Tripping up Intellectual Property: From waiver to a more flexible interpretation of compulsory licensing

Bryan Mercurio* & Pratyush Nath Upreti**

INTRODUCTION

The innovative biopharmaceutical industry reacted with remarkable pace in responding to the COVID-19 pandemic by producing vaccines and treatments in an unprecedented period of time. During development, and despite early progress, India and South Africa proposed that the World Trade Organization (WTO) waive the core rights contained in the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)[1] to allow other Members and their companies to use, produce, and sell the COVID-19 related products and processes that would otherwise be protected as the intellectual property rights (IPRs) of innovator companies. The so-called IP waiver circulated at the TRIPS Council in October 2020, was proposed on the assumption that unlocking IP would increase the global supply of vaccines and treatments by allowing more companies in more locations to manufacture and produce such products.[2] While accepted by NGOs and other

DOI: https://doi.org/10.15779/Z38GB1XJ2X

* Simon F.S. Li Professor of Law, The Chinese University of Hong Kong; RGC Senior Research Fellow (2023–27). This research is supported by the Hong Kong RGC Senior Research Fellow Scheme 2022/23 for a project entitled: Access to Vaccines in a Post-COVID-19 World: Sustainable Legal and Policy Options (Project No. SRFS2223-4H01). The views expressed in this publication do not necessarily represent the views of others involved in the project.

** Senior Lecturer in Law, School of Law, Queen's University Belfast, United Kingdom.

Both authors contributed equally to this article and are listed alphabetically.

1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, April 1994, 1869 U.N.T.S. 3; 33 ILM. 1197 (1994).

2. Communication from India and South Africa, WTO Doc. IP/C/W/669, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19* (October 2, 2020).. See also the revised version of the proposal dated 25 May 2021: Communication from the African Group, Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, Venezuela and Zimbabwe, WTO Doc. IP/C/W/669/Rev.1, WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19* (May 21, 2021).

commentators,[3] this assumption was challenged by innovators and scientists.[4] Unsurprisingly, governments were also divided on the waiver's necessity as well as on the contours of the proposed waiver.

Ultimately, while a majority of Members supported the original IP waiver proposal, it did not garner consensus among the WTO membership.[5] With the strong support and encouragement of WTO Director-General, Ngozi Okonjo-Iweala, Members were able to reach a compromise and agree to the Ministerial Decision on the TRIPS Agreement (Ministerial Decision).[6] The Decision bears little resemblance to the original IP waiver proposal and is a mere temporary waiver of some of the requirements set out in Article 31 and Article 31b of the TRIPS Agreement.[7]

The move away from an IP waiver and towards a solution based on existing WTO disciplines and flexibilities is more practical and avoids most of the complicating issues relating to a waiver. This is not to say that the Ministerial Decision is a perfect solution to issues of access to vaccines; it is not. There is a growing amount of literature analyzing the Ministerial Decision.[8] The purpose of this article is not to rehash the political debate, but to argue that the move away

---

3. See generally Siva Thambisetty *et al*., *Addressing Vaccine Inequity During the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond*, 81 CANBRIDGE L.J. 384–416 (2022).

4. For a detailed discussion on the proposal, see Bryan Mercurio, *WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review*, 62 VA. J. INT'L L. 10 (2021),10–32; Reto M. Hilty et al., Covid-19 and the Role of Intellectual Property (Position Statement of the Max Planck Institute for Innovation and Competition of May 7, 2021), https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_statement_Covid_IP_waiver.pdf (last visited June 20, 2022); James Bacchus, *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines*, Free Trade Bulletin No. 78, CATO INSTITUTE (Dec. 16, 2020) https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines (last visited June 20, 2022). See also Christoph Ann *et al.*, *The waiving of intellectual property: a poor response to a real problem*, THE STANISLAS DE BOUFFLERS INSTITUTE (May 19, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3850550 (last visited June 20, 2022).

5. WTO is a consensus-based organization, see footnote 1 to the Marrakesh Agreement; 'The [WTO] body concerned shall be deemed to have decided by consensus on a matter submitted for its consideration, if no Member, present at the meeting when the decision is taken, formally objects to the proposed decision'. See *Marrakesh Agreement Establishing the World Trade Organization*, https://www.wto.org/english/docs_e/legal_e/04-wto_e.h (last visited June 20, 2022).

6. WTO, Draft Ministerial Decision on the TRIPS Agreement, Ministerial Conference, 12th Session, WT/MIN(22)/W/15/Rev.2 (June 17, 2022).

7. *Id.*, paras 2–3. For more discussion on compulsory licensing and public health, *see* VAN ANH LE, COMPULSORY PATENT LICENSING AND ACCESS TO MEDICINES: A SILVER BULLET APPROACH TO PUBLIC HEALTH? (Palgrave Macmillan, 2021); Monica Thomas, *To Waive or not to Waive: International Patent Protection and the COVID-19 Pandemic*, 49 L. ISSUES ECON. INTEGRATION 7 (2022).

8. *See* generally, James Love, *The June 17, 2022 WTO Ministerial Decision on the TRIPS Agreement*, *KEI ONLINE*, (June 17, 2022), https://www.keionline.org/37830 (last visited June 20, 2022); Dalindyebo Shabalala, *Here Again?! – The WTO COVID19 Waiver Ministerial Decision – June 2022* (June 17, 2022), https://dalishabalala.wordpress.com/2022/06/17/here-again-the-wto-covid19-waiver-ministerial-decision-june-2022/ (last visited June 20, 2022).

from an IP waiver was appropriate, and collective efforts to improve production capabilities, licensing, and distribution, and reduce bottlenecks should be co-ordinated and institutionalized.[9] There are growing voices against the final outcome of negotiations, therefore there is no doubt that waiver is likely to emerge in the future, with the only uncertainty being whether it occurs with a mutation of the COVID-19 virus or a future pandemic. Much has been written on the topic since the Ministerial Decision, however, highlighting the fundamental issues with an IP waiver is important to inform and engage in future debate and ensure time is not wasted in addressing the next crisis or pandemic. This is not to argue that the current IP system is perfect, in fact there is much to do to ensure that IP facilitates access to public health, but it is equally important to remember the possible consequences of waiving IPRs in addressing future crises.[10]

Part II provides context by reviewing the background of the negotiations, the various proposals, and the Ministerial Decision. Part III argues that an IP waiver is not a suitable means to achieve a sustainable increase in access to vaccines, and focuses on three reasons for this conclusion: (1) problems associated with forcing the transfer of trade secrets; (2) negative impact on the incentive to research; and (3) doubts about the ability of a waiver to deliver cheaper or increase sustainable access to vaccines.

I. THE BACKGROUND TO THE IP WAIVER PROPOSAL, NEGOTIATIONS AND DECISION

In October 2020, India and South Africa proposed a waiver from the implementation, application, and enforcement of Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement, which respectively address copyright, industrial designs, patents and trade secrets.[11] Arguing that IPRs are a barrier to accessing

9. For discussion and analysis of the Ministerial Decision, *see* 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); Reto M. Hilty et al., *Position Statement of the Decision of the WTO Ministerial Conference on the TRIPS* Agreement, MAX PLANCK INSTITUTE FOR INNOVATION AND COMPETITION, https://www.ip.mpg.de/en/research/research-news/position-statement-on-the-decision-of-the-wto-ministerial-conference-on-the-trips-agreement.html (last visited August 10, 2022).

10. More recent literature discusses on improving IP, see generally SUSY FRANKEL ET AL., IMPROVING INTELLECTUAL PROPERTY: A GLOBAL PROJECT (2023); TAINA PIHLAJARINNE, JUKKA MÄHÖNEN & PRATYUSH NATH UPRETI, INTELLECTUAL PROPERTY RIGHTS IN THE POST PANDEMIC WORLD: AN INTEGRATED FRAMEWORK OF SUSTAINABILITY, INNOVATION AND GLOBAL JUSTICE (2023).

11. WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, *supra* note 2. The revised waiver proposal clarifies the scope of the waiver of Section 1, 4, 5 and 7 of Part II of the TRIPS Agreements by adding 'in relation to 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'. See WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (Revised)*, *supra* note 2.

COVID-19 vaccines and treatment — yet also acknowledging that, "[t]o date, there is no vaccine or medicine to effectively prevent or treat COVID-19" – the sponsors and their supporters believed that the TRIPS Agreement provided a "limited option to overcome the barriers" that IP may impose for the prevention, containment and treatment of COVID-19.[12]

In this regard, the sponsors asserted that the flexibilities enshrined in the TRIPS Agreement were inadequate as they were "never designed to address a health crisis of this magnitude" and that certain Members face "legal and institutional difficulties" in implementing flexibilities.[13] The sponsors took particular issue with the complexity involved in issuing compulsory licenses which limit the agreement's value and usefulness during a pandemic.[14]

The second major argument the sponsors and waiver proponents made is that IP and exclusive licensing agreements restrict the scale-up of manufacturing, lockout generic suppliers, and undermine competition that would reduce the price of vaccines.[15] Sponsors and proponents likewise doubted the feasibility of industry and government efforts to create voluntary sharing mechanisms[16] as well as the willingness of innovators to share IP and technologies in, among others, the COVID-19 Technology Access Pool (C-TAP) pool.[17]

---

12. WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Response to Questions*, supra note 11, at ¶ 1.1.3.

13. Communication from Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, Venezuela and Zimbabwe, WTO Doc. IP/C/W/672, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Response to Questions* (15 January 2021) at 16–18 read with WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, supra note 2, at 10. See further Amiti Sen, *WTO members divided over India-South Africa proposal for TRIPS waiver during COVID-19*, THE HINDU BUSINESS LINE (October 17, 2020), https://www.thehindubusinessline.com/economy/wto-members-divided-over-india-south-proposal-for-trips-waiver-during-covid-19/article32878713.ece (last visited June 20, 2022).

14. WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Response to Questions*, supra note 11, at ¶ 1.1.3.

15. *Id.*at 1.2.7 and 2.9.59. *See also* Kathryn Ardizzone, Role of the U.S. Federal Government in the Development of GS-5734/Remdesivir, *KEI Briefing Note 2020:1* (March 20, 2020).

16. WTO, Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/M/96, 16 October 2020, Item 15 Proposal for a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 Document IP/C/W/669 (Communication from India and South Africa), https://pmindiaun.gov.in/public_files/assets/pdf/TRIPS_Agreemnet.pdf (last visited June 20, 2022).

17. *See* Council for Trade-Related Aspects of Intellectual Property Rights, July 17, 2020, WTO Doc. IP/C/W/666, Intellectual Property and Public Interest: Beyond Access to Medicines and Medical Technologies Towards a More Holistic Approach to TRIPS Flexibilities, Communication from South Africa, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W666.pdf&Open=True (last visited June 20, 2020), ¶ 8.

The proposal attracted sponsorship and support from most developing countries and the LDC Group,[18] but numerous developed countries were opposed.[19] Several developing countries, including influential Members such as Brazil, China, Chile and Mexico, were initially unenthusiastic and almost indifferent to the proposal.[20]

Discussions proceeded slowly, and the proposal seemed doomed until May 2021, when Ambassador Katherine Tai announced the United States' support for the negotiation of a waiver for COVID-19 *vaccines*.[21] While the US shift caused some WTO Members – including China – to change their position and support waiver negotiations, other Members remained opposed. The most vocal and notable opposition came from the European Commission (EC), United Kingdom (UK) and Switzerland. While the latter two were reported to be opposed to a waiver of any sort,[22] the EC preferred changes that better allowed for the use of the already existing TRIPS flexibilities, in particular that of compulsory licensing.[23] That being said, European Union (EU) member States were not

18. *See TRIPS Council to Continue to discuss temporary IP waiver, revised proposal expected in May*, WTO NEWS (April 30, 2021), https://www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm (last visited June 20, 2022).

19. *See, e.g.*, UK Statement to the TRIPS Council: Item 15 Waiver Proposal for COVID-19 (UK Mission to the WTO, UN and Other International Organisations, Geneva; October 16, 2020)- 'A waiver to the IP rights set out in the TRIPS Agreement is an extreme measure to address an unproven problem'. The UK is of the view that pursuing the proposed path would be counterproductive and would undermine a regime that offer solutions to the issues at hand), https://www.gov.uk/government/news/uk-statement-to-the-trips-council-item-15 (last visited June 20, 2022).

20. *Covid: Germany rejects US-backed proposal to waive vaccine patents*, BBC NEWS (May 6, 2021), https://www.bbc.com/news/world-europe-57013096 (last visited June 20, 2022). Countries like Canada, Australia, Norway, Switzerland, the United Kingdom are some of the developed countries which initially opposed the waiver. Ibid. For detailed discussion on the proposal, *see* Mercurio, *supra* note 4.

21. *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, Press Release (May 5, 2021) https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver (last visited June 20, 2022). Unsurprisingly, support in the US government for the waiver is not universal. For example, sixteen US Senators issued a letter against the US decision to support waiver, *see* https://www.ipwatchdog.com/wp-content/uploads/2021/05/Tillis-Cotton-letter-to-USTR-Commerce-re.-TRIPS-Waiver-Clean-1.pdf (last visited June 20, 2022).

22. *See* UK Statement to the TRIPS Council, *supra* note 19.

23. European Commission, Opening statement by Executive Vice-President Valdis Dombrovskis at the European Parliament plenary debate on the Global Covid-19 challenge (May 19, 2021) https://ec.europa.eu/commission/commissioners/2019-2024/dombrovskis/announcements/opening-statement-executive-vice-president-valdis-dombrovskis-european-parliament-plenary-debate_en (last visited June 20, 2022). *See also* Philip Blenkinsop and Carl O'Donnell, *EU supports COVID vaccine patent waiver talks, but critics say won't solve scarcity*, REUTERS (May 6, 2021), https://prod.reuters.com/world/europe/eu-willing-discuss-covid-19-vaccine-patent-waiver-eus-von-der-leyen-2021-05-06/ (last visited June 20, 2022).

completely united. Germany maintained that IP was the key to innovation and solution for the pandemic, and therefore steadfastly opposed a waiver.[24]

Garnering consensus on an IP waiver was challenging, however, the revised proposal submitted by India and South Africa on May 21, 2021 did not provide a path for global consensus. Far from building on the momentum gained from the US' reversal of position, the revised proposal did not adjust product coverage, scope, notification requirements, or safeguards and was drafted in such a way that would have allowed the waiver to remain in effect until every WTO Member decided it was no longer needed. Essentially, under the revised proposal, the waiver could remain in effect for an indefinite period.[25]

With Director-General Okonjo-Iweala pushing for a resolution, the US, EU, India, and South Africa controversially began informally negotiating a compromise agreement in late 2021.[26] These negotiations resulted in an "Outcome Document," which was leaked in March 2022 and formally introduced and circulated by the Director-General in the TRIPS Council in May 2022.[27] Far from the original proposal, the Document departed in significant ways from an IP waiver. Instead, the Document was similar to the EU's favored approach of loosening restrictions on compulsory licensing. This Document became the negotiating text in the lead-up to the Ministerial Conference.

Following a week of negotiations, Members reached consensus on the Ministerial Decision.[28] The Decision resembles the Outcome Document, with some important changes. The Decision is not a waiver of IPRs but a clarification of existing flexibilities and a limited exception to exportation restrictions contained in the compulsory licensing provisions of Article 31 and Article 31b is. The Decision primarily focuses on Article 31(f), which limits the authorized use of the license "predominantly for the supply of the domestic market," and Article 31bis – initially adopted as a waiver by the WTO General Council on 30 August 2003 and transformed into a permanent amendment in 2017 – which under certain

---

24. *Germany rejects U.S. proposal to waiver patents on COVID-19 vaccines*, REUTERS (May 6, 2021) https://prod.reuters.com/business/healthcare-pharmaceuticals/germany-opposes-us-plan-waive-patents-covid-19-vaccines-2021-05-06/ (last visited June 20, 2022).

25. *See* WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (Revised)*, *supra* note 2.

26. *See Members updated on high-level talks aimed at finding convergence on IP COVID-19 response*, WTO NEWS, (March 10, 2022), https://www.wto.org/english/news_e/news22_e/trip_10mar22_e.htm (last visited June 20, 2022).

27. WTO Council for Trade Related Aspects of Intellectual Property Rights, 'Communication from the Chairperson on TRIPS COVID-19', WTO/IP/C/W/688 (May 3, 2018), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W688.pdf&Open=True (last visited 20 June 2022). For a crucial review of the Outcome document, see Siva Thambisetty et al., "The COVID-19 TRIPS Waiver Proposal in Critical Review: An Appraisal of the WTO DG Text (IP/C/W/688) and Recommendations for Minimum Modifications" https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4124497 (last visited June 20, 2022).

28. WTO, Draft Ministerial Decision on the TRIPS Agreement, *supra* note 6.

circumstances allows for the exportation of pharmaceuticals under compulsory licenses to Members with insufficient or no manufacturing capabilities.

More specifically, the Ministerial Decision allows an "eligible Member"[29] to limit the exclusive rights provided for in Article 28 of the TRIPS Agreement by authorizing the use of patented IP "required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic," subject to the compulsory licensing provisions contained in Article 31 as clarified and waived in the Ministerial Decision.

The core of the Decision is contained in paragraph 2(b), and allows eligible Members to "waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market." It allows "any proportion of the products manufactured under the authorization" to the markets of other eligible Members, including thorough "international or regional joint initiatives"[30] , without the need to seek consent from the rights holder. Both the latter requirements deviate from the provisions of Article 31 of the TRIPS Agreement. The Decision applies only to vaccines, but paragraph 8 instructs Members to decide whether to extend coverage to the production and supply of COVID-19 diagnostics and therapeutics within six months of the date of the Decision – and will remain in force for a period of five years, subject to extension from the General Council.[31]

The Decision represents a compromise among Members at the WTO, but is not even close to resembling the original IP waiver proposal. The Decision has been criticized for defining "eligible Member" too narrowly and for including limitations and notification requirements that may limit its practical value to potential users.[32] Supporters counter that the Decision will facilitate easier access to vaccines and also serve an important role in ensuring innovator companies supply vaccines at virtual cost to less developed Member countries.[33] It remains

29. Agreement on Trade-Related Aspects of Intellectual Property Rights *supra* note 1 (for the purpose of this Decision, all developing country Members are eligible Members. Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. Such binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10 May 2022, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website).

30. This wording would include efforts such as COVAX.

31. WTO, Draft Ministerial Decision on the TRIPS Agreement, *supra* note 6, at ¶ 6.

32. Agreement on Trade-Related Aspects of Intellectual Property Rights *supra* note1. For a crucial review of the Outcome document, *see* Siva Thambisetty et al., The COVID-19 TRIPS Waiver Proposal in Critical Review: An Appraisal of the WTO DG Text (IP/C/W/688) and Recommendations for Minimum Modifications, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4124497 (last visited June 20, 2022).

33. *See, e.g.*, *Statement from Ambassador Katherine Tai on an Intellectual Property Response to the COVID-19 Pandemic* (June 17, 2022), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/june/statement-ambassador-katherine-tai-intellectual-property-response-covid-19-pandemic (last visited June 20, 2022); *UK statement following the conclusion of the WTO*

to be seen whether the Decision is more symbolic than substantive, or whether it was even needed to begin with, as there is currently a sufficient supply of COVID vaccines.

II.FUNDAMENTAL ISSUES WITH AN IP WAIVER

While the Ministerial Decision may be imperfect, its approach and focus on Article 31 and Article 31bis nevertheless remains the better path for the WTO to achieve a sustainable increase in access to vaccines. We reach this conclusion for three reasons: First, problems associated with forcing the transfer of trade secrets; second, negative impacts on the incentive to research; and third, doubts about the ability of a waiver to deliver cheaper and increased sustainable access to vaccines. Each will be addressed in turn.

A. Trade Secrets Protection

Trade secrets arguably play a more important role than patents in the development of vaccines. While a patent application requires disclosure of information to the extent that it enables the functioning of inventions, the patentee is not required to disclose everything that efficiently reproduces the invention.[34] In simple terms, while the patent application may disclose the "recipe," more skill and knowledge may be needed in order to manufacture a safe and high-quality version of the finished product. Therefore, disclosure of trade secrets is an essential component in scaling up vaccine production.

1. Meaning and rationale of trade secrets protection

Trade secrets are IPRs on information that have a commercial value and can be sold or licensed.[35] Trade secrets protection evolved through common law and specific statutes.[36] International IP treaties recognize trade secrets protection. For instance, Article 39 of the TRIPS Agreement contains three requirements for protection: (i) *Secrecy* – the information must be secret and not available in the public domain; (ii) *Commercial Value* – the secrets must have an economic value; and (iii) *Reasonable Efforts to Maintain Secrecy* – the rights holder must take

Ministerial Conference (June 17, 2022), https://www.gov.uk/government/news/uk-statement-following-the-conclusion-of-the-wto-ministerial-conference (last visited June 20, 2022).

34. Sean Flynn, Erica Nkrumah & Luca Schirru, *Non-Patent Intellectual Property Barriers to COVID-19 Vaccines, Treatment and Containment*, PIJIP/TLS RESEARCH PAPER SERIES No. 71, 12–13 (2021), https://digitalcommons.wcl.american.edu/research/71/ (last visited June 20, 2022).

35. *See Trade Secrets*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, https://www.wipo.int/tradesecrets/en/ (last visited June 20, 2022).

36. For an overview of trade secrets protection, *see* Margaret Jackson, *Keeping secrets: International developments to protect undisclosed business information and trade secrets*, 1 INFO. COMMC'N & SOC'Y 467(1998); Michael Risch, *Why Do We Have Trade Secrets?*, 11 INTELL. PROP. LAW REV. 3 (2007).

necessary efforts to ensure that the information is kept secret.[37] These requirements have been embodied in national laws and developed through courts in several jurisdictions.[38]

The economic justification for trade secrets protection lies in incentives; that is, an incentive to invest and develop valuable information and use of that information without the risk of knowledge spillovers.[39] In other words, trade secrets encourage the development of new inventions and valuable knowledge by assuring a return on investment.[40] The protection of such valuable information plays an important role in life sciences and pharmaceutical innovation.[41] In regards to pharmaceuticals, trade secrets cover clinical trial data, biological databases, and cell-lines,[42] among others.[43]

Trade secrets are an important incentive for the biomedical industry in order to ensure that innovators can achieve a return on R&D costs.[44] Moreover, trade secrets in one area of research will likely have benefits in other areas – for instance, messenger RNA (mRNA) technologies used in the leading COVID-19 vaccines were developed to target cancer. It is also crucial to consider that unlike a patent, trade secrets do not prevent competitors from using information and developing an invention. Trade secret protection only applies so long as the information remains secret. Given that the pharmaceutical industry protects essential elements of its processes and procedures through trade secrets, the efforts required to protect trade secrets often include substantial organizational, human and financial resources. For these reasons, companies would be resistant

37. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197. read with Paris Convention for the Protection of Industrial Property art. 10bis, July 14, 1967, 21 U.S.T. 1583, T.I.A.S. 6923. For a detailed discussion, *see Enquires Into Intellectual Property's Economic Impact*, OECD, 127–172 (2015), https://www.oecd.org/sti/ieconomy/KBC2-IP.Final.pdf (last visited June 20, 2022).

38. For example, in the EU trade secrets are regulated by the EU Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure, 8 June 2016. Whereas, in the US trade secrets is regulated by the Defend Trade Secrets Acts of 2016. *See generally* David S. Almeling et al., *A Statistical Analysis of Trade Secret Litigation in Federal Courts*, 45 *Gonzaga L. Rev.* 292 (2019).

39. OECD, *supra* note 37, at 134–35.

40. *See* Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, *in* The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research 109–139 (Rochelle C. Dreyfuss & Katherine J. Strandburg eds., 2011).

41. *See* Tara Nealey, Ronald M. Daignault & Yu Cai, *Trade Secrets in Life Science and Pharmaceutical Companies*, 20:5 Cold Spring Harbor Persp. Med. 1 (2015).

42. Cell lines are permanently established cell culture that can proliferate indefinitely. For more detail, *see Cell Lines*, Pharma IQ, https://www.pharma-iq.com/glossary/cell-lines (last visited June 20, 2022).

43. Steven Hollman, *Trade Secret Protection & the COVID-19 Cure: Observations on Federal Policy-Making & Potential Impact on Biomedical Advances*, The National Law Review (Sept. 14, 2020), https://www.natlawreview.com/article/trade-secret-protection-covid-19-cure-observations-federal-policy-making-potential (last visited June 20, 2022).

44. *Id.*

to disclose know-how even should a waiver of IPRSs be approved at the international level.[45]

2. How could a government effectuate a waiver of undisclosed information?

The waiver proposal sought to suspend provisions related to undisclosed information[46] – that is, trade secrets – but it was never clear how governments would require secrets to be revealed and disseminated, and how this process would be regulated. Trade secrets only hold value for as long as they remain secret. The first challenge would be to put in place a mechanism to ensure that such secrets are transferred to the government. A related issue would be whether companies would somehow be given back their trade secrets after the crisis passes or whether forced disclosure would extinguish all rights, as they would be in the public domain or at the very least "disclosed" and no longer secret.[47]

The draft also fails to set forth what would happen if drug companies do not disclose the existence of a secret. Practically speaking, it seems impossible that a government could force the transfer of a secret when it is unaware of both the secret's existence and content. Other issues with forced technology transfer are the unintended consequences and social costs. To illustrate with a famous example, in the 1970s, India used foreign exchange laws to force the Coca-Cola company to disclose its know-how. The result was the exit of Coca-Cola from India until the 1990s which had detrimental effects to India's economy.[48]

Given the rapid development of mRNA in creating effective vaccines, it is not surprising that various aspects of mRNA manufacturing technologies are protected as trade secrets.[49] As mRNA manufacturing technologies are core assets of pharmaceutical companies (and were so even before the outbreak of COVID-19), these companies are not motivated to disclose those secrets to the State, even if the waiver is implemented. Unfortunately, waiver proponents never discussed

---

45. *See* Hilty et al., *supra* note 4, at 2.

46. Council for Trade-Related Aspects of Intellectual Prop. Rights, *Communication from South Africa, Examples of IP Issues and Barriers in COVID-19 Pandemic*, WTO Doc. IP/C/W670 (Nov. 23, 2020).

47. Philip Stevens & Mark Schultz, *The Role of Intellectual Property in Preparing for Future Pandemics*, GENEVA NETWORK, 7 (Feb. 28, 2022), https://geneva-network.com/research/the-role-of-intellectual-property-rights-in-preparing-for-future-pandemicss/ (last visited June 20, 2022).

48. Yogesh Pai, *WTO IP waiver too simplistic: Global vaccine tech-transfer needs other strategies*, EXPRESS PHARMA (Apr. 28, 2021) https://www.expresspharma.in/guest-blogs/wto-ip-waiver-too-simplistic-global-vaccine-tech-transfer-needs-other-strategies/ (last visited June 20, 2022).

49. *See* Norbert Pardi et al., *mRNA vaccine– a new era in vaccinology*, 17 NATURE REV. DRUG DISCOVERY 261, 261–279 (2018). For example, BioNtech uses trade secrets to protect mRNA manufacturing technologies. BioNTech SE, Registration Statement (Form F-1) (July 21, 2020), https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm (last visited June 20, 2022).

what incentives must be put in place to encourage companies to disclose trade secrets.

Forced disclosure would likely mean forever losing all rights to the information—but it is unclear how such a mechanism would work. The nature of trade secret protection does not allow for the implementation of a mechanism such as the "mailbox" system adopted by India in its transitional period for product patents, whereby it had an obligation to accept the patent applications and keep them dormant until 2005.[50] Considering that the original proposal sought a waiver "until widespread vaccination is in place globally, and the majority of the world's population has developed immunity,"[51] and that the revised proposal could, if implemented, stay in place for an indefinite period of time,[52] it would be difficult to construct a system whereby the innovators would be able to recoup or recover their trade secrets. Moreover, while mechanisms like that of the "mailbox" could possibly work for other kinds of IPRs, they do not work for trade secret protection where the value is in the secret which, once exposed, remains valueless. Despite it being unclear whether it is possible to construct a mechanism to make the waiver effective, it is worth reiterating that waiver proponents remained silent on this important practicality and offered no plausible suggestions for a way forward.

Even if the operationalisation of the disclosure of trade secrets is put in place, the manufacturing process for vaccines is complex because it requires the use of facilities and equipment with a high degree of specialization.[53] The proposed waiver appeared based on the presumption that developing countries have the infrastructure, institutional capacity, and good governance needed to ensure safety, quality, and efficacy, yet even proponents justified the need on the basis of developing countries not being able to implement TRIPS flexibilities into their system.[54] Unfortunately, medicinal safety standards in development and LDCs are often lacking or virtually nonexistent.[55] Thus, it is crucial to human health and

---

50. For information on the mailbox system, *see* Arno Hold & Bryan C. Mercurio, *After the Second Extension of the Transition Period for LDCs: How Can the WTO Gradually Integrate the Poorest Countries into TRIPS?*, *in* SCIENCE AND TECHNOLOGY IN INTERNATIONAL ECONOMIC LAW: BALANCING COMPETING INTERESTS 260 (Bryan Mercurio & Kuei-Jung Ni eds., 2013).

51. *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, *supra* note 2, at 13.

52. *See Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, *supra* note 2.

53. *See* Mercurio, *supra* note 4, at 29.

54. Sisule F. Musungu & Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, SOUTH CENTRE and WORLD HEALTH ORGANIZATION, 33 (April 2006) (discussing how Zimbabwe has been unable to maximize TRIPS flexibilities due to local administrative procedures).

55. *See* Report by the Director-General, *Addressing the global shortage of, and access to, medicines and vaccines*, WHO Doc. EB142/13 (Jan. 12, 2018); *WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products*, WORLD HEALTH ORGANIZATION (2017), https://apps.who.int/iris/bitstream/handle/10665/326708/9789241513425-eng.pdf?ua=1 (last visited June 20, 2022). For a general overview of drug safety in developing countries, *see* Yaser Al-Worafi et al., *Drug Safety in Developing Countries: Achievements and Challenges* (2020).

safety that prior to the operationalisation of a waiver and the disclosure of trade secrets, a system is created to address inherent safety issues which can be associated with the unfettered production of vaccines. This will, inevitably, require countries to amend laws or create new legal rules and regulations. As many of these countries have not even legislated for all of the TRIPS flexibilities despite having nearly twenty years to do so,[56] it is highly unlikely these same countries would immediately and effectively legislate for the safe manufacture and dissemination of generic vaccines.

Given the lack of clarity regarding the operationalisation of the disclosure of trade secrets, forced disclosure could potentially attract a claim of breach of an international investment agreement leading to investor-State dispute settlement and the possibility of monetary damages to the aggrieved investor.[57] In such a claim, an innovator company could allege that the forced transfer of trade secrets has resulted in a violation of their legitimate expectations of legal stability and predictability in regulatory changes.[58] While this argument may prove to be unsuccessful, Members should have considered the interplay between trade and investment law prior to any discussion on a waiver that allows for the forced disclosure of trade secrets.

B. Incentive to Innovate

While there is emerging economic evidence pointing to the negative effects of overprotection on competition and questioning the link between IPRs and innovation,[59] even the most skeptical economists place the pharmaceutical and chemical industries in a special category.[60] The pharmaceutical industry is characterized as capital- and R&D-intensive, high risk, time-consuming, and expensive.[61] At the same time, the marginal cost of reproducing the finished

56. *See generally* Bryan Mercurio, Tolulope Adekola, & Chimdessa Tsega, *Pharmaceutical Patent Law and Policy in Africa: A Survey of Selected SADC Member States* (2023) 43 L. STUD. 331 (2023).

57. For a general discussion on IP and investor-State arbitration, *see* Pratyush Nath Upreti, *Intellectual Property Objectives in International Investment Agreements* (2022); Daria Kim, *Protecting Trade Secrets Under International Investment Law: What Secrets Investors Should Note Tell States*, 15 J. MARSHALL REV. OF INTELL. PROP. L. 228 (2016): Pratyush Nath Upreti*, Intellectual Property Rights in Investor-State Dispute Settlement: Connecting the Dots through the Philip Morris, Eli Lilly, and Bridgestone Awards*, 31AM. REV. OF INT'L ARB. 337, (2021).

58. For detailed analysis, *see* Bryan Mercurio & Pratyush Nath Upreti, *The Legality of a TRIPS Waiver for COVID-19 Vaccines under International Investment Law*, 71 INT'L & COMP. L. Q. 323 (2022).

59. *See, e.g.*, Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L. J. 1693 (2008); Adam Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 RSCH.. POL'Y 531 (2000); Michele Boldrin & David K Levine, *The Case against Patents*, 27 J. OF ECON. PERSP. 3 (2013). *See also* MICHELE BOLDRIN & DAVID K LEVINE, AGAINST INTELLECTUAL MONOPOLY (2008).

60. *Id.*

61. Jaci McDole & Stephen Ezell, *Ten Ways IP has Enabled Innovations That Have Helped Sustain the World Through the Pandemic*, Information Technology & Innovation Foundation (2021),

product is often relatively inexpensive. That is, there is a high cost of innovation and low cost of imitation. For this reason, the pharmaceutical industry model is often described as being wholly reliant on IP. The elimination of patents would likely deter firms from heavily investing in risky R&D leading to less innovation.[62] Thus, for the pharmaceutical industry some form of government intervention is necessary in order to maintain innovation.[63] These studies demonstrate what is commonly known—patents are important for the pharmaceutical and healthcare industry and necessary to ensure a steady flow of new pharmaceutical innovations.[64]

To this end, the Max Planck Institute for Innovation and Competition expressed concern that a waiver would have a detrimental effect on incentives for drug innovation:

> It is important to consider potential effects of a comprehensive waiver of IP protection on innovation incentives in vaccine development (including emerging variants of Covid-19), as well as in *other* areas of medical research… A waiver of IP protection could leave the society vulnerable to such emerging variants of Covid-19 if the current IP holders/vaccine developers abandoned research efforts as a result of such a waiver. In this regard, a waiver… appears to be highly disproportionate in its scope.[65]

The Max Planck Position statement articulates the uncertainty that a waiver would have likely created by effectively delinking the innovation incentive rationale provided by the patent system.[66] Indeed, the success of COVID vaccines

---

https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through (last visited June 20 2022).

62. Shamnad Basheer, *The Invention of an Investment Incentive for Pharmaceutical Innovation*, 15 J. WORLD INTELL. PROP. 305 (2012).

63. Several studies point to the essential role of patents in promoting pharmaceutical innovation. *See, e.g.*, C.T. TAYLOR, A. SILBERSTON, & Z.A. SILBERSTON, THE ECONOMIC IMPACT OF THE PATENT SYSTEM: A STUDY OF THE BRITISH EXPERIENCE 197–199 (1973); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173 (1986); Ashish Arora, Marco Ceccagnoli, & Wesley M. Cohen, *R&D and the Patent Premium*, 26 INT'L J. INDUS. ORG. 1163 (2008).

64. *See also* DAVID SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICALS INDUSTRY (1976); Iain Cockburn & Genia Long, *The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals*, 25 EXPERT OP. THERAPEUTIC PATENTS 739 (2015) (discussing 2007–2008 LES survey that found "eighty-nine percent of respondents in the healthcare (including biotechnology, pharmaceuticals and medicals) industry characterized patents as 'extremely important' in 'creating a competitive advantage for your organization'"). *See also* Henry G Grabowski, Joseph A DiMasi, & Genia Long, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFF. 302 (2015); Yang Guo et al., *Patent Indicators: A Window to Pharmaceutical Market Success*, 23 EXPERT OP. THERAPEUTIC PATENTS 765 (2013).

65. Hilty et al., *supra* note 4, at 6.

66. *See generally* Lili Zhang, Ying Guo, & Ganlu Sun, *How patent signals affect venture capital: The evidence of bio-pharmaceutical start-ups in China*, 145 TECH. FORECASTING & SOC. CHANGE 93 (2019); Dirk Czarnitzki, Bronwyn Hughes Hall, & Hanna Hottenrott, *Patents as Quality Signals? The Implications for Financing Constraints on R&D*, Dusseldorf Institute for Competition Economics, Discussion Paper No. 133 (2014) https://www.dice.hhu.de/fileadmin/redaktion/Fakultaeten/Wirtschaftswissenschaftliche_Fakultaet/DICE/Discussion_Paper/133_Czarnitzki_Hall_Hottenrott.pdf (last visited June 20, 2022).

is the result of R&D supported by a stable IP framework. The success of pharmaceutical innovation relies heavily on R&D, and often the results are not immediate. For example, the development of mRNA that resulted in Pfizer-BioNTech and Moderna Vaccines started more than twenty-five years ago, and the company which developed the breakthrough did so after more than twelve years of R&D.[67]

That being the case, some scholars supporting the waiver contend that the "incentive-reward" justification of patent protection cannot be applied in a time of crisis.[68] According to Thambisetty et al.:

> Even if one accepts the rhetoric of 'IP as innovation incentives' generally, our position is that it makes very little sense in the extraordinary context of COVID-19 related IP, especially in relation to patents and trade secrets on vaccines. This is because the COVID-19 vaccine market has been created to a large degree by public subsidies. Advance market orders… have de-risked vaccine developments to such a degree in this context it makes very little sense to privatise the fruits of public funding with the additional "incentive" of private monopoly rights…there is a tangible risk that privately held IP monopolies and profit maximization strategies may actually create the wrong incentives in the short term in a pandemic context, prioritizing the production and distribution…[69]

Here, public subsidies alone did not lead to the development of vaccines, but rather the subsidies assisted in advancing and commercializing the pre-existing R&D.[70] This is not to argue that pharmaceutical companies are immune from safeguarding the public good; rather, without the IP regime we would not have witnessed the development of COVID vaccines in such a short period.

While mRNA technology has been studied for some time, it took an investment of billions of dollars to reach the point where it can be utilized in the human body.[71] Pharmaceutical companies did receive government support to

---

67. Thomas Cueni, *The Risk in Suspending Vaccine Patent Rules*, THE NEW YORK TIMES, Dec. 10, 2020, https://www.nytimes.com/2020/12/10/opinion/coronavirus-vaccine-patents.html%20accessed%2029%20June%202021 (last visited June 20, 2022).

68. Thambisetty et al., *supra* note 3.

69. *Id. See also* Samuel Cross et al., *Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine?* (2021), https://www.medrxiv.org/content/10.1101/2021.04.08.21255103v1.full.pdf (last visited 20 June 2022); Katarina Foss-Solbrekk, *The IP Waiver and COVID–19: Reasons for Unwavering Support*, J. INTELL. PROP. L. & PRAC. (2021). Waiver proponents further contend that there are ethical, utilitarian and deontological arguments suggesting that an IP waiver would not affect innovation. *See* Nancy S Jecker & Caesar A Atuire, *What's yours is ours: waiving intellectual property protections for COVID-19 vaccines*, 47 J. MED. ETHICS 595 (2021); Rachel Thrasher, *Why Innovation Would Survive a COVID-19 TRIPS Waiver*, IP WATCHDOG (2021), https://www.ipwatchdog.com/2021/03/24/innovation-survive-covid-19-trips-waiver/id=131194/ (last visited June 20, 2022).

70. *See generally* Daniel Gervais, *The TRIPS Waiver Debate: Why, and where to from here?* IPKAT (2021) https://ipkitten.blogspot.com/2021/05/guest-post-trips-waiver-debate-why-and.html (last visited June 20, 2022).

71. Rein Verbeke et al., *Three Decades of Messenger RNA Vaccine Development*, 28 NANOTODAY 1 (2019); Damian Garde & Jonathan Saltzman, *The Story of mRNA: How a once-dismissed idea become a leading technology in the Covid vaccine race*, STAT (2020)

cover some of the costs of R&D for COVID-19 vaccine development,[72] but we fail to see how this should be a reason to deny the companies the right to make a profit. The government subsidies, in essence, allowed for rapid in vitro and clinical trials and can be viewed as a pre-payment for bulk purchases of vaccines should the company succeed in its development; some efforts were successful, and most were not. While the public subsidies increased the speed at which the vaccines came onto the market, the pricing for vaccines is fair and reasonable.[73] The role that IP incentives have played in the advancement of pharmaceuticals and COVID-19 vaccines should not be so easily discounted.

Returning to the main point, there is no evidence suggesting that an IP waiver would have decreased costs, increased access, or reduced distribution inequalities. It is unclear whether a waiver would have been effective, and while it may seem rational or even appropriate to consider new approaches to deal with a once-in-a-generation pandemic, the analysis must consider the potential for failure and risk of non-recovery of cost.[74] In this regard, Kovac and Rakovec caution that "the notorious transaction cost and asymmetric information problem are exacerbated in times of uncertainty (the COVID-19 pandemic-panic) [and that] making hasty changes to the current IP law regime, such as suspending patent rights, during a pandemic and under current severe information asymmetries might prove to be counterproductive and distortive."[75] This raises the question of whether we should put the incentives mechanism that has played an important role in innovations for decades—especially during the current pandemic—at risk based on a speculative assumption that the waiver will achieve its aims with no longer-term negative consequences.

The "special" nature of the pharmaceutical industry does not mean that the status quo must be maintained. There is evidence that pharmaceutical companies engage in strategic patenting to avoid competition in the market and strengthen monopoly by maintaining high prices.[76] Methods to reduce or eliminate patent "evergreening" should be enhanced at the domestic level.[77] Moreover, scholarship in the economic, legal, philosophy, and public health disciplines has for some time questioned whether patent protection provides the proper incentives

---

https://www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/ (last visited June 20 2022).

72. In the United States, the Biomedical Advanced Research and Development Authority have funded companies for research and clinical trials. *See* Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf (last visited June 20, 2022).

73. *See infra* Section C.

74. Mitja Kovac & Lana Rakovec, *The COVID-19 pandemic and long-term incentives for developing vaccines: Patent law under stress*, 25 J. WORLD INTELL. PROP. 292 (2022).

75. *Id.*

76. Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?*, 51 INT'L REV. INTELL. PROP. & COMPETITION L. 1062 (2020).

77. *See generally* Matthew B. Stanbrook, *Limiting "Evergreening" For a Better Balance of Drug Innovation Incentives*, 185 CANADIAN MED. ASS'N J. 939 (2013).

for R&D and whether it benefits consumers, citizens, or governments.[78] Numerous alternative incentives have been proposed, including open-licensing,[79] prize funds,[80] and a global health impact fund.[81]

Thus, while a normative argument can be made to question whether the "incentive reward" rationale should be reconsidered moving ahead,[82] a radical change to the structure while it is working as intended in the middle of the worst public health crisis in a hundred years and at a time when supply is meeting demand at reasonable prices did not seem to be the most sensible, practical, prudent, or safest option.

C. Cost of and access to vaccines

Waiver skeptics point to dozens of examples of innovator companies engaging in large-scale voluntary licensing to boost the production and distribution of COVID-19 vaccines[83] and point to evidence suggesting little spare

---

78. *See, e.g.*, Joel Hay, *Prices, Regulation and Innovation in Pharmaceuticals and Biotechnology*, *in* THE VALUE OF INNOVATION: IMPACT ON HEALTH, LIFE QUALITY, SAFETY, AND REGULATORY RESEARCH (Irina Farquhar ed., 2008).

79. Bernard Munos, *Can Open-Source R&D Reinvigorate Drug Research?*, 5 NAT. REV. DRUG DISCOVERY 723 (2006).

80. Joseph E Stiglitz, *Scrooge and Intellectual Property Rights: A Medical Prize Fund Could Improve the Financing of Drug Innovations*, 333 BRITISH MED. J. 1279 (2006); Stiglitz, *supra* note 54, at 1693; James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519 (2007); Ann Weilbaecher, *Diseases Endemic in Developing Countries: How to Incentive Innovation*, 18 ANN HEALTH L. 281 (2009); Valbona Muzaka, *Prizes for Pharmaceuticals? Mitigating the social ineffectiveness of the current pharmaceutical patent arrangement*, 34 THIRD WORLD Q. 151 (2013).

81. Aidan Hollis & Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All*, REP. INCENTIVES GLOB. HEALTH (2008).

82. Peter Drahos, *Public Lies and Public Goods: Ten Lessons from When Patents and Pandemic Meet*, EUI LAW WORKING PAPERS, (2021) https://cadmus.eui.eu/bitstream/handle/1814/71560/EUI_WorkingPaper_Law_2021_5.pdf?sequence=1&isAllowed=y (last visited June 20, 2022); Duncan Matthews, *Reappraising the Relationship between Intellectual Property Rights and Human Rights: A COVID-19 Pandemic Response*, QUEEN MARY LAW RESEARCH PAPER No. 366/2021 (September 9, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3918325 (last visited June 20, 2022); See also Susy Frankel, COVID-10, Vaccines and International Knowledge Governance on Trial, 12 QUEEN MARY J. INTELL. PROP. 441 (2022).

83. For example, by mid-2020 AstraZeneca had already arranged voluntary licensing with numerous generic drug companies, including the Serum Institute of India, Fiocruz in Brazil, Biokangat in China, and R-Pharm in Russia. *See AstraZeneca takes next steps towards broad and equitable access to Oxford University's potential COVID-19 vaccine* (2020), https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html (last visited June 20, 2022); Marcelo Rochabrun, *Brazil sign agreement to produce AstraZeneca's experimental COVID-19 vaccine*, REUTERS (2020), https://www.reuters.com/article/us-health-coronavirus-brazil-vaccine-idUSKBN23Y0NB (last visited 20 June 2022); Roxanne Liu & Ludwig Burger, *AstraZeneca in first COVID-19 vaccine deal with Chinese company*, REUTERS (2020), https://www.reuters.com/article/uk-health-coronavirus-astrazeneca-kangta-idUKKCN2520YJ (last visited June 20, 2022); *Russia's R-Pharm signs deal to make UK-developed COVID-19 vaccine*,

high-quality and reputable manufacturing capacity exists.[84] Moreover, the COVAX Facility led by the Coalition for Epidemic Preparedness Innovations, Gavi, and the World Health Organization, has delivered vaccines to more than 144 countries, including low-income economies, since its first international delivery in February 2021.[85] As of May 2022, the US government agreed to license eleven medical technologies developed at the National Institutes of Health into C-TAP, a move which not only undercuts one of the main arguments made in favor of a waiver but that also makes it easier for low- and middle-income countries to gain access to and produce vaccines, drugs, and diagnostics for COVID-19.[86]

As of June 2022, it is unclear whether there are any suitable, capable, and qualified manufacturing facilities seeking to license vaccine production and being denied the opportunity to do so. Moreover, newly developed manufacturing facilities are struggling to receive orders as demand is at present being fully met through existing facilities making use of licensing agreements.[87] In short, and unlike in mid-2021, supply is outstripping demand.

Likewise, it is not clear whether a waiver would allow generic drug manufacturers to produce vaccines at a cheaper price than are currently available. COVID-19 vaccines are being made available at reasonable prices.[88] In June

---

REUTERS (July 17, 2020), https://www.reuters.com/article/us-health-coronavirus-cyber-russia-vacci-idUSKCN24I1XF (last visited June 20, 2022).

84. Similarly, the pharmaceutical companies have cooperated by forgoing their benefits of market exclusivity to ensure effective expedited treatment of COVID-19. For example, Gilead rescinded the Orphan drugs designation granted for the antiviral remdesiver for the treatment of COVID-19 and Moderna declined to enforce COVID-19 related patents. *See Gilead Sciences Statement on Request to Rescind Remedesivir Orphan Drug Designation*, GILEAD (2020), https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-request-to-rescind-remdesivir-orphan-drug-designation (last visited Jun 20, 20222); '*Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic'*, MODERNA (2020), https://investors.modernatx.com/node/10066/pdf (last visited June 20, 2022).

85. *See COVAX reaches over 100 economies, 42 days after first international delivery*, GAVI (April 8, 2021), https://www.gavi.org/news/media-room/covax-reaches-over-100-economies-42-days-after-first-international-delivery (last visited June 20, 2022).

86. Jon Cohen, '*A pretty big deal': U.S. makes COVID-19 technologies available for use in developing countries*Science (2022), https://www.science.org/content/article/pretty-big-deal-u-s-makes-covid-19-technologies-available-use-developing-countries (last visited June 20, 2022).

87. *See UNICEF COVID-19 Vaccine Market Dashboard*, https://www.unicef.org/supply/covid-19-vaccine-market-dashboard (last visited 20 June 2022); For global and country-level data, *see Caronavirus* (*COVID-19) Vaccinations*, OUR WORLD IN DATA, https://ourworldindata.org/covid-vaccinations (last visited June 20, 2022).

88. *See, e.g., Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use* (2020), https://www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use (last visited June 20 2022); *See also* Lucy Hooker and Daniele Palumbo, *Covid vaccines: Will drugs companies make bumper profits?*, BBC NEWS (2020), https://www.bbc.com/news/business-55170756 (last visited June 20, 2022).

2022, UNICEF's Vaccine Market Dashboard reported that the price per vaccine dose ranged from $2 to $40—the majority of sales under $4 a dose went to developing countries, and the most expensive doses sold by Sinopharm, Sinovac, and Bharat Biotech to countries such as Kazakhstan, and private markets in Nepal and Thailand.[89] The prices of vaccines in South Asia and Africa normally vary between $2.88 and $6.75.[90]

Thus, and despite assertions regarding the high price of patented vaccines, the industry has not only rapidly produced vaccines for the novel coronavirus but is also making them available at reasonable prices. It is unclear, and doubtful, that locally manufactured versions of innovative vaccines produced under a waiver will be cheaper than those that are voluntarily licensed.[91]

Given that in spring 2022 vaccines were available at affordable prices, the necessity of a waiver becomes doubtful.[92] Instead, enhanced use of voluntary and compulsory licenses through Article 31bis and supplemented by the Ministerial Decision would be the better option to accomplish the objective of increasing access. Moreover, such options would do so without abandoning the system of property rights which has delivered life-saving vaccines with extraordinary swiftness.

CONCLUSION

This article argues that WTO Members were wise in not endorsing a blanket waiver proposal and instead adopting an approach that provides for a more flexible application of the compulsory licensing provisions contained in the TRIPS Agreement. While the Ministerial Decision may not prove to be a tectonic shift in IP lawmaking, it will facilitate easier access to vaccines and reduce costs as importing countries now have an additional tool to use in negotiating prices with innovator companies and licensees. Perhaps more importantly, the Ministerial Decision does not provide for a solution which could easily turn into a problem. This was the case with the IP waiver proposal in numerous respects, most of which stem from the starting premise that IP was or could be the most important barrier to vaccines.

This article analyzed three such issues. First, while the IP waiver proposal and its proponents acknowledged the importance of trade secrets in innovation

89. UNICEF COVID-19 Vaccine Market Dashboard, *supra* note 86.

90. Nilanjan Banik & Debashish Chakraborty, *COVID-19 and IPR Waiver: An Indian Perspective*, 56 ECON. & POL. WEEKLY 19 (2021).

91. This is already the case in India, where the vaccine developed by Bharat Biotech Ltd. in collaboration with the government is priced higher than the Indian version of the AstraZeneca vaccine. *See* Menaka Doshi, *Free to Rs 2,400: What a Covid vaccine will cost you*, BLOOMBERG QUINT (2021), https://www.bloombergquint.com/coronavirus-outbreak/the-price-of-covid-vaccines-covishield-and-covaxin-in-india (last visited June 20, 2022).

92. See *UNICEF COVID-19 Vaccine Market Dashboard*, https://www.unicef.org/supply/covid-19-market-dashboard (last visited 20 June 2022).

and the development of new pharmaceutical products, it was left unstated how a transfer of rights would be facilitated and failed to discuss the differences between trade secrets and other IPRs—namely, that once the trade secret has been disclosed it is no longer protected and can therefore be exploited by rivals for commercial advantage.

Second, the biopharmaceutical sector is one of the few that depend on IPRs for continued and sustainable innovation. The sector is wholly reliant on the innovation incentive rationale provided by the patent system, and the IP waiver or any such attempt to delink innovation from incentive places future investment in the sector and R&D at risk. This would have been extremely dangerous as not only will the COVID-19 virus continue to mutate, requiring vaccines to evolve in order to maintain efficacy, but also because it is likely that other pandemics will emerge in the future.

Third, in the space of little more than a year, an access crisis and worries of vaccine hoarding are no longer relevant as vaccine supply outstrips demand and in many countries unused vaccines are going out of date and being discarded. Likewise, with several rival vaccines and multiple producers in the marketplace due to extensive voluntary licensing, vaccine prices are reasonably priced across the globe. Therefore, it is doubtful that an IP waiver allowing for new entrants could have driven the price of vaccines lower than the current price.

The WTO Members were correct to shift away from a proposal which brought more potential risks than benefits, and to a model which seeks to ease existing restrictions and to better facilitate the importation of vaccines into developing countries. Work remains to be done, however, and Members would be wise to keep this issue on the agenda and continue seeking to better ensure access to vaccines both in times of crisis and beyond.