A CRITICAL APPRAISAL OF THE COVID-19 TRIPS WAIVER

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INTRODUCTION

In October 2020, India and South Africa submitted an unprecedented proposal to the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) of the World Trade Organization (WTO), calling for a temporary waiver to combat the global pandemic.[1] This waiver aims to suspend Sections 1, 4, 5 and 7 of Part II of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and related enforcement under Part III 'in relation to prevention, containment or treatment of COVID-19'. Lasting for a finite period to be determined by the General Council, the waiver would cover not only patents, but also other forms of intellectual property rights. In May 2021, the proponents, along with over 60 cosponsors, submitted a revised proposal, which set the duration to 'at least 3 years' and narrowed the range of products and technologies covered.[2]

At the time of writing, the TRIPS Council is deliberating the 2021 version of the proposal, with plans to submit it for adoption or further deliberation at the General Council, depending on the outcome of the ongoing deliberations.[3] Thus far, the proposal has earned support from 'more than 100 countries as well as over 300 civil society organizations, the World Health Organization, Unitaid, South Centre and other international organizations, lawmakers in various countries, many academics and political leaders'.[4] Nevertheless, it has also met strong opposition from a number of developed countries, including Australia, Brazil, Canada, the European Union, Japan, Norway, Switzerland, the United Kingdom and the United States.[5] Although the United States announced a

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[1] Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa' (IP/C/W/669, 2 October 2020).

[2] TRIPS Council, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa' (IP/C/W/669/Rev.1, 21 May 2021).

[3] Carlos M. Correa, Nirmalya Syam and Daniel Uribe, 'Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims under Free Trade and Investment Agreements' (South Centre, Research Paper No 135, 2021) 1–2.

[4] Ibid 1.

[5] The European Union went even further to submit an alternative proposal, which calls for adjusting Articles 31 and 31*bis* of the TRIPS Agreement to allow for the use of a single notification to cover multiple countries. TRIPS Council, 'Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic: Communication from the European Union to the Council for TRIPS' (IP/C/W/681, 18 June 2021). While this proposal and the waiver proposal are not mutually exclusive, consideration of the former could take away valuable time that can be used to negotiate the latter.

change of position in May 2021 following the arrival of the Biden Administration, and some developed countries have since followed suit,[6] the US support for text-based negotiations is limited to only vaccines and does not extend to other products and technologies that are needed to combat COVID-19.[7]

This chapter offers a critical appraisal of the COVID-19 TRIPS waiver proposal. It begins by identifying the arguments for the waiver. It then turns to arguments against the proposal, including those made by policymakers and commentators who question the waiver's effectiveness. It is instructive to closely scrutinise both sets of arguments, as they illustrate the complexities involved in policy debates at the intersection of intellectual property and public health. Considering that all delegations share the common objective of quickly ending the global pandemic, the challenges to reaching an international consensus on this proposal is indeed revealing. After documenting both sides of the waiver debate, this chapter concludes by exploring whether we should support the text-based negotiations on this instrument – and if so, whether we should also support its adoption.

Although the limited length of this chapter does not allow for an in-depth examination of the relationship between the proposed waiver and the central themes explored in this volume, it goes without saying that striking an appropriate balance in the intellectual property system to combat COVID-19 is at the heart of the debate on sustainability, innovation and global justice. The third UN Sustainable Development Goal explicitly mentions both the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration). A proper assessment of the wavier proposal will be important to not only the ongoing effort to combat the pandemic, but also future developments in the post-pandemic world.

THE WAIVER

Proposed in October 2020, the waiver is purpose-specific, with its application narrowly tailored to the 'prevention, containment or treatment of COVID-19' (Paragraph 1). 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'. At the time of the proposal, developing countries were not only concerned about the lack of affordable access to the needed vaccines, treatments and technologies, but they also feared that they would have difficulty competing with developed countries for these products and technologies. Their fears were not unfounded, considering their past experiences with vaccines during the H1N1 pandemic and the earlier H5N1 avian influenza outbreak as well as the continuous concerns about vaccine nationalism.[8] Adding insult to injury,

[6] Muhammad Zaheer Abbas, 'Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case' (South Centre, Research Paper No 136, 2021).

[7] Office of the US Trade Representative, 'Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver', 5 May 2021, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver, accessed 2 October 2021.

[8] David P. Fidler, 'Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1' (2010) 7 PLoS Med. e1000247, 1; Kai Kupferschmidt, '"Vaccine Nationalism" Threatens Global Plan to Distribute COVID-19 Shots Fairly' (*Science*, 28 July 2020), https://www.sciencemag.org/news/2020/07/vaccine-nationalism-threatens-global-plan-distribute-covid-19-shots-fairly, accessed 10 October 2021; Peter K. Yu, 'Virotech Patents, Viropiracy, and Viral Sovereignty' (2013) 45 Arizona State Law Journal 1563, 1608.

reports emerged that developing countries had been charged higher prices than developed countries for COVID-19 vaccines.[9] Taken together, all of these inequities easily 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 listed explicitly in the TRIPS Agreement, the waiver covers copyright and related rights, industrial designs, patents and the protection of undisclosed information (Paragraph 1). As India explained at the TRIPS Council, these rights are included because they protect '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'.[10] If adopted, the waiver would further suspend the enforcement of these rights as required by Part III of the TRIPS Agreement (Paragraph 1). The instrument, however, will not directly affect trademarks, geographical indications, plant variety protection, layout designs of integrated circuits and the neighbouring rights of performers, phonogram producers and broadcasting organisations (Paragraphs 1 and 2).

To provide the greatest flexibility, the original waiver left the duration open-ended, opting for the language 'for [X] years' (Paragraph 1). As Paragraph 13 of the Proposal stated, '[t]he waiver should continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity'. It is worth keeping in mind that the 2020 proposal was submitted at time when 'there [wa]s [still] no vaccine or medicine to effectively prevent or treat COVID-19', as stated in paragraph 4 of the proposal. The circumstances have since changed.

Paragraph 4 of the waiver text includes the usual language in Article XI(4) of the Agreement Establishing the World Trade Organization, 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'. Paragraph 5 further creates a moratorium on WTO challenges to measures introduced to implement the waiver. The provision states 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'.

In May 2021, India and South Africa, along with over 60 cosponsors, submitted a revised proposal, drawing on the feedback they had received from WTO members and other stakeholders and taking advantage of the United States' change of position. The revised text updated the original proposal in three ways. First, it provides more specificity to the products and technologies covered by the waiver – 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 for the prevention, treatment or containment of COVID-19' (Paragraph 1).

[9] TRIPS Council, 'Minutes of Meeting: Held in the Centre William Rappard on 10–11 March 2021' (IP/C/M/98/Add.1, 30 July 2021) para 284; Behrang Kianzad and Jakob Wested, '"No-one Is Safe until Everyone Is Safe" – Patent Waiver, Compulsory Licensing and COVID-19' (2021) 5 European Pharmaceutical Law Review 71, 73.

[10] TRIPS Council, 'Minutes of Meeting: Held in the Centre William Rappard on 15–16 October and 10 December 2020' (IP/C/M/96/Add.1, 16 February 2021).

Second, although the initial proposal included an open-ended duration that the General Council is to determine, the revised proposal states that the waiver 'shall be in force for at least 3 years' (Paragraph 2). After this initial period, the General Council is charged with reviewing whether the exceptional circumstances justifying the waiver still exist and, if not, when the waiver will terminate. This arrangement is stipulated in the Agreement Establishing the World Trade Organization.

Third, the revised proposal updated the language in the waiver's preamble, noting 'the continuous mutations and emergence of new variants of 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'. Although preambular language is not operative, it highlights the many challenges posed by the global pandemic and provides contextual guidance to future interpretations of the waiver.

THE CASE FOR THE WAIVER

Thus far, supporters of the COVID-19 TRIPS waiver have advanced a number of arguments. First, the TRIPS Agreement does not provide adequate accommodation to address the global pandemic.[11] Although Article 31 allows for the issuance of compulsory licenses and Article 31*bis* extends those licenses to countries with no or limited manufacturing capacity, any license issued under the TRIPS Agreement requires a determination on a country-by-country, product-by-product and case-by-case basis.[12] Even if the arrangements are less complex than the compulsory licensing regimes found in some WTO members,[13] developed countries face considerable challenges to taking advantage of 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, the TRIPS Agreement does not provide the needed compulsory licensing arrangements. It is therefore no surprise that during the COVID-19 pandemic, policymakers and commentators have called for greater adjustments to the Agreement to ensure that product and technology developers have the needed 'freedom to operate

[11] TRIPS Council, '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' (IP/C/W/673, 15 January 2021) 5–9; 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' (South Centre, Policy Brief No 92, 2021) 3; Médecins Sans Frontières, 'Compulsory Licenses, the TRIPS Waiver and Access to Covid 19 Medical Technologies' 6–9 (*Médecins Sans Frontières*, 26 May 2021), https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies, accessed 10 October 2021; Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang and Graham Dutfield, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic' (London School of Economics and Political Science, Law, Society and Economy Working Paper No 06/2021, 2021) 26–29.

[12] TRIPS Council (n 9) para 1416.

[13] Immediately coming to mind are the criticisms of the Canada's Access to Medicine Regime in relation to the challenges confronting generic manufacturer Apotex in the late 2000s when it undertook efforts to export the HIV/AIDS drug TriAvir to Rwanda under a compulsory license. Yu (n 8) 1585–6. More recently, Bolivia faced similar challenges concerning its interest in purchasing the COVID-19 vaccine Ad26.COV2.S from Biolyse Pharma in Canada. Abbas (n 6) 4.

without the risk of litigation or the fear that exported [products and technologies] could be seized in transit and impounded for alleged patent infringement'.[14]

Second, and relatedly, the products and technologies needed to combat COVID-19 involve intellectual property rights belonging to multiple rights holders, including those that the product or technology developers may not be aware of without undertaking prior art searches or other due diligence.[15] The development of COVID-19 vaccines, for example, implicates not only the patents in the relevant vaccines, but also a wide variety of intellectual property rights in the underlying platform technology – be it mRNA or adenovirus.[16] The challenges in clearing these rights has precipitated what Michael Heller and Rebecca Eisenberg have referred to as the 'tragedy of the anti-commons',[17] in which 'multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use'.[18] To 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 area of global public health. As researchers from the Erasmus University Medical Center in the Netherlands surmised in relation to the patent pool proposed to address the Severe Acute Respiratory Syndrome (SARS):

> [In the absence of a 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.[19]

Third, the mandatory nature and the high costs of WTO dispute settlement[20] have made many governments and their officials compliance-oriented.[21] Fearing that their countries will be dragged into the WTO 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 promote public health. To a large extent, the proposed waiver will enable

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[14] Thambisetty, McMahon, McDonagh, Kang and Dutfield (n 11).
[15] Correa (n 11) 3; Yousuf Vawda, 'The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonizing Intellectual Property' (South Centre, Policy Brief No 99, 2021) 3.
[16] Sven J.R. Bostyn, 'Why a COVID IP Waiver Is Not a Good Strategy', https://ssrn.com/abstract=3843327, accessed 10 October 2021.
[17] Michael Heller, *The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives* (New York: Basic Books 2010) 49–78; Michael A. Heller and Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science 698.
[18] Heller and Eisenberg (n 17) 698.
[19] James H.M. Simon, Eric Claassen, Carmen E. Correa and Albert D.M.E. Osterhaus, 'Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling' (2005) 83 Bulletin of the World Health Organization 707, 708.
[20] Håkan Nordström and Gregory Shaffer, 'Access to Justice in the WTO: A Case for a Small-Claims Procedure?' in Chantal Thomas and Joel P. Trachtman (eds), *Developing Countries in the WTO Legal System* (Oxford: Oxford University Press 2009) 205–06; Gregory Shaffer, 'Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection' in Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (New York: Cambridge University Press 2005) 899; Peter K. Yu, 'The Comparative Economics of International Intellectual Property Agreements' in Theodore Eisenberg and Giovanni B. Ramello (eds), *Comparative Law and Economics* (Cheltenham, UK and Northampton, MA, USA: Edward Elgar Publishing 2016) 302–03.
[21] Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford: Oxford University Press 2009) 242; Keith E. Maskus and Jerome H. Reichman, 'The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods' in Maskus and Reichman (n 20) 18.

policymakers to maximise their policy space at the intersection of intellectual property and public health.

Fourth, and relatedly, the concerns about non-compliance with intellectual property standards are not limited to the TRIPS Agreement. The 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 US Trade Act has empowered the US Trade Representative to take Section 301 actions 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'.[22] In the past two decades, the US Trade Representative has taken actions against countries issuing WTO-permissible compulsory licenses.[23] By pre-empting such actions, the proposed waiver would serve a similar function as the Executive Order 13 155 that the Clinton Administration adopted in May 2000. Issued after the 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 access to HIV/AIDS medicines and related medical technologies without fear of trade retaliation.[24]

Fifth, the adoption of the proposed waiver could induce pharmaceutical companies and other private enterprises to become more pro-active in issuing voluntary licenses, including those that are open or heavily discounted. Commentators and the mass media already noted the pledges AbbVie and Moderna made on their willingness, respectively, to forgo the enforcement of their patents in Kaletra and COVID-19 vaccines, Gilead's issuance of nonexclusive voluntary licenses to remdesivir and AstraZeneca's active engagement with developing countries to increase global access to vaccines.[25] 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.[26] It would therefore not be far-fetched to assume that they will behave similarly should the waiver be adopted.[27] As Jayashree Watal, a former WTO official and the TRIPS negotiator for India, observed, the proposed waiver serves as an 'indirect attempt to put pressure on the original manufacturers to cooperate'.[28]

Finally, considering the scale of the COVID-19 pandemic and its massive challenges to countries from around the world, adjustments to the TRIPS Agreement are both logical and understandable. Just as the Constitution should not be 'a suicide pact' – a memorable observation

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[22] 19 U.S.C. § 2411(d)(3)(B)(i)(II).
[23] TRIPS Council (n 9) para 1157; Jonathan Burton-MacLeod, 'Tipping Point: Thai Compulsory Licences Redefine Essential Medicines Debate' in Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge: Cambridge University Press 2010) 406–07.
[24] Yu (n 8) 1620.
[25] Bryan Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review' (2021) 62 Virginia Journal of International Law Online 9, 20–3; Phil Taylor, 'AbbVie Won't Enforce Patents for COVID-19 Drug Candidate Kaletra' (*Pharmaphorum*, 25 March 2020), https://pharmaphorum.com/news/abbvie-wont-enforce-patents-for-covid-19-drug-candidate-kaletra/, accessed 11 October 2021; Thambisetty, McMahon, McDonagh, Kang and Dutfield (n 11) 7.
[26] Carie Steele, 'The Biden Administration Supports Waiving Patents on Coronavirus Vaccines. Big Pharma Won't Be Happy.' (*Washington Post*, 5 May 2021), https://www.washingtonpost.com/politics/2021/05/05/biden-administration-supports-waiving-patents-coronavirus-vaccines-big-pharma-wont-be-happy/, accessed 10 October 2021.
[27] Bryan Mercurio, 'The IP Waiver for COVID-19: Bad Policy, Bad Precedent' (2021) 52 International Review of Intellectual Property and Competition Law 983, 986; Maximilian Steinbeis and Evin Dalkilic, 'Three Crises and One Waiver' (*Verfassungsblog*, 7 May 2021), https://verfassungsblog.de/three-crises-and-one-waiver/, accessed 10 October 2021.
[28] Steinbeis and Dalkilic (n 27).

made by Justice Arthur Goldberg in *Kennedy v. Mendoza-Martinez*[29] – the TRIPS Agreement should not prevent WTO members from addressing those public health emergencies that threaten their well-being, such as the COVID-19 pandemic. Moreover, given the transborder nature of global pandemics and the emergence of the delta, lambda and other variants in different parts of the world, the benefits of implementing the waiver will inure to the entire global community. As the webpage for the Access to COVID-19 Tools Accelerator rightly reminded us, 'No-one is safe until everyone is safe'.[30] 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 global pandemic.[31] The proposed waiver would build on this recommendation but pre-empt any potential challenge before the WTO Dispute Settlement Body concerning whether the waiver has met the 'essential security interests' and 'emergency in international relations' requirements in the provision.

THE CASE AGAINST THE WAIVER

Although one could make a very strong case for the proposed waiver, those opposing the waiver or questioning its effectiveness have advanced some convincing arguments. First, many of the problems relating to the shortage 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 the deficiencies in the public health infrastructure.[32] As former WIPO Director General Francis Gurry 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'.[33] Even with the adoption of the proposed waiver, it is unclear whether countries can quickly address many of the existing problems. To be sure, arguments that emphasise intellectual property-irrelevant problems are as unpopular as the past efforts of the pharmaceutical industry and their supportive commentators in attributing the lack of access to HIV/AIDS medicines to drug delivery problems and deficient public health infrastructures.[34] Nevertheless, it is not unreasonable to question the wisdom of taking such drastic measures as suspending intellectual property rights when there are lingering doubts over whether these measures would effectively address the

[29] 372 U.S. 144, 160 (1963).
[30] World Health Organization, 'The Access to COVID-19 Tools (ACT) Accelerator', https://www.who.int/initiatives/act-accelerator, accessed 3 October 2021.
[31] Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic* (South Centre, Research Paper No 116, 2020) 21; Carlos Correa, Letter to Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, Francis Gurry, Director-General of the World Intellectual Property Organization, and Roberto Azevêdo, Director-General of the World Trade Organization, 4 April 2020.
[32] Reto M. Hilty, Pedro Henrique D. Batista, Suelen Carls, Daria Kim, Matthias Lamping and 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', 1, https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_statement_Covid_IP_waiver.pdf, accessed 11 October 2021; Justin Hughes, 'Biden Decision on COVID Vaccine Patent Waivers Is More about Global Leadership' (*USA Today*, 6 May 2021), https://www.usatoday.com/story/opinion/2021/05/06/covid-vaccine-patents-biden-boosts-american-leadership-column/4932766001/, accessed 11 October 2021; Mercurio (n 25) 15–16; Ana Santos Rutschman and Julia Barnes-Weise, 'The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal' (*Bill of Health*, 5 May 2021), https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/, accessed 10 October 2021.
[33] Francis Gurry, 'Some Considerations on Intellectual Property, Innovation, Access and COVID-19', https://www.wipo.int/about-wipo/en/dg_gurry/news/2020/news_0025.html, accessed 2 October 2021.
[34] Amir Attaran and Lee Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?' (2001) 286 Journal of the American Medical Association 1886, 1891; Peter K. Yu, 'The International Enclosure Movement' (2007) 82 Indiana Law Journal 827, 850.

problem. Indeed, critics of the waiver have repeatedly demanded concrete evidence on how intellectual property rights have erected barriers to accessing pandemic-related vaccines, treatments and technologies.[35]

Second, the development of different products and technologies requires a range of incentive frameworks. The incentives needed for the development of COVID-19 vaccines is frequently quite different from those needed for the development of new therapeutic treatments or medical equipment.[36] Moreover, interventions to incentive frameworks can both benefit and harm innovation, depending on the situation at hand. As Jorge Contreras observed:

> 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.[37]

Thus, even if we acknowledge that the intellectual property system has presented some access barriers to the needed medical products and technologies – a position actively challenged by those opposing the waiver – it remains unclear, especially empirically, whether the waiver would, on balance, undermine 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. Answering this question will become even harder if we think ahead about what we should do to prepare for the next global pandemic, which many experts predict will happen within the next decade or two.[38] It is worth keeping in mind that many of those SARS-related products and technologies that have been used to accelerate our effort to combat COVID-19 were developed under a background of strong intellectual property rights. We will never know whether the research for those products and technologies, or how much of it, will be undertaken without such protection, the massive outpouring of public funding notwithstanding. 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'.[39] It is therefore unsurprising that a position paper from the Max Planck Institute for Innovation and Competition declared that '[a] waiver of IP protection would not serve the interest of the society, as it would create a disincentive for companies to pursue research in those areas'.[40]

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[35] In defence of the waiver's supporters, governments and their supportive non-governmental organisations have provided considerable evidence documented the many challenges intellectual property rights have posed to the development of COVID-19-related products and technologies. TRIPS Council, 'Examples of IP Issues and Barriers in COVID-19 Pandemic: Communication from South Africa' (IP/C/W/670, 23 November 2020); TRIPS Council (n 11); 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' (*Médecins Sans Frontières*, 3 December 2020), https://msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access, accessed 10 October 2021. Moreover, access barriers generated by intellectual property rights tend to exacerbate those access barriers that are unrelated to these rights. Thambisetty, McMahon, McDonagh, Kang and Dutfield (n 11) 40.

[36] Peter K. Yu, 'Modalities, Challenges, and Possibilities: An Introduction to the Pharmaceutical Innovation Symposium' (2021) 7 Texas A&M Journal of Property Law 1, 11.

[37] Jorge L. Contreras, 'Expanding Access to Patents for COVID-19' in Scott Burris, Sarah de Guia, Lance Gable, Donna E. Levin, Wendy E. Parmet and Nicolas P. Terry (eds), *Assessing Legal Responses to COVID-19* (Boston: Public Health Law Watch 2020) 158–9.

[38] Stefan Elbe, *Pandemics, Pills, and Politics: Governing Global Health Security* (Baltimore: Johns Hopkins University Press 2018) 34.

[39] Hilty, Batista, Carls, Kim, Lamping and Slowinski (n 32) 5.

[40] Ibid.

Third, because of the consensus-based process used in the WTO, it likely will take quite some time before members adopt this waiver. 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. Although WTO members adopted the Doha Declaration in November 2001 and a protocol to amend the TRIPS Agreement four years later, the proposed TRIPS amendment did not enter into effect until January 2017, after two-thirds of the WTO membership had ratified the amendment. If this past track record provides any guide, any waiver deliberation that is being undertaken to combat COVID-19 will likely impact the next pandemic, not the current one.

Fourth, many of the concerns and problems that have been identified in developing countries relate to implementation. Even if the waiver is quickly adopted – an outcome that seems unlikely given the pace of WTO negotiations – countries still need to implement the waiver proposal and put them into laws and regulations. Not only will there be the usual differences between the positions taken in Geneva and those held in state capitals,[41] the implementation process will likely lead to a replay of the international policy debate at the domestic level, bringing to mind the two-level game pioneered by political scientist Robert Putnam.[42] It is no coincidence that many countries that have endorsed the waiver have been reluctant to introduce compulsory licenses at the domestic level or to utilise the national security expectation under Article 73 of the TRIPS Agreement. So far, Israel, Hungary and Russia remain the only countries that have issued a compulsory license during the COVID-19 pandemic.[43] Whether the adoption of the proposed waiver will transform domestic debates remains to be seen. For many countries, what they can do at the implementation level will depend on not only their WTO obligations, but also on other obligations in bilateral, regional and plurilateral agreements, including those that contain TRIPS-plus provisions in the intellectual property and investment areas.[44] It is therefore no surprise that Carlos Correa and his South Centre colleagues have called on countries to negotiate 'complementary waivers from [these agreements] where there may be conflict with the implementation of the waiver'.[45] 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.[46]

Fifth, WTO negotiations are always filled with concessions and compromises. It is therefore highly unlikely that many developed countries that currently oppose the waiver will offer

[41] Deere (n 21) 122; Peter K. Yu, 'ACTA and Its Complex Politics' (2011) 3 WIPO Journal 1, 14.
[42] Robert D. Putnam, 'Diplomacy and Domestic Politics: The Logic of Two-Level Games' (1988) 42 International Organization 427.
[43] Kianzad and Wested (n 9) 74; Médecins Sans Frontières (n 11) 5–6.
[44] Correa, Syam and Uribe (n 3); Prabhash Ranjan, 'Trade-Related Aspects of Intellectual Property Rights Waiver at the World Trade Organization: A BIT of a Challenge', https://ssrn.com/abstract=3888980, accessed 11 October 2021.
[45] Correa, Syam and Uribe (n 3) 20.
[46] Ibid 5.

support without getting anything in return.[47] Considering the need for quid pro quo, one cannot help but wonder how the proposed waiver will affect the ongoing negotiations at the WTO and the World Intellectual Property Organization surrounding other limitations and exceptions to intellectual property rights. If the text-based negotiations on the proposed waiver would slow down other pro-development negotiations in the intellectual property domain – or in other trade-related areas – it is worth evaluating holistically whether the purported benefits of the proposed waiver would outweigh its costs, especially when a significant segment of the global population has been vaccinated.

Sixth, we have long criticised the ill-advised 'one size fits all' approach taken in the TRIPS Agreement and TRIPS-plus bilateral, regional and plurilateral agreements. Sadly, the proposed waiver has embraced this oft-criticised approach – except that it proceeds in the opposite direction. Such an approach is particularly problematic considering that few countries share the same pandemic experience at the same time or on the same scale, especially when geographical and seasonal differences are taken into account. With the wide disparities in both vaccine availability and vaccination rate, the experience each country has will likely vary significantly in the near future. The need for incentives and the availability of alternative support will also differ considerably. Taken together, all of these domestic variations will present major challenges to both the negotiation and implementation of the proposed waiver.

Finally, although least developed countries are sometimes mentioned in relation to the proposed waiver, they will not be in need of this waiver unless the pandemic lasts for a long period of time. The WTO has recently extended the transition period for these countries to 1 July 2034. Before this extension, the WTO already allows these countries to delay protections for pharmaceutical patents and undisclosed test data until 1 January 2033. Paragraph 3 of the waiver specifically states that the instrument will not 'prejudice … the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement'. Thus, if we are to properly assess the benefits provided by the proposed waiver, it may be fruitful to focus on only developed and developing countries, as opposed to all WTO members.

GOING FORWARD

Given the various arguments both for and against the proposed waiver, it remains challenging to determine whether one should support the instrument. Indeed, as with many debates in the intellectual property area, the side that bears the burden of proof will have great difficulty prevailing in the debate.[48] As David McGowan observed in the copyright law context: '[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.'[49]

To help clarify our options going forward, this chapter argues that we should divide the question into two sub-questions. We should first start ask whether we should support the text-

[47] Third World Network, 'Developing Countries Call for Text-Based Negotiations on TRIPS Waiver' (*TWN Info Service on WTO and Trade Issues*, 8 February 2021), https://www.twn.my/title2/wto.info/2021/ti210204.htm, accessed 17 October 2021.
[48] David McGowan, 'Copyright Nonconsequentialism' (2004) 69 Missouri Law Review 1, 2; Peter K. Yu, 'Anticircumvention and Anti-anticircumvention' (2006) 84 Denver University Law Review 13, 15.
[49] McGowan (n 48) 2.

based negotiations on the waiver. Once we answer in the affirmative, we should then explore whether we should support the waiver's adoption.

Considering that neither side has been a clear winner in the ongoing debate, the considerable and continuous struggle of many countries – in both the developed and developing worlds – during the COVID-19 pandemic should tip the balance. We have not seen such wide devastation, heavy health and human toll and considerable socio-economic fallout in the past few decades. The answer to the first question on text-based negotiations is therefore an easy yes. It is indeed no surprise that WTO members agreed to begin text-based negotiations in June 2021. Sadly, the negotiations have remained rather general at the time of writing, with discussions still focusing on the appropriateness and effectiveness of the waiver, as opposed to the substantive text and the actual parameters. Regardless of the outcome, those countries in need of the waiver deserve good-faith negotiations.

To be sure, one could question whether the current proposal is broader than the remedy needed to combat the global pandemic, and there will always be arguments for and against having intellectual property rights in the first place. Nevertheless, past WTO negotiations have shown a tendency for negotiators to split the difference so that all parties will be able to justify the compromise at home. If the proposal were to scale back to cover only what most WTO members would find acceptable, that proposal would likely be watered down even further by the time members had completed their negotiations.

During the TRIPS negotiations, developed countries' proposals were incorporated into the A text, while developing countries' proposals were incorporated into the B text. Even though the former had been more successful in pushing for their preferred language, the negotiators ended with a composite text that included both the A and B texts and that was filled with compromises and constructive ambiguities.[50] Likewise, in the run-up to the Sixth WTO Ministerial Conference in Hong Kong in December 2005, least developed countries and their allies pushed hard for an extension of the TRIPS transition period for 15 years. Despite this effort, developed countries were reluctant to support such an extension. WTO members eventually settled on an extension for only seven and a half years, half of what least developed countries requested.[51]

Given these past negotiated outcomes, it is not difficult to understand why the proponents of the COVID-19 TRIPS waiver wanted to advance a much broader proposal despite the anticipated opposition from some WTO members. It is also not far-fetched to assume that these proponents are keenly aware of the high unlikelihood of getting everything they proposed. Determining what countries should demand at the beginning of the negotiations is just very different from determining what countries should accept at the end. It is therefore important not to confuse the two when assessing whether WTO members should engage in text-based negotiations.

We should also keep in mind the existence of many possibilities within the negotiations. For example, even though critics of the waiver have repeatedly noted their concerns about the

[50] Daniel J. Gervais, 'Intellectual Property, Trade & Development: The State of Play' (2005) 74 Fordham Law Review 505, 507–08; Peter K. Yu, 'Are Developing Countries Playing a Better TRIPS Game?' (2011) 16 UCLA Journal of International Law and Foreign Affairs 311, 315–16.
[51] Peter K. Yu, 'TRIPS and Its Contents' (2020) 60 IDEA 149, 209.

forced disclosure of trade secrets and undisclosed regulatory data – a topic that has received considerable attention at the waiver debate[52] – it would be quite a leap to go from trade secret protection to forced technology transfer.[53] There are still many possibilities between these two options, both of which arguably lie on two ends of a continuum.

After exploring the first question about text-based negotiations, we can then engage with the follow-up question concerning whether we should support the waiver's adoption. This question is much harder than the first, as its answer will likely depend on timing, the actual parameters delineated in the final text and whether side deals have emerged in the intellectual property or other trade-related area that would allow countries to strike more creative compromises.

Moreover, circumstances continue to evolve. Thanks to the revision in May 2021, the waiver proposal that the TRIPS Council currently deliberates is already quite different from the original proposal India and South Africa submitted in October 2020. Whether that proposal will evolve yet again remains to be seen.

Should countries continue to recover from COVID-19 and should the pandemic transform into an endemic,[54] it is quite likely that more delegations will answer the second question in the negative. Should that become an issue, the proponents, the cosponsors and their supporters may want to think hard about whether they should change their strategy to focus on developing a waiver mechanism that would address not only COVID-19, but also all future global pandemics. This forward-looking approach is reminiscent of the ongoing effort to establish an international treaty on pandemics at the World Health Organization. That treaty, if developed, will likely be quite important in the post-pandemic world.

CONCLUSION

The COVID-19 pandemic has wreaked havoc throughout the world, costing millions of human lives and exacting a global economic toll of at least tens of trillions of dollars. Given such devastation, it is understandable why India and South Africa advanced the waiver proposal to suspend select intellectual property rights under the TRIPS Agreement. It is also not surprising to see more than a third of the WTO membership eagerly joining the proposal as co-sponsors. Indeed, as this chapter has shown, it is difficult to make a strong case against the launch of text-based negotiations on the proposed waiver at the WTO.

Nevertheless, a close scrutiny of the waiver proposal does reveal many challenges confronting both the negotiation and implementation of the proposal. By examining the key arguments for and against this proposal, the present chapter illustrates the many complexities involved in debates at the intersection of intellectual property and public health. It shows that policymakers and commentators may strongly disagree even when they share a common objective.

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[52] TRIPS Council, 'Minutes of Meeting Held in the Centre William Rappard on 20 July 2021' (IP/C/M/101, 23 July 2021) para 4.

[53] Commentators have called for or noted the possibilities for such involuntary disclosure. Thambisetty, McMahon, McDonagh, Kang and Dutfield (n 11) 23–4; Vawda (n 15) 3.

[54] Lara Herrero and Eugene Madzokere, 'COVID Will Likely Shift from Pandemic to Endemic – But What Does That Mean?' (*The Conversation*, 20 September 2021), https://theconversation.com/covid-will-likely-shift-from-pandemic-to-endemic-but-what-does-that-mean-167782, accessed 10 October 2021; Nicky Phillips, 'The Coronavirus Is Here to Stay – Here's What That Means' (*Nature*, 16 February 2021), https://www.nature.com/articles/d41586-021-00396-2, accessed 10 October 2021.

To a large extent, the waiver debate has foreshadowed many challenges we will face in international policy debates on issues relating to sustainability, innovation and global justice.

Finally, regardless of whether WTO members can ultimately adopt the proposed waiver, or adopt it in time to combat COVID-19, the debate generated by the proposal and the global pandemic has already advanced policy discussions at the intersection of intellectual property and public health. These discussions have covered issues ranging from the need for more flexibilities in the intellectual property system to the importance of local or regional production to the benefits of significant adjustments to TRIPS obligations. Policymakers and commentators have widely lamented the ineffectiveness and underutilisation of Article 31*bis*, yet nobody will deny the importance of the debate sparked by the Doha Declaration and the related effort to amend the TRIPS Agreement. The waiver proposal will likely have similarly positive impact regardless of the outcome.