

2022

## The Legal Character and Practical Implementation of a TRIPS Waiver for COVID-19 Vaccines

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### Cover Page Footnote

\* This article is based on research that was commissioned and supported by funding from the United Nations Economic and Social Commission for Asia and the Pacific. The views and opinions expressed in this article do not in any way necessarily reflect those of the authors' respective organizations. The authors would like to thank Kaarlo Castren, Sam Ricketson, Mark Davison, and William Liu for their helpful comments. Any errors or omissions are the authors' own. \*\* Professor, Associate Dean (Research), Faculty of Law, Monash University. Email: [andrew.mitchell@monash.edu](mailto:andrew.mitchell@monash.edu); [orcid.org/0000-0001-8399-8563](https://orcid.org/0000-0001-8399-8563). \*\*\* Director, Intellectual Property Division, World Trade Organization. Email: [antony.taubman@wto.org](mailto:antony.taubman@wto.org); [orcid.org/0000-0001-7608-523X](https://orcid.org/0000-0001-7608-523X). This article does not present any views or legal analysis that can be attributed to the WTO, its Secretariat, or its Members. Portions of this article, contributed by this author, draw on material prepared for a concurrent Ph.D. dissertation, entitled Towards the 'Collective Management' of TRIPS, at the University of South Australia. \*\*\*\* Researcher. Email: [theodoresamlidis@gmail.com](mailto:theodoresamlidis@gmail.com).

# The Legal Character and Practical Implementation of a TRIPS Waiver for COVID-19 Vaccines\*

Andrew D. Mitchell,\*\* Antony Taubman\*\*\*  
& Theodore Samlidis\*\*\*\*

*Almost two years after initial proposals for a COVID-19 waiver of TRIPS obligations, a Ministerial decision adopted at the 12th Ministerial Conference in June 2022 waived obligations under Article 31(f) and the System for pharmaceutical export under the TRIPS Annex, and clarified existing options under TRIPS for increasing access to COVID-19 vaccines. As support for a more expansive pandemic waiver continues and WTO waivers remain legitimate mechanisms under WTO law, further waivers may be contemplated as viable options to address obstacles identified in the current pandemic or future health crises. This article explores what additional options are or may be open to Members under a COVID-19 waiver in its current or proposed forms, and the practical considerations for implementing them. To guide practical choices in selecting appropriate and adapted responses to public health and other crises, this article also investigates more theoretical questions about*

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*the nature of a waiver, its legal character and effect, and its interaction with other international agreements.*

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## INTRODUCTION

More than eighteen months since the first approval of a COVID-19 vaccine for use by the general public,<sup>1</sup> vaccine manufacturing remains concentrated in select countries, contributing to limited vaccine production and inequitable distribution globally. Inadequate vaccination rates have cost lives, spurred virus variants, and imposed regressive economic hardship on populations.<sup>2</sup> Redressing this global imbalance, for both current and future health crises, requires accelerated technology transfer and wider distribution of production capacity, which means overcoming any intellectual property (“IP”) obstacles that may exist in addition to various other logistical, regulatory and supply-chain challenges to distribution.

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<sup>1</sup> *UK Medicines Regulator Gives Approval for First UK COVID-19 Vaccine*, GOV.UK (Dec. 2, 2020), <https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine> [<https://perma.cc/BK8D-J9N9>].

<sup>2</sup> *See generally*, Mohammad N. Uddin & Monzurul A. Roni, *Challenges of Storage and Stability of mRNA-Based COVID-19 Vaccines*, 9 *VACCINES* 1033 (2021).

Two decades ago, World Trade Organization (“WTO”) Members responded to concerns about obstacles to access to medicines posed by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement” or “TRIPS”) by the consensus adoption of the Doha Declaration on the TRIPS Agreement and Public Health (“Doha Declaration” or “Declaration”).<sup>3</sup> Among other things, the Declaration identified a number of policy options, or “flexibilities,” open to WTO members to leverage access.<sup>4</sup> While recognizing the right of WTO Members to use compulsory licenses and their freedom to determine the grounds for such measures, the Declaration identified the difficulties associated with using this mechanism by countries with no or limited pharmaceutical production capacity.<sup>5</sup> A solution to these difficulties was provided initially by a waiver of Article 31(f) of the TRIPS Agreement, subsequently formalized as an amendment to the Agreement. The solution took the form of a new kind of compulsory license, expressly tailored to the production of pharmaceuticals for export to countries reliant on imports. This amendment, now in force for most WTO Members, bypasses the restriction in Article 31(f) that normally limited production of medicines under compulsory licenses to predominantly serve domestic markets.<sup>6</sup>

Alongside renewed calls for the more effective use, clarification or reinforcement of *existing* ways to override IP exclusivity in the public interest,<sup>7</sup> the pandemic spurred a number of WTO Members

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<sup>3</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2001) [hereinafter Doha Declaration].

<sup>4</sup> The flexibilities explicitly identified in the Declaration are not exhaustive of the potential policy options that Members can take while complying with TRIPS. See Andrew Mitchell et al., *Intellectual Property and Vaccine Manufacturing: Utilising Existing TRIPS Agreement Flexibilities for COVID-19 and Other Public Health Crises*, 25 TUL. J. TECH. & INTELL. PROP. (forthcoming).

<sup>5</sup> *Doha Declaration*, *supra* note 3, ¶ 6.

<sup>6</sup> See General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (adopted Aug. 30, 2003).

<sup>7</sup> See Communication from the European Union to the Council for TRIPS, *European Union – Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic*, WTO Doc IP/C/W/681 (June 18, 2021) [hereinafter *Communication from the European Union*].

to pursue a new temporary waiver<sup>8</sup> of certain obligations under TRIPS in order to give governments a wider range of options to address the COVID-19 pandemic (“TRIPS waiver”).<sup>9</sup> The initial proposal for a broad-scope TRIPS waiver was tabled<sup>10</sup> at the WTO in October 2020. Almost two years later, at the 12th Ministerial Conference in June 2022, a significantly different outcome emerged in the form of a consensus Decision on the TRIPS Agreement.<sup>11</sup> As well as waiving obligations under Article 31(f), the Ministerial Decision implementing the waiver clarified existing options under the TRIPS Agreement in the context of the pandemic response, in order to facilitate and streamline measures enabling the diversification of vaccine production without the consent of rights holders.

Up until the 12th Ministerial Conference, an extensive debate between governments,<sup>12</sup> and amongst analysts and scholars,<sup>13</sup> on the need for, and likely effectiveness of, a TRIPS waiver dominated discussion about IP rights in the pandemic context. By contrast,

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<sup>8</sup> See Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Revised Decision Text*, WTO Doc IP/C/W/669/Rev.1 (May 25, 2021) [hereinafter *Revised Decision Text*].

<sup>9</sup> See Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 3 [hereinafter *Marrakesh Agreement*]; Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 3, Annex 1C (Agreement on Trade-Related Aspects of Intellectual Property Rights) [hereinafter *TRIPS Agreement*].

<sup>10</sup> See Communication from India and South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc IP/C/W/669 (Oct. 2, 2020) [hereinafter *Initial Waiver Text*].

<sup>11</sup> See World Trade Organization, Ministerial Decision on the TRIPS Agreement, WTO Doc WT/MIN(22)/30 WT/L/1141 (June 22, 2022) [hereinafter *Ministerial Decision*].

<sup>12</sup> See generally Council on Trade-Related Aspects for Intellectual Property Rights, Minutes, WTO Docs IP/C/M/97.

<sup>13</sup> This ongoing debate is robust. See, e.g., Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal, LSE Policy Briefing Paper No. 46, (July 13, 2021); Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic* 27 (LSE L. Soc’y, Econ. Working Papers No. 06/2021); James Bacchus, *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines*, 78 FREE TRADE BULL. 1, 1 (2020); Bryan Mercurio, *WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review* 62 VA. J. OF INT’L L. ONLINE 11 (2021); Bryan Mercurio, 52 INT’L REV. OF INTELL. PROP. AND COMPETITION L. 983.

relatively little attention had been paid to specific measures that Members could take under various forms of waiver, and the practical and legal limitations that may need to be overcome to give effect to governments' greater scope of agency should TRIPS obligations be temporarily eased.

These practical and legal questions are distinct from questions concerning the necessity or propriety of a TRIPS waiver and are of both systemic and theoretical significance. The waiver debate has shed light on the potential application of this mechanism in the context of a global health crisis. Given the general legal legitimacy of a waiver as a mechanism open to WTO Members,<sup>14</sup> it cannot be excluded that further waivers may be considered as viable options to address specific obstacles identified in response to future public health crises.

In this article, we consider what additional options are or may be open to Members under a public health TRIPS waiver in any one of its current or proposed forms, and the practical considerations for implementing each of them. We do so with a view to illuminating both current and future possibilities for a potentially powerful, but still not clearly elaborated, tool for access to priority medical technologies. Closely related and relevant to such practical considerations are broader, more theoretical questions about the nature of a waiver, its legal effect, and its interaction with other international legal instruments and with domestic law. We also explore potential answers to such theoretical questions in the hope that they might guide practical choices in selecting appropriate and adapted responses to public health and other crises.

Section II of this Article outlines the IP barriers said to give rise to the need for a TRIPS waiver.<sup>15</sup> Section III considers the nature of the existing TRIPS waiver decisions or proposals to provide context for the practical and legal considerations explored in Section IV. Amongst these considerations are the domestic law mechanisms

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<sup>14</sup> See Marrakesh Agreement, *supra* note 9, art. IX.3; see generally Isabel Feichtner, *The Waiver Power of the WTO: Opening the WTO for Political Debate on the Reconciliation of Competing Interests*, 20 EUR. J. INT'L L. 615, 645 (2009).

<sup>15</sup> Our analysis of how these barriers might be overcome utilizing flexibilities within the existing TRIPS framework, independently of a waiver, can be found elsewhere. See Mitchell et al., *supra* note 4.



needed for implementing a waiver, the role that broader domestic legal systems might play, and the potential effect of a waiver on other sources of international legal obligations, such as preferential trade agreements (“PTAs”) and bilateral investment treaties (“BITs”). In Section V, we question the security exception in Article 73(b) of TRIPS as a potential alternative to a TRIPS waiver by focusing on its distinct legal character and limited role in the pandemic context.

## I. INTELLECTUAL PROPERTY BARRIERS TO VACCINE MANUFACTURING AND DISTRIBUTION

### A. *Significance of the IP system for vaccine access*

The experience of many developing countries during the pandemic has led to concerted efforts to ensure vaccine equity and future resilience by ramping up and geographically diversifying production capacity for vaccines.<sup>16</sup> In turn, increasing and diversifying manufacturing capacity for developed vaccines requires effective transfer of technology, particularly for more novel vaccine platforms such as mRNA. Technology transfer may take various forms in practice, such as:

- making use of public domain information (including publications of patents not in force in the countries concerned);
- a diverse range of technology licensing and contractual arrangements; or
- close cooperative technology partnerships entailing human capital development and direct knowledge transfer.

These different mechanisms often involve ensuring effective access to IP-protected technologies. The development and production of novel vaccines may also require access to IP rights covering technologies not exclusively defined by their application to a particular

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<sup>16</sup> See *WHO-WTO Dialogue Steps Up Efforts for Increased COVID-19 Vaccine Production and Equitable Access*, WTO (Jul. 21, 2021), [https://www.wto.org/english/news\\_e/news21\\_e/igo\\_21jul21\\_e.htm](https://www.wto.org/english/news_e/news21_e/igo_21jul21_e.htm) (last visited Oct. 30, 2022).

disease, such as COVID-19, typically comprising technology platforms, production inputs and delivery technologies. These may be held by other firms not directly involved in the development of a specific vaccine. The IP dimension of technology transfer processes may therefore entail licensing or transfer of patent rights, sharing of knowhow and confidential information, and access to or reliance on clinical trial data required for market approval of the finished product. Further, the production and distribution of vaccines may involve technologies that utilize copyright and industrial design rights. We briefly discuss each of these IP subject matter and their potential role in vaccine inequity below.

### *B. Patents*

A patent claiming a product as a protected invention gives its owner the right to exclude third parties from making, using, offering for sale, selling that product, and from importing the product for those purposes; and a patent covering a process similarly gives its owner the right to prevent third parties from using the process, and from using, offering for sale, selling, or importing it for these purposes.<sup>17</sup> Vaccines and vaccine manufacturing processes are often protected by one or more patents in a number of jurisdictions.<sup>18</sup> Thus, firms wishing to manufacture vaccines may encounter barriers to production where the vaccine and its production processes are protected by patents under the domestic law of the country in which the firm seeks to exploit the invention. Similarly, patent rights granted in an importing country can prevent the importation of

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<sup>17</sup> See TRIPS Agreement, art. 28.1.

<sup>18</sup> Patent Analytics Hub identifies 1,422 applications and 290 unique patent families filed globally since 2000 relating to human coronavirus vaccines, with 50% of these patent families either being sought or in force. Patent Analytics Hub, *Patenting of Human Coronavirus Vaccines*, ITABLEAU PUB. IP AUSTL. (Sept. 21, 2020), <https://public.tableau.com/app/profile/patent.analytics.hub/viz/Humancoronavirusvaccines/Vaccines> [<https://perma.cc/9BKE-FQJQ>]; see also Mario Gaviria & Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NATURE BIOTECHNOLOGY 546, <https://doi.org/10.1038/s41587-021-00912-9> [<https://perma.cc/ZEK2-VANB>]; Ting-Wei (Alex) Chiang and Xiaoping Wu, *Innovation and Patenting Activities of COVID-19 Vaccines in WTO Members: Analytical Review of Medicines Patent Pool (MPP) COVID-19 Vaccines Patent Landscape (Vaxpal)*, World Trade Organization, Staff Working Paper ERSD-2022-01 (Feb. 10, 2022).

finished vaccines or production inputs without the patent holder's authorization.<sup>19</sup>

The factors behind inequitable access to vaccines are diverse and interrelated, extending well beyond the scope of the IP system, and the question of whether, and if so to what extent, IP rights have caused vaccine inequity continues to be highly contentious.<sup>20</sup> Patenting on inputs, processes and finished products has generally pushed up prices for medicines,<sup>21</sup> potentially causing effective barriers to access, but this has not necessarily been the case for COVID-19 vaccines: UNICEF<sup>22</sup> data suggests that prices have been relatively low and correlate somewhat to a national and regional income levels. Rather, the experience with vaccine procurement during the pandemic has led to calls for diversifying the geographical distribution of production capacity as a means of better assuring vaccine equity and future resilience.<sup>23</sup>

Upon publication of a patent application, the invention disclosed passes immediately into the public domain in those jurisdictions where a patent is not sought, because of the strictly territorial scope of patents under national and regional systems.<sup>24</sup> Thus, most patented technology information becomes publicly available in most WTO Members as soon as it is published, and early in the vaccine development process (publication generally taking place eighteen

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<sup>19</sup> See Antony Taubman, Hannu Wager & Jayashree Watal, *A HANDBOOK ON THE TRIPS AGREEMENT* 20 (2d ed., Cambridge Univ. Press 2020).

<sup>20</sup> See Sara Sousa Rosa et. al, *mRNA Vaccines Manufacturing: Challenges and Bottlenecks*, 39 *VACCINE* 16 (2021).

<sup>21</sup> The Doha Declaration (*supra* note 3) expressly recognized “concerns about [IP protection’s] effects on prices.” See also WHO, WIPO & WTO, *PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION* 198 (2d ed. 2020).

<sup>22</sup> See *COVID-19 Market Dashboard*, UNICEF, <https://www.unicef.org/supply/covid-19-market-dashboard> (last visited Oct. 30, 2022).

<sup>23</sup> See *COVAX: Key Learnings for Future Pandemic Preparedness and Response*, GAVI (Sept. 2022) [https://www.gavi.org/sites/default/files/covid/covax/COVAX\\_Key-Learnings-for-Future.pdf](https://www.gavi.org/sites/default/files/covid/covax/COVAX_Key-Learnings-for-Future.pdf) (last visited Oct. 30, 2022); Padmashree Gehl Sampath & Jon Pearman, *Local Production of COVID-19 Vaccines: A Strategy for Action*, *GLOBAL POL’Y* (Aug. 23, 2021) <https://www.globalpolicyjournal.com/articles/health-and-social-policy/local-production-covid-19-vaccines-strategy-action> (last visited Oct. 30, 2022).

<sup>24</sup> See TRIPS Agreement, *supra* note 9, art. 39.3

months after the first filing data).<sup>25</sup> The key impediment to utilizing an invention in cases where an invention is known but not protected is obtaining the necessary technical information to carry out the invention. In principle, a patent document must fully teach the person skilled in the art how to implement the invention,<sup>26</sup> and a patent can be invalidated for insufficient disclosure.<sup>27</sup> However, further knowhow is typically needed to make effective use of patented technology, especially in the complex area of pharmaceuticals (particularly for new technological platforms such as mRNA vaccines<sup>28</sup>), where it is difficult to replicate or reverse engineer detailed manufacturing knowhow.

When patents do present a barrier in countries where they are in force, governments have considerable scope to override their exclusivity in the public interest. One flexibility that receives frequent attention is the possibility of issuing compulsory licenses or other forms of non-voluntary use authorization (“NVUA”), such as government use orders and emergency decrees. These are interventions by government authorities conferring on third parties the right to use or sell an invention without authorization of the patentee, subject to remuneration.<sup>29</sup> The procurement scenarios that do *not* call for a compulsory license or other NVUA are wide-ranging, including:

- where the product is not patented;
- where products are appropriately priced and effectively and equitably available; and
- where necessary access has been secured, such as through a license, or other initiatives have been taken, such as non-assertion undertakings by the patent holder.

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<sup>25</sup> According to WIPO data, approximately 47% of 3,276,700 patent applications filed in 2020 were filed in high-income countries, 46% were filed in China, and only 7% were filed in LMICs (excluding China). WIPO IP STAT. DATA CTR., [www3.wipo.int/ipstats/](http://www3.wipo.int/ipstats/) [<https://perma.cc/E7U5-6DQE>].

<sup>26</sup> See TRIPS Agreement, *supra* note 9, art. 29.1.

<sup>27</sup> See *id.*

<sup>28</sup> See *The mRNA Vaccine Technology Transfer Hub*, WHO, <https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub> [<https://perma.cc/A2PF-STK6>] (last visited Oct. 30, 2022)

<sup>29</sup> See Antony Taubman, *Rethinking TRIPS: ‘Adequate Remuneration’ for Non-Voluntary Patent Licensing*, 11 J. INT’L ECON. L. 927, 932 (2008).

While inherently diverse in their form and administration in domestic laws—a practice confirmed and clarified in the 2022 Ministerial Decision—NVUAs can be broadly classed into two categories: (i) government use authorizations, or approval for patented technologies to be used for public purposes, and (ii) compulsory licensing in a narrower sense upon the request of a third party seeking to use, manufacture or import patented technology or to use a patented process.<sup>30</sup> The latter form of authorization may be granted where the original patentee refuses to license it voluntarily, at least where such refusal is found to be anticompetitive, or where there are other grounds for overriding the exclusive rights of a patentee, such as public health interests.<sup>31</sup> Government or public use authorizations and compulsory licenses can expand manufacturing capacity beyond the originator firm’s own production chain, and also facilitate wider international distribution—not necessarily to introduce competition and lower-priced medicines into the market, but also as a potential means of maximizing the use of available production capacity. This direct expansion of the production and supply of high-demand medicines may well constitute a specific public initiative, and especially where production, procurement, or distribution is undertaken in the furtherance of government functions, this would constitute a public non-commercial use provided for in Article 31(b) of TRIPS.<sup>32</sup> There is little doubt that the COVID-19 pandemic constitutes a national emergency or circumstance of extreme urgency, and the TRIPS Agreement already foresees a wide scope for governments to take relatively unencumbered action at such a time of crisis.

### C. Copyright and Industrial Designs

Copyright issues with respect to written material on product information documents, product labelling, and inserts, as well as software and data compilations utilized in the vaccine manufacturing and distribution process, also exist in the pandemic context.<sup>33</sup>

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<sup>30</sup> *Id.*

<sup>31</sup> See WHO, WIPO & WTO, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION, 236 (2020), [https://www.wto.org/english/res\\_e/booksp\\_e/who-wipo-wto\\_2020\\_e.pdf](https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf) [<https://perma.cc/H4XF-9UCC>].

<sup>32</sup> See TRIPS Agreement, *supra* note 13, art. 31(b).

<sup>33</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and*

Article 10(2) of TRIPS requires that “compilations of data or other material . . . which by reason of the selection or arrangement of their contents constitute intellectual creations” be protected.<sup>34</sup> As clarified by Article 9(2), copyright protects expressions and not ideas.<sup>35</sup> It would not normally protect individual items of data in themselves, such as raw statistics.<sup>36</sup>

Industrial design protection safeguards the outward appearance of manufactured products, but not the product itself.<sup>37</sup> Thus, the owner of a protected industrial design has the right to prevent third parties from commercial acts of producing, selling or importing articles that bear or embody a design that copies the protected design.<sup>38</sup> Industrial designs are likely less relevant to the manufacture and distribution of COVID-19 vaccines than the development and distribution of other medical products, such as diagnostic tools, ventilators, and personal protective equipment.<sup>39</sup>

Protected designs may, however, come into play for related articles: for instance, vaccines are primarily delivered through diluent containers, single- and multidose vials and pre-filled syringes, and transported using refrigerators, freezers, and cold boxes.<sup>40</sup> Industrial designs have been registered in some jurisdictions for items, such as vaccine transportation containers and freezer, syringes and other delivery items.<sup>41</sup> These may be procured at several points throughout

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*Treatment of COVID-19*, WTO Doc IP/C/W/684 (Sept. 30, 2021); Doris Estelle Long, *The Overlooked Role of Copyright in Securing Vaccine Distribution Equity* INFOJUSTICE (Sept. 6, 2021), <http://infojustice.org/archives/43621> [<https://perma.cc/VDW4-LV53>].

<sup>34</sup> See TRIPS Agreement, *supra* note 9, art. 10.2.

<sup>35</sup> See TRIPS Agreement, *supra* note 9, art. 9.

<sup>36</sup> See *id.*

<sup>37</sup> See Taubman, Wager & Watal, *supra* note 19, at 127.

<sup>38</sup> See TRIPS Agreement, *supra* note 9, art. 9.

<sup>39</sup> See, e.g., Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of COVID-19—Response to Questions*, TRIPS, WTO Doc. IP/C/W/672 (Jan. 15, 2021); WTO Secretariat, *TRIPS, the Intellectual Property System and COVID-19* (Oct. 15, 2020).

<sup>40</sup> See Michelle R. Holm & Gregory A. Poland, *Critical Aspects of Packaging, Storage, Preparation, and Administration of mRNA and Adenovirus-Vectored COVID-19 Vaccines for Optimal Efficacy*, 39 VACCINE 457 (2021).

<sup>41</sup> For instance, the WIPO Global Designs Database contains 457 records of designs for syringes in Locarno Class 24 (medical and laboratory equipment), as well as several

vaccine distribution and delivery by both private and public entities.<sup>42</sup> However, no specific IP obstacles for access to such devices have currently come to light (in contrast with supply chain scarcity for vaccine inputs).<sup>43</sup>

#### D. Confidential Information

The protection of confidential or undisclosed information (also termed “knowhow” or “trade secrets”) may affect access to knowledge or information. Such access is necessary to undertake the steps required to produce a vaccine, such as technical methods of production or use of the equipment involved, including their precise settings and arrangement, and biological and other materials used in vaccine development.<sup>44</sup>

Such information and knowhow constitute core components in the production of any vaccine, such as tacit knowledge about production methods. While much information required may be in the public domain, some specialist knowledge is more likely to be protected as confidential in the context of newer technology platforms, such as mRNA vaccines.<sup>45</sup> Vaccine technologies are best understood as a package of various inputs, comprising both patented inventions and/or knowhow, some of which may be confidential.<sup>46</sup> Even if there is no patent in force in a particular jurisdiction, or a compulsory license or other NVUA is granted with respect to a patent, access to confidential information and related knowhow may be necessary to ensure the effective implementation of the

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records of vaccine transportation and refrigeration apparatus. *Global Design Database*, WIPO, <https://www3.wipo.int/designdb/en/index.jsp> (last visited Oct. 30, 2022).

<sup>42</sup> WTO Secretariat, *Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19* (Oct. 19, 2021), [https://www.wto.org/english/tratop\\_e/covid19\\_e/bottlenecks\\_update\\_oct21\\_e.pdf](https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_update_oct21_e.pdf) [<https://perma.cc/85H9-HW9E>].

<sup>43</sup> *Id.*

<sup>44</sup> See Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer*, 16 J. INTELL. PROP. L. & PRACTICE 1242, 1246 (2021).

<sup>45</sup> *Id.* at 1246.

<sup>46</sup> See Geertrui Van Overwalle, *Uncorking Trade Secrets: Sparking the Interaction Between Trade Secrecy and Open Biotechnology*, in *THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH* 246, 250 (Rochelle Dreyfuss & Katherine Strandberg eds., 2011) (forthcoming).

technology platform.<sup>47</sup> Technology transfer sufficient to enable generic vaccine production can, therefore, be a complex process entailing positive communication of knowledge and the development of human capital, and the simple removal of legal barriers may not be sufficient to achieve these outcomes.<sup>48</sup>

#### *E. Clinical trial data*

Clinical trial or test data that demonstrates the safety and efficacy of new pharmaceuticals (including vaccines) is, in some countries, required to be submitted to regulatory authorities as a condition of approval for new products and new applications.<sup>49</sup> Such data may also include sensitive information regarding the manufacturing process, formulation, dosage, delivery method, indicated uses, and general safety information.<sup>50</sup> These regulatory procedures are distinct from the protection of IP, and many countries do not maintain entirely independent approval processes that call for submission of data. Many of these countries base domestic approval on approval in other countries, or to WHO emergency use or prequalification procedures (particularly in the context of urgent pandemic responses).<sup>51</sup>

However, in those countries where test data are required to be submitted, such data are—under TRIPS—protected from disclosure or unfair commercial use, provided they are undisclosed, relate to a new chemical entity, and required considerable effort to generate.<sup>52</sup> If firms are required to submit clinical trial data or required to rely on the originator's data to gain approval to distribute the vaccine, they may be constrained from producing follow-up COVID-19 vaccines. The TRIPS standards in this area apply when the domestic

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<sup>47</sup> See Gurgula & Hull, *supra* note 44, at 1243.

<sup>48</sup> See Padmashree Gehl Sampath & Jon Pearman, *Local Production of COVID-19 Vaccines: A Strategy for Action*, GLOBAL POL'Y, (Aug. 2021)

<sup>49</sup> See, e.g., Food Drug & Cosmetic Act, 21 U.S.C. § 355.

<sup>50</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 33 ¶ 35.

<sup>51</sup> See Neil McAuslane et al., *Emerging Markets and Emerging Agencies: A Comparative Study of How Key Regulatory Agencies in Asia, Latin America, the Middle East, and Africa Are Developing Regulatory Processes and Review Models for New Medicinal Products*, 43 DRUG INFO. J. 349, 349 (2009).

<sup>52</sup> See TRIPS Agreement, *supra* note 9, art. 39.3.



authorities undertake a distinct review of clinical trial data as a condition of regulatory approval.<sup>53</sup> Some bilateral and regional agreements provide for more extensive protection, which may expressly set a term of exclusivity over the originator's data, may apply to reliance on data submitted for approval in other jurisdictions, or may set limits over reliance on the originator's earlier regulatory approval.<sup>54</sup> Due to relatively low costs, and growing technical expertise, recent years have seen an increasing trend of localized clinical trials, including for COVID-19 vaccines.<sup>55</sup>

Different countries currently maintain a diverse range of approaches to both regulatory approval of vaccines (and reliance on approval in other jurisdictions or by the WHO), and to the protection of clinical trial data.<sup>56</sup> Divergent regulatory mechanisms and cumbersome regulatory procedures have, in themselves, been identified as an obstacle to the timely production and distribution of vaccines.<sup>57</sup> Addressing this concern in the context of the pandemic, the Ministerial Decision on the TRIPS Agreement (discussed below) articulates an understanding that TRIPS standards do not “prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine” produced under the Ministerial Decision.<sup>58</sup>

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<sup>53</sup> *Id.*

<sup>54</sup> See, e.g., Comprehensive and Progressive Agreement for Trans-Pacific Partnership art. 18.5 (Mar. 8, 2018) [hereinafter “CPTPP”].

<sup>55</sup> See Sheraz Ali et al., *Clinical Trials in Asia: A World Health Organization Database Study*, 10 PERSPS. CLINICAL RSCH. 121, 122 (2019).

<sup>56</sup> See Ellen 't Hoen, *Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity*, in ACCESS TO MEDICINES AND VACCINES (Carlos M. Correa & Reto M. Hilty eds., Springer 2022) 183, 186–87; Antony Taubman, *Unfair Competition and The Financing of Public-Knowledge Goods: The Problem of Test Data Protection*, 3 J. INTELL. PROP. L. & PRAC. 591, 595–96.

<sup>57</sup> See *Regulatory Responses to the COVID-19 Pandemic in Southeast Asia*, ORG. FOR ECON. COOP. AND DEV., (Oct. 11, 2021), [https://read.oecd-ilibrary.org/view/?ref=1112\\_1112857-ojschuakia&title=Regulatory-responses-to-the-COVID-19-pandemic-in-Southeast-Asia](https://read.oecd-ilibrary.org/view/?ref=1112_1112857-ojschuakia&title=Regulatory-responses-to-the-COVID-19-pandemic-in-Southeast-Asia) [<https://perma.cc/7N82-A62E>].

<sup>58</sup> See *Ministerial Decision*, *supra* note 11, ¶ 4.

## II. TRIPS WAIVER

### A. TRIPS Waivers: Past, Present and Future

Concern that applicable IP rights may pose a barrier to the acceleration and diversification of production and distribution of COVID technologies was the primary impetus for the original TRIPS waiver proposal by India and South Africa in October 2020, and the subsequent negotiations that ultimately led to the Ministerial Decision adopted at the 12th Ministerial Conference.<sup>59</sup> The original proposal (including its subsequent revisions) and the Ministerial Conference outcome are discussed in turn.

#### 1. Original waiver proposal

The original waiver proposal can be anatomized into three overarching, complementary elements, with distinct legal and practical characteristics:

- (i) the suspension of obligations to provide IP rights *as such* at a certain minimum standard and to ensure exceptions and limitations to such rights comply with certain broad principles (Part II of TRIPS);
- (ii) the suspension of the obligation to provide for the effective enforceability of covered IP rights, including through the availability of civil and criminal remedies, and enforcement of rights at the border (Part III of TRIPS); and
- (iii) a “peace clause” or agreement precluding Members from enforcing and seeking compliance with TRIPS obligations through the WTO dispute settlement mechanism.<sup>60</sup>

The original waiver proposal was subject to further revision by its proponents, leading to a revised decision text circulated by a communication requested by the delegations of eighteen WTO

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<sup>59</sup> See *Revised Decision Text*, *supra* note 8.

<sup>60</sup> *Id.* at 3–4.

Members and co-sponsored by over sixty Members.<sup>61</sup> The operative paragraph 1, which was revised “to add specificity to the decision text following concern that the original decision text was too broad,” would waive the obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement. The waiver was to be limited 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.<sup>62</sup> Additionally, pursuant to paragraph 6 of the proposed decision, Members would not be able to “challenge any measures taken in conformity with the provision of the waivers contained” in the decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through WTO dispute settlement mechanisms.<sup>63</sup>

In parallel with this more general TRIPS waiver proposal, the EU and some other Members signaled willingness to consider specific waivers of some TRIPS provisions, especially to streamline and facilitate the use of compulsory licenses and other NVUAs, particularly in relation to patents.<sup>64</sup> The main focus of the EU’s proposal, however, was a declaration clarifying Members’ existing rights under TRIPS.<sup>65</sup>

By June 2022, WTO Members had failed to reach consensus on a TRIPS waiver, including that proposed in 2020 and revised in 2021.<sup>66</sup> Despite wide support for the proposed waiver, and a range

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<sup>61</sup> See generally *id.*; see also Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19—Joint Statement of Co-Sponsors*, WTO Doc IP/C/W/677 (adopted May 18, 2021).

<sup>62</sup> See *Revised Decision Text*, *supra* note 8 ¶ 1.

<sup>63</sup> *Id.* at ¶ 6.

<sup>64</sup> Communication from the European Union to the Council for TRIPS, *supra*, note 7.

<sup>65</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *Draft General Council Declaration on the Trips Agreement and Public Health in the Circumstances of a Pandemic*, WTO Doc IP/C/W/681 (June 18, 2021).

<sup>66</sup> See DG Okonjo-Iweala *Urges Members to Seize Opportunity at MC12 to Deliver Meaningful Outcomes*, WTO (June 7, 2022), [https://www.wto.org/english/news\\_e/news22\\_e/gc\\_07jun22\\_e.htm](https://www.wto.org/english/news_e/news22_e/gc_07jun22_e.htm) [<https://perma.cc/5C8H-ACJG>].

of sponsors from the developing world, discussions between WTO Members were reportedly characterized by considerable differences.<sup>67</sup> The matter had reportedly remained highly dynamic and the specific outcomes uncertain, despite emerging evidence of a more general convergence on the objective of overcoming vaccine inequities.<sup>68</sup>

## 2. Ministerial Decision on the TRIPS Agreement

Discussions and negotiations regarding a waiver continued throughout 2021,<sup>69</sup> and in December 2021, informal text-based discussions began with hopes for a “meaningful proposal” that would be without prejudice to the negotiators’ respective positions and that would be presented transparently to the full membership in the Council for Trade-Related Aspects of Intellectual Property Rights (“TRIPS Council”).<sup>70</sup>

The first concrete product of these discussions to surface publicly was a draft text for a proposed Ministerial Conference decision that leaked on March 15, 2022 and contained a “TRIPS COVID-19 solution,” which took the form of numerous clarifications to the rights and obligations under TRIPS.<sup>71</sup> This solution was formally presented to the TRIPS Council Chair by the WTO Director-General and circulated to Members by the Chair’s communication dated

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<sup>67</sup> See *Members Continue Discussions on IP COVID-19 Response as High-Level Engagement Intensifies*, WTO (Dec. 16, 2021), [https://www.wto.org/english/news\\_e/news21\\_e/trip\\_16dec21\\_e.html](https://www.wto.org/english/news_e/news21_e/trip_16dec21_e.html) [<https://perma.cc/SG5A-84S5>].

<sup>68</sup> See e.g., David Lawder, *U.S. Trade Chief to Keep Pushing on Vaccine IP, WTO Reform After Meeting Delay*, REUTERS (Nov. 11, 2021), <https://www.reuters.com/world/us/us-trade-chief-tai-pushes-post-trump-vision-wto-ahead-geneva-talks-2021-11-26/> [<https://perma.cc/HN5X-ZPVH>]; *U.S. Urges All WTO Members to Support Intellectual Property Waiver for COVID-19 Vaccines*, REUTERS, (Oct. 22, 2021), <https://www.reuters.com/world/us/white-house-wto-members-must-support-intellectual-property-waiver-covid-vaccines-2021-10-21/> [<https://perma.cc/YEX2-R8SR>].

<sup>69</sup> See *generally Members Approach Text-Based Discussions for an Urgent IP Response to COVID-19*, WTO (June 9, 2021), [https://www.wto.org/english/news\\_e/news21\\_e/trip\\_09jun21\\_e.htm](https://www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm); *TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19*, WTO (July 20, 2021), [https://www.wto.org/english/news\\_e/news21\\_e/trip\\_20jul21\\_e.htm](https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm) [<https://perma.cc/57MK-SFNH>].

<sup>70</sup> See Richa Chintan, *Leaked WTO Draft Text on TRIPS Waiver Reveals ‘Compromise’*, NEWSCLICK (Mar. 23, 2022), <https://www.newsclick.in/Leaked-WTO-Draft-Text-TRIPS-Waiver-Reveals-Compromise> [<https://perma.cc/AH57-ZS3E>].

<sup>71</sup> See *id.*

May 3, 2022 (“Draft Text”).<sup>72</sup> The Draft Text was further negotiated and finalized before being circulated to ministerial delegates on June 10 for review and potential approval at the 12th Ministerial Conference.<sup>73</sup> Two revisions<sup>74</sup> of the Draft Text were published during the course of the Conference before a “Ministerial Decision on the TRIPS Agreement” was finally adopted on June 17, 2022 (“Ministerial Decision”).<sup>75</sup>

The first paragraphs of the Ministerial Decision state:

1. Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter “the Agreement”) by authorizing the use of the subject matter of a patent 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, in accordance with the provisions of Article 31 of [TRIPS], as clarified and waived in paragraphs 2 to 6 below.
2. For greater clarity, an eligible 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 such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime

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<sup>72</sup> See Council for TRIPS, *Communication from the Chairperson*, WTO Doc. IP/C/W/688 (May 3, 2022) [hereinafter Draft Text].

<sup>73</sup> See Ministerial Conference, June 12, 2022, WTO Doc. WT/MIN(22)/W/15WTO (June 10, 2022); *Draft Texts on WTO Response to Pandemic, IP Response Sent to Ministers for Decision*, World Trade Organization, (June 10, 2022), [https://www.wto.org/english/news\\_e/news22\\_e/covid\\_10jun22\\_e.htm](https://www.wto.org/english/news_e/news22_e/covid_10jun22_e.htm) [<https://perma.cc/554R-4FNK>].

<sup>74</sup> See Ministerial Conference, *Draft Ministerial Decision on the TRIPS Agreement*, WTO Doc. WT/MIN(22)/W/15/Rev.1 (June 17, 2022); Ministerial Conference, *Draft Ministerial Decision on the TRIPS Agreement*, WTO Doc. WT/MIN(22)/W/15/Rev.2 (June 17, 2022).

<sup>75</sup> See *Ministerial Decision*, *supra* note 11.

in place. For the purpose of [the Ministerial] Decision, the “law of a Member” referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders.<sup>76</sup>

The Ministerial Decision defines “eligible Member” as “all developing country Members,” but states that such Members with existing COVID-19 manufacturing capacity “are encouraged to make a binding commitment not to avail themselves of the Decision.”<sup>77</sup> This definition replaced the Draft Text definition, which referred to “any developing country Member that exported less than 10 percent of world exports of COVID-19 vaccine doses in 2021.”<sup>78</sup>

For the purposes of the Ministerial Decision, “subject matter of a patent” is defined as *including* “ingredients and processes necessary for the manufacture of the COVID-19 vaccine,” a definition that was chosen in place of “all finished COVID-19 vaccine products, ingredients and processes necessary for the manufacture of the COVID-19 vaccine.”<sup>79</sup>

The Ministerial Decision also makes the following additional clarifications of TRIPS provisions, as well as expressly waiving the requirements of Article 31(f):

- an eligible Member need not require the proposed user of the subject matter of a patent to make efforts to obtain an authorization from the right holder as set out in Article 31(b);<sup>80</sup>
- an eligible Member may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any proportion of the

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<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> See Ministerial Conference, *Draft Ministerial Decision on the TRIPS Agreement*, *supra* note 74.

<sup>79</sup> *Ministerial Decision*, *supra* note 11, at n.2.

<sup>80</sup> *Id.* at n.3(a).

products manufactured under the authorization in accordance with this Decision to be exported to eligible Members, including through international or regional joint initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization;<sup>81</sup>

- 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 . . . [and] Members may take into consideration existing good practices in instances of national emergencies, pandemics or similar circumstances;<sup>82</sup> and
- “[r]ecognizing the importance of the timely availability of and access to COVID-19 vaccines,” Article 39.3 of TRIPS “does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision.”<sup>83</sup>

The Ministerial Decision also requires Members, when implementing the terms of the Decision, to:

- “undertake all reasonable efforts to prevent the re-exportation of the products manufactured under the authorization in accordance with the

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<sup>81</sup> *Id.* at n.3(b).

<sup>82</sup> *Id.* at n.3(d). (“Includes the remuneration aspects of the 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).”)

<sup>83</sup> *Id.* at n.4.

Decision that have been imported into their territories under th[e] Decision;”<sup>84</sup>

- “ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorization in accordance with th[e] Decision, and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement;”<sup>85</sup> and
- “communicate to the Council for TRIPS any measure related to the implementation of th[e] Decision, including the granting of an authorization.”<sup>86</sup>

The Decision is to have effect for five years, but the General Council may extend that period, taking into consideration the exceptional circumstances of the COVID-19 pandemic.<sup>87</sup> Within six months from the date of the final Decision, Members must decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics.<sup>88</sup> Finally, Members cannot challenge any measures taken in conformity with the Decision under subparagraphs 1(b) and 1(c) of Article XXIII of the GATT 1994.<sup>89</sup>

We do not seek to provide an extensive critique or analysis of the Ministerial Decision, but draw on it to provide greater context for discussion of its legal character and practical effect (both generally and compared to the original waiver proposal) and for insights into the broader question of how and to what extent national government authorities can curb the exclusive effect of IP rights,

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<sup>84</sup> *Id.* at n.3(c). The first sentence of the analogous paragraph in the previous Draft Text simply read: “Eligible Members shall undertake all reasonable efforts to prevent the re-exportation of the COVID-19 vaccine that has been imported into their territories under the Decision.” Draft Text, *supra* note 72, at ¶ 3(d).

<sup>85</sup> *Ministerial Decision*, *supra* note 11, at n.3(c).

<sup>86</sup> *Id.* at n.5.

<sup>87</sup> *Id.* at n.6.

<sup>88</sup> *Id.* at n.8.

<sup>89</sup> *Id.* at n.7.



especially in a global health crisis. This latter aspect has been a consistent underlying issue in the policy debate sparked by the pandemic.<sup>90</sup>

a. Previous paragraph 3(a): Article 31(a)

The Draft Text had stated that “with respect to Article 31(a), an eligible Member may issue a single authorization to use the subject matter of multiple patents necessary for the production or supply of a COVID-19 vaccine.”<sup>91</sup> While removed by negotiators, if retained, this sentence would have clarified what is made implicitly clear by the text of Article 31 and paragraph 31(a) of the TRIPS Agreement: each *authorization* of the use of patented subject matter must be considered on its individual merits; it is not a requirement that each individual authorization to use each specific patent must be considered and granted on its individual merits, a restrictive approach that would impede expeditious action, and would be inconsistent with established practice.<sup>92</sup> The latter, overly restrictive interpretation has led to concerns that each authority to use must be considered and granted on a product-by-product basis and in respect of each individual authorized user.<sup>93</sup>

Also dropped during negotiations was a requirement to “list all patents covered” by the authorization.<sup>94</sup> As discussed below, Article 31 does not prescribe the particular form that an authorization must take, and it need not take the form of a compulsory license, nor does it require all patents or patent applications affected to be identified in advance, again consistent with established practice.<sup>95</sup>

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<sup>90</sup> See Antony Taubman, *Solidarity as a Practical Craft: Cohesion and Cooperation in Leveraging Access to Medical Technologies Within and Beyond the TRIPS Agreement*, 29 ASIA-PACIFIC SUSTAINABLE DEV. J. (forthcoming Dec. 2022)

<sup>91</sup> Draft Text, *supra* note 72, at ¶ 3(a).

<sup>92</sup> See, e.g., *IPCom v. Vodafone* [2020] EWHC (Pat.) 132 (Eng.).

<sup>93</sup> See, e.g., WTO Doc IP/C/W/672, *supra* note 39, ¶3; Chang-fa Lo, *Compulsory Licensing: Threats, Use and Recent Trends*, in CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW: SETTING THE FRAMEWORK AND EXPLORING POLICY OPTIONS 144, 151 (Bryan Mercurio & Daria Kim eds., Routledge 2017).

<sup>94</sup> Draft Text, *supra* note 72, at ¶ 3(d).

<sup>95</sup> See *The Patents Act 1997* (UK); Mitchell et al., *supra* note 4, at 15–16, 22.

b. Paragraphs 1 and 3(a): Article 31(b)

That a Member has a right, in certain circumstances, to authorize the use of patented subject matter without the need for the right holder's prior consent, or negotiation with that rights holder, is already provided for in Article 31(b).<sup>96</sup> Although the exception to this requirement in Article 31(b) is limited to cases of national emergency or other circumstances of extreme urgency, or cases of public non-commercial use, the Ministerial Decision is limited to COVID-19 vaccines, the use and sale of which would no doubt already be covered by one of more of these conditions, noting also that the Doha Declaration clarified both that Members have the "right to determine what constitutes a national emergency or other circumstances of extreme urgency" and that public health crises do in any case represent such a situation.<sup>97</sup> Hence, this clarification in the context of the COVID-19 pandemic represents a wider understanding in the TRIPS Agreement applicable in a much broader range of circumstances than those covered by the Decision. Hence, while paragraph 2 of the Ministerial Decision is framed as being "for greater clarity,"<sup>98</sup> paragraph 9 also clarifies that the Ministerial Decision is without prejudice to the interpretation of TRIPS flexibilities "outside the scope of [the] Decision."<sup>99</sup>

c. Paragraph 2: Article 31

Paragraph 2 of the Ministerial Decision is of considerable practical significance to the extent it clarifies a frequently misunderstood aspect of Article 31 and Section 5 of TRIPS, and thus directly addresses a commonly observed obstacle to the full use of patent flexibilities under the TRIPS Agreement. Paragraph 2 clarifies that NVUAs need not be affected through existing compulsory licensing laws, and may be given effect by means of any instrument available in the law of a Member, whether or not that Member has a compulsory license regime in place.<sup>100</sup> While paragraph 2 refers to "government use authorizations" in addition to executive orders,

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<sup>96</sup> See TRIPS Agreement, *supra* note 9, art. 31(b).

<sup>97</sup> Doha Declaration, *supra* note 7, ¶5(c).

<sup>98</sup> Ministerial Decision, *supra* note 11, at n.2.

<sup>99</sup> *Id.* at n.9.

<sup>100</sup> *Id.* at n.2.

emergency decrees and judicial or administrative orders, each of these instruments are more accurately characterized as different species of government use authorizations.<sup>101</sup>

As is often overlooked, government NVUAs can be issued on various grounds and need not expressly refer to a patent at all: Article 31(b), for instance, makes clear that for public non-commercial use, the government or contractor need not make a patent search before undertaking the authorized use of patented subject matter. NVUAs may take the form of a specific license under a patent (i.e. a compulsory license), or a more general authorization.<sup>102</sup> This is because Article 31 does not formally speak of compulsory licenses or any specific form of license. Instead, it sets out principles and requirements that govern any non-voluntary authorized use of patented subject matter, beyond the exceptions covered by Article 30.

d. Paragraphs 3(b), 3(c) and 5: Article 31(f)

The sole true waiver of TRIPS provisions in the Ministerial Decision, contained in paragraph 3(b), is of the requirement in Article 31(f) of TRIPS that authorized use by a Member under Article 31 be predominantly for the supply of the Member's domestic market.<sup>103</sup> Additionally, footnote 3 to the Ministerial Decision, which did not previously appear in the Draft Text, provides that “[i]n exceptional circumstances, an eligible Member may re-export COVID-19 vaccines to another eligible Member for humanitarian and not-for-profit purposes, as long as the eligible Member communicates in accordance with paragraph 5.”<sup>104</sup>

The effect of paragraph 3(b) and footnote 3 of the Ministerial Decision is to provide a streamlined means for vaccine production predominantly for export as an alternative to the System set up Article 31*bis* of TRIPS (the solution called for in Paragraph 6 of the Doha Declaration). The key differences are (i) a switch to a supply-driven model of production for export, which is potentially more responsive to pandemic circumstances because receiving countries

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<sup>101</sup> *Id.* at n.2.

<sup>102</sup> *See id.* at 16.

<sup>103</sup> *Id.* at n.3(b).

<sup>104</sup> *Id.*

need not first notify their import requirements; (ii) a postponement of notification requirements until after shipments take place; (iii) entitlement to supply “international or regional joint initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by [an] authorization”, creating an additional avenue for supply suitable for pandemic circumstances that would not be directly available under Article 31bis (while this is procedurally possible through the relatively simple step of aggregating demand and submitting a joint notification of needs, the pandemic waiver enables a more nimble and responsive pathway);<sup>105</sup> and (iv) re-exportation of COVID-19 vaccines by importing eligible Members “for humanitarian and not-for-profit purposes”, an additional flexibility responding to the circumstances of the pandemic.<sup>106</sup>

e. Paragraph 3(d): Article 31(h)

Paragraph 3(d) of the Ministerial Decision provides that the determination of adequate remuneration under Article 31(h) of TRIPS may take account of the humanitarian and not-for-profit purposes of specific vaccine distribution programs “in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members,” and a footnote refers to remuneration guidance earlier published by several international organizations.<sup>107</sup> While not redefining or replacing existing flexibilities accorded to them under TRIPS, this provision may afford greater confidence to Members in incorporating humanitarian considerations into their adequacy determinations, but it should not be seen as the source of their power to do so.

f. Paragraph 4: Article 39.3

The Ministerial Decision adds some clarity to what was paragraph 4 of the Draft Text, which was phrased much more broadly in the following terms: “[n]othing in Article 39.3 . . . shall prevent a Member from taking measures necessary to enable the effectiveness

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<sup>105</sup> Mitchell et al., *supra* note 4, at 28–38.

<sup>106</sup> See *Ministerial Decision*, *supra* note 11, at n.3(d).

<sup>107</sup> See *id.*, n.3(d), at n.4.

of any authorization issued as per this Decision.”<sup>108</sup> Aside from clarifying what the “effectiveness” of a Decision-based authorization amounts to (rapid regulatory approval of vaccines), there are no substantive differences between these two wordings.<sup>109</sup> Both provisions add little to the following flexibilities already contained in TRIPS:

test data need only be protected against “unfair commercial use,” which naturally excludes both non-commercial use and commercial use that is not “unfair” (including, as we have argued elsewhere, use that is equitably remunerated)<sup>110</sup>; and test data need not be protected against disclosure, where a lack of such protection is deemed necessary to protect the public.<sup>111</sup>

g. Paragraph 9: “without prejudice”

The Decision does not displace existing options Members have under the TRIPS Agreement, its paragraph 9 expressly providing that the Decision is:

. . . without prejudice to the flexibilities that Members have under the TRIPS Agreement, including flexibilities affirmed in the Doha Declaration on the TRIPS Agreement and Public Health, and without prejudice to their rights and obligations under the TRIPS Agreement, except as otherwise provided for in paragraph 3(b).<sup>112</sup>

While paragraph 9 further provides that the Decision does not prejudice “the interpretation of the above-mentioned flexibilities, rights and obligations outside the scope of this Decision,” it does arguably shed light indirectly on the range of practical options generally available under TRIPS.<sup>113</sup> We have referred to these flexibilities briefly in the foregoing discussion, but a full survey and examination of them within the pandemic context can be found elsewhere.<sup>114</sup>

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<sup>108</sup> Draft Text, *supra* note 72, at n.4.

<sup>109</sup> *Ministerial Decision*, *supra* note 79, at n.4; *id.* n.4.

<sup>110</sup> Mitchell et al., *supra* note 4, at 54; *see also* Taubman, *supra* note 29, at 927.

<sup>111</sup> Mitchell et al., *supra* note 4, at 27.

<sup>112</sup> *Ministerial Decision*, *supra* note 79, at n.9.

<sup>113</sup> *Id.*

<sup>114</sup> *See generally* Mitchell et al., *supra* note 4.

## B. *The Legal Character, Implications and Limitations of a Waiver*

### 1. The scope and legal character of a pandemic waiver

The Ministerial Decision is distinctly different in scope and application to the original waiver proposed in 2020: it addresses vaccine technology only (with a process under way to potentially extend it to therapeutics and diagnostics);<sup>115</sup> it focuses on patent rights and means of curtailing their exclusive effect along with the role of clinical trial data protection, but does not address other areas of IP; it seeks to provide positive normative guidance and not merely to suspend legal standards; and its waiver element is precisely focused on specific obstacles potentially posed to the use of COVID-19 technologies, rather than a broad, non-specific removal of legal obligations. This section examines the legal character and potential implications of both the original waiver proposal and the Ministerial Decision, as well as considerations relevant to their practical implementation.

In contrast to the relatively limited scope of the Ministerial Decision, the initial and revised COVID waiver proposals would suspend a wide range of obligations under TRIPS and thus open up options for various measures at the domestic level that—by definition—would not otherwise be available to Members with TRIPS-compliant laws and legal systems. Options canvassed in the debate have included suspending intellectual property right (“IPR”) protection over COVID-19-related material, designs and inventions; halting the processing of applications for protection, such as new COVID-19 technologies; and creating wider exceptions to IP rights than are currently understood to be available under TRIPS.<sup>116</sup> In

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<sup>115</sup> See WTO, *TRIPS Council Welcomes MC12 TRIPS Waiver Decision, Discusses Possible Extension* (July 6, 2022), [https://www.wto.org/english/news\\_e/news22\\_e/trip\\_08jul22\\_e.htm](https://www.wto.org/english/news_e/news22_e/trip_08jul22_e.htm) (last visited Oct. 30, 2022).

<sup>116</sup> See, e.g., Council for Trade-Related Aspects of International Property Law, *Minutes of Meeting*, WTO Doc. IP/C/M/98 (July 30, 2018); Council for Trade-Related Aspects of International Property Law, *Minutes of Meeting*, WTO Doc. IP/C/M/99 (May 11, 2019); Council for Trade-Related Aspects of International Property Law, *Minutes of Meeting*, WTO Doc. IP/C/M/100 (Oct. 20, 2021); Council for Trade-Related Aspects of International Property Law, *Minutes of Meeting*, WTO Doc. IP/C/M/101 (July 23, 2021); Council for Trade-Related Aspects of International Property Law, *Minutes of Meeting*, WTO Doc. IP/C/M/102 (Oct. 5, 2021); Council for Trade-Related Aspects of International

addition to the suspension of domestic IP claims and WTO dispute resolution mechanisms discussed above, the waiver proposal as revised in June 2021 would *prima facie* allow Members, at least in principle, to:<sup>117</sup>

- prevent the grant or recognition of otherwise eligible IP rights;
- prevent the processing of otherwise legitimate applications for patents or industrial designs to the extent that they cover relevant COVID-19 subject matter;
- refuse to grant protections and patents over designs and inventions, or suspend existing ones, again to the extent that they cover relevant COVID-19 subject matter;
- discriminate in the enjoyment of patent rights on the grounds of field of technology;
- provide exceptions to IP rights that are broader than Articles 13, 26 and 30 would otherwise allow;
- determine that normal remedies for infringement of legitimate IP rights are not available in respect of certain COVID-19-related acts (such as vaccine production);
- suspend certain procedural steps that would otherwise be required for the grant of compulsory licenses and other NVUAs, such as:
  - disregarding the need to subsequently notify the right holder in the event of commercial use (Article 31(b));
  - permitting production mainly for export and not domestic use without the

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Property Law, *Minutes of Meeting*, WTO Doc. IP/C/M/103 (Feb. 24, 2022); see generally Council for Trade-Related Aspects of International Property Law, *Response to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19 in Document IP/C/W/671*, WTO Doc. IP/C/W/673 (Jan. 15, 2021); Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, ¶ 92, WTO Doc IP/C/M/103 (Jan. 6, 2022) (particularly the reproduced documents cited in the oral status report to the General Council which had been circulated in document JOB/IP/53).

<sup>117</sup> See generally *Revised Decision Text*, *supra* note 8, ¶ 1.

- requirements of 31bis being satisfied (31(f)); and
- suspending an obligation to compensate the right holder, including through *ex post* remuneration (31(h)); and
- permit uses of undisclosed information and clinical trial data in ways that would otherwise constitute dishonest commercial practices (Article 39.2)<sup>118</sup> or unfair commercial use (Article 39.3).<sup>119</sup>

A waiver proposal of this scope can be analyzed both in terms of its means of implementation and practical consequences at the domestic level and in terms of its operation within the international legal framework established by the Marrakesh Agreement. In undertaking this analysis, we do not seek to advocate or promote any of the specific options that would be formally or theoretically opened up by a broadscale waiver, or the far-reaching policy questions about the impact, practicality and wider legitimacy of adopting such measures. The domestic implementation of TRIPS waivers also potentially raises complex practical questions not touched on in our analysis, such as its application to platform or multi-use technologies.

A waiver of WTO obligations under Article IX:3 is one of three legislative competences of the Ministerial Conference under the Marrakesh Agreement, alongside the power to adopt authoritative interpretative decisions (Article IX.2) and the power to adopt amendment decisions (Article X.1).<sup>120</sup> A WTO waiver is typically characterized as a temporary exception to WTO obligations, rather than a positive source of rights or obligations. Some reasons given are that waivers only apply in “exceptional circumstances;”<sup>121</sup> they apply only to particular Members and certain obligations; and they

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<sup>118</sup> See Antony Taubman, *Fair Enough? Reconciling Unfair Competition with Competition Policy*, in *COMPETITION POLICY AND INTELLECTUAL PROPERTY IN TODAY'S GLOBAL ECONOMY* (Robert Anderson et al. eds., Cambridge Univ. Press 2021).

<sup>119</sup> See Taubman, *supra* note 56, at 595–96.

<sup>120</sup> See Feichtner, *supra* note 14, at 618.

<sup>121</sup> See James Harrison, *Legal and Political Oversight of WTO Waivers*, 11 J. OF INT'L ECON. L. 411, 419–420 (2008); Feichtner, *supra* note 14, at 620.



are distinct from WTO tribunals' relatively limited jurisdiction over the Covered Agreements.<sup>122</sup> On this view, waivers do not create substantive rights, except to the extent they permit action by Members that would otherwise be prohibited by a waived obligation, and suspend the possibility of a complaint being filed under the WTO's dispute settlement system. In this sense, a waiver is a shield that can be used against any relevant claim raised and not a sword that can be used as the basis for a claim.

There are few procedural or substantive requirements for a valid waiver: the waiver must be adopted in "exceptional circumstances" by consensus of the Ministerial Conference within 90 days of submission, or otherwise by a three-fourths majority.<sup>123</sup> The fact that a waiver is expressly stated to be a response to "exceptional circumstances" would likely suffice to establish their existence, as a recital to that effect would reflect the collective view of the Membership as a whole. For this reason, both the original waiver proposals and the Ministerial Decision begin by noting "the exceptional circumstances of the COVID-19 pandemic."<sup>124</sup>

While the validity of a TRIPS waiver is unlikely to be challenged on such procedural or substantive grounds, more fundamental questions arise about the extent to which each of the waivers proposed or adopted align with how a WTO waiver is intended to function.

The original waiver proposed was designed as something much broader than a source of immunity or defense that could be relied upon in WTO dispute settlement. As outlined above, by expressly seeking to waive international obligations to protect and enforce IP rights through national laws, it was intended to open up positive avenues for limiting the scope, availability, and enforcement of IP rights at the domestic level, alongside the suspension of dispute resolution at the multilateral level. In contrast, as we have noted, the Ministerial Decision both: (i) provides positive normative support for the wider use of governments' existing entitlements under the TRIPS Agreement, through clarification of their practical

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<sup>122</sup> See Harrison, *supra* note 121.

<sup>123</sup> See Marrakesh Agreement, *supra* note 9, art. IX ¶3.

<sup>124</sup> *Ministerial Decision*, *supra* note 11.

implementation; and (ii) creates an additional array of domestic options, through its waiver of the Article 31(f) restriction on production under an NVUA predominantly for the domestic market, thus furnishing Members with an additional means of pharmaceutical production for export alongside Article 31bis.<sup>125</sup>

The clear contrast between the scope and character of the Ministerial Decision with the scope and character of the original waiver proposal underscores not only the wide range of mechanisms that may be available in principle, but also the value of analyzing the sharply different implications they have for practical implementation. Equally, the stark empirical fact—albeit the subject of much critical commentary<sup>126</sup>—is that, in this instance, a very open, broad-brush waiver could not be successfully negotiated whereas a more precise and focused one could.<sup>127</sup> This state of affairs touches on a broader policy question about the function of such waivers, and whether they should be framed as a broad, prophylactic measure to inoculate against a wide range of potential domestic barriers, or whether they should be crafted and focused to address particular legal difficulties encountered when framing, planning or undertaking specific domestic actions. To use the medical analogy, should a waiver be a broad-spectrum vaccine to protect against potential problems in a general way; or should it be a therapy to be applied once a more precise diagnosis of the legal problem has been undertaken? The question is more than theoretical: it touches also on the potential complexities and uncertainties of domestic implementation, as well as the practicality of reaching a timely consensus across the WTO's broad Membership.

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<sup>125</sup> See *Ministerial Decision*, *supra* note 11, 3(b).

<sup>126</sup> See Statement, South Centre, TRIPS Waiver: An Insufficient Multilateral Response. TRIPS-Consistent National Actions are Called for (June 21, 2022), <https://mailchi.mp/southcentre/southnews-south-centre-statement-trips-waiver-an-insufficient-multilateral-response-trips-consistent-national-actions-are-called-for> [<https://perma.cc/KV7Z-M76J>]; Médecins Sans Frontières, *COVID-19 Tools is a Disappointing Failure for People* (June 17, 2022), <https://www.msf.org/lack-real-ip-waiver-covid-19-tools-disappointing-failure-people> [<https://perma.cc/BDZ3-TW7E>].

<sup>127</sup> See generally Peter Yu, *The COVID-19 TRIPS Waiver and the WTO Ministerial Decision*, in *IPR IN TIMES OF CRISIS: LESSONS LEARNED FROM THE COVID-19 PANDEMIC* (Jens Schovsbo ed., 2022) (forthcoming 2023), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4150090](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4150090) [<https://perma.cc/4V8A-FMT2>].

## 2. Limitations of a TRIPS waiver

Both the original waiver proposal and the Ministerial Decision share limitations that inhere within waivers more broadly. First, there are some issues that a waiver cannot address at all. For example, a waiver would not alleviate the challenges surrounding the forced disclosure of confidential information.<sup>128</sup> There would also be no or negligible benefit in waiving certain TRIPS provisions that already provide Members with latitude to impose higher standards than TRIPS requires. For example, Article 29 provides for a minimum standard of disclosure that Members may choose to surpass in their domestic law. It is also noteworthy that all LDC WTO Members are not required to apply any substantive provisions of TRIPS until at least July 2034,<sup>129</sup> and so even the broad waiver proposal would not add to the flexibility already extended to them.

Moreover, a waiver—however implemented—would not in itself dispense with regulatory requirements or procurement procedures relating to vaccines and other pharmaceuticals because such matters are not directly governed by TRIPS nor by the IP system generally.<sup>130</sup> Thus, a waiver could not overcome any obstacles to vaccine production, distribution and export that relate to the market approval of medicines from a safety and efficacy perspective. This suggests that regulatory questions would need to be addressed in conjunction with the implementation of a waiver. The controversy over the supply to Bolivia of vaccines by the Canadian firm Biolyse clearly illustrates this point. Bolivia has concluded an agreement with Biolyse for the supply of vaccines and has notified its needs for vaccines to the TRIPS Council as required for an Article 31*bis* license for production for export.<sup>131</sup> However, as at the time of

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<sup>128</sup> See Thambisetty et al., *supra* note 13, at 17; RETO M. HILTY ET AL., COVID-19 AND THE ROLE OF INTELLECTUAL PROPERTY: POSITION STATEMENT OF THE MAX PLANCK INSTITUTE FOR INNOVATION AND COMPETITION 3 (2021).

<sup>129</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66.1 for Least Developed Country Members: Decision of the Council for TRIPS of 29 June 2021*, WTO Doc IP/C/88 (June, 29 2021).

<sup>130</sup> See RETO M. HILTY ET AL., *supra* note 128.

<sup>131</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *Notification of Need to Import Pharmaceutical Products Under the Special Compulsory Licensing System*, WTO Doc. IP/N/9/BOL/1 (May 11, 2021).

writing, a compulsory license has not been issued,<sup>132</sup> and the Canadian Government has not taken the prior step of adding the vaccine to Schedule 1 of Canada's Patent Act,<sup>133</sup> required for a compulsory license for export under the Canadian Access to Medicines Regime (CAMR). While details of the matter are currently unclear and have been the subject of some controversy,<sup>134</sup> one reported issue has been the need for Canadian government authorities to establish that vaccines produced by Biolyse would be safe and effective: thus a spokesperson for the Canadian Government's Innovation, Science and Economic Development program stated that "[a] company seeking authorization under Canada's Access to Medicines Regime must be able to manufacture the drug and conduct necessary trials to establish that the drug meets Canadian safety and efficacy requirements before authorization would be granted".<sup>135</sup> This is ultimately a regulatory matter and not an IP issue, even though the ostensible obstacle to production appears to be the lack of a license. If there is an undischarged obligation to confirm that the firm can produce vaccines that meet regulatory standards, this situation would remain the case under a waiver, even if Canada were to take steps to suspend IP rights pursuant to it, because these steps *in themselves* would not remove regulatory standards applied to medicines. It would be possible, of course, for governments to elect to permit vaccines to be produced expressly for export without complying with domestic regulatory standards, although governments may prove hesitant to permit production and export of vaccines that would not comply with their own domestic standards. In any event, this regulatory dimension would need to be considered and addressed, with or without, and before, after or during, a waiver addressing only the IP dimension. It has been suggested that political reluctance may also be

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<sup>132</sup> See Benjamin Blanco, *With One Simple Decision, The Canadian Government Can Save Lives*, Aljazeera (Sept. 28, 2021) <https://www.aljazeera.com/opinions/2021/9/28/the-canadian-government-can-save-bolivian-lives> (last visited Oct. 30, 2022).

<sup>133</sup> Canada, *Patent Act* R.S.C. 1985, c. P-4.

<sup>134</sup> See, e.g., MUHAMMAD ZAHEER ABBAS, CANADA'S POLITICAL CHOICES RESTRAIN VACCINE EQUITY: THE BOLIVIA-BIOLYSE CASE 11 (2021).

<sup>135</sup> See Zachary Brennan, *How to Manufacture COVID-19 Vaccines Without the Help of J&J, Pfizer or Moderna? Biolyse Sees the Difficulties Up Close*, ENDPOINTS NEWS (May 17, 2021), <https://endpts.com/how-to-manufacture-covid-19-vaccines-without-the-help-of-jj-pfizer-or-moderna-biolyse-sees-the-difficulties-up-close/> (last visited Oct. 30, 2022).

a factor behind the failure to schedule COVID-19 vaccines and then issue a CAMR compulsory license:<sup>136</sup> if that is the case, in the event of a TRIPS waiver, it does not automatically follow that a government would take the more controversial step of applying domestic measures beyond the bounds of TRIPS, as against using an existing mechanism that is legally established<sup>137</sup> and widely supported.<sup>138</sup>

Finally, while the original waiver could entitle Members to reduce the terms of IP rights or revoke such rights altogether, the time-limited character of a waiver and the possibility of domestic legal, procedural, and other constraints may complicate such steps. For example, there could be legal and procedural difficulties in reinstating rights or titles over IP subject matter such as patents and industrial designs that have been revoked. We discuss these specific limitations below, in the context of waiver implementation.

### C. Implementing a Waiver

As TRIPS is not self-executing, and IP rights are defined, administered, and enforced under domestic law, any waiver of TRIPS provisions at the international level would not lead directly to any curtailment or suspension of IP rights or their enforcement. For governments to take advantage of a waiver would require implementation at the domestic level—whether through a legislative amendment or other executive or administrative action.<sup>139</sup>

Some discussion of the waiver proposal seems to have been predicated on the assumption that a waiver of TRIPS obligations amounts to an automatic waiver or suspension of IP rights as such. Thus, a waiver has been seen as a fast-track approach to overcoming

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<sup>136</sup> See Evidence, Standing Committee on Foreign Affairs and International Development, House of Commons, Canada Number 019, 1st Session, 44<sup>th</sup> Parliament (9 May, 2022); Ahmar Khan, *Canada Lacks 'Political Will' to Waive COVID-19 Vaccine Patents, Bolivian Minister Says*, GLOBAL NEWS, Oct. 6, 2021, <https://globalnews.ca/news/8243635/bolivian-minister-canada-covid-vaccine-waiver/> (last visited Oct. 30, 2022).

<sup>137</sup> See TRIPS Agreement, *supra* note 9, art. 31(b).

<sup>138</sup> As of September 1, 2022, the amended TRIPS Agreement applied to 136 of 164 WTO Members. See TRIPS Council, *Annual Review of the Special Compulsory Licensing System*, IP/C/94 (forthcoming).

<sup>139</sup> See Carlos M. Correa, *TRIPS Agreement and Access to Drugs in Developing Countries*, 3 INT'L L.J. HUMAN RIGHTS 25, 32 (2005).

IP barriers to access that would be swifter and more immediate than domestic processes (e.g. NVUAs).<sup>140</sup> However, even in jurisdictions with a strong tradition of “direct effect” of international treaty law, and despite a number of judicial decisions directly applying TRIPS in the absence of implementing legislation,<sup>141</sup> we are unaware of any legal mechanism that would lead directly from a waiver of TRIPS obligations to the effective absence or unenforceability of IP rights under domestic law. Further systemic research may be needed to clarify this situation, as it is a key aspect of understanding a TRIPS waiver as a practical tool for both current and future scenarios.

Further, current waiver proponents have emphasized the potential diversity of national mechanisms for implementing a waiver. As observed by waiver proponents, “there is no [one] size fits all approach to national implementation,” given the distinct nature of each Member’s legal and constitutional system.<sup>142</sup> However, if a waiver is intended to promote greater coordination and cooperation between governments in the spirit of solidarity, then a highly heterogeneous approach to implementation in different national systems may impede any potential benefits while consuming considerable administrative or legislative bandwidth and political capital.

Here, we provide a general overview of the potential mechanisms for implementing the original waiver proposed as revised in June 2021. In order to highlight some relevant practical considerations, we outline what each of these options might mean for Australia, as an example of a Member with a highly developed IP system, a high level of engagement at the international level, and a complex constitutional system, and we contrast this analysis with a range of selected jurisdictions in the Asia Pacific region.

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<sup>140</sup> See Academic open letter, *supra* note 13; WTO Doc IP/C/W/672, *supra* note 39, ¶¶143–49.

<sup>141</sup> See Mark Miller, *Trips Agreement and Direct Effect in European Community Law: You Can Look . . . But Can You Touch*, 74 NOTRE DAME L. REV. 597, 617–19 (1999).

<sup>142</sup> Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 39, ¶ 751; see also Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 33, ¶ 53.

### 1. Peace Clause: Suspension of International Dispute Resolution

The original COVID waiver proposal, as analyzed above, would have suspended the availability of multilateral dispute resolution alongside the formal waiver of the obligation to give effect to TRIPS' specific provisions. Various forms of agreement to suspend or refrain from taking certain action in international dispute resolution are known informally as "peace clauses." These are generally concluded on the understanding that the agreement may lead to greater domestic willingness to take actions that would otherwise infringe, or purportedly infringe, international obligations. Past WTO practice has been somewhat diverse in this respect and can be characterized according to two broad categories of measure:

- (i) agreements to altogether exclude certain disputes from the scope of multilateral dispute settlement; and
- (ii) agreements to exercise restraint in initiating dispute settlement proceedings.

An example of the first category in the context of TRIPS is the exclusion of non-violation and situation complaints, initially under Article 63.2 and subsequently through successive Ministerial Conference decisions. The second type is exemplified in Article 24.1 of the WTO Dispute Settlement Understanding ("DSU"), which provides that "Members shall exercise due restraint in raising [dispute settlement] matters involving a [LDC] Member" and that "complaining parties shall exercise due restraint" in seeking compensation or retaliation against an LDC.<sup>143</sup> However, the original waiver proposal would clearly provide for agreement on a prohibition of dispute settlement as such, and not simply due restraint.

A peace clause of some kind would entail Members foregoing what would otherwise be a political choice to invoke their rights under the DSU to instigate dispute procedures against another WTO Member; it would not require formal legal change at the domestic

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<sup>143</sup> WTO Agreement: Dispute Settlement Understanding, Apr. 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) [hereinafter Dispute Settlement Understanding].

level. If, as one of us has explored,<sup>144</sup> practical agency of national governments and their willingness to pursue pragmatic options may be partly guided by a risk assessment as to the consequences of dispute settlement action, this mechanism may provide reinforcement for taking potentially difficult choices, while not in itself creating distinct options *per se*.

From a practical perspective, it is noteworthy that dispute settlement complaints taken in particular by developed countries against developing country Members have been minimal since around the year 2000.<sup>145</sup> Further, the current absence of an operational WTO Appellate Body (“AB”) means that any outcome arising from panel proceedings is potentially suspended through the possibility of “appeal into the void.”<sup>146</sup> The uncertainty over whether, when, and how this state of affairs may be resolved would presumably lead to some reluctance to take significant domestic action, especially to build up vaccine production capacity.

As we have already explored earlier in this article, it is not clear whether a “peace clause” would taint the character of a “waiver” under Article IX:3. A decision under Article IX:3 is a decision to waive obligations of one or more Members—it is not an agreement or understanding to refrain or abstain from dispute resolution.

## 2. Suspension of domestic enforcement action

Potential mechanisms for blunting Part III obligations under TRIPS include removing available remedies such as injunctive or interlocutory relief and limiting other remedies. For example, this may involve setting a cap on available compensation or remedies for infringements relating to COVID-19 subject matter. While the focus would be on waiving Part III of TRIPS, removing or limiting remedies may also be achieved by defining exceptions to IP rights under

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<sup>144</sup> See Antony Taubman, *A PRACTICAL GUIDE TO WORKING WITH TRIPS* 92 (Oxford Univ. Press, 2011).

<sup>145</sup> See *Developing Countries in WTO Dispute Settlement*, WTO, [https://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_settlement\\_cbt\\_e/c11s1p1\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/dispu_settlement_cbt_e/c11s1p1_e.htm) [<https://perma.cc/9XUW-ALP7>].

<sup>146</sup> See Chad P Brown & Petros C Mavroidis, *Is This the End?: The WTO Case Law of 2019*, 20 *WORLD TRADE REV.* 383, 383 (2019).



Part II of TRIPS in terms of a lack of capacity to enforce such rights (e.g. regulatory review exceptions).

The suspension or modification of enforcement action for COVID-19 subject matter would not be without practical limitations. In Australia, for example, it would require at least an amendment to various enforcement mechanisms found in Australia's statutory IP law and various general law entitlements to bring enforcement action against the disclosure of confidential information on the basis of contractual or equitable principles. As discussed in the next two sections, such mechanisms would also raise questions under domestic constitutional law and the possibility of violations under other international agreements.

### 3. Temporary suspension of IP legislation

Some TRIPS waiver advocates have contemplated the suspension of existing IP rights or the suspension of the processing of patent and other applications.<sup>147</sup> This would entail removing the legal effect, registration, or recognition of IP rights that would otherwise legitimately be recognized or made available. This may be contrasted with the suspension of domestic enforcement action, because it would preclude or delay the grant or registration of instruments that constitute the source of certain exclusive IPRs (e.g. patents, registered industrial designs, and copyright registrations). In some jurisdictions, executive action may be sufficient to implement this, while in others, it would be necessary to enact some form of legislation. Proponents of a waiver have maintained that legislative amendment "need not be a time-consuming exercise."<sup>148</sup>

However, practical difficulties would likely interfere with this approach. For instance, in the patent field, a number of critical technologies are platform technologies with much wider application than COVID-19 alone.<sup>149</sup> This gives rise to related issues about the difficulty of managing these patents and patent applications. Would they be revoked, suspended, or refused purely due to their

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<sup>147</sup> See, e.g., Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 39, ¶ 80.

<sup>148</sup> See Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 33, ¶ 54–56.

<sup>149</sup> See generally Chiang & Wu, *supra* note 18.

application to COVID-19? Would administrative or judicial authorities have the capacity to determine the applicable scope of a platform technology to COVID-19 vis-à-vis other medical indications? Similar considerations would arise in respect to other technologies such as vaccine storage, transportation, and delivery. While use patents (which might be defined in terms of use of a technology to address COVID-19 in particular) would be more easily addressed by this kind of mechanism, they would not enable a complete solution in many cases if other broader technology platforms remain part of the access equation.

*D. Conflict or waiver of laws?*

1. Constitutional questions

Even where a TRIPS waiver would permit certain action under TRIPS, constitutional principles may limit governments' capacity to take such action lawfully at the domestic level. Depending on the jurisdiction concerned, the removal or modification of enforcement rights or remedies, the unremunerated use of IP subject matter or test data or the forced disclosure of confidential information could conceivably constitute takings of property for which no just or reasonable compensation has been provided. Much would depend on the constitutional language used and the existing body of law that governs its meaning and interpretation.

The Australian case of *JT International v. Commonwealth of Australia* illustrates how these factors can be determinative of specific outcomes.<sup>150</sup> In *JT International*, the plaintiffs claimed that Australia's plain packaging laws effected the acquisition of property other than on just terms, contrary to section 51(xxxi) of Australia's Constitution.<sup>151</sup>

The court found that restrictions on the use of trademarks brought about by Australia's *Tobacco Plain Packaging Act 2011* (Cth) did not constitute an "acquisition of property" for the purposes of section 51(xxxi), because the Commonwealth did not *acquire* any

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<sup>150</sup> *JT Int'l SA v. Commonwealth of Australia*, [2012] 250 CLR 1 (Austl.).

<sup>151</sup> *Id.* at ¶ 47.

property.<sup>152</sup> Instead, the Commonwealth merely placed limitations on relevant trademark owners' negative rights to prevent the unauthorized use of their trademarks by third parties.<sup>153</sup> It was significant that such limitations *did* amount to a "taking" of the plaintiff's intellectual property but that they did not "involve the accrual of a benefit of a proprietary character to the Commonwealth."<sup>154</sup> The intellectual property rights were property for the purposes of section 51(xxxi), and were taken from the plaintiffs by force of the TPP Act, but did not create in the Commonwealth a proprietary relationship in the tobacco product packaging or the rights that inhered in it.<sup>155</sup>

The constitutions of some other Asia-Pacific countries, selected for comparative discussion, contain similar taking provisions. However, these provisions utilize various formulations and would likely be subject to differing interpretations or applications in different circumstances, such as in the context of controls,<sup>156</sup> limitations on rights as in *JT International*, or in the context of non-voluntary use (Table 1). For example, the terms "requisition" and "use" found in the constitutions of Bangladesh, Malaysia and Nepal are likely to cover the non-voluntary use of IP rights or test data, as well as the forced disclosure of confidential information.<sup>157</sup>

Regulation that interferes with IP rights in a manner akin to Australia's plain packaging laws is more likely to be *prima facie* captured by a provision like India's, which refers to the "deprivation" of property.<sup>158</sup> A deprivation does not necessarily require a corresponding acquisition of the same property or the accrual of a corresponding benefit by another party.<sup>159</sup> Similarly, as has been demonstrated by a line of investor-state dispute settlement arbitration decisions, the term "expropriation," as found in the constitutions of Cambodia and Nepal, can be interpreted in different ways, and may include the mere deprivation of an economic benefit even where no

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<sup>152</sup> *Id.* at ¶ 43.

<sup>153</sup> *Id.* at ¶ 34.

<sup>154</sup> *Id.* at ¶ 44 (French, J.); *see also id.* ¶¶ 47, 60, 62, 72 (Gummow, J.).

<sup>155</sup> *Id.* at ¶ 44 (French, J.).

<sup>156</sup> *Id.* at 34.

<sup>157</sup> *See, e.g., id.* at 101 (Crennan, J.) (citing *Health Insurance Commission v. Peeverill* [1994], 179 CLR 226, 235).

<sup>158</sup> India Const. art. 31A.

<sup>159</sup> *Australia Constitution* § 51(xxxi).

taking occurs.<sup>160</sup> This is not to suggest that plain packaging laws in India might be successfully challenged on any of these bases, as India's Constitution contains several nuances that would likely play a role in any defense of plain packaging measures.<sup>161</sup> Rather, these nuances are demonstrative of the constitutional complexities that exist across different jurisdictions and that must be considered on a case-by-case basis in the context of health measures, including in the implementation of a COVID-19 or other public health waiver.

These examples illustrate how different constitutional systems may impact the effective implementation of a broad-scope waiver across numerous jurisdictions. However, these are not necessarily insurmountable issues that need to be resolved at the international level prior to agreement on a waiver. Instead, they should signal a need for governments to consider how more general waiver provisions might be implemented with a degree of refinement at the domestic level, to ensure that measures operate compatibly with the domestic legal environment in which they are to have effect.

Table 1. Constitutional “taking” provisions in the Asia-Pacific

Country	Constitutional requirement
Australia	The Parliament shall, subject to this Constitution, have power to make laws for the peace, order, and good government of the Commonwealth with respect to . . . (xxx) the acquisition of property on just terms from any State or person for any purpose in respect of which the Parliament has power to make laws. <sup>162</sup>
Bangladesh	Any acquisition, nationalization or requisition of property must be compensated by an amount and in a manner specified by law, but the adequacy of that compensation cannot be questioned. <sup>163</sup>

<sup>160</sup> See *Técnicas Medioambientales Tecmed, S.A. v. The United Mexican States*, Case No. ARB (AF)/00/2, Award, ¶ 114 (ICSID May 29, 2003); *Cortec Mining Kenya Ltd. v. Republic of Kenya*, Case No. ARB/15/29, Award, ¶ 323 (ICSID Oct. 22, 2018).

<sup>161</sup> See, e.g., India Const. art. 19, cl. 2; see generally Amit Yadav et al., *Plain Packaging of Tobacco Products: The Logical Next Step for Tobacco Control Policy in India*, 3 *BMJ GLOBAL HEALTH* 5 (2018).

<sup>162</sup> *Australia Constitution* s 51(xxx).

<sup>163</sup> *Bangladesh Constitution* § 42.

Cambodia	“Expropriation from ownership” must be exercised in the public interest as provided by law and subject to the payment of fair and just <i>ex ante</i> compensation. <sup>164</sup>
India	Substantial deprivations of property must be done in accordance with law, for a public purpose, and be compensated. <sup>165</sup>
Malaysia	The compulsory use or acquisition of property must be accompanied by adequate compensation. <sup>166</sup>
Nepal	An acquisition or requisition of, or encumbrance created on, property must be in the public interest and be subject to compensation, the basis of which must be prescribed by law. <sup>167</sup>
Thailand	“Expropriation” of property must be for public interest purpose and subject to the payment of fair compensation. <sup>168</sup>
Vietnam	In cases made absolutely necessary by reason of national defense, security or national interest, in case of emergency and for protection against natural calamity, the State can make a forcible purchase of or can requisition pieces of property of individuals or organizations against compensation, taking into account current market prices. <sup>169</sup>

## 2. Broader international obligations

The TRIPS Agreement is not, of course, the sole source of individual Members’ international obligations relating to the protection of IP in their domestic systems. It follows that the temporary suspension of TRIPS obligations does not necessarily create full freedom of choice to wind back, limit or suspend IP rights in national

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<sup>164</sup> Cambodia Constitution art. 44.

<sup>165</sup> India Const. art. 31A, *supra* note 162; *see* Dwarkadas Srinivas of Bombay v. The Sholapur Spinning and Weaving Co., 1954 AIR 119 (1953) (Ind.); The State of West Bengal v. Subodh Gopal Bose, 1954 AIR 1954 SC 92 (1953) (Ind.).

<sup>166</sup> Malaysia Constitution art. 32.

<sup>167</sup> Nepal Constitution s 25, cl. 2-3.

<sup>168</sup> Thailand Constitution s 42.

<sup>169</sup> Vietnam Constitution art. 32.

systems. A complex matrix of overlapping regional trade and economic agreements is a source of further IP protection standards that may have a bearing on vaccine manufacture and distribution options.<sup>170</sup> This section reviews some systemic considerations relevant to these agreements.

a. Other multilateral conventions

The TRIPS Agreement itself refers to and applies several of the multilateral IP conventions administered by the World Intellectual Property Organization (“WIPO”). The most significant for present purposes are the Berne Convention and the Paris Convention, foundational elements of international IP law that are substantively incorporated into TRIPS,<sup>171</sup> but also separately and independently adhered to by almost all WTO Members.<sup>172</sup> Article 2 of TRIPS provides that “[n]othing in Parts I to IV of this Agreement shall derogate from existing obligations” under, *inter alia*, the Paris and Berne Conventions.<sup>173</sup>

On the face of it, a waiver covering Part II, Section 1 of TRIPS (on substantive copyright protection) would address the obligation in Article 9 of TRIPS to comply with Articles 1 to 21 of the Berne Convention, provisions that provide the bulk of substantive TRIPS law on copyright. A waiver covering Parts II and III of TRIPS may also engage the obligation in Article 2 to comply with Articles 1 through 12, and Article 19, of the Paris Convention, “[i]n respect of” Parts II, III and IV of TRIPS. This is especially relevant to certain standards on compulsory licensing of patents<sup>174</sup> and the protection of undisclosed information and clinical trial data, the latter of

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<sup>170</sup> See Raymundo Valdés & Maegan McCann, *Intellectual Property Provisions in Regional Trade Agreements: Revision and Update*, in REGIONAL TRADE AGREEMENTS AND THE MULTILATERAL TRADING SYSTEM 497–607 (Rohini Acharya ed., 2016).

<sup>171</sup> See Antony Taubman, ‘Trade-related’ After All? Reframing the Paris and Berne Conventions as Multilateral Trade Law, in ACROSS INTELLECTUAL PROPERTY 129–43 (Graeme W. Austin et al. eds., 2020).

<sup>172</sup> See WIPO, STATES PARTY TO THE PCT AND THE PARIS CONVENTION AND MEMBERS OF THE WORLD TRADE ORGANIZATION, [https://www.wipo.int/pct/en/paris\\_wto\\_pct.html](https://www.wipo.int/pct/en/paris_wto_pct.html) [<https://perma.cc/UL2E-2W68>] (last updated Apr. 6, 2022).

<sup>173</sup> TRIPS Agreement, *supra* note 9, art. 2.

<sup>174</sup> Paris Convention for the Protection of Industrial Property, as last revised at the Stockholm Revision Conference, art. 5A, Mar. 20, 1883, 21 U.S.T. 1583.

which is framed in TRIPS as an implementation of Article 10 of the Paris Convention.<sup>175</sup>

The implications of a waiver of TRIPS provisions for a country's separate and parallel obligations under the Paris and Berne Conventions have not been fully explored. However, many LDCs are parties to both these treaties while also benefiting from both extensions of time for the implementation of, and specific waivers under, TRIPS.<sup>176</sup> The closest analogy that has arisen in WTO practice has been the authorization by the Dispute Settlement Body ("DSB"), in three dispute settlement cases, for some Members to suspend various elements of IP protection for nationals from the Members concerned otherwise required under TRIPS as a remedy for their failure to implement dispute settlement findings.<sup>177</sup> In turn, this has raised the issue of whether, and if so on what legal basis,<sup>178</sup> the DSB's authorization should flow through to suspending relevant obligations separately under the Paris and Berne Conventions.

In the first case, which concerned Ecuador's complaint against the European Communities ("EC") (as it was then called) regarding the import and sale of bananas, the arbitration decision found that Ecuador may request obligations under the TRIPS Agreement, "to the extent that suspension requested under the GATT and the GATS . . . is insufficient to reach the level of nullification and

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<sup>175</sup> TRIPS Agreement, *supra* note 9, art. 39.

<sup>176</sup> For example, Bangladesh is a signatory of the *Berne Convention* and *Paris Convention*, and as an LDC, also benefits from the extension of time for implementation of the TRIPS Agreement. See Council for TRIPS, *supra* note 129.

<sup>177</sup> Decision of the Arbitrators on European Communities, *Regime for the Importation, Sale and Distribution of Bananas—Recourse to Arbitration by the European Communities under Article 22.6 of the DSU*, ¶173, WTO Doc. WT/DS27/ARB/ECU (adopted Mar. 24, 2000) [hereinafter *EC—Bananas—Recourse to Arbitration*]; Decision of the Arbitrators on United States, *Measures Affecting the Cross-Border Supply of Gambling and Betting Services—Recourse to Arbitration by the United States under Article 22.6 of the DSU*, ¶5.7, WTO Doc. WT/DS285/ARB (adopted Dec. 21, 2007); Decision of the Arbitrators on United States, *Subsidies on Upland Cotton—Recourse to Arbitration by the United States under Article 22.6 of the DSU and Article 4.11 of the SCM Agreement*, ¶5.230, WTO Doc. WT/DS267/ARB/1 (adopted Aug. 31, 2009).

<sup>178</sup> For an extensive discussion, see Conference Paper, Antony Taubman, 'Self-Help,' *Justified Disobedience and the Suspension of TRIPS Obligations*, WORKSHOP ON INTELL. PROP. ORDERING BEYOND BORDERS (Ctr. Intell. Prop. & Info. L. (CIPIL) et al. 2019) (copy on file with authors).

impairment indicated.”<sup>179</sup> This finding raised the question of the relation between the suspension of TRIPS obligations and the conventions administered by WIPO.

The Arbitrators noted that the parties disagreed on whether the non-derogation provision that is Article 2.2 of TRIPS “prevents or permits the suspension of TRIPS obligations which have a relation to” the cited WIPO conventions: the Paris and Berne Conventions, the Rome Convention and the Treaty on Intellectual Property of Integrated Circuits (“IPIC Treaty”).<sup>180</sup> However, they observed that Article 2.2 only refers to Parts I to IV, and not Part V of TRIPS, which contains provisions on “Dispute Prevention and Settlement.” Based on their reading of Article 64 of TRIPS and Article 22.3 of the DSU, the Arbitrators concluded that suspension of certain TRIPS obligations was consistent with all the requirements of Article 22 of the DSU and that “no other provision of the WTO agreements indicate that an authorization by the DSB of that request would in theory be prohibited under WTO law.”<sup>181</sup>

The Arbitrators did not consider that their jurisdiction under the DSU extended to determining whether a Member’s suspension of certain TRIPS obligations, on the DSB’s authorization, would be inconsistent with that Member’s international obligations arising from treaties other than WTO agreements (e.g. the Paris, Berne and Rome Conventions, which Ecuador had ratified).<sup>182</sup> They concluded that it is “if at all, entirely for Ecuador and the other parties to such treaties to consider whether a specific form chosen by Ecuador for implementing such suspension of certain TRIPS obligations gives rise to difficulties in legal or practical terms under such treaties.”<sup>183</sup>

This discussion represents the most extensive analysis in WTO decisions concerning the implications of cross-retaliation for separate legal obligations under WIPO conventions. In the ensuing DSB

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<sup>179</sup> Decision of the Arbitrators on European Communities, *Regime for the Importation, Sale and Distribution of Bananas—Recourse to Arbitration by the European Communities under Article 22.6 of the DSU*, ¶173, WTO Doc. WT/DS27/ARB/ECU (adopted Mar. 24, 2000) [hereinafter *EC–Bananas–Recourse to Arbitration*].

<sup>180</sup> *Id.* ¶ 148.

<sup>181</sup> *Id.* ¶ 151.

<sup>182</sup> *Id.* ¶ 152.

<sup>183</sup> *Id.*



debate, the EC expressed concerns about the Arbitrators' "flexible interpretation of the procedural provisions of the DSU, [particularly] with regard to due process considerations" and "the way the Arbitrators had addressed the possible use of cross-retaliation in general and its application to TRIPS, in particular, when taking into account the specific nature of [IPRs]."<sup>184</sup> The EC expected "a stronger reasoned argument as a basis for authorizing retaliatory measures under one agreement when the violation occurred under another."<sup>185</sup> However, the consequence of non-compliance with WIPO conventions was left unmentioned.

International treaty law, in particular the law on countermeasures, does at least in principle provide for certain avenues for reconciling a suspension of WIPO treaty obligations in the context of dispute settlement.<sup>186</sup> We identify the following as some of the relevant legal issues that could arise in the context of an agreed TRIPS waiver: (i) the character of a waiver decision as a "subsequent agreement" under Article 31(3)(a) of the *Vienna Convention on the Law of Treaties* ("VCLT"); (ii) the principle of estoppel; and (iii) the apparent consent of the parties to the consequences of such a waiver, as well as the expectation that the waiver decision should be effective in practice.<sup>187</sup> Some of these issues are further elaborated upon later in this article.

#### b. Bilateral and regional trade agreements

A TRIPS waiver may also raise similar questions relating to Members' obligations under the numerous bilateral and regional PTAs that provide substantive obligations to protect IP. Almost all of the PTAs in force between WTO Members have been concluded subsequently to TRIPS. While a waiver of TRIPS provisions would naturally increase IP flexibilities at the international level, various PTAs may increase Members' obligations while diminishing their rights and flexibilities under the TRIPS Agreement, as initially

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<sup>184</sup> Dispute Settlement Body, *Minutes of Meeting Held in the Ctr. William Rappard on April 7 2000*, ¶ 38, WTO Doc. WT/DSB/M/78 (May 12, 2000).

<sup>185</sup> *Id.*

<sup>186</sup> See Taubman, *supra* note 178.

<sup>187</sup> Vienna Convention on the Law of Treaties art. 31(3)(a), *opened for signature* May 23, 1969, 1155 U.N.T.S. 331 [hereinafter "VCLT"].

drafted.<sup>188</sup> Bilateral and regional obligations relating to IP take diverse legal forms, including:

- direct, general reaffirmations of TRIPS obligations;<sup>189</sup>
- separate bilateral obligations to protect and to enforce IP rights to a certain level, without express reference to TRIPS; and
- specific ‘TRIPS-plus’ obligations, which either elaborate on or extend certain TRIPS provisions (e.g. by limiting grounds for compulsory licensing of patents).<sup>190</sup>

An additional factor, not present in the Paris and Berne Conventions, is the availability of dispute settlement proceedings under most of these agreements. Although WTO panels and the Appellate Body have tended to interpret Article 3.2 of the DSU as limiting “their ability to derive any exceptions to WTO law from *inter se* agreements, or from any international obligations not having a multilateral character,”<sup>191</sup> this provision and its interpretation by WTO bodies are unlikely to apply similarly to *extra* WTO disputes, where the basis of a claim is a bilateral or plurilateral trade obligation that is temporarily waived at the WTO.

In the event that Members seek to implement a more expansive TRIPS waiver in their domestic systems, they may be confronted with claims that there have been breaches of such separate trade agreements. While this may extend to the prospect of dispute settlement under these agreements, we consider that there is a slim likelihood of actual disputes being brought in the context of a temporary

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<sup>188</sup> See Andrew D. Mitchell & Tania Voon, *Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict*, 43 J. WORLD TRADE 571, 596 (2009).

<sup>189</sup> See e.g., CPTPP, *supra* note 54, art. 18.50.3.

<sup>190</sup> See e.g., Free Trade Agreement, Austl.-U.S., May 18, 2004 [2005] A.T.S 1, art. 17(9)(7); see generally, Bryan Mercurio, *TRIPS-Plus Provisions in FTAs: Recent Trends*, in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM 215, 231 (Lorand Bartels & Federico Ortino eds., Oxford Univ. Press 2006).

<sup>191</sup> Geraldo Vidigal, *From Bilateral to Multilateral Law-making: Legislation Practice, Evolution and the Future of Inter Se Agreements in the WTO*, 24 EUR. J. INT’L L. 1027, 1043 (2013).

measure to address a pandemic, particularly given the very low rate of dispute settlement under such agreements thus far.

However, should these issues arise, there are several avenues or approaches to addressing potential legal implications, including those relevant to substantive obligations and their potential enforcement through dispute settlement action. These include:

- the specific reference, in some PTAs, to public health exclusions under TRIPS, such as references to the Doha Declaration, as well as side letters concluded to this effect;<sup>192</sup>
- the consent of the parties that is implicit in a WTO agreement on a waiver, which could be argued to flow through to bilateral obligations on the basis that the waiver could not be effectively implemented if overlapping bilateral obligations supervened;<sup>193</sup>
- potential reliance on the VCLT;<sup>194</sup> and
- the principle of estoppel.<sup>195</sup>

Article 1.1 of TRIPS may be seen at first blush to provide a mechanism for resolving treaty conflicts that could apply to a TRIPS waiver and PTAs. Article 1.1 provides that “Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.”<sup>196</sup> However, Article 1.1 applies to “more extensive protection” that is implemented in Members’ domestic law, rather than international standards agreed to by PTA parties under an *inter se* agreement.<sup>197</sup> Thus, rather than relegating the status of PTA provisions below those of a

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<sup>192</sup> See e.g., CPTPP, *supra* note 58, arts. 18.6.1, 18.50.3.

<sup>193</sup> For an overview of “consent” in international law-making, see Samantha Besson, *State Consent and Disagreement in International Law-Making: Dissolving the Paradox*, 29 LEIDEN J. INT’L L. 289, 295–96 (2016).

<sup>194</sup> See *infra* Part III.D.3.

<sup>195</sup> See *infra* Part III.D.4.

<sup>196</sup> TRIPS Agreement, *supra* note 9, art. 1.1.

<sup>197</sup> Henning Grosse Ruse-Khan, *From TRIPS to FTAs and Back: Re-Conceptualising the Role of a Multilateral IP Framework in a TRIPS-Plus World* (Max Planck Inst. for Innovation and Competition Rsch. Paper No. 18-02, 2018).

waiver, Article 1.1 simply clarifies Members' entitlement to implement in their domestic laws higher standards of protection than the minimum standards of protection that TRIPS provides.<sup>198</sup>

c. Bilateral investment treaties

In addition to claims under trade agreements, the suspension or cancellation of IP rights could lead to a claim that BIT obligations are infringed, either as an illegitimate expropriation of IP rights or on the basis of procedural fairness or fair and equitable treatment.<sup>199</sup> Numerous BITs expressly include IP as a protected asset.<sup>200</sup> Under fair and equitable treatment, investors might claim to have had their reasonable expectations frustrated by a significant alteration to the domestic legal environment.<sup>201</sup> Many BITs provide for dispute settlement, including the possibility of investor-state dispute settlement.<sup>202</sup> One investor's unsuccessful case concerned a company's claim that a trend of judicial decisions had thwarted legitimate expectations as to the availability of IP rights.<sup>203</sup>

As Mercurio and Upreti note, it is important to distinguish between a waiver of TRIPS obligations, which would not violate trade obligations, and domestic State action to waive or temporarily alter investors' IPRs, which may amount to a violation of international investment law commitments.<sup>204</sup> While a waiver is a temporary measure in the WTO context, domestic law implementing a waiver may well amount to a total alteration of the legal framework, at least

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<sup>198</sup> See TRIPS Agreement, *supra* note 9, art. 1.1.

<sup>199</sup> See generally, Prabhash Ranjan, *TRIPS Waiver: A BIT of a Challenge for India*, WIRE (May 22, 2021), [thewire.in/trade/trips-waiver-a-bit-of-a-challenge-for-india](https://thewire.in/trade/trips-waiver-a-bit-of-a-challenge-for-india) [<https://perma.cc/B6NY-DZK3>].

<sup>200</sup> The United Nations Conference on Trade and Development Investment Policy Hub identifies 2794 BITs, and 424 Treaties with Investment Provisions (TIPs), a majority of which have some coverage of IP rights, either expressly or implicitly. See *Investment Policy Hub, International Investment Agreements Navigator*, UNCATD, [investmentpolicy.unctad.org/international-investment-agreements](https://investmentpolicy.unctad.org/international-investment-agreements) [<https://perma.cc/RBU8-MG45>].

<sup>201</sup> See generally Bryan Mercurio & Pratyush Nath Upreti, *The Legality of A TRIPS Waiver for COVID-19 Vaccines Under International Investment Law*, 71 INT'L & COMPAR. L. Q., 323 (2022).

<sup>202</sup> See *id.* at 324.

<sup>203</sup> *Eli Lilly and Co. v. The Gov't of Can.*, ICSID Case No. UNCT/14/2 (Mar. 16, 2017).

<sup>204</sup> Mercurio & Upreti, *supra* note 201.

with respect to IPRs that apply to COVID-19 vaccine technologies. As the Ministerial Decision has little effect on existing TRIPS provisions and thus limited scope for alteration of domestic laws, it is very unlikely to form the basis of a legitimate expectations claim.<sup>205</sup> However, a broader waiver that allows for the full suspension of certain IP rights would be more susceptible to a successful legitimate expectations claim under fair and equitable treatment (assuming such expectations are found to be legitimate).

BIT negotiators have foreseen the possibility of a compulsory license amounting to an expropriation of assets under a BIT, and therefore a number of BITs expressly clarify that compulsory licensing in compliance with TRIPS is permitted. For instance, a recent BIT provides that its provisions on expropriation do not apply “to the issuance of compulsory licenses granted in relation to [IPRs], or to the revocation, limitation, or creation of [IPRs], to the extent that such issuance, revocation, limitation, or creation is consistent with TRIPS Agreement.”<sup>206</sup> However, this suggests that issues may arise should NVUAs not be, or taken not to be, TRIPS-consistent. We have not been able to identify any provision that expressly addresses the question of a separate waiver of TRIPS obligations. On one conceivable view, the TRIPS Agreement may be taken by a tribunal as it is found at the date of the claim, such that an alteration to IP rights that is consistent with a waiver of relevant TRIPS provisions is *ipso facto* consistent with the TRIPS Agreement.<sup>207</sup>

The answer is perhaps somewhat clearer in cases where BIT provisions refer much more broadly to consistency with “international agreements on intellectual property,”<sup>208</sup> or “multilateral agreements in respect of . . . [IPRs] to which the contracting Parties are parties.”<sup>209</sup> Although a model agreement, Canada’s Foreign Investment Promotion and Protection Agreement Model is plainly explicit, as it

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<sup>205</sup> *Id.* at 336.

<sup>206</sup> Ass’n of Se. Asian Nations [ASEAN], *Special Admin. Region Investment Agreement*, art. 10, ¶ 5, Dec. 11, 2017.

<sup>207</sup> See *supra* section IIID3(i).

<sup>208</sup> See, e.g., Bilateral Agreement for the Promotion and Protection of Investment, Colom.-U.A.E., art. 7, Nov. 12, 2017.

<sup>209</sup> Agreement for the Promotion and Protection of Investment, Jap.-Papua N.G., art. 19, ¶ 2, Apr. 26, 2011.

refers to measures “consistent with the TRIPS Agreement and any waiver or amendment of that Agreement accepted by that Party.”<sup>210</sup>

Given the distinctive character of a TRIPS waiver—as a temporary measure at a time of a global health crisis—it may prove unlikely that actual cases would be pursued, whether by governments or affected investors. Moreover, BIT provisions that carve out obligations in situations of national emergency may also be invoked. For instance, some recent BITs provide that “[n]on-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety and the environment, do not constitute indirect expropriations.”<sup>211</sup> That said, the potential avenues discussed above in relation to PTAs may also be open to governments whose domestic implementation of a pandemic waiver becomes subject to challenge under one or more BITs.

### 3. VCLT

Certain VCLT provisions may provide greater clarity around the interaction between a TRIPS waiver and other international economic agreements. Resolving conflicts between a waiver and rights and obligations subsisting in these agreements may be reduced to resolving inconsistencies between different international treaties in force between the same parties. This situation is partly addressed by Article 30.2 of the VCLT, which reads: “when a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.”<sup>212</sup> Moreover, where a treaty does not contain that specification, Articles 30.3 and 30.4(a) have the combined effect of sustaining the application or effect of the earlier treaty to the extent it is compatible with a later treaty between the same parties on the same subject matter.<sup>213</sup>

Potentially relevant to the interpretation and application of Article 30.2 are Articles 40 and 41.1 of the VCLT, which concern the

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<sup>210</sup> Canada’s 2021 Model Foreign Investment Promotion and Protection Agreement (FIPA), art. 9, ¶ 6.

<sup>211</sup> Canada, Consolidated Trans-Pacific Partnership [TPP], Annex 9-B, art. 3, ¶ b (2016).

<sup>212</sup> VCLT, art. 30.2.

<sup>213</sup> VCLT, arts. 30.3, 30.4.

amendment of multilateral treaties and agreements to make *inter se* modifications to a treaty respectively. Pursuant to Article 41.1:

[t]wo or more of the parties to a multilateral treaty may conclude an agreement to modify the treaty as between themselves alone” if:

- (a) the possibility of such a modification is provided for by the treaty; or
- (b) the modification in question is not prohibited by the treaty and:
  - (i) does not affect the enjoyment by the other parties of their rights under the treaty or the performance of their obligations;
  - (ii) does not relate to a provision, derogation from which is incompatible with the effective execution of the object and purpose of the treaty as a whole.<sup>214</sup>

Additionally, Article 57 allows for the suspension of the “operation of a treaty in regard to all the parties or to a particular party” provided it is done in conformity with the provisions of the treaty or at any time by consent of all the parties after consultation.<sup>215</sup> Article 58 allows treaty parties to suspend provisions of a treaty *inter se* if requirements similar to those in Article 41.1 are satisfied.<sup>216</sup>

Notwithstanding its undoubted legitimacy, it is unclear whether a WTO waiver made pursuant to Article IX.3 but not incorporated into a WTO Agreement as a formal amendment constitutes either:

- (i) a “treaty” for the purposes of Article 30.2 (either becoming subsumed under the WTO Agreement itself, or a separate treaty);
- (ii) an “amendment” for the purposes of Article 40;
- (iii) an *inter se* “modification” for the purposes of Article 41; or
- (iv) a “suspension” for the purposes of Articles 57–58.<sup>217</sup>

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<sup>214</sup> VCLT, art. 41.

<sup>215</sup> VCLT, art. 57.

<sup>216</sup> VCLT, art. 58.

<sup>217</sup> VCLT, art. 30.2, 40–41, 57–58.

This characterization is important because it may determine whether a waiver takes priority over the provisions of another earlier or subsequent agreement. Therefore, we first consider the legal status of a TRIPS waiver specifically for the purposes of these VCLT provisions, before discussing how each might operate to resolve conflicts between a waiver and non-WTO agreements.<sup>218</sup>

It is worth reiterating that the TRIPS Agreement is not a standalone agreement, but is instead just one of the Multilateral Trade Agreements<sup>219</sup> or Covered Agreements annexed to, and that form parts of, the Marrakesh Agreement.<sup>220</sup> Each must be read consistently with one another, and the general procedural and interpretative rules set out in the Marrakesh Agreement must be applied in carrying into effect or interpreting any one of its Annexes (unless otherwise provided for elsewhere in the Agreement).<sup>221</sup> For the purposes of this section, we refer to the Marrakesh Agreement and the TRIPS Agreement separately, to distinguish the latter from the main treaty text.

a. TRIPS waiver: “treaty”, “amendment”, “modification” or “suspension” under the VCLT?

A “treaty” under the VCLT means “an international agreement concluded between States in written form and governed by international law, *whether embodied in a single instrument or in two or more related instruments and whatever its particular designation.*”<sup>222</sup> It is clear from this definition that a “treaty” may be constituted by more than one instrument, provided these instruments are “related.” Presumably, the instruments must be so “related” as to constitute “an . . . agreement” between States, as opposed to numerous separate agreements. It is unclear whether “related instruments” need to be contemporaneous with one another; however, it is likely

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<sup>218</sup> That a waiver can be likened to the forms of treaty revisions referred to in the VCLT is made implicit by the Appellate Body. See Appellate Body Report, *Peru—Additional Duty on Imports of Certain Agricultural Products*, WTO Doc. WT/DS457/AB/R (July 20, 2015) [hereinafter *Peru—Agricultural Products*]. To our knowledge, this has not been discussed in any great detail.

<sup>219</sup> See Marrakesh Agreement, *supra* note 13, art. II, ¶ 2.

<sup>220</sup> See Marrakesh Agreement, *supra* note 13.

<sup>221</sup> *Id.* at art. II.

<sup>222</sup> VCLT, art. 2(a).



that the reference in Article IX.3 to a waiver decision of the Ministerial Conference is sufficient to bring any such decision within the scope of a “related” instrument for VCLT purposes.

On this interpretation, the TRIPS Agreement, encompassing any subsequent waiver of its provisions under an Article IX.3 decision, may amount to a composite “treaty” for VCLT Article 31.2 purposes. A WTO waiver’s legal and functional nature as a source of immunity in the context of dispute settlement<sup>223</sup> may cast doubt on this conclusion because a waiver may then be characterized simply as a separate agreement that affects the means of *enforcing* the TRIPS Agreement, but that does not form part of the treaty itself. However, this would overlook the fact that the TRIPS Agreement and the procedural provisions of the Marrakesh Agreement form part of one integrated treaty, and that a treaty’s legal force generally lies in the means of its enforcement rather than the content of its substantive provisions.

In *Australia—Tobacco Plain Packaging*, the Panel considered that paragraph 5 of the Doha Declaration may be considered a “subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions” for the purposes of Article 31.3(a) of the VCLT.<sup>224</sup> In reaching this conclusion, the Panel had regard to the Appellate Body’s conclusion in *US—Clove Cigarettes* that:

[b]ased on the text of Article 31(3)(a) . . . we consider that a decision adopted by Members may qualify as a “subsequent agreement between the parties” regarding the interpretation of a covered agreement or the application of its provisions if: (i) the decision is, in a temporal sense, adopted subsequent to the relevant covered agreement; and (ii) the terms and content of the decision express an agreement between

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<sup>223</sup> See Feichter, *supra* note 14; Harrison, *supra* note 121.

<sup>224</sup> Panel Report, *Australia—Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, ¶ 7.2409, WTO Doc. WT/DS457/R (adopted June 28, 2018) [hereinafter *Australia—Plain Packaging*].

Members on the interpretation or application of a provision of WTO law.<sup>225</sup>

The Panel considered that the Declaration is a “declaration,” rather than a “decision,” but that it was “adopted by a consensus decision of WTO Members, at the highest level . . . subsequent to the adoption of the WTO Agreement, Annex 1C of which comprises the TRIPS Agreement.”<sup>226</sup> According to the Panel, the terms and contents of the decision adopting the Doha Declaration expressed an agreement between Members on the approach to be followed in interpreting the provisions of the TRIPS Agreement. The AB subsequently clarified that it was unnecessary to determine whether the Declaration was a “subsequent agreement” because paragraph 5(a) of the Declaration reflects customary international law rules of treaty interpretation.<sup>227</sup>

Notwithstanding that instance of judicial restraint, it is not inconceivable that a WTO waiver could constitute a “subsequent agreement” under Article 31.3(a) of the VCLT. If so, it is possible that it would not be captured by the term “treaty” used in Article 30.2 and therefore would not be taken as having priority for those purposes. However, a waiver being characterized as “subsequent agreement” would not thereby necessarily preclude it from being a part of the relevant “treaty.” A treaty may be embodied in more than one instrument, and Article 31.2 provides that the context for the purpose of interpreting a treaty shall comprise “any agreement” or “any instrument” made in connection with the conclusion of the treaty, indicating that such terms are not mutually exclusive.

Article 40 concerns the “amendment” of multilateral treaties.<sup>228</sup> Amendments are dealt with separately from waivers under Article X of the Marrakesh Agreement. As has been noted in the WTO context, the “complexity of Article X . . . reveals the prudence and thoughtfulness of contracting parties when they considered how the

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<sup>225</sup> Panel Report, United States—*Measures Affecting the Production and Sale of Clove Cigarettes*, ¶ 58, WTO Doc. WT/DS406/AB/R (adopted Apr. 4, 2012).

<sup>226</sup> *Id.*

<sup>227</sup> See Andrew David Mitchell & Theodore Samlidis, *The Implications of the WTO Tobacco Plain Packaging Disputes for Public Health Measures*, 70 INT’L & COMPAR. L. Q. 1011, 1025 (2021).

<sup>228</sup> VCLT, art. 40.

covered treaties could be amended.”<sup>229</sup> Thus WTO negotiators saw it fit to prescribe distinct rules of procedure for amendments and waivers.

Aside from being at odds with the internal logic and framework of the Marrakesh Agreement, the characterization of a TRIPS COVID-19 vaccine waiver as an amendment to the WTO Agreement is at odds with the way in which a waiver functions as an immunity to a claim of violation.<sup>230</sup> A waiver under Article IX.3 does not take the substantive character of an “amendment” within the ordinary meaning of that term as used in the VCLT because it is not a positive alteration of the treaty terms. In our view, it is a limited suspension of the rights and obligations arising from those terms, which is provided for by the treaty text. In any case, assuming that a waiver did constitute an “amendment” for Article 40 purposes, Article 40 would provide little assistance in resolving relevant conflicts. Article 40 primarily governs the procedural requirements for amendments and their effect for States who do not become a party to the amending agreement.<sup>231</sup>

Article 41 was intended by VCLT drafters to prevent *inter se* modifications to multilateral agreements undermining the object and purpose of those agreements.<sup>232</sup> It is highly questionable that a waiver constitutes a modification at all, and also that a mechanism provided for by the treaty could be capable of undermining its own object and purpose. Nevertheless, placing these fundamental difficulties aside, the requirement in Article 41.1(a) that the modification be provided for by the treaty text is clearly satisfied by the presence of Article IX.3 of the Marrakesh Agreement. Moreover, although text-based negotiations for a waiver (like any WTO decision) have

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<sup>229</sup> Tarcisio Gazzini, *Can Authoritative Interpretation Under Article IX:2 of the Agreement Establishing the WTO Modify the Rights and Obligations of Members?*, 57 INT’L & COMP. L. Q. 169, 175 (2008).

<sup>230</sup> See Hunter Nottage & Thomas Sebastian, *Giving Legal Effect to the Results of WTO Trade Negotiations: An Analysis of the Methods of Changing WTO Law*, 9 J. INT’L ECON. L. 989, 1001 (2006).

<sup>231</sup> VCLT, art. 40.

<sup>232</sup> See Kerstin Odenhal, *Article 41: Agreements to Modify Multilateral Treaties Between Certain of the Parties Only*, in VIENNA CONVENTION ON THE LAW OF TREATIES: A COMMENTARY 719, 720 (O. Dörr & K. Schmalenbach eds., 2018). See VCLT, art. 41(1)(b)(ii).

been carried out on the basis of consensus, a waiver under Article IX.3 is theoretically only for the benefit of certain Members (notwithstanding the possibility that obligations may be waived for all Members<sup>233</sup>).

However, it is very difficult to properly characterize a WTO waiver as an agreement between only certain parties, or an agreement to “modify the treat as between [those parties] alone” because:

- any decision made by the Ministerial Conference is made by the Conference as a single authority that is representative of all Members—either by consensus or by majority vote,<sup>234</sup>
- an agreement to waive WTO obligations may not necessarily only be between the same Members whose obligations are waived (for example, a decision to waive obligations is effectively that of all Members, but may only apply to LDCs); and
- the decision operates to waive only certain Members’ obligations, but it is binding on and affects all Members, as all Members are denied the opportunity to enforce those obligations.

It is both contrary to the initial purpose of Article 41 and inconsistent with the terms of Article IX.3 to characterize a WTO waiver as an *inter se* modification. Instead, Article 41.1 was intended and is very likely to capture bilateral or plurilateral agreements that share the same parties and cover the same subject matter as a multilateral treaty (e.g. PTAs/BITs).

Article IX.3 of the Marrakesh Agreement has been explicitly identified as an example of a treaty provision that permits the “suspension” of a treaty for VCLT Article 57 purposes.<sup>235</sup> Article IX.3 could well be an example of a provision that permits the suspension

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<sup>233</sup> See Mitchell & Voon, *supra* note 188, at 581.

<sup>234</sup> Marrakesh Agreement, *supra* note 9, art. IX.1.

<sup>235</sup> See Thomas Giegerich, *Article 57: Suspension of the Operation of a Treaty Under Its Provisions or by Consent of the Parties*, in *Vienna Convention on the Law of Treaties: A Commentary*, in VIENNA CONVENTION ON THE LAW OF TREATIES: A COMMENTARY 993, 1061, 1065–66 (O. Dörr & K. Schmalenbach eds., 2018).

of the “operation” of a treaty, even if only partially. In any case, it would not be inconsistent to characterize Article IX.3 as a provision that provides for suspension, and a WTO waiver as a suspension of the operation of a treaty, while also characterizing the Ministerial decision, being the instrument effectuating that suspension, as an “instrument” that forms part of a “treaty” for Article 30 purposes. Articles 57 and 30 operate independently of one another—one governs internally the operation of a treaty, while the other governs externally the priority of application between different, conflicting treaties.<sup>236</sup>

Ultimately, the preceding analysis does not provide a clear answer as to the true characterization of a WTO waiver for VCLT purposes. However, it does show that, despite this uncertainty, these VCLT provisions can operate harmoniously with one another in various circumstances. Their operation in the context of a waiver is explored in the next sections.

b. Article 30.2 of the VCLT

Article 30.2 only applies when a treaty specifies that it is “subject to or not to be considered as incompatible with, an earlier or later treaty.”<sup>237</sup> Importantly, many PTAs and BITs clarify that they are not in derogation of, or prejudicial to, the rights and obligations that its parties have under the WTO or TRIPS Agreement, and some go further by clarifying that this applies to the WTO Agreement as amended or modified from time to time.<sup>238</sup> The *prima facie* consequence is that PTAs/BITs with provisions clarifying the primacy of the WTO Agreement are unlikely to override the effect of a TRIPS waiver, assuming that a TRIPS waiver forms part of the “treaty” under Article 30.2 and can properly be considered as such together with the TRIPS Agreement. The waiver would take priority over the TRIPS-plus or waiver-inconsistent provisions in PTAs/BITs that contain these clarifications. This would appear to be so even if the

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<sup>236</sup> See Kerstin Odenhal, *Article 30: Application of Successive Treaties Relating to the Same Subject Matter*, in VIENNA CONVENTION ON THE LAW OF TREATIES: A COMMENTARY 504, 508 (O. Dörr & K. Schmalenbach eds., 2018).

<sup>237</sup> VCLT, art. 30.2.

<sup>238</sup> See e.g., CPTPP, *supra* note 54, arts. 1.2.1, 1.3 n.2; see also *supra* note 210.

PTA/BIT constituted a valid modification of the TRIPS Agreement under Article 41.1.

However, determining which treaty is the earlier or later has been done by looking to the date of its adoption, its entry into force, or its ratification by or for each of the parties.<sup>239</sup> If that approach was followed, it would subordinate a novel waiver of TRIPS provisions below that of a PTA or BIT that had been adopted, entered into force or ratified subsequently to TRIPS. The same would apply where a PTA or BIT contained no such clarification about which treaty prevails, as Article 30.4(a) gives priority to a later treaty in the event of any inconsistency. In such cases, the only available recourse might be to establish that the economic agreement in question, or one or more of its provisions, is not a valid modification under Article 41.1.

Article 30 would also be of little assistance where a waiver merely removed the possibility of dispute resolution with respect to certain obligations, but that possibility continued under a PTA/BIT. A non-WTO tribunal would have to decide whether a lack of jurisdiction elsewhere is justification for denying its own: “whether it could disapply the treaty which provides the principal terms of reference for its own jurisdiction.”<sup>240</sup> Tribunals have somewhat artificially framed such questions in terms of whether the treaties and their enforcement systems have the “same subject matter.”<sup>241</sup> Article 41.1 and dispute resolution are discussed further below in sections D3(iii) and D4.

### c. Article 41.1 of the VCLT

As concluded above, a WTO waiver itself is very unlikely to constitute an *inter se* modification of the TRIPS Agreement under Article 41.1. Rather, Article 41 was intended to address PTAs/BITs

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<sup>239</sup> See Odenhal, *supra* note 236, at 509; EW Vierdag, *The Time of the ‘Conclusion’ of a Multilateral Treaty: Article 30 of the Vienna Convention on the Law of Treaties and Related Provisions*, 59 BRITISH YEARBOOK INT’L L. 75, 92 (1988); Claude Chase, *Norm Conflict Between WTO Covered Agreements—Real, Apparent Or Avoided?* (2012) 61 INT’L & COMPAR. L. Q. 791, 799–800.

<sup>240</sup> See Alexander Orakhelashvili, *Article 30 of the 1969 Vienna Convention on the Law of Treaties: Application of the Successive Treaties Relating to the Same Subject-Matter*, 31 ICSID REV. 344, 361.

<sup>241</sup> See, e.g., *Eastern Sugar BV v. The Czech Republic*, SCC Case No. 088/2004, ¶ 180 (Mar. 27, 2007); see generally *id.* at 357.

that cover the same subject matter as a multilateral agreement to which its parties are signatory. The question that arises in this context is whether a given PTA/BIT constitutes a valid modification of the TRIPS Agreement under Article 41.1, having regard to the TRIPS Agreement as altered by a waiver.

With respect to Article 41(1)(a), Article XXIV:5 of GATT 1994 allows modification of the WTO Agreements as between FTA parties. However, such modifications are unlikely to fall within the ambit of Article 41(1)(a), as they are limited to MFN treatment.<sup>242</sup> Nevertheless, the TRIPS Agreement does not appear to *prohibit inter se* modifications, meaning the opening condition of Article 41(1)(b) is satisfied.<sup>243</sup>

Whether a PTA does not affect the enjoyment by other parties of their rights under the treaty or performance of their obligations (pursuant to Article 41(1)(b)(i)) would depend on the rights and obligations in question. Assuming that those rights include rights waived under an Article IX.3 waiver:

FTA provisions that diminish the flexibilities granted by the TRIPS Agreement in connection with . . . compulsory licensing may not meet the conditions of Article 41(1)(b)(i) and (i) of the VCLT. Limiting rights to grant compulsory licenses under Article 31 of the TRIPS Agreement (as interpreted and extended by the Declaration and the Decision) might appear to affect only the FTA parties themselves. In fact, this would also potentially affect the enjoyment by other WTO Members of their rights to benefit from compulsory licenses (contrary to Article 41(1)(b)(i)), particularly if the FTA parties are potential exporters under the system established by the Decision. Further, derogation from the provisions in the TRIPS Agreement granting flexibility with respect

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<sup>242</sup> See Mitchell & Voon, *supra* note 188, at 596–97. For contrary discussion on this point in a non-TRIPS context, see Thomas Cottier & Marina Foltea, *Constitutional Functions of the WTO and Regional Trade Agreements*, in REGULATORY TRADE AGREEMENTS AND THE WTO SYSTEM, 43, 55 n.39 (Lorand Bartels & Federico Ortino eds., 2006).

<sup>243</sup> See Mitchell & Voon, *supra* note 188, at 596–97.

to . . . compulsory licensing . . . is arguably incompatible with the effective execution of the object and purpose of the TRIPS Agreement, contrary to Article 41(b)(ii).<sup>244</sup>

While these comments were made in the context of the Decision establishing the Paragraph 6 System (at a time when it had not been formally incorporated into TRIPS), we see no reason why they should not apply equally in respect of a new waiver for COVID-19 vaccines. Furthermore, test data exclusivity period may also affect countries not party to a PTA but that rely on a PTA party or parties for regulatory approval.<sup>245</sup>

With respect to Article 41(1)(b)(ii), certain FTA rights and obligations “can deny core flexibilities essential to ensure that TRIPS does not prevent WTO Members from protecting public health” and thus potentially undermine the objectives in Articles 7 and 8 of TRIPS.<sup>246</sup> In this regard, it is difficult to see how PTA/BIT provisions that are inconsistent with a waiver would not already be inconsistent with the objectives in Articles 7 and 8.

#### d. Applicability of the VCLT to WTO waivers

The AB’s Report in *Peru—Agricultural Products* adds a layer of complexity to this already convoluted picture. In that dispute, the Appellate Body considered that specific provisions addressing amendments, waivers, or exceptions for regional trade agreements in the Marrakesh Agreement (i.e., Articles IX and X, and Article XXIV of the GATT 1994) provide a *lex specialis* that prevails over the VCLT’s general provisions, including Article 41.<sup>247</sup>

As one commentator has noted, the AB’s decision in *Peru—Agricultural Products* is far-reaching because it “may imply that all types of the listed WTO carve-outs override Article 41”

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<sup>244</sup> See *id.* at 598.

<sup>245</sup> See Ruse-Khan, *supra* note 197.

<sup>246</sup> See *id.* at 51.

<sup>247</sup> See Appellate Body Report, *Peru—Additional Duty on Imports of Certain Agricultural Products*, ¶¶ 5.111–5.113, WTO Doc. WT/DS457/AB/R (July 20, 2015); see generally Sherzod Shaikhodjaev, *The ‘Regionalism vs Multilateralism’ Issue in International Trade Law: Revisiting the Peru–Agricultural Products Case*, 16 Chinese J. INT’L L. 109, 115 (2017).



notwithstanding that Article 41” covers *inter se* revisions, but not unilateral waivers or treaty amendments affecting all parties.”<sup>248</sup> Ruse-Khan suggests that, because TRIPS does not contain provisions akin to Article XXIV of GATT or Article V,” the door is open [in the TRIPS context] to resort to the general rule in Article 41 VCLT.”<sup>249</sup> This conclusion is questionable because it disregards the unity that the Marrakesh Agreement shares with each of its Annexes, including the TRIPS Agreement.<sup>250</sup>

Two important considerations potentially affect the relevance of *Peru—Agricultural Products* for present purposes. First, the more specific provisions in the Marrakesh Agreement do not seem to provide particular solutions to the conflict of laws issues outlined in previous sections of this article, and therefore no *lex specialis* in the sense identified by the AB.

Second, as a TRIPS waiver would relinquish Members of certain obligations under TRIPS, rather than create more onerous obligations, one of only very few circumstances in which these hierarchical provisions are likely to be invoked would be where a Member was required to defend its implementation of the waiver under a PTA/BIT.<sup>251</sup> In this regard, conclusions reached by WTO adjudicators on the application of the VCLT in the WTO context may not be relevant to the tasks of non-WTO adjudicators in resolving inconsistencies between WTO waivers and other non-WTO agreements. Adjudicators in other legal fora, such as PTA dispute settlement tribunals or investment arbitrators, may find little reason to follow the reasoning of the AB in *Peru—Agricultural Products*. This would likely produce a more favorable outcome for WTO Members seeking to rely on a WTO waiver in avoiding enforcement of non-WTO

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<sup>248</sup> See *id.* at 121.

<sup>249</sup> See Ruse-Khan, *supra* note 197, at 40.

<sup>250</sup> Cf. Henning Grosse Ruse-Khan, *The Role of Customary International Law, in* INTELLECTUAL PROPERTY PROTECTION BEYOND BORDERS (Axel Metzger & Henning Grosse Ruse-Khan eds., forthcoming 2022). For Ruse-Khan, the “broader contextual framework within which international IP treaties operate” should be considered, lest WTO law operate in “clinical isolation.” See also Ruse-Khan, *supra* note 197, at 38–39 (explaining the *argumentum a contrario* from the *lex specialis* that the Appellate Body applied in *Peru—Agricultural Products*).

<sup>251</sup> See Nottage & Sebastian, *supra* note 230, at 1002. A TRIPS waiver is particularly unique in that it reduces what are already minimum standards under TRIPS. *Id.*

obligations, because a waiver may be taken to have priority over other agreements under the VCLT.

Whether these legal technicalities make any practical difference to the effectiveness of a COVID-19 TRIPS waiver may depend on other practical and political questions. It is difficult to imagine that a WTO Member would ever seek to enforce cognate PTA obligations that have been waived under a WTO Agreement. Doing so would arguably be contrary to the principle of *pacta sunt servanda* as enshrined by Article 26 of the VCLT, on the basis that the State has failed to honor the TRIPS Agreement, as waived, in good faith.<sup>252</sup> This is less clear in the BIT context, where the claimant is ordinarily a private investor rather than a State party.<sup>253</sup>

As alluded to above, the foregoing discussion does not account for circumstances in which a WTO waiver merely removes the right to dispute settlement with respect to a certain obligation (at either the domestic or international level) but that same right subsists under a PTA/BIT. In such a case, no question as to the hierarchy or displacement of substantive obligations would arise. It would be a question of divergences across separate legal regimes as to the jurisdiction to hear disputes on similar subject matter. This raises the question whether a TRIPS waiver that operated through suspension of dispute settlement mechanisms would require simultaneous amendments to, or waivers of, other international economic agreements. The next section discusses the possibility of invoking the principle of estoppel under customary international law to address this issue.

#### 4. Estoppel

The role of estoppel within the WTO has received some attention in the jurisprudence and in academic sources.<sup>254</sup> However,

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<sup>252</sup> See generally Andrew D. Mitchell, *Good Faith in WTO Dispute Settlement*, 7 MELB. J. INT'L L. 339, 346–47 (2006); Cottier & Foltea, *supra* note 242, at 53 n.31.

<sup>253</sup> See International Center for Settlement of Investment Disputes, *The ICSID Caseload – Statistics* (Aug. 4, 2022), <https://icsid.worldbank.org/resources/publications/icsid-caseload-statistics> (last visited Oct. 30, 2022) (almost exclusively investor-state disputes).

<sup>254</sup> See Andrew D. Mitchell & David Heaton, *The Inherent Jurisdiction of WTO Tribunals: The Select Application of Public International Law Required by the Judicial Function*, 31 MICH. J. INT'L L. 559, 565 (2010); see also Simon A B Schropp & David

discussion has focused primarily on multiple claims across separate regimes,<sup>255</sup> or alternatives to adjudication that lead to a binding decision or mutually agreed solution.<sup>256</sup> Much like the interaction between WTO waivers and PTA/BITs more generally, estoppel has received little attention as a tool for reconciling inconsistencies in the specific context of a waiver.

Could estoppel be invoked on the basis that a WTO waiver founded a representation that PTA/BIT dispute resolution proceedings would not be brought? As a practical matter, if estoppel were invoked on this basis, it would be invoked by a Member seeking the benefit of a waiver in a PTA/BIT forum using principles of international customary law, rather than at the WTO. This notwithstanding, it is worth noting that WTO tribunals have limited the scope and operation of estoppel within the WTO to what have been identified as the “narrow parameters set out in the DSU.”<sup>257</sup> Notwithstanding that PTA (and BIT) tribunals may draw upon WTO principles in non-WTO dispute settlement, we consider how estoppel might apply in the waiver context while assuming that it would not be subject to the same restrictions on its use at the WTO.

The requirements of a successful estoppel claim within international public law are said to be:

- (i) an unambiguous statement of fact (i.e., a representation);

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Palemeter, *Commentary on the Appellate Body Report in EC–Bananas III (Article 21.5): Waiver–Thin, or Lock, Stock, and Metric Ton?*, 9WORLD TRADE REV. 7, 15–16 (2010); Vidigal, *supra* note 191, at 1043–44.

<sup>255</sup> See Appellate Body Report, *European Communities—Export Subsidies on Sugar*, ¶ 312, WTO Docs. WT/DS265/AB/R, WT/DS266/AB/R, WT/DS283/AB/R (Apr. 28, 2005); Panel Report, *Argentina—Definitive Anti-Dumping Duties on Poultry from Brazil*, ¶¶ 7.38, 7.41, WTO Doc. WT/DS241/6 (May 22, 2003) [hereinafter *Argentina—Poultry*].

<sup>256</sup> See Appellate Body Report, *United States—Continued Suspension of Obligations in the EC—Hormones Dispute*, ¶ 340, WTO Doc. WT/DS322/AB/R (Oct. 16, 2008); Appellate Body Report, *European Communities—Regime for the Importation, Sale and Distribution of Bananas (Second Recourse to Article 21.5 of the DSU By Ecuador)*, ¶ 212, WTO Docs. WT/DS27/AB/RW2/ECU, WT/DS27/AB/RW/USA (Nov. 26, 2008).

<sup>257</sup> The AB has reasoned that there is “little in the DSU that explicitly limits the rights of WTO Members to bring an action.” *EC–Bananas—Recourse to Arbitration*, *supra* note 177 ¶ 227 (quoting Appellate Body Report, *Export Subsidies on Sugar*, *supra* note 255). For a general overview and criticisms of these limitations, see Mitchell and Heaton, *supra* note 254, at 608–15.

- (ii) that is voluntary, unconditional and authorized;  
and
- (iii) which is relied on in good faith to the detriment of the other party or to the advantage of the party making the statement.<sup>258</sup>

As the question of detrimental reliance would very much depend on the circumstances of the case, we focus exclusively on whether a waiver could reasonably constitute a representation for these purposes. Arguments that a representation has not been made by adoption of a WTO waiver could be based on the claim that a decision of the Ministerial Conference does not constitute a representation made by a Member, or that an instrument in the form of a TRIPS waiver is not a representation.

The first claim encounters difficulties because it disregards the multilateral character of Ministerial decisions, which stand authoritatively for the decisions and representations of constituent Members.<sup>259</sup> The second claim is more likely to turn on whether a representation can be implied, and whether the adoption of an instrument is sufficient to constitute an implied representation.

In *EC—Asbestos*, it was argued that the EC should be estopped from departing from its purported representation that the TBT Agreement applied to the impugned Decree, because it had made a representation to that effect by notifying the Committee on the Technical Barriers to Trade about the Decree and through certain statements it made during consultations.<sup>260</sup> However, the Panel considered that TBT notifications are made for reasons of transparency and do not have any recognized legal effect.<sup>261</sup> The Panel's requirement of "legal effect" clearly reflects its desire to stay well within the

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<sup>258</sup> See James Crawford, *BROWNLIE'S PRINCIPLES OF PUBLIC INTERNATIONAL LAW* 406–07 (9th ed., Oxford Univ. Press 2019); see also Panel Report, *Argentina—Definitive Anti-Dumping Duties on Poultry from Brazil*, *supra* note 255 at ¶ 7.20.

<sup>259</sup> See Marrakesh Agreement, *supra* note 9, arts. IV, IX.1.

<sup>260</sup> See Mitchell & Heaton, *supra* note 254, at 610 (citing Panel Report, *European Communities—Measures Affecting Asbestos and Products Containing Asbestos*, ¶ 8.60, WTO Doc. WT/DS135/R (Sept. 18, 2000)). It should be noted Members' representations during consultations are "without prejudice" and therefore estoppel would not apply to such representations. Dispute Settlement Understanding, art. 4.6.

<sup>261</sup> See Mitchell & Heaton, *supra* note 254, at 610

parameters of the DSU in deciding its own jurisdiction and ultimately which instruments can “bind the Panel.”<sup>262</sup> In any case, a decision to waive obligations under Article IX.3 clearly satisfies the Panel’s requirement of “legal effect.”<sup>263</sup>

In *Argentina—Poultry*, the Panel denied Argentina’s claim that Brazil’s previous acceptance of arbitral awards invalidated Brazil’s complaint against Argentina.<sup>264</sup> The Panel quoted the Panel in *EEC (Member States)—Bananas I* and concluded that “estoppel can only ‘result from the express, or in exceptional cases implied consent of the complaining parties,’” and that “the facts alleged by Argentina are not sufficient to conclude that Brazil has ‘consented’ whether explicitly or implicitly, not to bring this dispute before the WTO.”<sup>265</sup> The Panel’s reasoning was that the Protocol of Brasilia contained “no provision limiting the rights of parties to request a panel under WTO agreements with respect to a measure that had already been the subject of a dispute under the Protocol.”<sup>266</sup>

In the non-WTO context, the Permanent Court of International Justice (“PCIJ”) in *Legal Status of Eastern Greenland* accepted that Norway’s entry into several bilateral and multilateral international agreements that described Greenland as part of Denmark constituted a reaffirmation by Norway of Denmark’s sovereignty over Greenland.<sup>267</sup> This was sufficient for Norway to have “debarred herself from contesting Danish sovereignty over the whole of Greenland.”<sup>268</sup> The PCIJ’s successor, the International Court of Justice (“ICJ”), has taken a comparatively more constrained view of estoppel requirements. In *Land and Maritime Boundary Case*, the ICJ stated that “estoppel would only arise if by its acts or declarations Cameroon had consistently made it fully clear that it had agreed to

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<sup>262</sup> *See id.*

<sup>263</sup> *See id.*

<sup>264</sup> *See* Panel Report, *Argentina—Poultry*, *supra* note 255, ¶¶ 7.38, 7.41.

<sup>265</sup> *Id.* at ¶ 7.27.

<sup>266</sup> *Id.*

<sup>267</sup> *See* Mitchell & Heaton, *supra* note 254, at 612 (citing *Legal Status of Eastern Greenland* (Den. v. Nor.), 1933 P.C.I.J.J. (ser.A/B) No. 53, at 22 (Ape. 5)).

<sup>268</sup> *Id.*

settle the boundary dispute . . . by bilateral avenues alone.”<sup>269</sup> Similarly, in the *North Sea Continental Shelf Case*, the ICJ said that “a very definite, very consistent course of conduct” would have to be established for a state to be bound by a treaty to which it had not formally acceded.<sup>270</sup>

While estoppel was not made out in *EC—Asbestos* or *Argentina—Poultry*, these decisions together with *Legal Status of Eastern Greenland* indicate that the adoption of an agreement, notification or other instrument may, in some circumstances, be sufficient to amount to an implied representation. In the language of the *North Sea Continental Shelf Case*, a legally binding waiver decision may well amount to a “very definite” course of conduct.<sup>271</sup> However, the claims of estoppel at the WTO discussed above failed primarily because of the focus placed on the legal effect or *substantive content* of the instruments adopted.<sup>272</sup> These considerations are likely to be relevant in any estoppel claim that is based on the adoption of a TRIPS waiver.

Relevantly, even if the adoption of a decision by the Ministerial Conference does constitute a representation at international customary law, the question arises: “representation as to what?” A waiver is a source of negative rights that provides Members with a shield against certain claims.<sup>273</sup> Technically speaking, waivers do not guarantee immunity from a suit or other proceedings.<sup>274</sup> Therefore, a waiver may not itself amount to a representation not to bring dispute resolution proceedings, unless the waiver in question directly addresses the right to dispute resolution proceedings. Relevantly, the original 2020 proposal did so by precluding challenges of “any measure[s] taken in conformity with the provisions of the waivers . . . through the WTO’s Dispute Settlement Mechanism.”<sup>275</sup>

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<sup>269</sup> See Mitchell, *supra* note 252, at 348 (citing Land and Maritime Boundary between Cameroon and Nigeria (Cameroon v Nigeria), Preliminary Objections, ICR. Rep. 275, 303).

<sup>270</sup> *North Sea Continental Shelf* (Ger. v. Den.; Ger. v. Neth.), Judgment, ICJ Rep. 3, 25 (Feb. 20, 1969).

<sup>271</sup> See *id.*

<sup>272</sup> See Feichtner, *supra* note 14; Harrison, *supra* note 121.

<sup>273</sup> See Harrison, *supra* note 121, at 415.

<sup>274</sup> See *id.*

<sup>275</sup> *Revised Decision Text*, *supra* note 8, at 4.

Even then, what implications does this have for the validity or conformity of a waiver to Article IX:3, which applies only to waive the *obligations* of Members and not rights to institute proceedings?

Finally, assuming, *arguendo*, that a TRIPS waiver is an implicit representation that a Member will not bring dispute resolution proceedings in respect of a waived obligation, it would be a representation not to bring such proceedings at the WTO rather than proceedings to enforce a PTA obligation at another forum. While the principle of *res judicata* may apply in situations of cross-jurisdictional claims,<sup>276</sup> that principle would have no application where no WTO claim has previously been brought or settled.

In *Argentina—Poultry*, the Panel found that plurilateral rules “impose[d] no restriction on Brazil’s right to bring subsequent WTO dispute settlement proceedings in respect of the same measure,” but also that it was not “bound by the rulings of non-WTO dispute settlement bodies.”<sup>277</sup> From this, Vidigal concludes that “restrictions on the jurisdiction (or on the legal findings) of WTO panels may not derive from *inter se* modifications, but require a basis in multilateral norms.”<sup>278</sup> Whether the converse applies to non-WTO dispute settlement bodies with respect to a waiver of WTO dispute resolution mechanisms has no clear answer. It may be that a PTA tribunal would simply pay deference to representations made at the WTO—perhaps in an attempt to maintain comity in the sphere of international economic law, or perhaps because of the WTO Agreements’ distinct multilateral character. As Articles 30, 41, and other provisions of the VCLT demonstrate, this character is recognized to some degree by customary international law and the VCLT as having a higher rank in the hierarchy of international laws than that which inheres in plurilateral and bilateral agreements.<sup>279</sup>

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<sup>276</sup> The role of *res judicata* in WTO dispute settlement was left uncertain by the Appellate Body’s limited analysis in *Brazil—Measures Affecting Imports of Retreaded Tyres*, ¶ 7.271, WTO Doc WT/DS332/AB/R (Dec. 3, 2007). See generally Vidigal, *supra* note 191, at 1050–51.

<sup>277</sup> Panel Report, *Argentina—Poultry*, *supra* note 258, ¶¶ 7.38, 7.41.

<sup>278</sup> See Vidigal, *supra* note 191, at 1044.

<sup>279</sup> For discussion of the “hierarchical principle” at customary international law, see Kerstin Odenhal, *supra* note 236, at 511.

Implementation of a broad-brush TRIPS waiver at the domestic level may require navigation through complex legal issues, both domestic and international, that may impede, delay or render uncertain the practical benefits of a stand-alone waiver of TRIPS obligations. That said, specific waivers that do not provide for the effective removal or suspension of IP rights altogether, but rather enable measures to override their exclusive effect in the broader public interest, by analogy with or building in a complementary fashion upon existing limitations and exceptions may be more adapted to practical implementation in a manner compatible with constitutional requirements and overlapping non-WTO obligations. As one of us has argued,<sup>280</sup> the central, organizing issue may be construed as determining and enabling the necessary scope for effective agency on the part of national governments, and shaping the response around these more clearly defined needs; arguably, this is one of the practical lessons from the process leading up to the Ministerial Decision.

### III. SECURITY EXCEPTION

The security exception in Article 73(b) of TRIPS has been identified by some commentators as providing an avenue for introducing IP measures that are sensitive to public health requirements, to increase manufacturing capacity for vaccines.<sup>281</sup> Article 73(b) provides:

Nothing in this Agreement shall be construed:

...

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

...

(iii) taken in time of war or other emergency in international relations . . .<sup>282</sup>

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<sup>280</sup> See Taubman, *supra* note 90.

<sup>281</sup> It is noteworthy that Article 73(b) has not been formally identified by any WTO Member as a viable option in addressing IP barriers to the pandemic response.

<sup>282</sup> TRIPS Agreement, *supra* note 19, art. 73(b).



Ultimately, there are significant legal, practical and political limitations to invoking Article 73(b) of TRIPS as a potential alternative to a TRIPS waiver or as a reliable source of flexibility in ensuring access to essential health products.

Rather than a source of flexibility in the substantive rights and obligations enjoyed and imposed on Members, or a suspension of specific TRIPS standards, Article 73(b) operates as a defense in the event of WTO challenge. The exception has been analyzed extensively, primarily outside but now also within the pandemic context. In past dispute settlement cases considering security exceptions in WTO Agreements,<sup>283</sup> panels have found that a Member may decide what constitutes its “essential security interests” and whether a measure is “necessary” to protect those interests,<sup>284</sup> subject to the Member interpreting and applying those terms in good faith.<sup>285</sup>

Derived from a general requirement of good faith interpretation is a minimum “requirement of plausibility” that ensures the “essential security interest” relied upon by the defendant Member has some plausible connection with any one of the circumstances or subject matters listed in the exception.<sup>286</sup> The existence of such circumstances (and whether the interest claimed has a plausible connection with them) is to be determined objectively, and therefore constitutes the exception’s only truly justiciable element. We limit our brief analysis of Article 73(b) to the issue of what constitutes an “emergency in international relations”—the only limb we consider to have a potential *direct* plausible connection with a public health crisis.<sup>287</sup>

Abbott, in analyzing this issue, relies primarily on the WHO’s statement declaring the COVID-19 crisis a Public Health Emergency of International Concern, citing “interaction between

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<sup>283</sup> The GATT and TRIPS security exceptions are the only two WTO security exceptions to have been adjudicated: Panel Report, *Russia—Measures concerning Traffic in Transit*, WTO Doc. WT/DS512/R (Apr. 5, 2019) and Panel Report, *Saudi Arabia—Measures concerning the Protection of Intellectual Property Rights*, WTO Doc. WT/DS567/R (June 16, 2020).

<sup>284</sup> Panel Report, *Russia—Traffic in Transit*, *supra* note 283, ¶¶ 7.146–7.147.

<sup>285</sup> *Id.* at ¶ 7.132.

<sup>286</sup> Panel Report, *Saudi Arabia—Protection of Intellectual Property Rights*, *supra* note 283, ¶¶ 7.230, 7.242.

<sup>287</sup> TRIPS Agreement, *supra* note 9, art. 73(b).

States . . . the allocation of medicines (including vaccines) and medical devices among States” and ultimately framing “emergency in international relations” as an issue of inequitable access to health care.<sup>288</sup> More plausible grounds posited by Abbott for classifying the pandemic as an international relations emergency are the “sharp slowdown in international trade and travel” and “hostility and threats.”<sup>289</sup> Without entering into the debate surrounding the security exception’s general parameters under WTO disciplines, we find an objective characterization of the pandemic and vaccine inequity as an “emergency in international relations” to be somewhat strained.

In *Russia—Measures Concerning Traffic in Transit*, the Panel defined “international relations” as “generally to mean ‘world politics’, or ‘global political interaction, primarily among sovereign states’,” and determined that an “emergency in international relations” refers “generally to a situation of armed conflict, or of latent armed conflict, or of heightened tension or crisis, or of general instability engulfing or surrounding a state.”<sup>290</sup> The Panel considered that these are situations that “give rise to particular types of interests . . . i.e. defense or military interests, or maintenance of law and public order interests.”<sup>291</sup>

The Panel reasoned that “as the existence of an emergency in international relations is an objective state of affairs, the determination of whether the relevant action was ‘taken in time of’ an ‘emergency in international relations’ . . . is that of an objective fact, subject to objective determination.”<sup>292</sup> The Panel interpreted the term “taken in time of” (in contrast to “relating to” for the other subparagraphs) to describe a temporal connection between the action and the events of emergency in international relations. Therefore, for a measure to fall under the third limb, it must be a measure “*taken in time* of war or other emergency in international relations.”<sup>293</sup>

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<sup>288</sup> Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic* 7 (S. Centre, Rsch. Paper No. 116, 2020).

<sup>289</sup> *Id.*

<sup>290</sup> Panel Report, *Russia—Traffic in Transit*, *supra* note 284, ¶¶ 7.73, 7.76.

<sup>291</sup> *Id.* ¶ 7.76.

<sup>292</sup> *Id.* ¶ 7.77.

<sup>293</sup> *Id.* ¶ 7.5.5.

While a pandemic or vaccine inequity are each certainly unlikely to constitute a situation of “armed conflict” or “heightened tension,” it could be that they at least constitute a “crisis” or even “general instability engulfing or surrounding a state.”<sup>294</sup> However, fitting a pandemic and vaccine inequity into a broad interpretation of these terms seems to ignore the context in which the Panel used them. In this regard, the Panel clarified that:

the matters addressed by [the other] subparagraphs give rise to *similar or convergent concerns*, which can be formulated in terms of the specific security interests [which] . . . are all *defense and military interests*, as well as *maintenance of law and public order interests*. An “emergency in international relations” must be understood as *eliciting the same type of interests* as those arising from the other matters addressed in the enumerated subparagraphs of Article XXI(b).<sup>295</sup>

The Panel also stated that “the reference to ‘war’ in conjunction with ‘or other emergency in international relations’ . . . and the interests that generally arise during war . . . suggest that political or economic differences between Members are not sufficient, of themselves, to constitute an emergency in international relations.”<sup>296</sup>

These clarifications by the Panel reveal that the words “crisis” and “general instability engulfing or surrounding a state” are to be understood in the context of threats arising out of a conflict, or the threat of a conflict, between nations. Even if an increase in hostility and violence could be linked to the pandemic as a whole, it is unlikely that measures implemented to increase IP access for the purposes of increasing the manufacture and distribution of COVID-19 vaccines could be justified on the basis of a security exception along these lines. The connection between increasing vaccine access and preventing violence or social unrest in response to the pandemic’s various social and economic impacts would be far too weak to satisfy the minimum requirement of plausibility. Moreover, to our

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<sup>294</sup> *Id.* ¶ 7.76.

<sup>295</sup> *Id.* ¶ 7.74 (emphasis added).

<sup>296</sup> *Id.* ¶ 7.75.

knowledge, such violence and social unrest has been observed in the pandemic context solely as a response to domestic policy choices, rather than as a product of conflict between nations.

Leaving the interpretation and application of Article 73(b) aside, the practical limitations of this mechanism as an access tool can be illustrated by the proposal to use the security exception to suspend the effect of Article 31(f), thus circumventing the need to rely on Article 31*bis* in enabling government authorization of vaccine production mainly for export without a patent holder's consent.<sup>297</sup> This scenario would not arise if a Member authorized use partly to address a domestic emergency and partly for export. It would presumably entail establishing some form of understanding with each recipient Member that it had established that its essential security interests were at stake during a time of emergency in international relations, and somehow framing export as necessary to address these essential security interests. One commentator has suggested that is:

doubtful whether [a Member] can invoke Article 73(b)(iii) to justify the suspension of the enforcement of patent rights in its own territory in order to protect the essential security interests of [another Member] by exporting patented medicines or vaccines [to it].<sup>298</sup>

Given the options available for streamlined and coordinated use of Article 31*bis*—and its present implementation in many exporting producers' laws—this option raises considerable practical questions, apart from the legal ones. Hence, we question whether Article 73(b) would be practically effective in responding to public health issues. This is particularly so given political sensitivities surrounding the exception, and the expansive array of options available to Members for these purposes elsewhere within the TRIPS Agreement. Given that the essential need is for greater solidarity and cooperation among Members, in the spirit of the “Solidarity Call for Action,” the

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<sup>297</sup> See Emmanuel Kolawole Oke, *Is the National Security Exception in the TRIPS Agreement a Realistic Option in Confronting COVID-19?*, EJIL:TALK! (Aug. 6, 2020), <https://www.ejiltalk.org/is-the-national-security-exception-in-the-trips-agreement-a-realistic-option-in-confronting-covid-19/> [https://perma.cc/SH7J-6S7P].

<sup>298</sup> *Id.*

signal that individual Members' national security interests should prevail over vaccine equity may also run counter to much needed political convergence on a more cooperative and collaborative pandemic response.

## CONCLUSION

The option of a further, tailored waiver of specific TRIPS obligations remains a potential future option to overcome identified obstacles to vaccine access, either for individual countries or for groups of them in cooperation. Should the need or momentum for a broader and more targeted waiver arise, the question may be how to coordinate it in a way that makes it amenable to WTO consensus. Although the right to request WTO waivers plainly remains available for any Member, there are likely to be perceived political obstacles to making a further waiver proposal, as well as challenges for coordinating and presenting a common position before the WTO. Bound up with these political obstacles are the legal and practical challenges discussed in this article, which have significance beyond any potential COVID-19 waiver.

One such challenge is the need to decide whether a waiver would be implemented at the international level (e.g., through 'peace clauses'), the domestic level (e.g., through the suspension of IP rights and remedies), or both. The implications of each vis-à-vis domestic constitutional and IP law is one relevant consideration. Among other challenges and considerations is the need to understand, in advance, how the implementation of a waiver would interact with multilateral conventions and bilateral and regional trade agreements, as well as the enforcement of BITs by investors. While PTA State parties may be reluctant to enforce obligations they have waived at the WTO, investors may be less inclined to forego their rights under BITs.

It is, of course, possible to theorize how the VLCT and customary international law principles may help to disentangle some of the ostensible conflicts between a waiver and other international agreements. If, however, Members wish to resolve public health crises cohesively, then the theoretical and practical implications explored

in this article may need to be considered by WTO Members in advance of multilateral proposals and negotiations.

The Ministerial Decision is unlikely to give rise to many of these limitations because, in limiting its effect to a waiver of Article 31(f), it does not reach beyond the limits placed on compulsory licenses in Article 31 to the grant of IPR protection, numerous rights arising from that protection, or possibility of dispute resolution at international or domestic levels. Nevertheless, as seems to be implicit in the Ministerial Decision, the existing flexibilities available under TRIPS as clarified and confirmed by the Doha Declaration—when properly and suitably utilized—are likely to remain effective tools in ensuring widespread access to essential health products.