenses under fair, reasonable, and non-discriminatory terms.²⁶⁵ Such a remedy would make good sense for disputes arising out of pandemic-time deferral.

4. *International Dispute Settlement*

At the international level, designing an appropriate dispute settlement mechanism becomes more complicated. Instead of asking what a party can do when its intellectual property rights have been deferred during the pandemic, or

262. See *About the Court*, U.S. CT. OF FED. CLAIMS, <https://www.uscfc.uscourts.gov/about-court> (last visited Jan. 28, 2023) (providing information about the court).

263. See 28 U.S.C. § 1498(a) (providing for “the recovery of . . . reasonable and entire compensation for such use and manufacture, . . . including reasonable fees for expert witnesses and attorneys”); see also Williams & Ghrist, *supra* note 196, at 34–35 (discussing the remedies available under 28 U.S.C. § 1498). It is important to recognize that § 1498 focuses on the government’s use or manufacture of the patented products and technologies. This statute does not provide compensation if intellectual property rights are suspended.

264. Contreras, *supra* note 86, at 159 (citation omitted).

265. For discussions of FRAND licenses, see generally Jorge L. Contreras, *A Market Reliance Theory for FRAND Commitments and Other Patent Pledges*, 2015 UTAH L. REV. 479; Thomas F. Cotter, *Comparative Law and Economics of Standard-Essential Patents and FRAND Royalties*, 22 TEX. INTELL. PROP. L.J. 311 (2014); Jay P. Kesan & Carol M. Hayes, *FRAND’s Forever: Standards, Patent Transfers, and Licensing Commitments*, 89 IND. L.J. 231 (2014); Srividhya Ragavan, Brendan Murphy & Raj Davé, *FRAND v. Compulsory Licensing: The Lesser of the Two Evils*, 14 DUKE L. & TECH. REV. 83 (2015).

what monetary compensation that party should receive if extension alone is insufficient to address the party's loss, the international dispute settlement mechanism must determine whether the member state at issue has complied with its international obligations. That determination includes whether it has gone beyond what the deferral arrangement allows. For a global pandemic like COVID-19, having a dispute settlement mechanism that can account for the different pandemic experiences will likely be quite important. After all, a Phase 6 pandemic may emerge, peak, or wind down in different countries at different times.²⁶⁶

Fortunately, there are many choices for setting up this international dispute settlement mechanism. Should the deferral proposal be incorporated into a TRIPS-based instrument, similar to the now rejected COVID-19 TRIPS waiver, the WTO Dispute Settlement Body will provide the needed mechanism.²⁶⁷ Should this deferral proposal be established outside the WTO, however, the proposal could utilize state-to-state dispute settlement mechanisms in existing bilateral and regional trade agreements,²⁶⁸ investment tribunals established in recent EU free trade agreements,²⁶⁹ or even dispute settlement services provided by WIPO and other international and regional organizations.²⁷⁰

B. PRECEDENTS

Although some policymakers and commentators strongly oppose the suspension of intellectual property rights through the COVID-19 TRIPS waiver, there are good examples of such suspension at both the international and domestic levels. These examples are relevant to not only the waiver, but also the suspension portion of the deferral proposal.

At the international level, the WTO allows for the suspension of intellectual property obligations when countries undertake permissible cross-retaliation.²⁷¹

266. See Broadbent & Smart, *supra* note 106; Patrick & Bearak, *supra* note 106.

267. See TRIPS Agreement, *supra* note 6, art. 64 (mandating the use of the WTO Dispute Settlement Body to resolve disputes arising under the Agreement).

268. See United States–Mexico–Canada Agreement ch. 31, Can.–Mex.–U.S., Nov. 30, 2018, <https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement> (providing the dispute settlement mechanism).

269. See Yu, *Crossfertilizing ISDS with TRIPS*, *supra* note 204, at 341 n.92 (collecting sources that advance proposals to establish international investment courts).

270. WIPO provides important arbitration and mediation services, especially for resolving disputes over internet domain names. See *WIPO | ADR, WORLD INTELL. PROP. ORG.*, <https://www.wipo.int/amc/en/center/index.html> (last visited Jan. 28, 2023) (“The WIPO Arbitration and Mediation Center offers time- and cost-efficient alternative dispute resolution . . . options, such as mediation, arbitration, expedited arbitration, and expert determination to enable private parties to settle their domestic or cross-border commercial disputes.”).

271. As Professor Abbott explains:

The term “retaliation” is not used in the WTO Agreement or the WTO Dispute Settlement Understanding in reference to suspension of trade concessions. However, it has been used by arbitrators determining appropriate levels of suspension under Article 22.6 of the [Dispute Settlement Understanding in *European Communities—Regime for the Importation, Sale and Distribution of Bananas*].

Article 22.1 of the WTO Dispute Settlement Understanding specifically acknowledges that “[c]ompensation and the suspension of concessions or other obligations are temporary measures available in the event that the recommendations and rulings are not implemented within a reasonable period of time.”²⁷² Although it remains challenging to introduce laws and policies that will suspend obligations to a violating WTO member without introducing negative collateral impacts on other WTO members,²⁷³ the panel in *United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services* did allow Antigua and Barbuda to suspend their intellectual property obligations to the United States due to the latter’s refusal to conform its internet gambling laws to the WTO panel decision.²⁷⁴

At the domestic level, intellectual property rights have been suspended in the case of copyright or patent misuse. In those cases, the defendant is not allowed to enforce the rights unless “the improper practice has been abandoned and . . . the consequences of the misuse . . . have . . . dissipated.”²⁷⁵ As the United States Supreme Court explained in *Morton Salt Co. v. G.S. Suppiger Co.*, the intellectual property rights holder “like . . . other holders of an exclusive privilege granted in the furtherance of a public policy, may not claim protection of his [or her] grant by the courts where it is being used to subvert that policy.”²⁷⁶ Although the misuse doctrine began in patent law, it spread to copyright law in 1990 in *Lasercomb America, Inc. v. Reynolds*.²⁷⁷ Since then, commentators have

Frederick M. Abbott, *Cross-Retaliation in TRIPS: Options for Developing Countries* 39 n.1 (ICTSD Programme on Disp. Settlement, Issue Paper No. 8, 2009). For discussions of retaliation and cross-retaliation in the WTO, see generally *id.*; THE LAW, ECONOMICS AND POLITICS OF RETALIATION IN WTO DISPUTE SETTLEMENT (Chad P. Bown & Joost Pauwelyn eds., 2010); Shamnad Basheer, *Turning TRIPS on Its Head: An “IP Cross Retaliation” Model for Developing Countries*, 3 L. & DEV. REV. 141 (2010); Rachel Brewster, *The Surprising Benefits to Developing Countries of Linking International Trade and Intellectual Property*, 12 CHI. J. INT’L L. 1, 35–51 (2011); Peter K. Yu, *Are Developing Countries Playing a Better TRIPS Game?*, 16 UCLA J. INT’L L. & FOREIGN AFFS. 311, 339–42 (2011).

272. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 22.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401.

273. See Recourse to Arbitration by the European Communities Under Article 22.6 of the DSU, *European Communities—Regime for the Importation, Sale and Distribution of Bananas*, ¶ 156, WTO Doc. WT/DS27/ARB/ECU (Mar. 24, 2000) (“Distortions in third-country markets could be avoided if Ecuador would suspend the intellectual property rights in question only for the purposes of supply destined for the domestic market.”); see also Joost Pauwelyn, *The Dog That Barked but Didn’t Bite: 15 Years of Intellectual Property Disputes at the WTO*, 1 J. INT’L DISP. SETTLEMENT 389, 419–20 (2010) (discussing the implication of having cross-retaliation “only for the purposes of supply destined for the domestic market”).

274. See Recourse to Arbitration by the United States Under Article 22.6 of the DSU, *United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WTO Doc. WT/DS285/ARB (Dec. 21, 2007).

275. *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 493 (1942).

276. *Id.*

277. 911 F.2d 970, 972–79 (4th Cir. 1990); see also John T. Cross & Peter K. Yu, *Competition Law and Copyright Misuse*, 56 DRAKE L. REV. 427, 456 (2008) (“U.S. courts have long recognized an independent doctrine of patent misuse. The doctrine provides a defense to patent infringement in cases in which the patentee has misused its statutory rights. Yet, notwithstanding the similarity between patents and copyrights, it took some time for courts to apply similar principles in the field of copyright. The breakthrough came in the 1990 decision of *Lasercomb America, Inc. v. Reynolds*.” (citation omitted)).

called for the application of the misuse doctrine in other intellectual property contexts, such as anti-circumvention protection²⁷⁸ and trade secrets.²⁷⁹

Compared with suspension, extension or restoration is even more common in the intellectual property field. One can easily find precedents at both the international and domestic levels.²⁸⁰ International intellectual property agreements generally focus on the creation of floors or minimum standards.²⁸¹ As a result, countries are free to extend the term of intellectual property rights as they wish.²⁸² The only major constraint that the TRIPS Agreement has placed on WTO members is that the extension cannot discriminate against foreign authors and inventors.²⁸³ In the past two decades, an extension that has been widely incorporated into bilateral, regional, and plurilateral trade agreements negotiated by the United States is the Hatch-Waxman extension mentioned earlier.²⁸⁴ Even China recently amended its patent law to offer such an extension,²⁸⁵ despite its longstanding resistance to strengthening patent protection for pharmaceuticals.²⁸⁶

278. See Dan L. Burk, *Anticircumvention Misuse*, 50 UCLA L. REV. 1095, 1132–40 (2003) (calling for the recognition of a new claim of anticircumvention or paracopyright misuse); Julie E. Cohen, *Reverse Engineering and the Rise of Electronic Vigilantism: Intellectual Property Implications of “Lock-Out” Programs*, 68 S. CAL. L. REV. 1091, 1181–98 (1995) (discussing the application of the misuse defense to claims of intellectual property in lock-out programs that prevent the authorized access to computer hardware or game consoles).

279. See Deepa Varadarajan, *The Uses of IP Misuse*, 68 EMORY L.J. 739, 775–98 (2019) (making a case for the development of a trade secret misuse doctrine).

280. For discussions of patent term extension, see generally Bagley, *supra* note 253; Toshiaki Imura, *Patent Term Extension in Japan: Focusing on the Pacif Capsule Decision*, in PHARMACEUTICAL INNOVATION, *supra* note 253, at 220; Ryoko Iseki, *Patent Term Extension in Japan: An Academic and Comparative Perspective*, in PHARMACEUTICAL INNOVATION, *supra* note 253, at 183; Sarah R. Wasserman Rajec, *The Harmonization Myth in International Intellectual Property Law*, 62 ARIZ. L. REV. 735, 774–77 (2020).

281. See Peter K. Yu, *TRIPS Enforcement and Developing Countries*, 26 AM. U. INT’L L. REV. 727, 744 (2011) (“By design, the TRIPS Agreement was established as a minimum standards agreement.”). See generally J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT’L LAW. 345 (1995) (discussing how the TRIPS Agreement established universal minimum standards in the intellectual property area).

282. See TRIPS Agreement, *supra* note 6, art. 1.1 (“Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.”).

283. See Berne Convention, *supra* note 57, art. 5(1) (adopting the principle of national treatment); Paris Convention for the Protection of Industrial Property art. 2(1), Mar. 20, 1883, 828 U.N.T.S. 305 (revised at Stockholm July 14, 1967) (same); see also Yu, *supra* note 221, at 352 (“[T]he nondiscrimination principle of national treatment . . . requires member states to grant to foreigners the same rights they grant to their own nationals.”). There are a few exceptions, however. See, e.g., Berne Convention, *supra* note 57, art. 7(8) (“[U]nless the legislation of that country otherwise provides, the term shall not exceed the term fixed in the country of origin of the work.”).

284. See *supra* text accompanying note 250.

285. Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People’s Republic of China] (promulgated by the Standing Comm. Nat’l People’s Cong., Mar. 12, 1984, Oct. 17, 2020, effective June 1, 2021), art. 42, CLI.1.346982(EN) (Lawinfochina); see also Peter K. Yu, *China’s Innovative Turn and the Changing Pharmaceutical Landscape*, 51 U. PAC. L. REV. 593, 604 (2020) (discussing the proposed extension of the patent term for pharmaceutical products in China).

286. See Yu, *supra* note 285, at 597 (noting the exclusion of “pharmaceutical products . . . and substances obtained by means of a chemical process” in article 25 of the 1984 Chinese Patent Law).

At the domestic level, there are many examples of term extension or restoration in different bodies of intellectual property law. In the United States, for instance, the repeated term extension of copyright protection caused a publisher of public domain works and his allies to challenge the constitutionality of the Sonny Bono Copyright Term Extension Act in *Eldred v. Ashcroft*.²⁸⁷ That statute sought to create parity with the European Union, which extended the copyright term in an effort to harmonize the varying durations of protection offered by different EU members.²⁸⁸ Coincidentally, some of these variations were caused by wartime extensions, which were introduced to compensate rights holders for the lost opportunities to exploit copyright due to factors out of their control.²⁸⁹ Although COVID-19 is different from a world war, both extensions recognize the need to prolong the duration of intellectual property rights to compensate rights holders for their uncontrollable losses during a global crisis.

Apart from copyright term extension, U.S. copyright law has restored protection to creative works that have fallen into the public domain. To ensure compliance with the TRIPS Agreement, the Uruguay Round Agreements Act of 1994 restored copyright protection to foreign works that remained protected in the source country but unprotected in the United States due to specified reasons, such as when the work failed to comply with the formalities requirements in U.S. copyright law.²⁹⁰ The constitutionality of such restoration was challenged in *Golan v. Holder*, where the United States Supreme Court upheld the restoration in section 104A of the U.S. Copyright Act.²⁹¹

In the patent area, the TRIPS Agreement has changed the term of protection in many countries.²⁹² In the United States, the term changed from seventeen years from the date of grant to twenty years from the date of application.²⁹³ In addition, many countries now offer protection for undisclosed test or other data that pharmaceutical and agrochemical companies submit to regulatory agencies for marketing approval.²⁹⁴ Some critics have viewed the market exclusivity

287. 537 U.S. 186 (2003).

288. See *id.* at 196 (“This [life-plus-seventy] standard harmonizes the baseline United States copyright term with the term adopted by the European Union in 1993.”).

289. See Paul Edward Geller, *Zombie and Once-Dead Works: Copyright Retroactivity After the E.C. Term Directive*, 18 ENT. & SPORTS LAW. 7, 7 (2000) (“In some countries, this term was lengthened by wartime extensions, for example, six years in Italy. Then Germany, in its 1965 Copyright Act, extended the copyright term to life plus 70 years. This term provided the model that the E.C. Term Directive later followed for all E.C. copyright terms.” (citation omitted)); Silke von Lewinski, *The EC Duration Directive: An Example of the Complexity of EC Copyright Harmonization*, in 4 INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE 257, 274 (Peter K. Yu ed., 2007) (noting “an extension of the term of protection due to wartime”).

290. 17 U.S.C. § 104A.

291. 565 U.S. 302 (2012).

292. See TRIPS Agreement, *supra* note 6, art. 33 (“The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”).

293. 35 U.S.C. § 154(c)(1).

294. See TRIPS Agreement, *supra* note 6, art. 39.3 (providing protections for undisclosed test or other data for pharmaceutical and agrochemical products); see also Peter K. Yu, *Data Exclusivities and the Limits to TRIPS*

provided to products whose patents have already expired as an unfair extension of the patent term.²⁹⁵

In sum, many international and domestic precedents support both the suspension and extension portions of the deferral proposal. The existence of this wide array of precedents suggests that policymakers, judges, and dispute settlement bodies are well equipped to handle complications involving temporal adjustments to intellectual property rights. These precedents also alleviate concerns that the deferral proposal would create substantial uncertainty and unpredictability in the intellectual property system by introducing an untested model.

C. STRENGTHS

The primary strength of this proposal is that it addresses the main concerns of both the waiver's proponents and opponents. It thereby provides a better compromise than both the COVID-19 TRIPS waiver and the Ministerial Decision.

For the waiver's supporters, the deferral proposal notes their concerns about the global inequities brought about by the existing international intellectual property system. Like the waiver, the proposed deferral begins with the temporary suspension of intellectual property rights covered during the pandemic. The crucial difference between the two is that the latter compensates rights holders by extending rights that would have been suspended during the pandemic.

To be sure, the waiver's supporters may be disappointed that the deferral proposal only partially achieves the waiver's intended goals. Like the waiver, the proposed deferral would suspend the relevant intellectual property rights during the pandemic. Unlike the former, however, the latter would not allow developing countries to capitalize on the opportunity provided by the pandemic to recalibrate the international intellectual property system. While this Author is sympathetic to the plight of developing and least developed countries and recognizes the need for recalibration to help address global inequities,²⁹⁶ it is

Harmonization, 46 FLA. ST. U. L. REV. 641, 647–85 (2019) (discussing the market exclusivity obligations under the TRIPS Agreement and TRIPS-plus bilateral, regional, and plurilateral agreements).

295. See Srividhya Ragavan, *Data Exclusivity: A Tool to Sustain Market Monopoly*, 8 JINDAL GLOB. L. REV. 241, 252–53 (2017) (discussing the complications when the drug is in the public domain or when the granted patent for the drug has been subsequently invalidated); Yu, *supra* note 294, at 663–64 (discussing how data or market exclusivity law could provide substitutional protection for pharmaceutical products that patent law no longer protects).

296. For the Author's discussions of development-related issues in the intellectual property context, see generally Peter K. Yu, *Development Bridge over Troubled Intellectual Property Water*, in INTELLECTUAL PROPERTY AND DEVELOPMENT: UNDERSTANDING THE INTERFACES—LIBER AMICORUM PEDRO ROFFE 97 (Carlos Correa & Xavier Seuba eds., 2019); Peter K. Yu, *Realigning TRIPS-Plus Negotiations with UN Sustainable Development Goals*, in INTELLECTUAL PROPERTY AND SUSTAINABLE MARKETS 38 (Ole-Andreas Rogstad & Inger B. Ørstavik eds., 2021); Peter K. Yu, *A Tale of Two Development Agendas*, 35 OHIO N.U. L. REV. 465 (2009); Peter K. Yu, *Five Decades of Intellectual Property and Global Development*, 8 WIPO J. 1

important not to conflate the two debates when considering the need for pandemic-time adjustments. After all, not all of the waiver's supporters endorse efforts to use the opportunity provided by the pandemic to recalibrate the international intellectual property system.

Moreover, for many developing countries, having the ability to suspend intellectual property rights during the pandemic will still be highly beneficial even if such suspension does not result in a recalibration of the international intellectual property system after the pandemic. Indeed, the waiver's potential to recalibrate this system is one of the reasons why the proposal attracted such strong opposition and mistrust, which eventually caused WTO members to settle for the compromise proposal advanced through the Quad consultations. When the waiver was being considered, many critics viewed it as "part of a continuing effort to weaken intellectual property more generally."²⁹⁷

For the waiver's opponents, the deferral proposal is equally attractive, as it directly responds to the concern that the suspension of intellectual property rights would reduce incentives for research and development generated by the existing intellectual property system. The extension portion of the deferral proposal would also help compensate rights holders for the losses inflicted when intellectual property rights are suspended during a major public health exigency, such as a Phase 6 pandemic. To the extent that incentives are badly needed for medical advances to combat the pandemic, the deferral arrangement—and the understanding that the rights will be mostly delayed with the potential for compensation—will help preserve some incentives. These incentives could nicely complement the additional pandemic-related stimuli provided by governments, intergovernmental and nongovernmental bodies, and private businesses and foundations, as well as the altruism of researchers and supportive businesses and organizations.

Even better, the deferral proposal will help address some of the implementation challenges relating to regulatory takings, expropriations of foreign investments, and a lack of fair and equitable treatment. As Part II.B has explained, some of the key implementation challenges come from the fact that uncompensated suspension could amount to a regulatory taking or an expropriation of property in some jurisdictions.²⁹⁸ Not only do potential takings lead to lawsuits, but they also militate against the adoption of domestic legislation needed to implement the waiver.

Similar benefits can accrue at the international level. To begin with, the TRIPS Agreement does not state whether patent protection can be deferred or interrupted under extraordinary circumstances, such as a Phase 6 pandemic.

(2016); Peter K. Yu, *Intellectual Property Training and Education for Development*, 28 AM. U. INT'L L. REV. 311 (2012).

297. Abbott et al., *supra* note 84, at 4; *see also* Mercurio, *supra* note 7, at 30 ("If the proposal for a waiver is approved, India and South Africa will have accomplished their long-standing goal of rolling back [intellectual property rights] and changing the bargain struck during the Uruguay Round, but at a devastating cost.").

298. *See* discussion *supra* Part II.B.2.

Article 33 states that “[t]he term of [patent] protection available shall not end before the expiration of a period of twenty years counted from the filing date.”²⁹⁹

To be sure, WTO members are not supposed to delay or interrupt patent protection to undermine the level of protection. During such a major public health exigency, however, the potential shutdown of the global economy would greatly minimize the negative impact. As a result, it is unclear whether the proposed deferral would violate the TRIPS Agreement. To the extent that rights holders fear that a deferral would deprive them of an expected benefit despite the lack of a TRIPS violation, the WTO does not currently provide any recourse for such deprivation due to the longstanding moratorium on non-violation and situation complaints over the TRIPS Agreement.³⁰⁰

Many countries, especially those in the developing world, remain concerned about the threats of investor-state disputes in relation to waiver-related legislation.³⁰¹ Although some commentators are quite confident that host countries will eventually prevail in these disputes,³⁰² many developing countries will likely embrace a wait-and-see approach, similar to how they handled tobacco plain-packaging legislation around the time when Philip Morris was filing investor-state complaints against Australia and Uruguay.³⁰³ By offering post-pandemic extensions, the deferral proposal, once implemented, will help avoid investor-state disputes while reducing the likelihood of what commentators have referred to as “regulatory chill”³⁰⁴—“a chilling effect that undermines a country’s sovereign ability to regulate harmful conducts.”³⁰⁵

As if the foregoing strengths did not make the deferral proposal attractive enough, the proposal, if designed appropriately, could complement the proposed

299. TRIPS Agreement, *supra* note 6, art. 33.

300. A non-violation complaint allows a WTO member to “challenge any measure applied by another Member, even if it does not conflict with [the TRIPS Agreement], provided that it results in ‘nullification or impairment of a benefit.’” *Legal Basis for a Dispute*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/dispu_settlement_cbt_e/c4s2p1_e.htm (last visited Jan. 28, 2023). Since the adoption of the TRIPS Agreement, the moratorium on non-violation complaints has been extended repeatedly, and most recently at MC12. See World Trade Organization, *TRIPS Non-Violation and Situation Complaints: Ministerial Decision*, WTO Doc. WT/MIN(22)/26 (June 22, 2022).

301. See discussion *supra* Part II.B.3.

302. See generally Mercurio & Upreti, *supra* note 201; Grosse Ruse-Khan & Paddeu, *supra* note 7.

303. See *TPP’s ISDS: Moving from State-to-State to Company-to-World Dispute Resolution*, LEGAL READER (May 1, 2015), <http://www.legalreader.com/tpps-isds-moving-from-state-to-state-to-company-to-world-dispute-resolution> (surmising that New Zealand “decided against changing their smoking laws out of fear of . . . retribution through [investor-state dispute settlement]”).

304. See, e.g., LONE WANDAHL MOUYAL, *INTERNATIONAL INVESTMENT LAW AND THE RIGHT TO REGULATE: A HUMAN RIGHTS PERSPECTIVE* 67–68 (2016) (providing examples of “regulatory chill”); Kyla Tienhaara, *Regulatory Chill and the Threat of Arbitration: A View from Political Science*, in *EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION* 606 (Chester Brown & Kate Miles eds., 2011) (using political science to analyze the “regulatory chill” hypothesis); U.N. CONF. ON TRADE & DEV., *WORLD INVESTMENT REPORT 2015: REFORMING INTERNATIONAL INVESTMENT GOVERNANCE* 128 (2015) (considering “regulatory chill” to be a concern of investor-state dispute settlement).

305. Yu, *Investment-Related Aspects*, *supra* note 204, at 859.

waiver or other similar proposals.³⁰⁶ Even though this Article introduces the deferral proposal as an alternative to overcome the negotiation and implementation challenges surrounding the waiver—and in view of the recent rejection of the COVID-19 TRIPS waiver at MC12—the deferral and waiver proposals are not mutually exclusive. Had the waiver been adopted at the WTO, those countries that were ineligible or that had opted out could introduce the deferral proposal in lieu of the waiver. Some countries could also use the deferral proposal to implement the waiver. In short, this proposal will benefit both proponents and opponents of the waiver by giving them more policy options—or, from a negotiation standpoint, increasing the size of Professor Putnam’s “win-set.”³⁰⁷

D. LIMITATIONS

Despite its many strengths, the deferral proposal has some limitations. First, while the proposal will work well for those forms of intellectual property rights that have a defined term of protection, such as copyrights, industrial designs, and patents, it will not work well for rights that have an undefined or indefinite term of protection, such as trade secrets and trademarks. During the COVID-19 pandemic, trademark protection was not a major barrier to accessing health products and technologies, even though there were certainly pandemic-related trademark counterfeiting issues.³⁰⁸ Because competitors had retained their ability to develop similar products and technologies using different brands, the waiver’s proponents did not include trademarks in their proposal.³⁰⁹

Trade secret protection, by contrast, can be quite complicated. Because trade secrets can last as long as the secrets remain protected,³¹⁰ any loss during a deferral would likely be unrecoverable. Moreover, those secrets, once publicly disclosed, would no longer be eligible for protection, and limited disclosure

306. Such complementarity is similar to how the waiver can coexist with existing flexibilities in the TRIPS Agreement, including the compulsory licensing arrangements. See Thambisetty et al., *supra* note 7, at 408 (“[W]e must . . . avoid the error of viewing the TRIPS waiver and compulsory licensing as an either/or situation. There can be reciprocity between the two approaches.”).

307. Putnam, *supra* note 227, at 442; see also Andrew Moravcsik, *Introduction: Integrating International and Domestic Theories of International Bargaining*, in *DOUBLE-EDGED DIPLOMACY*, *supra* note 227, at 3, 24 (“In the two-level-games framework, the most fundamental constraint on the statesman is the size of the win-set . . .”).

308. See, e.g., Press Release, FBI, FBI Warns Health Care Professionals of Increased Potential for Fraudulent Sales of COVID-19-Related Medical Equipment (Mar. 27, 2020), <https://www.fbi.gov/news/press-releases/press-releases/fbi-warns-health-care-professionals-of-increased-potential-for-fraudulent-sales-of-covid-19-related-medical-equipment> (issuing warning about counterfeit personal protective equipment during the COVID-19 pandemic). See generally Irene Calboli, *Trademarks and the COVID-19 Pandemic: An Empirical Analysis of Trademark Applications Including the Terms “COVID,” “Coronavirus,” “Quarantine,” “Social Distancing,” “Six Feet Apart,” and “Shelter in Place,”* 54 AKRON L. REV. 401 (2020) (discussing the tsunami of trademark applications caused by the COVID-19 pandemic).

309. See *TRIPS Waiver Proposal*, *supra* note 4, annex, ¶ 1; *Revised TRIPS Waiver Proposal*, *supra* note 4, ¶ 1.

310. See Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311, 352 (2008) (“Trade secrets . . . are protected for an indefinite term, until they are no longer secret.”).

could eventually lead to complete disclosure. Fortunately, with the outpouring of public resources and the dispute settlement mechanism built into the proposal, the award of reasonable royalties could alleviate some of the losses caused by the suspension of trade secret protection.³¹¹ In addition, government agencies such as the European Medicines Agency and Health Canada have provided helpful precedents by proactively publishing the clinical trial data submitted to them.³¹² Commentators have also offered proposals on limited disclosure that would strike a more appropriate balance between proprietary and access interests.³¹³

As this Author has noted in prior work, there is quite a gap between the suspension of trade secret protection and the forced disclosure of proprietary information, both of which may be viewed as part of a continuum.³¹⁴ To the extent that the suspended protection has not resulted in forced disclosure, the harm to rights holders is likely to be more limited than the waiver's opponents have claimed. After all, throughout the waiver debate, commentators have widely agreed on the tremendous difficulty for governments to force Moderna,

311. See *supra* text accompanying notes 262–63.

312. See EUR. MEDS. AGENCY, EMA/144064/2019, EUROPEAN MEDICINES AGENCY POLICY ON PUBLICATION OF CLINICAL DATA FOR MEDICINAL PRODUCTS FOR HUMAN USE (2019), https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf; HEALTH CAN., PUBLIC RELEASE OF CLINICAL INFORMATION: GUIDANCE DOCUMENT (2019), <https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/profile-public-release-clinical-information-guidance/document.html>; see also Cynthia M. Ho, *Avoiding the TRIPS Trap: A Path to Domestic Disclosure of Clinical Drug Data Consistent with International Norms*, 54 CORNELL INT'L L.J. (forthcoming 2021) (manuscript at 155–64) (discussing how domestic laws permitting the public disclosure of clinical trial data are consistent with obligations under the TRIPS Agreement); Yu, *supra* note 294, at 666–67 (discussing the European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use).

313. See, e.g., Peter Lee, *New and Heightened Public-Private Quid Pro Quos: Leveraging Public Support to Enhance Private Technical Disclosure*, in INTELLECTUAL PROPERTY AND NEXT PANDEMIC, *supra* note 156 (manuscript at 11) (“As a condition of obtaining regulatory approval, developers of [vaccines, diagnostics, and therapeutics] must often submit detailed manufacturing information to regulators. Such submissions can compel the codification of tacit knowledge and the disclosure of codified trade secrets.”); Christopher Morten, *Publicizing Corporate Secrets*, 171 U. PA. L. REV. (forthcoming 2022) (manuscript at 30–54) (proposing the concept of controlled “information publicity” and calling on regulators to cultivate carefully bounded “gardens” of secret information). See generally Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 CALIF. L. REV. 493 (2021) (discussing how regulatory agencies can disclose clinical trial data without undermining privacy protection and incentives for innovation).

314. See Yu, *supra* note 7. Even within the category of tacit or uncoded knowledge, there is considerable variance. As Peter Lee explains, “tacitness is not a binary on-off designation but a question of degree. At one end of the spectrum lies purely tacit knowledge, which is incapable of codification. At the other end of the tacitness spectrum is latent knowledge, which is technically codifiable yet not presently codified.” Lee, *supra* note 313 (manuscript at 8); see also Udo Zander & Bruce Kogut, *Knowledge and the Speed of the Transfer and Imitation of Organizational Capabilities: An Empirical Test*, 6 ORG. SCI. 76, 79 (1995) (noting that “[i]t would be nonsensical to believe that there is a single dimension called tacitness” and that tacit knowledge can be analyzed based on characteristics such as codifiability, teachability, complexity, system dependence, and product observability). See generally Ajay Agrawal, *Engaging the Inventor: Exploring Licensing Strategies for University Inventions and the Role of Latent Knowledge*, 27 STRATEGIC MGMT. J. 63 (2006) (discussing ways for licensees to access and exploit uncoded but codifiable “latent knowledge” by engaging inventors during the development phase).

Pfizer, or other rights holders to transfer technology and know-how relating to vaccine production.³¹⁵ Given such difficulty, the trade secret leakage induced by the suspension portion of the deferral proposal is likely to be quite limited.

Relating to the complications involving trade secret protection is the second limitation: the proposal's inability to provide developing countries with the needed manufacturing know-how during the pandemic.³¹⁶ Just as the suspension of trade secret protection would not automatically amount to forced technology transfer, such suspension might also not lead to the transfer of the needed know-how. To the extent that developing countries need know-how to manufacture COVID-19-related vaccines, therapeutics, and technologies, complementary measures at the regional or international level, such as the development of technology transfer hubs,³¹⁷ will have to be introduced. It is worth keeping in mind that article 66.2 of the TRIPS Agreement states explicitly that "[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."³¹⁸ Paragraph 11.2 of the Ministerial Decision on Implementation-Related Issues and Concerns, which was adopted at the Fourth WTO Ministerial Conference in Doha, Qatar, states further that "the provisions of Article 66.2 of the TRIPS Agreement are mandatory."³¹⁹

The final limitation concerns the difficult cases that will emerge no matter how well established the dispute settlement mechanisms have been. Examples of these cases include disputes over the definition of the end of the pandemic, the continuation of follow-on innovations that started during the pandemic, allocation of rights, and remuneration arrangements. While finding appropriate solutions to resolve these challenging disputes is no easy feat, courts have dealt with similarly difficult situations before. For instance, U.S. courts have determined whether a rights holder can continue to distribute derivative works after the author, or his or her heirs, has terminated the rights in the underlying

315. See Peter K. Yu, *The U.S.-China Forced Technology Transfer Dispute*, 52 SETON HALL L. REV. 1003, 1044–45 (2022) (discussing the difficulty in forcing transfer of technology and know-how in the pandemic context); Bostyn, *supra* note 7, at 9 (discussing the challenges in forcing rights holders to disclose trade secrets and other know-how); see also Lee, *supra* note 313 (manuscript at 9) (finding it highly problematic that the disclosure of inventions by biopharmaceutical companies does not enable technical artisans to effectively practice these inventions).

316. Thanks to Rochelle Dreyfuss and Peter Lee for asking questions in this direction.

317. See, e.g., *FAQ—the mRNA Vaccine Technology Transfer Hub*, WORLD HEALTH ORG., <https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/faq> (last visited Jan. 28, 2023) (providing information about the mRNA Vaccine Technology Transfer Hub established by the WHO).

318. TRIPS Agreement, *supra* note 6, art. 66.2.

319. World Trade Organization, *Implementation-Related Issues and Concerns: Decision of 14 November 2001*, ¶ 11.2, WTO Doc. WT/MIN(01)/17 (Nov. 20, 2001); see also Doha Declaration, *supra* note 95, ¶ 7 ("We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2.").

works.³²⁰ Some jurisdictions have also adopted a *domaine public payant* system to allow works entering the public domain to continue to receive remuneration for a limited duration.³²¹

Finally, implementing the deferral proposal will require legislative changes similar to those required by the waiver proposal. While the precedents discussed in Part III.B can be used as references for the implementation of the deferral proposal,³²² countries in non-self-executing jurisdictions, such as the United States, will still have to introduce new legislation to implement this proposal. Nevertheless, because the proposal requires only the deferral, not giving up, of extant rights, rights holders will likely mount less resistance to this proposal than to the waiver. With such reduced resistance, the deferral proposal will have a greater chance of successful domestic implementation in the United States and other parts of the world.

CONCLUSION

Although COVID-19 has caused wide devastation and disruption unseen since the Second World War, virologists, public health experts, and other commentators have predicted that another global pandemic will likely occur in the next decade or two.³²³ Indeed, with SARS, H1N1, H5N1, Ebola, and Zika, Stefan Elbe has summed up “our experience of the twenty-first century so far . . . [as an] epidemic of epidemics.”³²⁴ His prescient observation was made before the COVID-19 pandemic. To better prepare for future pandemics or other major global crises, it is important that we learn the lessons provided by the present pandemic and develop a mechanism that will help address global crises similar to what we have experienced over the past three years.

While the deferral proposal in this Article was developed with the COVID-19 pandemic and global public health in mind, there is no reason why a similar arrangement cannot be developed for other global catastrophes, such as unanticipated, massive worldwide flooding brought about by climate change. When such catastrophes occur, the primary instinct of governments is to adjust laws, policies, and international treaty obligations. The readier we are, the more

320. See, e.g., *Stewart v. Abend*, 495 U.S. 207, 211 (1990) (considering “whether the owner of the derivative work infringed the rights of the successor owner of the pre-existing work by continued distribution and publication of the derivative work during the renewal term of the pre-existing work”).

321. See Christine Haight Farley, *Protecting Folklore of Indigenous Peoples: Is Intellectual Property the Answer?*, 30 CONN. L. REV. 1, 49–50 (1997) (discussing *domaine public payant*); see also J.H. Reichman, *The Duration of Copyright and the Limits of Cultural Policy*, 14 CARDOZO ARTS & ENT. L.J. 625, 649 (1996) (“[A] more enlightened view [than the extension under the Sonny Bono Copyright Term Extension Act] might have installed an additional twenty-year *domaine public payant*, during which period users might have enjoyed free access to works that had otherwise entered the public domain on condition that they paid equitable compensation directly to authors, but not to publishers.”).

322. See discussion *supra* Part III.B.

323. See sources cited *supra* note 22.

324. ELBE, *supra* note 22, at 1.

effective and quicker our responses will be, and the better off society will be—whether at the domestic or international level.

From an intellectual property standpoint, it will also be highly beneficial to use the deferral proposal to ready our laws and policies for future global crises—or improve our emergency preparedness in the intellectual property arena. The more prepared the intellectual property system is, the fewer urgent or ad hoc adjustments we will need, and the more robust and resilient the system will become.³²⁵ The deferral proposal advanced in this Article is therefore important whether we think about the next pandemic, other major global crises, or the future development of the intellectual property system.

325. See Yu, *supra* note 28, at 293–94 (discussing the resilience of the international intellectual property system).