


FROM THE TRENCHES

From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments

Bryan Mercurio^{1*}  and Pratyush Nath Upreti²

¹Faculty of Law, Chinese University of Hong Kong, 6/F Lee Shau Kee Building, Shatin, Hong Kong and ²School of Law, Queen's University Belfast, UK

*Corresponding author: Email: b.mercurio@cuhk.edu.hk

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Abstract

This article critically examines the proposed waiver of intellectual property (IP) rights for COVID-19 vaccines under the World Trade Organization Agreement's Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was initiated in October 2020 when the pandemic raged and vaccines were unavailable. However, the landscape has now changed and the waiver may no longer be necessary. The Outcome Document, introduced in the TRIPS Council in May 2022, along with Ministerial Decision of June 2022 recognizes this by focusing on easing the requirements to use TRIPS-flexibilities to accomplish wider and cheaper access. In so doing, the Ministerial Decision reinforces the notion that TRIPS flexibilities can be a useful part of the policy toolkit, even in times of crisis. After providing an overview of the context and outlining justifications for the waiver proposal, the article analyses and identifies key implications and possible effects of the Ministerial Decision. The article concludes that while the Document may not be a perfect solution to the issue of access to vaccines, flexible application of TRIPS-flexibilities is a better resolution in the current environment, especially given the need for further innovation to combat COVID-19 and future pandemics.

Keywords: Intellectual property rights; pharmaceutical patents; vaccines; TRIPS waiver; TRIPS flexibilities; Public health; COVID-19

1. Introduction

Whether and to what extent international intellectual property rights (IPRs) are a barrier to the equitable distribution of COVID-19 vaccinations and treatment remains an open question. The contentious debate between the role of IP and public health has been ongoing since the advent of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),¹ with the latest incarnation occurring in the wake of the COVID-19 pandemic, where the question of whether the TRIPS Agreement rules block access to vaccines and treatments resurfaced. While on the national level, countries as diverse as Chile, Ecuador, Canada, Israel, Germany, and Indonesia adopted emergency legislation providing the possibility of a compulsory license on patent-related medical technologies,² debate on the international stage reached the apogee of

¹Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

²Measures taken early in the pandemic are detailed in A. Houldsworth (2022) 'The Key Covid-19 Compulsory Licensing Developments so Far', IAM (7 April 2022), www.iam-media.com/article/the-key-covid-19-compulsory-licensing-developments-so-far.

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discussion in October 2020 when India and South Africa proposed a waiver from the application of certain provisions of the TRIPS Agreement.³

Despite initial opposition, the United States (US) reversed its position in May 2021 and announced it would support discussions leading to a waiver. While others remained opposed, the US shift generated debate on the rationale of the proposal and provided an impetus to negotiate the terms of the waiver. This shift allowed for a group of four Members consisting of the US, European Union (EU), South Africa, and India to negotiate a compromise ‘Outcome Document’ that the Director-General of the WTO introduced at the TRIPS Council in May 2022.⁴ The Document, very different and more restrictive than the original waiver proposal, formed the basis for Ministerial Decision on the TRIPS Agreement (Ministerial Decision) taken on 17 June 2022 during the 12th Ministerial Conference.⁵

The COVID-19 landscape has also changed since October 2020. At that time, the pandemic raged and no vaccines were available on the market. Developed countries representing 13% of the world’s population had secured 51% of COVID-19 vaccines in advance purchases,⁶ and fears of inequitable access to vaccines and treatments were genuine. By July 2022, COVID-19 had infected over 545 million people and killed over 6.3 million,⁷ but the availability of vaccines that help prevent the spread and reduce the severity of COVID-19 has dramatically changed the course of the pandemic and allowed most of the world to resume (near) normal operations.

With 36 vaccines approved for use by at least one national regulatory authority and 10 vaccines included in the WHO’s Emergency Use listing, nearly 60% of the world is considered fully vaccinated.⁸ More than 20 billion doses have been secured at the national level or through the global alliance of vaccine distribution known as the COVAX facility,⁹ and vaccine supply in 2022 is anticipated to reach 16.7 billion.¹⁰ There are now few, if any, credible reports of vaccine shortages.¹¹ Far from shortages, many developing countries are now dealing with the problem of disposing of unused expired doses and delaying future deliveries while new manufacturing facilities are struggling to attract clients and receive orders for manufacture.¹²

The aim of this article is not to advocate for or against a waiver, or even to analyse the myriad of arguments used in support of each position. There is a growing literature doing both such things.¹³

³WTO, ‘Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19’, Communication from India and South Africa, WTO Doc. IP/C/W/669 (2 October 2020) [‘Waiver Proposal’]. See also the revised version of the proposal: WTO, ‘Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19’, 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 (21 May 2021) [‘Revised Waiver Proposal’].

⁴WTO Council for Trade Related Aspects of Intellectual Property Rights, ‘Communication from the Chairperson on TRIPS COVID-19’, WTO/IP/C/W/688 (3 May 2018) [‘Outcome Document’], <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W688.pdf&Open=True>.

⁵WTO, ‘Draft Ministerial Decision on the TRIPS Agreement’, Ministerial Conference, 12th Session, WT/MIN(22)/W/15/Rev.2 (17 June 2022).

⁶‘Small Group of Rich Nations Have Bought Up More than Half the Future Supply of Leading COVID-19 Vaccine Contenders’, Oxfam (17 September 2020), www.oxfam.org/es/node/14233.

⁷See WHO Coronavirus (COVID-19) Dashboard, <https://covid19.who.int/>.

⁸See UNICEF COVID-19 Vaccine Market Dashboard, www.unicef.org/supply/covid-19-vaccine-market-dashboard.

⁹*Ibid.*

¹⁰*Ibid.* By July 2022, 12 billion doses had been administered. For global and country-level data, see <https://ourworldindata.org/covid-vaccinations>.

¹¹See V. Owade (2022) ‘TRIPs and COVID-19: Is an IP Waiver (Un)necessary?’, *Intellectual Property Quarterly* 1, 30–43 (discussing more than 300 partnerships established to increase global manufacturing output of COVID-19 vaccines).

¹²See e.g. L. Diseko, ‘Covid in Africa: Why the Continent’s Only Vaccine Plant is Struggling’, BBC News (6 May 2022), www.bbc.co.uk/news/world-africa-61347091.

¹³For literature advocating for a waiver, see e.g. S. Thambisetty et al. (2022) ‘Addressing Vaccine-Inequity during the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond’, *The Cambridge Law Journal*, 1–42, accepted manuscript available at <https://doi.org/10.1017/S0008197322000241>. For literature cautioning against a waiver, see e.g. R.M. Hilty et al. (2021) ‘Covid-19 and the Role of Intellectual Property’, Position Statement of the Max Planck

Instead, the purpose of this article is simply to review and evaluate the text and implications of the Ministerial Decision. After setting out the context in Section 2, Section 3 outlines and reflects upon the Ministerial Decision, which proposes the flexible use of compulsory licencing as a way of ensuring accessibility to vaccines. Section 4 evaluates the implications and possible effects of the Decision. Section 5 concludes that while the Decision may not be a perfect solution to the issue of access to vaccines, the flexible application of TRIPS-flexibilities is a better solution in the current environment, especially given the need for further innovation to combat COVID-19 and future pandemics. The Decision, combined with efforts to increase and improve production capabilities, licensing, and distribution, and reduce bottlenecks and blockages, is a pragmatic and sustainable approach to deliver vaccines to those in need and help overcome the COVID-19 pandemic.

2. The Context: The Making of the TRIPS Waiver Debate

2.1 The Original Proposal

On 2 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.¹⁴ The proposal attracted sponsorship and/or support from most developing countries and the LDC Group.¹⁵

Proponents essentially focused on two justifications for the introduction of the waiver proposal. First, they argued that the TRIPS Agreement provides a 'limited option to overcome the barriers' that IP may impose for the prevention, containment, and treatment of COVID-19.¹⁶ While acknowledging that the flexibilities enshrined in the TRIPS Agreement allow policy space for public health,¹⁷ proponents maintained that the flexibilities were 'never designed to address a health crisis of this magnitude' and that developing countries face 'legal and institutional difficulties' in implementing flexibilities.¹⁸ In this regard, the proponents claimed many countries are unable to fulfil the formalities required to initiate the process owing to the lack of legal framework within the country's domestic system¹⁹ and that the complexity involved with the issuance of compulsory licenses limits its usability in a pandemic.²⁰

Institute for Innovation and Competition of 7 May 2021, www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_statement_Covid_IP_waiver.pdf; B. Mercurio (2021) 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review', *Virginia Journal of International Law* 62, 10–32; J. Bacchus (2020) 'An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines', Free Trade Bulletin No. 78, CATO Institute (16 December 2020), www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines; C. Ann et al. (2021), 'The Waiving of Intellectual Property: A Poor Response to a Real Problem', The Stanislas de Boufflers Institute (19 May 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3850550. For alternative approaches, see K. Zaman (2022) 'The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence', *European Journal of Risk Regulation* 13(2), 295–310.

¹⁴WTO, 'Waiver Proposal', supra n. 3. The revised waiver proposal clarifies the scope of the waiver of Sections 1, 4, 5, and 7 of Part II 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, 'Revised Waiver Proposal', supra n. 3.

¹⁵See, 'TRIPS Council to Continue to discuss temporary IP waiver, revised proposal expected in May', *WTO News* (30 April 2021), www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm.

¹⁶WTO, 'Waiver Proposal', supra n. 3, at 10.

¹⁷WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Response to Questions', Communication from Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, Venezuela, and Zimbabwe, WTO Doc. IP/C/W/672 (15 January 2021).

¹⁸Ibid., at 16–18 read with WTO, 'Waiver Proposal', supra n. 3, at 10.

¹⁹See A. Sen (2020) 'WTO Members Divided over India–South Africa Proposal for TRIPS Waiver During COVID-19', *The Hindu Business Line* (17 October 2020), www.thehindubusinessline.com/economy/wto-members-divided-over-india-south-proposal-for-trips-waiver-during-covid-19/article32878713.ece.

²⁰WTO, 'Waiver Proposal – Response to Questions', supra n. 17, at para. 1.1.3.

Second, proponents asserted that IP and exclusive licensing agreements threatened to restrict the scale-up of manufacturing, lockout diversified suppliers, and undermine competition that would result in lower prices.²¹ The licensing agreements, proponents asserted, prevent other generic manufacturers from acquiring the technology and positioning themselves to manufacture supplies to meet global demand. Likewise, proponents questioned the viability of industry and government efforts to create and maintain voluntary sharing mechanisms²² and questioned the willingness of innovators to share IP and technology in, among others, the COVID-19 Technology Access Pool (C-TAP) pool.²³

The proposal faced opposition or scepticism from several developed and a handful of developing countries, who deemed the proposal as unnecessary, potentially harmful to supply chains and pharmaceutical innovation, lacking clarity on important topics such as trade secrets, and unable to provide increased access or reduced pricing.²⁴

The waiver floundered until 5 May 2021, when the United States Trade Representative (USTR), Katherine Tai, announced that the Biden administration would support the negotiation of a waiver for COVID-19 vaccines.²⁵ While the reversal sent a message that the US will not pursue others who support and implement the waiver,²⁶ it did not necessarily mean that others opposed to a waiver would immediately abandon their concerns. While China did reverse its position, others such as the European Commission indicated that it is open to discussing a waiver proposal but preferred changes that will allow better use of the flexibilities existing in the TRIPS Agreement, and in particular that of compulsory licensing.²⁷ Moreover, at least one member state of the EU, Germany, remained steadfastly opposed to the narrative that makes IP a constraint to COVID vaccinations; rather, Germany emphasized IP as a source of innovation and way out of the crisis.²⁸

To be clear, the US indicated that it would ‘actively participate in text-based negotiations’²⁹ but it did not support the broad proposal on offer. Given the consensus-based nature of the institution and complexity of the issues, Members were always going to be hard-pressed to complete the negotiations in a timely manner.³⁰ This became even more evident when India and South Africa submitted a revised proposal on 22 May 2021 which contained no limit as to product coverage,

²¹Ibid., at 1.2.7 and 2.9.59. See also K. Ardizzone (2020) ‘Role of the US Federal Government in the Development of GS-5734/Remdesivir’, KEI Briefing Note 2020:1 (20 March 2020).

²²WTO, ‘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.

²³See WTO, ‘Council for Trade-Related Aspects of Intellectual Property Rights: Intellectual Property and Public Interest: Beyond Access to Medicines and Medical Technologies towards a More Holistic Approach to TRIPS Flexibilities’, Communication from South Africa, IP/C/W/666, 17 July 2020, para. 8.

²⁴See WTO, ‘Waiver Proposal– Response to Questions’, supra n. 17.

²⁵Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver’, Office of the United States Trade Representative, Press Release (5 May 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.

²⁶See B. Mercurio (2021) ‘The IP Waiver for COVID-19: Bad Policy, Bad Precedent’, *International Review of Intellectual Property and Competition Law* 52(8), 986.

²⁷European Commission, ‘Opening statement by Executive Vice-President Valdis Dombrovskis at the European Parliament Plenary Debate on the Global Covid-19 Challenge’ (19 May 2021), https://ec.europa.eu/commission/commissioners/2019-2024/dombrovskis/announcements/opening-statement-executive-vice-president-valdis-dombrovskis-european-parliament-plenary-debate_en. See also P. Blenkinsop and C. O’Donnell (2021) ‘EU Supports COVID Vaccine Patent Waiver Talks, but Critics Say Won’t Solve Scarcity’, *Reuters* (6 May 2021), <https://prod.reuters.com/world/europe/eu-willing-discuss-covid-19-vaccine-patent-waiver-eus-von-der-leyen-2021-05-06/>.

²⁸Germany Rejects US Proposal to Waiver Patents on COVID-19 Vaccines’, *Reuters* (6 May 2021), <https://prod.reuters.com/business/healthcare-pharmaceuticals/germany-opposes-us-plan-waive-patents-covid-19-vaccines-2021-05-06/>.

²⁹Statement from Ambassador Katherine Tai’, supra n. 25.

³⁰While WTO rules allow for Members to vote on proposals (on the basis of one value, one vote), with a three-quarters majority needed in order for the waiver to be adopted, in practice the WTO has never abandoned ‘consensus

scope, notification requirements, or safeguards, and essentially would have allowed the waiver to remain in effect for what could be an indefinite period.³¹

2.2 The Outcome Document

In an effort to advance discussions, the US, EU, India, and South Africa took the controversial step of informally negotiating a compromise agreement between themselves (with the help and encouragement of the WTO Secretariat).³² Pushed forward by Director-General Ngozi Okonjo-Iweala, negotiations culminated in an ‘Outcome Document’, which was leaked in March 2022 and formally circulated in the TRIPS Council in May 2022. The Document radically departed from the initial proposals and was more akin to the EU’s desired solution of easing restrictions on compulsory licensing – in fact, the Document did not propose an IP waiver at all. Instead, the Document would have allowed developing country Members to deviate from Article 28 of the TRIPS Agreement by authorizing the use of patented IP ‘required for the production and supply of COVID-19 vaccines’ to its domestic market as well as to the markets of other eligible Members and international or regional joint initiatives, without the need to seek consent from the rights holder. In this respect, the Outcome Document also deviated from Article 31 of the TRIPS Agreement.

The Document contained some bracketed text, indicating that certain issues remained undecided. Despite participating in the negotiations, none of the participating Members sought to introduce the proposal in the TRIPS Council. Undeterred, the Director-General took the unprecedented step of introducing and circulating the text herself on 3 May 2022.³³

The Outcome Document was heavily negotiated in the days leading to and during the 12th Ministerial Conference,³⁴ with several developing countries voicing concerns over eligibility and the scope of the waiver, China over its exclusion as an exporter of more than 10% of vaccines, and Switzerland and the United Kingdom (UK) over the process and usefulness of waiving IPRs.³⁵ Activists and NGOs came out against the Document for its limitation in scope to vaccines and for undercutting the original proposal while other observers, diplomats, and even some officials engaged in the negotiation process no longer saw any value in a waiver given the dramatic change in the vaccine situation since 2021 with there now being ‘an apparent surplus of COVID-19 vaccines’.³⁶

3. The Ministerial Decision: More Flexible Use of Compulsory Licensing

Following negotiating sessions throughout the Ministerial Conference and several iterations of the Outcome Document, Members reached agreement on the text of the Ministerial Decision. Much like the Outcome Document, the Ministerial Decision cannot be described as a waiver, but more

decision-making’ in favor of a vote. Thus, the reality is that any proposal must gain consensus among all Members. See S. Lester, B. Mercurio, and A. Davies (2028) *World Trade Law*, Bloomsbury, 82–83.

³¹See WTO, ‘Revised Waiver Proposal’, supra n. 3.

³²See, ‘Members updated on high-level talks aimed at finding convergence on IP COVID-19 response’, WTO News, 2022, www.wto.org/english/news_e/news22_e/trip_10mar22_e.htm.

³³See ‘Outcome Document’, supra n. 4.

³⁴For example, bilaterals.org published a leaked collection of textual proposals and suggestions as of 25 May 2022, www.bilaterals.org/IMG/pdf/covid-19_trips_working_document_as_of_25_may_2022.pdf.

³⁵B. Baschuk (2022) ‘China Rejects Its Exclusion from WTO Vaccine Waiver Proposal’, Bloomberg (6 May 2022), <https://news.bloomberglaw.com/ip-law/china-rejects-its-exclusion-from-wto-vaccine-waiver-proposal>.

³⁶Lawmakers, Advocacy Groups Raise Concerns with TRIPS Waiver Compromise’, World Trade Online (1 April 2022), <https://healthpolicy-watch.news/trips-council-finally-to-discuss-waiver-compromise/>. In April 2022, one of the authors spoke with several such diplomats and officials that made this observation on vaccine availability. See also ‘Okonjo-Iweala Hails TRIPS Compromise as Industry Remains Opposed’, World Trade Online (16 March 2022), <https://insidetrade.com/daily-news/okonjo-iweala-hails-trips-compromise-industry-remains-opposed>.

as a limited exception to restrictions to export under a compulsory licence. More specifically, the Decision focuses on Article 31(f), which limits authorized use of the licence ‘predominantly for the supply of the domestic market’. The Decision builds on this, as well as Article 31bis – adopted as a waiver by the WTO General Council on 30 August 2003 and transformed into a permanent amendment in 2017 – which allows for the exportation of pharmaceuticals under compulsory licence to Members with insufficient or no manufacturing capabilities, provided certain procedural requirements are met. To some commentators, the procedural requirements have significantly reduced the effectiveness of the provision while others view the language as a success, not because it resulted in additional compulsory licences but because it facilitated voluntary licence agreements and a steep price reduction in imported products.³⁷

The Ministerial Decision is not a replication of the Outcome Document, as it incorporates several important changes negotiated throughout the Ministerial Conference.³⁸ The Decision begins by allowing an ‘eligible member’ 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 as clarified and waived in the document. The Decision applies only to vaccines – but paragraph 8 instructs Members to decide whether to extend coverage to the production and supply of diagnostics and therapeutics within six months of the date of the Decision – and will remain in force for a period of 5 years, subject to extension from the General Council.

More specifically, and like the Outcome Document, paragraph 2(b) allows eligible Members to ‘waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market’ and thus allows ‘any proportion of the products manufactured under the authorization’ to the markets of other eligible Members, including thorough ‘international or regional joint initiatives’ (this wording would include efforts such as COVAX), without the need to seek consent from the rights holder. Similar to Article 31bis, the Decision contains a provision on anti-diversion requiring Members to ‘undertake all reasonable efforts to prevent the re-exportation of the products manufactured under the authorization in accordance with this Decision that have been imported into their territories under this Decision’, and correspondingly requiring Members to provide effective legal means to prevent importation of such products. Interestingly, and in more permissive language than Article 31bis, Footnote 3 allows for an exception to the re-exportation limitation in that it provides ‘in exceptional circumstances, an eligible Member may re-export COVID-19 vaccines to another eligible Member for humanitarian and not-for-profit purposes’.

While Article 31bis allowed Members to opt-out of the provision or declare they would only use the mechanism in emergencies, the Decision appears to per se limit the eligibility of importing and exporting Members, with Footnote 1 reading:

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

³⁷See, E.M. Igbokwe and A. Tosato (2022) ‘Access to Medicine and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31bis’, University of Pennsylvania Institute for Law and Economics, Research Paper No. 22-08, 2022, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4039264.

³⁸For instance, the Decision deleted the requirement that a Member using the system will have to list all the patents that it will waive through a single authorization for multiple patents, which appeared in paragraph 3(a) of the Outcome Document, with footnote 3 stating: ‘This paragraph is under consideration whether to keep or delete.’ The requirement would have perhaps been too onerous to meet and make compliance with the waiver more difficult. The Decision also removed the somewhat ambiguous references trade secrets stating that such Members may be assisted by WIPO’s patent landscaping work, including on ‘underlying technologies’, ‘Outcome Document’, supra n. 4.

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.

Thus, while only developing countries are eligible Members, those with the capacity to manufacture COVID-19 vaccines are encouraged to opt-out. As will be discussed further in Section 4, such a limitation seems more so aimed at expanding industrial capacity rather than related to health outcomes; in short, it is difficult to see how this limitation assists in pandemic relief.

Paragraph 5 provides for notification by requiring eligible Members to communicate to the Council for TRIPS any measure related to the implementation of this Decision, including the granting of an authorization. The notification requirements under the Decision seem less burdensome than those required by Article 31bis. For instance, notification does not have to pre-date the measure, but rather can be made ‘as soon as possible after the adoption of the measure’. Footnote 5 provides what information must be addressed in the notification.

Several paragraphs of the Decision serve to re-enforce and clarify flexibilities that currently exist in the TRIPS Agreement. For instance, paragraph 2 simply clarifies that a Member may authorize the use of the subject matter of a patent under Article 31 without the right holder’s consent through any instrument available in the law of the Member, including but not limited to legislative acts, executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, regardless of whether the Member has a compulsory license regime in place.

Likewise, paragraph 3(a) provides that an eligible Member need not require the proposed user of the licence to make efforts to obtain an authorization from the right holder as set out in Article 31(b) of the TRIPS Agreement – however, that paragraph already contains an exception and may be waived ‘in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use’. Given the negotiation of a waiver agreement for COVID-19, any measure taken to combat the pandemic would surely have qualified as a national emergency or situation of extreme urgency. Likewise, in stating that ‘Article 39.3 of the Agreement does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision’, paragraph 4 of the Decision arguably simply clarifies that a safeguard exists in Article 39.3. That being said, the provision makes it clear that Article 39.3 is not and will not serve as an impediment to an eligible Member from taking measures necessary to effectuate an authorization taken under the waiver.

Similarly, paragraph 3(d) retains an existing flexibility but clarifies that the determination of adequate remuneration under Article 31(h) ‘may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members’. Moreover, stating that ‘eligible Members may take into consideration existing good practices in instances of national emergencies, pandemics, or similar circumstances’ does not change existing practice, but by pointing (in footnote 4) to the relevant aspects of WHO-WIPO-WTO Study on Promoting Access to Medical Technologies and Innovation (2020) and the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1) the Decision offers guidance to setting national standards for eligible Members.

Measures taken in conformity with the waiver cannot be challenged under subparagraphs 1(b) (non-violation) and 1(c) (any other situation) of Article XXIII of the GATT 1994.³⁹ Moreover, the Decision is without prejudice to the flexibilities that Members have under the TRIPS Agreement and Doha Declaration on the TRIPS Agreement and Public Health, and without

³⁹Ministerial Decision’, *supra* n. 5, para. 7.

prejudice to their rights and obligations under the TRIPS Agreement (except as otherwise provided for in paragraph 3(b)).⁴⁰

The Decision can be viewed as a triumph of cooperation and a symbol of the success of the 12th Ministerial Conference, but clearly cannot be characterized as a waiver. Rather, the Decision is a clarification and broadening of Article 31 and Article 31bis of the TRIPS Agreement. Most notably, the Decision purports to comply with Article 31(h) and paragraph 5 of Article 31bis in a way that would ease the financial burden on the generic manufacturer and allow for the production and distribution of vaccines at affordable prices to low and middle-income countries.⁴¹ And while it is not expected to immediately expand access to or reduce the price of vaccines, in demonstrating flexibility in the application of a key TRIPS-flexibility the Decision serves to undermine a key argument made in support of a waiver.

4. Implications and Possible Effects of the Ministerial Decision

4.1 *The WTO Cannot Respond Quickly to Crisis*

The WTO has a long history of contentious, even torturous, negotiations on everything from agriculture to services to IPRs. All WTO negotiations languish, and many fail. The most notable failure is the Doha Round of trade negotiations, with the organization barely progressing since its creation in 1995. The legal framework remains essentially unchanged, with the two exceptions being the addition of a Trade Facilitation Agreement (2017)⁴² and a waiver turned amendment to TRIPS easing access to Article 31 for Members with insufficient or no manufacturing capabilities.⁴³ The waiver took effect in 2003 and the General Council adopted a Decision on the ‘Amendment of the TRIPS Agreement’ to which the Protocol Amending the TRIPS Agreement was attached in 2005, but it was only in 2017 that it became an amendment upon formal acceptance of two-thirds of the Members.⁴⁴

One of the reasons for the negotiating paralysis is that the WTO is a ‘consensus-based organization’, meaning nothing can change unless all Members agree to the change (or more accurately, no Member objects to the change). This is embodied in 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.⁴⁵

Consensus decision-making has been referred to by a WTO panel as ‘a general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments’.⁴⁶ While there is

⁴⁰Ibid, para. 9.

⁴¹This was also a part of the EU’s proposal. See, European Union, ‘Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property’, Communication from the European Union to the Council for TRIPS (4 June 2021), at 11, https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf.

⁴²The WTO Trade Facilitation Agreement entered into force on 22 February 2017 following its ratification by two-thirds of the WTO membership, www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm.

⁴³The TRIPS Agreement was amended through the Protocol of 6 December 2005 that entered into force on 23 January 2017, www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm.

⁴⁴Ibid.

⁴⁵Marrakesh Agreement Establishing the World Trade Organization, www.wto.org/english/docs_e/legal_e/04-wto_e.h.

⁴⁶See Panel Report, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, WT/DS381/R, para. 7.676.

certainly merit in not proceeding without complete consensus of the membership, the cost is a slow, watered down progress and means sometimes accepting that no progress is possible.⁴⁷

This reality was well-known when India and South Africa proposed a waiver in October 2020. Taking the proposal in good faith, the anticipated result of a waiver could have been an increase in vaccine production and access to the vaccine. But the proposal was also a radical departure from the TRIPS standards and lacked certainty of a result; thus, opposition, questioning, and further refinement was entirely foreseeable. Despite global urgency, that the negotiations carried on for more than 20 months should have surprised no astute or even casual onlooker. While the negotiations have moved on from the initial proposal, the situation on the ground has moved faster and thus at the critical point in time the WTO remained on the side-lines without a clear outcome on the horizon.

This experience, and indeed the history of WTO negotiations, should make it clear that the WTO is not the appropriate forum to address the global crisis such as the COVID-19 pandemic.

Given that views on the role of IPRs in times of crisis differ, reaching consensus on a TRIPS waiver was always going to be a difficult task. While Members did eventually agree to a compromise text extending flexibilities, precious time was devoted to waiver discussions when the world needed action. Two important factors must be considered in going forward. First, the fact that vaccine production and distribution have increased exponentially since October 2020 and the world is now at a point where supply is outstripping demand calls into question the immediate-term value of a waiver for this crisis.⁴⁸ Second, despite immense public pressure, some Members remain reluctant to abandon the global minimum IPR protections made possible through the TRIPS Agreement.⁴⁹ The political economy of the TRIPS Agreement and the differences between both developed and developing country Members is well documented,⁵⁰ which makes finding consensus at the WTO where concessions are zero-sum, where one gains and the other loses. While certain governments, commentators and scholars may wish to roll-back the substance of the TRIPS Agreement, the waiver negotiations should have made it abundantly clear that this is unlikely to occur in the short or medium term.

4.2 Efforts to Restructure Pharmaceutical R&D and Distribution Should Be Revitalized

Even though Members reached consensus and expanded flexibilities pertaining to Article 31, the Decision comes two years after the introduction of the original proposal, which defeats the main purpose – rapid distribution of COVID-19 vaccines and treatments. This serves as yet another reminder that the WTO is a trade organization and cannot be expected to resolve all world issues.

In regard to health, the WHO is better suited for prompt response to the global health crisis. In this regard, the ongoing discussion on the international pandemic treaty under the WHO framework is the right way forward. On 30 March 2021, 25 heads of government and international agencies committed to working together ‘towards a new international treaty for pandemic preparedness and response’.⁵¹ The main purpose of the instrument is early detection

⁴⁷On consensus decision-making, see P. Low (2011) ‘WTO Decision-Making for the Future’, Staff Working Paper ERSD-2011-05.

⁴⁸UNICEF COVID-19 Vaccine Market Dashboard, supra n. 8; Owade, supra n. 11.

⁴⁹The reluctance of a few Members – most notably Switzerland and the UK – to agree to any waiver proposal continued throughout the negotiations, and can last be documented at the discussion of the Outcome Document held on 6 May 2022. WTO, ‘TRIPS Council hears initial reactions to Quad’s outcome document on IP COVID-19 response’, News Item, www.wto.org/english/news_e/news22_e/trip_06may22_e.htm.

⁵⁰For a critical review, see S.K. Sell (2003) *Private Power, Public Law: The Globalization of Intellectual Property Rights*. Cambridge University Press; P.N. Upreti (2022) ‘A TWAIL Critique of Intellectual Property and Related Disputes in Investor-State Dispute Settlement’, *Journal of World Intellectual Property* 25(1), 220–237.

⁵¹WHO, ‘Global leaders unite in urgent call for international pandemic treaty’ (30 March 2021), www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-international-pandemic-treaty; See also R. Labonté et al. (2021) ‘A Pandemic Treaty, Revised International Health Regulations, or both?’, *Globalization and Health* 17, 128, 1–4.

and prevention of pandemics, including a stronger international health framework within the WHO that would attempt to ensure universal and equitable access to medical solutions.⁵²

The WHO, together with governments and international organizations, should also consider alternatives for funding biomedical research and development (R&D) for viruses and diseases, especially those that disproportionately affect developing countries.⁵³ Despite a call for a treaty in this regard being one of the recommendations adopted in May 2012 by the World Health Assembly,⁵⁴ negotiations never commenced due to lack of support among the WHO Members, particularly from key industrialized countries.⁵⁵ Even though there was no concrete outcome from the past proposals for the negotiation of an international treaty, the COVID-19 pandemic provides members and concerned stakeholders a unique opportunity to re-engage in negotiating international treaties on pandemic and a global framework for medical R&D.

Likewise, scholarship in the economic, legal, and public health disciplines has for some time questioned whether patents provide the proper incentives for R&D and whether the system benefits consumers.⁵⁶ Numerous alternative incentives have been proposed, including open licensing,⁵⁷ prize funds,⁵⁸ and a global health impact fund.⁵⁹ It is beyond the scope of this article to scrutinize such initiatives or design an alternative to the patent system; the point is simply that plausible claims have been made questioning the ineffectiveness of patents in product delivery and distribution and efforts should be made to further investigate and take seriously the proposed alternatives in order to better prepare for the next global pandemic. While such efforts may require further amendment to the TRIPS Agreement, the time is ripe to seek solutions to future problems.

4.3 Flexibilities Can and Should Play an Important Role in the TRIPS Agreement

The original waiver proposal stated that the existing IP system is a barrier to accessing COVID-19 vaccines and treatment, yet also acknowledges that, '[t]o date, there is no vaccine or medicine to

⁵²European Council, 'An International Treaty on Pandemic Prevention and Preparedness', www.consilium.europa.eu/en/policies/coronavirus/pandemic-treaty/.

⁵³G. Velásquez and N. Syam (2021) 'A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South?', SouthCentre Policy Brief No. 93 (May 2021) 8–10, www.southcentre.int/wp-content/uploads/2021/05/PB-93-A-New-WHO-International-Treaty-on-Pandemic-Preparedness-and-Response-REV-2.pdf.

⁵⁴This issue was first initiated in 2006 when Brazil and Kenya proposed a draft resolution on the 'Global Framework on Essential Health Research and Development'. See WHO, '[Global framework on] essential health research and development', Agenda item 4.10, 27 January 2006, WHO/EB117.R13. The proposal sought to establish 'an open-ended working group of interested Member states to consider proposals to [establish a global framework for supporting] [strengthen incentives and mechanisms for] needs-driven research, consistent with appropriate public interest issues [and [taking note of the work] [building on the analysis] of the WHO Commission on Intellectual Property Rights, Innovation and Public Health]'. The proposal furthermore aimed to 'suggest alternative simplified systems for protection of intellectual property, with a view to enhancing accessibility to health innovations and building capacity for product development, uptake and delivery in developed and developing countries'. See also 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property', Agenda item 11.6, WHA61.21 (24 May 2008).

⁵⁵See T.I.S. Gerhardsen (2006) 'US Declares Opposition to WHO R&D Resolution as Proponents Raise Questions', Intellectual Property Watch (22 May 2006), www.ip-watch.org/2006/05/22/us-declares-opposition-to-who-rd-resolution-as-proponents-raise-questions; Velásquez and Syam, supra n. 53, at 6.

⁵⁶See e.g. J. Hay (2008) 'Prices, Regulation and Innovation in Pharmaceuticals and Biotechnology', in I. Farquhar et al. (eds.), *The Value of Innovation: Impact on Health, Life Quality, Safety, and Regulatory Research*. Emerald Publishing, pp. 81–99.

⁵⁷B. Munos (2006) 'Can Open-Source R&D Reinvigorate Drug Research?', *Nature Reviews Drug Discovery*, 5(9), 723.

⁵⁸J. Stiglitz (2006) 'Scrooge and Intellectual Property Rights: A Medical Prize Fund Could Improve the Financing of Drug Innovations', *British Medical Journal*, 333, 1279; A.V. Muzaka (2013) 'Prizes for Pharmaceuticals? Mitigating the Social Ineffectiveness of the Current Pharmaceutical Patent Arrangement', *Third World Quarterly* 34(1), 151–169.

⁵⁹A. Hollis and T. Pogge (2008) 'The Health Impact Fund: Making New Medicines Accessible for All', Report of Incentives for Global Health.

effectively prevent or treat COVID-19'.⁶⁰ This is, of course, a contradiction. Far from preventing access to vaccines and treatments, the IP system encouraged spending on R&D and not only identified the cause of the deadly pandemic but also produced multiple vaccines within the space of a year.

To argue that IP is now a stumbling block to access disregards the importance such rights played in the creation of the medical advancements and the fact that the system contains in-built flexibilities designed to deal with the global crisis. The flexibilities include: (i) the methods of implementing TRIPS obligations, (ii) substantive standards of protection, (iii) mechanism of enforcement, and (iv) areas not covered by the TRIPS Agreement.⁶¹ For example, under Article 31 of the TRIPS Agreement a WTO Member 'has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted'.⁶² Moreover, Article 31bis allows Members with insufficient or no manufacturing capacity to make use of provision by importing drugs under a compulsory license.⁶³

Such flexibilities are an important structural feature of IP, and reflective of the objects and purposes of the IP system. To this end, the rights and protections granted by the TRIPS Agreement must be read in the context of the objectives and principles of the agreement, as set out in Articles 7 and 8: Article 7 provides that the 'protection and enforcement of intellectual property rights (shall be) in a manner conducive to social and economic welfare' while Article 8 states that Members 'may, in formulating or amending their laws and regulations, adopt measure necessary to protect public health ... provided that such measures are consistent with the provisions of the Agreement'. Articles 7 and 8 received further re-enforcement in the Doha Ministerial Declaration, which instructed the TRIPS Council to take into consideration Articles 7 and 8 of the TRIPS Agreement as a guideline in their work program.⁶⁴ Most importantly, Paragraph 4 of the Doha Declaration reaffirms the commitment to safeguard policy space – 'the Agreement can and should be interpreted in a manner supportive of WTO Members' right to public health and in particular, to promote access to medicine ...'.⁶⁵ Recently, the WTO Appellate Body in *Australia – Tobacco Plain Packaging Disputes* again re-affirmed that Articles 7 and 8 of the TRIPS are the appropriate balancing tools for interpreting TRIPS provisions.⁶⁶

Read together, these provisions make it clear that Members are free to pursue legitimate public policy objectives. Moreover, and despite assertions to the contrary, the TRIPS flexibilities, such as compulsory licensing, pharmaceutical transition measure, parallel importation, and the research exceptions, have all been utilized and proven to be effective.⁶⁷ For example, one study identifies 176 uses of TRIPS flexibilities by 89 countries between 2001–2016, of which around 60% involved the use of compulsory or government use licenses and over one-fifth the LDC pharmaceutical transition measure.⁶⁸

⁶⁰WTO, 'Waiver Proposal', supra n. 3, at 4.

⁶¹WIPO, 'Public Policy-related Assistance-Flexibilities', www.wipo.int/ip-development/en/policy/flexibilities.html.

⁶²WTO (2001) 'Doha Declaration on the TRIPS Agreement and Public Health of 20 November 2001', WTO Doc. WT/MIN(01)/DEC/2 (20 November 2001), para. 5(b).

⁶³For a general discussion, see J. Watal and L. Caminero (2018) 'Least-Developed Countries, Transfer of Technology and the TRIPS Agreement', WTO Staff Working Paper, NO. ERSD-2018-01, www.wto-ilibrary.org/content/papers/25189808/219.

⁶⁴WTO Doha Ministerial Declaration (14 November 2001), WT/MIN (010/DEC/1; para. 19. See also WTO, 'Doha Declaration on the TRIPS Agreement and Public Health', supra n 62, at 4.

⁶⁵WTO, 'Doha Declaration on the TRIPS Agreement and Public Health', supra n. 62, para. 4.

⁶⁶See Appellate Body Report, *Australia – Certain Measures Concerning Trade Marks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/AB/R; WT/DS441.AB/R (9 June 2020). For general discussion of the dispute, see P.N. Upreti (2020) 'Trade Mark Restrictions under the TRIPS Agreement: The WTO Panel Findings on Australia's Tobacco Plain Packaging Legislation', *Journal of World Trade* 54(2), 239–264.

⁶⁷E.F.M. 't Hoen et al. (2018) 'Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016', *Bulletin of the World Health Organization*, 96(3), 185–193.

⁶⁸Ibid, 188.

The Ministerial Decision builds upon the existing compulsory license framework to provide easier access for Members in need of vaccines. The Decision does so in several ways. First, the Decision establishes that any eligible Member may make use of the new regime, irrespective of whether their laws contain provisions on compulsory licensing and the terms and conditions therein.⁶⁹ Second, the Decision implicitly acknowledges that the COVID-19 pandemic fulfils the requirement of a ‘national emergency’ under Article 31 so that arrangements can be made without prior efforts to obtain authorization from the right holder as per the requirements of Article 31(b) of the TRIPS Agreement – e.g. without the need to negotiate for a licence to produce and use the patented products and processes.⁷⁰ Likewise, the Decision waives the requirements of Article 31(f) that would otherwise mandate that supply under the compulsory licence be predominantly for the domestic market, thus allowing any proportion of the use to be exported to eligible Members as well as to international or regional joint initiatives.⁷¹ These are all beneficial improvements to the current legal framework that will more easily facilitate use of the system and, correspondingly, production in and importation into low and middle-income country Members.

4.4 The Ministerial Decision Is an Imperfect Document and Will Not Resolve all Pandemic-Related Issues

While the advances contained in the Ministerial Declaration are welcome, it must be acknowledged that the Decision contains gaps that may hamper its aims. While some have more broadly criticized the approach taken in respect of Article 31,⁷² Members in the main have expressed contentment. For example, in a statement following the completion of the negotiations, US Ambassador Tai was predictably upbeat, stating the negotiations:

produced accommodations to the intellectual property rules for COVID-19 vaccines that can facilitate a global health recovery ... Members were able to bridge differences and achieve a concrete and meaningful outcome to get more safe and effective vaccines to those who need it most ... During a global pandemic, under difficult circumstances, the WTO moved quickly to address a major global challenge and respond to the strong desire of our African partners to produce a meaningful outcome.⁷³

UK International Trade Secretary, Anne-Marie Trevelyan, also appeared triumphant but offered a more realistic assessment, stating:

we were clear that the solution to the access of Covid-critical goods lay beyond Intellectual Property, such as principles in applying export restrictions, increased transparency supporting trade facilitation and tariff reduction. While we pressed for the WTO Declaration to go further, we welcome the fact that members found common ground and committed to keep

⁶⁹‘Ministerial Decision’, supra n. 5, para. 2.

⁷⁰Ibid, para. 3(a). TRIPS, Art. 31(b) requires ‘the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time’. However, this requirement is waived in the case ‘of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use’.

⁷¹‘Ministerial Decision’, supra n. 5, para. 3(b).

⁷²See e.g. D. Shabalala (2022) ‘Here Again?! – The WTO COVID19 Waiver Ministerial Decision – June 2022’, IP& (17 June 2022), <https://dalishabalala.wordpress.com/2022/06/17/here-again-the-wto-covid19-waiver-ministerial-decision-june-2022/>; Oxfam, ‘Responding to News that Governments at the World Trade Organization (WTO) Have Agreed a Deal on Patents for COVID-19 Vaccines in Developing Countries’ (17 June 2022), <https://reliefweb.int/report/world/responding-news-governments-world-trade-organization-wto-have-agreed-deal-patents-covid-19-vaccines-developing-countries>.

⁷³Statement from Ambassador Katherine Tai on an Intellectual Property Response to the COVID-19 Pandemic’ (17 June 2022), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/june/statement-ambassador-katherine-tai-intellectual-property-response-covid-19-pandemic>

working to improve our preparedness for future pandemics. The UK is a long-standing champion of equitable access to vaccines. However, we could only accept an outcome on TRIPS that was operable and did not undermine the existing Intellectual Property framework ... Let me be clear: this is not about waiving IP rights. This decision should make it easier for developing countries to export the vaccines they produce within existing flexibilities.⁷⁴

On the other hand, India's Minister of Commerce & Industry, Consumer Affairs, Food and Public Distribution and Textiles, Shri Piyush Goyal, expressed disappointment at the outcome in a baffling statement in which he seemingly (yet unwittingly) admitted both the futility of a waiver and its relevance. Lamenting that the Decision shall only remain in force for a period of five years, Goyal stated that 'by the time we get an investor, get funds raised, draw plans, get equipment and set up a plant, it will probably take 2.5–3 years to do that'.⁷⁵ This statement is contradictory to India's position throughout the negotiations that a waiver would result in an immediate increase in the supply of vaccines and thus resolve issues of vaccine access and inequality. If, indeed, it takes 2.5–3 years to set up a plant then even a complete IP waiver would not result in the timely increase in supply of vaccines, thus undercutting a key justification for the waiver.

Goyal went on to further undercut the position of waiver advocates when he admitted that 'in India, we have vaccines which are expiring' and that '[v]accines have already lost relevance, 2 years they spent without giving a solution and it is too late, not even a situation where you can say better late than never. It is just too late. There is no demand for vaccines anymore'.⁷⁶ Yet again, one wonders why India continued seeking an IP waiver if it knew that vaccine supply had met and exceeded demand. Goyal's statement has value, however, in that it captures the politics of the waiver negotiations, as well as the importance of post-negotiation posturing and public relations.

The aim of this subsection is not to analyse or critique every provision of the agreement, but merely to highlight three issues where gaps may hamper the ambitions of the Decision.

(a) Restricted reading of Article 31bis

The Ministerial Decision is designed to clarify the scope of Article 31 so as to remove hurdles to increasing the production and distribution of vaccines. However, in so doing the Decision also includes restrictions. Most notably, the Decision imposes geographical restriction as the text applies only to 'eligible' Members. Footnote 1 further provides:

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.

⁷⁴UK statement following the conclusion of the WTO Ministerial Conference' (17 June 2022), www.gov.uk/government/news/uk-statement-following-the-conclusion-of-the-wto-ministerial-conference

⁷⁵Statement by Shri Piyush Goyal during the WTO 12th Ministerial Conference at the meeting with co-sponsors of TRIPS Waiver' (14 June 2022), <https://pib.gov.in/PressReleasePage.aspx?PRID=1834066>

⁷⁶Ibid.

This aspect of the decision was heavily discussed and debated. The result is broader than the Outcome Document, which had proposed in bracketed text that developing country Members which export capacity opt-out of the Decision and that ‘developing country Members who exported more than 10% of world exports of COVID-19 vaccine doses in 2021 are not eligible Members’.⁷⁷ Such a restriction would only have affected one Member, China. China objected to being formally excluded, but, as has been the case in other sectors, had no problem voluntarily agreeing not to make use of provisions otherwise available for developing countries. For its part, the US insisted on making China’s declaration binding. The resulting compromise allows Members to make voluntary but binding statements, and specifically refers to a meeting date where China voluntarily made such a statement.⁷⁸

The agreed-upon limitation departs from the original waiver proposal, which did not envision geographical limits. More importantly, the emphasis on ‘eligible’ Members narrows the reading of the Doha Declaration on the TRIPS Agreement and Public Health, where Members recognized that:

WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.⁷⁹

The restriction seems to be a limitation based not on health objectives but more political gamesmanship, which likewise runs counter to the sentiment of the Doha Declaration’s endorsement on compulsory licensing.⁸⁰ The encouragement of those with ‘existing capacity to manufacture COVID-19 vaccines’ to opt-out of the Decision is likewise perplexing from a health standpoint. In essence, the Decision excludes the leading vaccine manufacturing countries, and correspondingly the sophisticated technology necessary to manufacture complex vaccines. On this point, Shabalala concludes:

This begs the question of just who will then be the producer of COVID19 vaccines. It is precisely those countries with current production capacity that we would want to expand and export to eligible importing countries ... It might make sense for importing members to be limited to developing country members but NOT for exporting members, if the goal is to increase production and export to developing countries.⁸¹

At an NGO briefing session held during the Ministerial Conference, Okonjo-Iweala implied that industrial policy was as important for health and reportedly ‘justif[ied] this outcome on the grounds that it would be desirable protectionism to achieve the objective of promoting vaccine manufacturing capacity in Africa and other developing countries’.⁸² Similarly, EU Director-General for Trade Sabine Weyand echoed this justification when stating on Twitter: ‘There is a reason why in particular African countries wanted what was on the table: It gives them leverage to negotiate with pharma companies.’⁸³ Here, she was likely referencing not only increased manufacturing in Africa but also the increased ability of countries to negotiate

⁷⁷‘Outcome Document’, supra n. 4, at para. 1 FN 1.

⁷⁸‘Ministerial Decision’, supra n. 5, para. 1, FN 1.

⁷⁹WTO, ‘Doha Declaration on the TRIPS Agreement and Public Health’, supra n. 62, para. 6.

⁸⁰This point is also highlighted by S. Thambisetty et al. (2022) ‘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.

⁸¹Shabalala, supra n. 72.

⁸²J. Love (2022) ‘The June 17, 2022 WTO Ministerial Decision on the TRIPS Agreement’, KEI online (17 June 2022), www.keionline.org/37830.

⁸³Tweet from @WeyandSabine at 8:15pm (HK time) on 18 June 2022.

reduced prices with innovator countries, as has been the case since the adoption of the Doha waiver turned Article 31bis.

(b) The Ministerial Decision fails to acknowledge LDCs and Article 66(2)

The Ministerial Decision adopts a solution-based approach to equitable distribution of vaccines in developing countries by putting Article 31 at the centre of the debate. What is lacking, however, is any link to encourage the use of flexibilities incorporated in Article 66 relating to LDCs. In particular, Article 66(2) states:

Developed country Members *shall* provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base. (emphasis added)

This paragraph entails the positive obligation of developed countries to provide incentives to enterprises and institutions in LDCs to promote and encourage technology transfer (including health-related technologies). In practice, the paragraph has produced disappointing results and has not resulted in much technology transfer.⁸⁴ The Ministerial Decision represented an opportunity for Members to reiterate the commitment to engage in health-related technology transfer in the context of equitable distribution of vaccine production. While this may not be an immediate solution to the equitable distribution of COVID-19 vaccines, it would be an important stepping stone in preparing for the next pandemic.

(c) The 'Mailbox' approach

Critics of the Ministerial Decision have keyed in on its limited focus on patents,⁸⁵ in contrast to the original waiver proposal which included copyright, industrial designs, and trade secrets. The focus on patents is understandable given the solution relates exclusively to Article 31, which is devoted to compulsory licensing of patents. The question remains whether there is a health-related need to consider alternatives or additional measures to address these concerns.

While the authors remain unconvinced on the necessity of waiving any IPRs, one wonders whether negotiations could have produced an outcome more closely based on the original proposal. One such alternative approach that Members could have discussed is the implementation of a mechanism akin to the 'mailbox' system India adopted in its transitional period for product patents. Under the system, India was obligated to accept patent applications and keep them dormant until 2005.⁸⁶ Similarly, WTO Members could have assessed whether a tweaked version of such a system would be useful in this pandemic. For instance, Members could have agreed that for so long as the waiver is effective, all IPRs or all follow-on innovations based upon the relevant waived IPRs would be kept dormant.⁸⁷ Such a system could have been designed to preserve the

⁸⁴For a general discussion, see D.M. Fox (2019) 'Technology Transfer and the TRIPS Agreement: Are Developed Countries Meeting Their End of the Bargain?', *Hastings Science and Technology Law Journal*, 10(1), 3–38; Watal and Caminero, *supra* n. 63.

⁸⁵Thambisetty et al., *supra* n. 80.

⁸⁶For information on the mailbox system, see A. Hold and B. Mercurio (2013) 'After the Second Extension of the Transition Period for LDCs: How Can the WTO Gradually Integrate the Poorest Countries into TRIPS?', in B. Mercurio and K.-J. Ni (eds.), *Science and Technology in International Economic Law: Balancing Competing Interests*, Routledge, 260–290.

⁸⁷For a general discussion on important of follow-on innovation, see N. Estèves, A. Wernick and S. Carls (forthcoming 2023) 'The Potential of Follow-On Innovation Financing Instruments to Support a Sustainable Transition' in T. Pihlajarinne, J. Mahonen and P.N. Upreti (eds.), *Intellectual Property Rights in the Post Pandemic World: An Integrated Framework of Sustainability, Innovation and Global Justice*. Edward Elgar.

length and duration of the terms of protection. For example, if a patent is waived for three years, the system would ensure that these three years were not counted for the total duration of protection thereby providing security for a patent holder that it would recoup their investments upon the expiration of the waiver. By drafting the system in such a way, innovators may have been more incentivized to disclose IP involved in health-related technologies.

There are, of course, drawbacks to this approach. Most notably, while the mailbox system is easy to envisage for patents, it is harder to design and may not be effective for trade secret protection where the value is in the secret which, once exposed, is without value to the holder. It is unclear whether it is possible to construct such a mechanism without undermining the rationale for trade secret protection. Another hurdle to the mailbox system is temporal in nature, while the Decision imposes temporal limitation of five years, the original proposal sought a waiver ‘until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity’⁸⁸ and the revised proposal likewise envisaged what would likely have become an indefinite period of time as the default position.⁸⁹ Under such an open-ended model, it would be difficult to construct a system whereby the innovator companies are able to recoup or recover their IPRs; thus obtaining buy-in from innovators would be difficult if not impossible.

4.5 The WTO should Work towards Minimizing Barriers to Trade in Vaccines and Other Pandemic-Related Products and Equipment

Throughout the pandemic, the WTO has engaged in efforts to identify and reduce barriers to vaccines and related products. Such efforts include the production of various reports and sector-specific studies designed to deliver information and increase transparency⁹⁰ as well as the joint WTO-IMF Vaccine Trade Tracker providing data on the trade and supply of COVID-19 vaccines.⁹¹ The WTO has also joined together with the IMF, World Bank Group, and WHO on the ‘Multilateral Leaders Task Force on COVID-19’ in an effort to ‘accelerate access to COVID-19 vaccines, therapeutics and diagnostics by leveraging multilateral finance and trade solutions, particularly for low- and middle-income countries’.⁹² Efforts to identify and reduce barriers to trade should continue.

One such barrier worth highlighting is regulatory bottlenecks. In several countries, regulatory bottlenecks have been responsible for delays in granting market authorization for new vaccines.⁹³ Identifying and monitoring regulatory barriers are essential in the prompt distribution of vaccines. To this end, the WTO’s initiative listing possible trade-related bottlenecks on products to combat COVID-19, including inputs used in vaccine manufacturing and distribution, is relevant in minimizing those bottlenecks.⁹⁴

⁸⁸WTO, ‘Waiver Proposal’, supra n. 3, at 13.

⁸⁹WTO, ‘Revised Waiver Proposal’, supra n. 3, para. 2 (‘waiver shall be in for at least 3 years ... The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver’).

⁹⁰See, ‘COVID-19 and World Trade’, www.wto.org/english/tratop_e/covid19_e/covid19_e.htm.

⁹¹See ‘WTO-IMF COVID-29 Vaccine Trade Tracker’ (28 April, 2022), www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm.

⁹²See, ‘Multilateral Leaders Task Force on COVID-19 Vaccines, Therapeutics, and Diagnostics’, [/www.covid19taskforce.com/en/programs/task-force-on-covid-19-vaccines](http://www.covid19taskforce.com/en/programs/task-force-on-covid-19-vaccines).

⁹³For example, Japan approved the first mRNA vaccine in February 2021 but was not able to introduce other vaccines owing to delays in the regulatory approval process. M. Kosaka et al. (2021) ‘Delayed COVID-19 Vaccine Roll-Out in Japan’, *The Lancet* 397(10292), 2334–2335. Regulatory delays also led to a shortage of mRNA vaccines in India as the Delta variant was raging through the country. ‘A Joint Declaration on the Importance of IPRs to COVID Vaccine Manufacturing Scale-up and Future Pandemic Preparedness’, Geneva Network (6 December 2021), <https://geneva-network.com/research/a-joint-declaration-on-the-importance-of-iprs-to-covid-vaccine-manufacturing-scale-up-and-future-pandemic-preparedness/>.

⁹⁴World Trade Organization, ‘Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measure on Critical Products to Combat COVID-19’ (20 July 2021), www.wto.org/english/tratop_e/covid19_e/bottlenecks_report_e.pdf.

Efforts to facilitate the distribution of vaccines remains crucial, especially as new variants may continue to arise for the foreseeable future.⁹⁵ Thus, attention should remain focused on multilateral coordination and even the promotion of additional investment to increase vaccine supply capacity globally.⁹⁶ As a leading multilateral organization, the WTO has an opportunity to use the pandemic to reframe how it operates and become more vocal and active on issues of global importance, all while remaining true to its *raison d'être*.

5. Final Thoughts

The IP system delivered multiple effective vaccines to a novel coronavirus with unprecedented speed. With IPRs playing a key role in delivering vaccines, it always seemed inexplicable that WTO Members would agree to abandon the TRIPS-model.⁹⁷ The Ministerial Decision represents a step away from the idea that IPRs are a barrier to equitable access and instead attempts to clarify and ease access to existing flexibilities related to compulsory licensing. Implicitly, this shift reflects the idea that the system can facilitate equitable distribution of vaccines. But the Decision remains far from perfect, and expectations that it will lead to an immediate increase in the supply of vaccines is misplaced. The Decision could, however, increase voluntary licenses, diversify production, and potentially urge states to exercise compulsory licenses, if and when needed, to tackle and defeat the pandemic. Perhaps the most important outcome is that the Decision proves that the system allows for flexible interpretation, and updating, in order to meet changing circumstances such as those required by a global pandemic. But changes to the IP system are insufficient for ensuring effective global vaccination. Technical and logistic problems, as well as complexities associated with vaccine deployment and the growing problem of vaccine hesitancy, are real barriers to access.⁹⁸ Therefore, the key lies in understanding these barriers to ensure equitable distribution of vaccines. In this regard, the Decision, combined with efforts to increase and improve production capabilities, licensing, and distribution and reduce bottlenecks and blockages could go some way to ensure sustainable access to vaccines and treatments and end the pandemic.

⁹⁵S.A. Kemp et al. (2021) 'SARS-CoV-2 Evolution During Treatment of Chronic Infection', *Nature* 592, 277–282.

⁹⁶J.C. Castillo et al. (2021) 'Market Design to Accelerate COVID-19 Vaccine Supply', *Science* 371(6534), 1107–1109.

⁹⁷See A. Moore (2021) 'COVID Vaccines: Why Waiving Patents Won't Fix Global Shortage—Scientist Explains', *The Conversation* (4 May 2021), <https://theconversation.com/covid-vaccines-why-waiving-patents-wont-fix-global-shortage-scientist-explains-158643>.

⁹⁸V.A. Le and L. Samson (2021), 'Are IPRs and patents the real barriers to COVID-19 vaccine supplies?', *Manchester Journal of International Economic Law* 18(2), 192–204.