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The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health

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The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health

*Eric M. Solovy**

TABLE OF CONTENTS

Introduction.....	254
I. Summary.....	255
II. Interpretation and Legal Status of the Doha Declaration	258
A. Interpretation	258
1. Paragraph 1.....	258
2. Paragraph 2.....	259
3. Paragraph 3.....	259
4. Paragraph 4.....	260
5. Paragraph 5.....	262
6. Paragraph 6.....	265
7. Paragraph 7.....	266
B. Legal Status	267
III. Implementation of Paragraph 6 of the Doha Declaration	272
IV. Use of TRIPS Agreement “Flexibilities,” as Expanded Pursuant to the Doha Declaration, to Issue Compulsory Licenses, and Implications Thereof	277
A. Limited and Finite Nature of Exceptions.....	277

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B.	Compulsory Licensing Pursuant to TRIPS Article 31 <i>bis</i> and the August 2003 Decision	278
1.	Practical Experience with the System	279
2.	WTO Members’ Review of the System	281
C.	Impact of Compulsory Licensing	284
V.	Lessons Learned from the Doha Declaration, and Relevance to the Debate Over Protection of IP Rights Covering COVID-19 Vaccines and Therapeutics.....	287
A.	Benefits During a Global Pandemic of Innovation and Collaboration Incentivized and Protected by IP Rights..	289
B.	Recognition of Multiple Non-IP-related Measures that Act as Barriers to Access to Vaccines and Medicines.....	296
C.	Evaluation of a Misguided Proposal to Expand the Permissible Scope of Compulsory Licensing During the COVID-19 Pandemic.....	298
VI.	Conclusion	300

INTRODUCTION

It has now been two decades since the World Trade Organization (“WTO”) Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health (“Doha Declaration” or “Declaration”) in Doha, Qatar, on November 14, 2001.¹ Through this Declaration, WTO Members set out their understanding of the relationship between the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement” or “the Agreement”) and global health; recognized the existence of certain “flexibilities” in the TRIPS Agreement; and identified a “problem” that they believed merited “an expeditious solution.”²

Of course, the twentieth anniversary of the Doha Declaration occurs in the midst of the COVID-19 global pandemic and at a time when WTO Members, including through the WTO TRIPS Council, have been considering the relationship between intellectual property (IP) protection and global health more intensely than they have since negotiating the Doha Declaration itself.³ Many WTO Members have emphasized the important

¹ See, e.g., World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/Dec/2, 41 I.L.M. 755 (2001) [hereinafter Doha Declaration].

² *Id.* ¶ 6.

³ See, e.g., *TRIPS Council Agrees to Continue Discussions on IP Responses to COVID-19*, WTO: 2021 NEWS ITEMS (July 20, 2021), https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm (noting that “[w]hile delegations remain committed to the common goal of providing timely and secure access to high-quality, safe, efficacious and affordable vaccines and medicines for all, disagreement persisted on the fundamental question of what is the appropriate and most effective way to address the shortage and inequitable

role that IP rights have played in the rapid development and availability of COVID-19 vaccines and therapeutics. But other WTO Members, along with certain NGOs and academics, have used the global pandemic as an opportunity to call for a *reduction* in global IP protection and *increased* use of compulsory licenses—i.e., licenses to patents issued by a government to third parties without the consent of the right holders—beyond what is permitted by the TRIPS Agreement (as amended, in line with the Doha Declaration).

In the twenty years since its adoption, certain elements of the Doha Declaration have been the subject of both tremendous praise and significant criticism. As the debate raged on, WTO Members moved forward to formally implement a key aspect of the Doha Declaration. Namely, as detailed below, to address the “problem” that Paragraph 6 of the Declaration required “an expeditious solution”—i.e., the practical limitations of compulsory licensing for WTO Members with “insufficient or no manufacturing capacities in the pharmaceutical sector”⁴—the WTO General Council adopted a decision in August 2003 (“August 2003 Decision”) that waived certain requirements of the TRIPS Agreement, subject to fulfilment of a number of important preconditions and safeguards.⁵ The Members ultimately agreed to amend the TRIPS Agreement, itself, to make that change permanent.⁶

I. SUMMARY

This article begins (in **Section II**) with a review of the language of the Doha Declaration, including in view of subsequent statements and developments clarifying WTO Members’ understanding of its terms. A proper reading of the Doha Declaration reveals that it is meant to reaffirm the rights and obligations already provided by the TRIPS Agreement, and that it does not provide new exceptions to TRIPS Agreement obligations. In referring back to the object and purpose of the TRIPS Agreement, the Declaration reaffirms that the TRIPS Agreement balances the interests of innovators with those of potential users of their innovations, including with respect to medicines. While listing a number of built-in “flexibilities,” the Doha Declaration emphasizes that they can be applied only “while maintaining [the] commitments in the TRIPS Agreement.” Further, the Doha Declaration provided a few specific instructions to WTO Members. The direction in Paragraph 6, in particular, ultimately led WTO Members to amend the TRIPS Agreement to address the concern that “WTO members

access to vaccines and other COVID-related products”).

⁴ Doha Declaration, *supra* note 1, ¶ 6.

⁵ WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (Sept. 1, 2003) WT/L/540, 43 I.L.M. 509 (2004) [hereinafter August 2003 Decision].

⁶ Decision of the General Council, Amendment of the TRIPS Agreement, WT/L/641 (Dec. 8, 2005), https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

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

With respect to the legal status of the Doha Declaration within the WTO system, it is intended to be only a legally non-binding statement of intent, and lacks the characteristics of a “subsequent agreement” within the meaning of Article 31(3) of the Vienna Convention on the Law of Treaties (“Vienna Convention”). While the WTO dispute settlement panel in *Australia—Tobacco Plain Packaging* took the view that at least one aspect of the Doha Declaration should be considered a subsequent agreement, the WTO Appellate Body failed to endorse that view. Contemporaneous statements by several key WTO Members help to confirm that the Doha Declaration did not, itself, modify obligations under the TRIPS Agreement.

Next, this article (in **Section III**) considers the formal decisions, including the amendment to the TRIPS Agreement, taken by the WTO in line with the Doha Declaration, including Paragraph 6 thereof. Through an August 2003 Decision of the WTO General Council, WTO Members opted to waive certain existing obligations under the TRIPS Agreement, including the limitation on compulsory licensing for exports to countries that cannot manufacture necessary pharmaceutical products themselves (subject to several conditions). With particular respect to the waiver of the requirement in Article 31(f) of the TRIPS Agreement, the August 2003 Decision permits an exporting Member to grant a compulsory license “to the extent necessary for the purpose of production of a pharmaceutical product(s) and its export to an eligible importing Member(s).” In order to take advantage of this waiver, however, the exporting and importing WTO Members must satisfy several requirements that would provide notice to other WTO Members and serve to limit the risk that the exported products will be improperly diverted. As clarified by the then-Chairperson of the WTO General Council, the August Decision must not be used as a means to broadly limit patent protection, and the benefits that naturally flow from such protection, or of subverting the disciplines of the TRIPS Agreement. In December 2005, WTO Members agreed that the key aspects of the August 2003 Decision should be permanently incorporated into an amendment to the TRIPS Agreement, upon acceptance of two-thirds of WTO Members. The amendment was formally accepted in January 2017.

After first recalling that the exceptions in the TRIPS Agreement are limited and finite, **Section IV** explores WTO Members’ recent experience with recourse to compulsory licensing—including, e.g., the class of compulsory licenses permitted pursuant to the amendment to the TRIPS Agreement and the August 2003 WTO General Council Decision. In fact, the experience with the system created by the August 2003 Decision, and later by the amendment, has been one of limited use. The limited recourse to that system (including to export HIV/AIDS medicines from Canada to Rwanda under compulsory license), as well as the limited use of compulsory licensing

generally, tends to demonstrate that compulsory licensing of any kind is often a deeply flawed means to the critically important end of increasing access to medicines, even if such licenses are issued in accordance with the TRIPS Agreement. As several WTO Members have argued, the limited use is not surprising given that the vast majority of essential medicines are not patented, and that developing countries may acquire medicines through voluntary licenses for those that do benefit from IP protection. In some cases, as found in a recent study sponsored by the World Intellectual Property Organization (“WIPO”), compulsory licenses may be counterproductive in the *short term*, as they can result in higher prices than what may be charged through voluntary licensing and international procurement. Further, they may also be counterproductive in the *long term*: when a WTO Member abuses its power to compulsory license, or to threaten to issue compulsory licenses, such abuse serves to lower the overall credibility of that country’s patent system, and the incentives for innovation that its IP regime may create. This ultimately would be expected to limit development of new medicines and, in turn, access.

Section V then turns to consider the lessons learned from the experience of WTO Members implementing and evaluating the Doha Declaration over the past two decades, and the relevance of those lessons to today’s debate over the relationship between the TRIPS Agreement and the development and distribution of COVID-19 vaccines and therapeutics. In particular, the innovations supported, incentivized, and licensed as a consequence of strong global IP protection, as reaffirmed by the Doha Declaration, have saved millions of lives around the globe. For example, the history of the development of both the Pfizer-BioNTech and Moderna vaccines, is one that solidifies the importance of IP protection for development of innovative products that advance public health, and for fostering the voluntary collaborations facilitated by that protection.

Section V recalls the numerous barriers to access to COVID-19 therapeutics and vaccines that are not related to IP rights, many of which were previously recognized at the time of adoption of the Doha Declaration. Such barriers are often obscured during policy debates over IP rights. Finally, Section V criticizes a proposal by several academics to establish a global mass compulsory licensing mechanism covering all COVID-19-related technologies and related clinical test data; this proposal appears to be deeply flawed and would serve to detract from the goals of eradicating the COVID-19 virus and treating those who are infected.

Section VI concludes, urging that, as they did twenty years ago when adopting the Doha Declaration, WTO Members must today continue to acknowledge the benefits of IP protection for global health, while finding ways to maximize access to the technologies incentivized by such protection, without leaving the world unprepared for the next pandemic.

II. INTERPRETATION AND LEGAL STATUS OF THE DOHA DECLARATION

Adopted by the WTO Ministerial Conference in 2001, the Doha Declaration recognized the serious global health issues facing the world—including developing and least developed countries (“LDCs”)⁷—at that time. It set out WTO Members’ views on the relationship between those health issues and the protection of IP rights required by the TRIPS Agreement.⁸ This section first closely examines the language of the Doha Declaration and its meaning (subsection A), and then considers the legal status of the Doha Declaration in the WTO legal system (subsection B).

A. Interpretation

The Doha Declaration begins with (i) several general statements regarding developments in global health, and the relationship between IP and the creation of and access to medicines to address those developments. It then includes (ii) a reaffirmation of several principles already in the TRIPS Agreement, and (iii) instructions directing WTO Members to take two specific types of new actions.

1. Paragraph 1

With respect to the general statements, the Doha Declaration begins, in Paragraph 1, by recognizing “the gravity of the public health problems afflicting many developing and least developed countries,” and specifically refers to HIV/AIDS, tuberculosis, malaria and “other epidemics.”⁹

The ordinary meaning of the term “epidemic” (as a noun) is “epidemic disease,” with “epidemic” (as an adjective) defined as “[p]revalent among a people or a community at a special time, and produced by some special causes not generally present in the affected locality.”¹⁰ Notably, all of the conditions referenced in this paragraph are those that can be passed on from person to person within a community. As a “pandemic” is a type of “epidemic” with similar characteristics to some of the conditions listed in Paragraph 1, this provision would appear to be broad enough to cover COVID-19.¹¹

⁷ The WTO recognizes as LDCs those forty-nine countries designated by the United Nations, thirty of which are WTO Members: Angola; Bangladesh; Benin; Burkina Faso; Burundi; Central African Republic; Chad; Congo, Democratic Republic of the; Djibouti; Gambia; Guinea; Guinea Bissau; Haiti; Lesotho; Madagascar; Malawi; Maldives; Mali; Mauritania; Mozambique; Myanmar; Niger; Rwanda; Senegal; Sierra Leone; Solomon Islands; Tanzania; Togo; Uganda; Zambia. See WTO, Briefing Notes, *Towards Free Market Access for Least-Developed Countries*, https://www.wto.org/english/thewto_e/minist_e/min01_e/brief_e/brief03_e.htm.

⁸ See Doha Declaration, *supra* note 1, ¶ 4.

⁹ *Id.* ¶ 1.

¹⁰ *Epidemic*, OXFORD ENGLISH DICTIONARY ONLINE (last visited Oct. 25, 2021).

¹¹ A “pandemic” is defined as a type of epidemic, namely an “epidemic over a very large

While the scope of the Declaration is not explicitly limited to the types of epidemics listed in Paragraph 1, this provision provides relevant context to understand the type of health problems that Members intended to address.

2. Paragraph 2

The Declaration turns, in Paragraph 2, to the TRIPS Agreement, and “stress[es] the need for” it “to be part of the wider national and international action to address these problems,” namely, the public health problems referenced in Paragraph 1.¹² This begs the question of how a treaty like the TRIPS Agreement can be part of the “action” to address health problems. The WTO Members attempt to answer that question in the subsequent paragraphs.

3. Paragraph 3

Paragraph 3 of the Doha Declaration makes the critically important point that “intellectual property protection is important for the development of new medicines.”¹³ As applied to the specific context of medicines, this is fully consistent with Article 7 of the TRIPS Agreement, which acknowledges that “protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation.”¹⁴

Through Paragraph 3 of the Doha Declaration, WTO Members also “recognize the concerns about [IP protection’s] effect on prices.”¹⁵ This clause implicitly links IP rights with the ability of right holders to charge higher prices for products covered by those IP rights in order to, e.g., recoup the tremendous cost of research and development (“R&D”) required to develop and test those products. That said, as discussed further below, it is important to note that the price of pharmaceutical products is impacted by a multitude of factors, including, inter alia, technical barriers to trade, time-consuming and costly domestic regulatory frameworks, costs of internal distribution within a given country, taxes, and tariffs.¹⁶

Again, the relationship between IP rights and access to the results of the

area; affecting a large proportion of a population.” *Pandemic*, OXFORD ENGLISH DICTIONARY ONLINE (last visited Oct. 25, 2021). In March 2020, the World Health Organization (WHO) first indicated that COVID-19 was to be classified as a pandemic. See *Director General’s Opening Remarks at the Media Briefing on COVID-19*, WHO (Mar. 11, 2020), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.

¹² Doha Declaration, *supra* note 1, ¶ 2.

¹³ *Id.* ¶ 3.

¹⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, https://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS Agreement].

¹⁵ Doha Declaration, *supra* note 1, ¶ 3.

¹⁶ See *infra* Section V.B.

innovation that they incentivize is also covered by Article 7 of the TRIPS Agreement, which refers to the “mutual advantage of producers *and users of technological knowledge* and in a manner *conducive to social and economic welfare*, and to a balance of rights and obligations.”¹⁷

4. Paragraph 4

Turning to the principles, perhaps the most quoted portion of the Doha Declaration is Paragraph 4, which states the agreement of WTO Members:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.

*In this connection, we reaffirm the right of WTO members to use to the full, the provisions in the TRIPS Agreement, which provide flexibility.*¹⁸

This provision makes it clear that, rather than, itself, adding any flexibilities, the Doha Declaration is only a “reaffirm[ation]” of rights already understood to be provided by the TRIPS Agreement.¹⁹ The references to what the TRIPS Agreement “does not and should not” prevent Members from doing, and the way in which the TRIPS Agreement “can and should” be interpreted and implemented, also indicate that the provision is a statement of what the TRIPS Agreement does in its current state, and without any need for change (subject to the action item in Paragraph 6). This understanding is solidified by the introductory text of Paragraph 5 (before listing of the “flexibilities”), which provides that such flexibilities can be applied only “*while maintaining our commitments in the TRIPS Agreement.*”²⁰

The Trilateral WTO/WHO/WIPO Report on Promoting Access to Medical Technologies and Innovation (“Trilateral Study”) reflects the same understanding, stating that the Doha Declaration “referred to,” “highlights,” “confirms,” and “lists” existing aspects of the TRIPS Agreement.²¹

In contrast, a paper published by the UN Development Programme (co-authored by Correa & Matthews) has argued that Paragraph 4 of the Doha Declaration somehow provides that “governments not only *may* but also *have*

¹⁷ TRIPS Agreement, *supra* note 14, art. 7 (emphasis added).

¹⁸ Doha Declaration, *supra* note 1, ¶ 4 (emphasis added).

¹⁹ See generally Eric M. Solovy & Pavan Krishnamurthy, *TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General’s High-Level Panel Report on Access to Medicines*, 50 GEO. WASH. INT’L L. REV. 1 69, 91-96 (2017).

²⁰ Doha Declaration, *supra* note 1, ¶ 5 (emphasis added).

²¹ WTO, WIPO, & WHO, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION 91, 93 (2d ed. 2020) [hereinafter Trilateral Study].

the duty to use the TRIPS flexibilities.”²² But such an interpretation would go against a fundamental principle of the TRIPS Agreement, as set out in Article 1.1, that Members “may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement.”²³ Had the WTO Members intended to modify that provision through the Doha Declaration, they would have specifically indicated as such and subsequently moved to amend the TRIPS Agreement accordingly. Article 1.1 clarifies that the TRIPS Agreement sets the minimum level of protection that WTO Members must meet, and that they have the discretion to provide greater levels of protection. For example, it is up to a WTO Member to determine whether or not it wishes to take advantage of a particular exception (or “flexibility”) in the TRIPS Agreement, and whether it will provide a higher level of protection for one or more types of IP rights (as long as such additional protection does not violate other provisions of the Agreement).

The South Centre (an NGO that often advocates for decreased global IP protection) has characterized Paragraph 4 of the Doha Declaration as providing “for a clear rule of interpretation . . . such that any measure that is necessary to protect public health cannot be held to violate the provisions of TRIPS . . . *even when the measure derogates from certain obligations under the TRIPS Agreement.*”²⁴ In other words, this NGO reads the Doha Declaration as providing that any measure deemed “necessary to protect public health” is exempted from discipline by the TRIPS Agreement. There is nothing in Paragraph 4, or anywhere else in the Doha Declaration, that would justify such an extraordinary reading. And there would have been no need for WTO Members to act on Paragraph 6 of the Doha Declaration, through ultimately amending the TRIPS Agreement, had the Doha Declaration somehow created such a broad public health exception for IP protection.

There is likewise no support for the proposition advanced by some, including the Government of India, that the Doha Declaration signifies that “public health concerns overrode intellectual property rights.”²⁵ In reality, the Declaration reaffirmed that the TRIPS Agreement already balances the interests of innovators with the interests of potential users of their innovations, including with respect to medicines.

²² CARLOS CORREA & DUNCAN MATTHEWS, THE UNITED NATIONS DEVELOPMENT PROGRAMME, THE DOHA DECLARATION TEN YEARS ON AND ITS IMPACT ON ACCESS TO MEDICINES AND THE RIGHT TO HEALTH 17 (Dec. 20, 2011).

²³ TRIPS Agreement, *supra* note 14, art. 1.1.

²⁴ SOUTH CENTRE, SOUTH CENTRE POLICY BRIEF NO. 7, THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH TEN YEARS LATER: THE STATE OF IMPLEMENTATION 4 (2011), https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf (emphasis added) [hereinafter SOUTH CENTRE POLICY BRIEF NO. 7].

²⁵ Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 66, WTO Doc. IP/C/57 (Dec. 10, 2010) [hereinafter *Annual Review of the Decision on the Implementation of Paragraph 6*].

5. Paragraph 5

Paragraph 5 of the Doha Declaration goes on to “recognize” four different types of “flexibilities” that are already available in the TRIPS Agreement.

First, Paragraph 5(a) recognizes the fact that, “[i]n applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”²⁶

This sub-paragraph effectively mimics (and, in significant part, copies word-for-word) the last clause of the customary rule of international law as codified in Article 31(1) of the Vienna Convention.²⁷ That article provides that a “treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty *in their context and in the light of its object and purpose*.”²⁸ The specific reference in the Doha Declaration to the “object and purpose of the Agreement as expressed, in particular, in its objectives and principles” is a reference to Article 7 of the TRIPS Agreement (entitled “Objectives”) and Article 8 (entitled “Principles”).

Article 7 of the TRIPS Agreement provides:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.²⁹

As explained by Solovy and Krishnamurthy:

Article 7 clarifies the intent of the drafters to “balance”—to the “mutual advantage” of producers *and* users—the need to establish incentives for creation and promotion of new technology, without unduly restricting the dissemination of that technology once created. Thus, the very essence of the innovation-access debate is crystallized in the terms of Article 7 of the TRIPS Agreement, itself, with WTO Members urged to find “balance.” That “balance” is currently reflected in the TRIPS Agreement, with its combination of obligations and exceptions.³⁰

²⁶ Doha Declaration, *supra* note 1, ¶ 5(a).

²⁷ Vienna Convention on the Law of Treaties, *opened for signature* May 23, 1969, 1155 U.N.T.S. 331.

²⁸ *Id.* (emphasis added).

²⁹ TRIPS Agreement, *supra* note 14, art. 7.

³⁰ Solovy & Krishnamurthy, *supra* note 19, at 90.

Article 8.1 of the TRIPS Agreement states, “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”³¹

The text of Article 8.1 makes it crystal clear that it does not provide an “exception” to the TRIPS Agreement for measures that aim “to protect public health and nutrition” or “to promote the public interest.”³² Rather, pursuant to its final clause, any such measures must be “consistent with the provision of [the TRIPS] Agreement.”³³ Indeed, the use of the word “necessary” in the phrase “necessary to protect public health and nutrition” indicates that it is relevant to consider whether a measure aimed at protecting public health is actually capable of achieving that objective.³⁴

Sub-paragraphs 5(b) and (c) of the Doha Declaration relate to Article 31 of the TRIPS Agreement, entitled “Other Use Without Authorization of the Right Holder,” which permits governments to issue compulsory licenses of patents, subject to a number of conditions. Article 31 contains twelve different paragraphs setting out the conditions to be followed when issuing a compulsory license; these conditions are then supplemented by Article 31*bis*. Article 31 contains “by far, the longest list of specific considerations for any single limitation or exception to substantive IP rights in the TRIPS Agreement.”³⁵ Among the conditions is a requirement in Article 31(b) to make efforts for a reasonable period of time to “obtain authorization from the right holder on reasonable commercial terms and conditions.”³⁶ Further, “the scope and duration” of the compulsory license “shall be limited to the purpose for which it was authorized,”³⁷ and authorization for a compulsory license must terminate when the circumstances leading to its issuance “cease to exist and are unlikely to occur.”³⁸ There is also a requirement for “adequate

³¹ TRIPS Agreement, *supra* note 14, art. 8.1.

³² *Id.*

³³ *Id.*

³⁴ See, e.g., Appellate Body Report, *Brazil—Measures Affecting Imports of Retreaded Tyres*, ¶ 151, WTO Doc. WT/DS332/AB/R (adopted Dec. 17, 2007) (finding that an import ban of used tires was not necessary to protect human, animal or plant life or health because it was not “apt to produce a material contribution to the achievement of its objective” of reducing disease and environmental harm); Appellate Body Report, *Korea—Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, ¶ 165, WT/DS161/AB/R, WT/DS169/AB/R (adopted Jan. 10, 2001) (finding that a measure is not “necessary” within the meaning of GATT Article XX(b) “if an alternative measure which [a Member] could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available to it”).

³⁵ Solovy & Krishnamurthy, *supra* note 19, at 120.

³⁶ TRIPS Agreement, *supra* note 14, art. 31(b).

³⁷ *Id.* art. 31(c).

³⁸ *Id.* art. 31(g).

remuneration” to the right holder to compensate for the compulsory license.³⁹ Any compulsory license “shall be considered on its individual merits,” and should be “non-exclusive,” as well as generally “non-assignable.”⁴⁰

Subparagraph 5(b) of the Doha Declaration reaffirms that each Member “has the right to grant compulsory licences.”⁴¹ This principle is already established by Article 31, itself. Subparagraph 5(b) then goes on to recall that Members likewise have “the freedom to determine the grounds upon which such licences are granted,” which again appears to implicitly recall that Article 31 does not include a specific list of acceptable grounds for compulsory licensing.⁴² However, given the multiple conditions in Article 31 and the overall object and purpose of the TRIPS Agreement (as set out in Articles 7 and 8, discussed above), Article 31 must be understood as providing only a limited exception to the exclusive rights accorded pursuant to Article 28 of the TRIPS Agreement.

Next, subparagraph 5(c) provides that each Member “has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”⁴³ The list of diseases here mimics that which is first found in Paragraph 1 of the Declaration. The reference to “national emergency or other circumstances of extreme urgency” relates specifically to Article 31(b) of the TRIPS Agreement, which provides that, in such circumstances, a Member need not require (as a prerequisite to issuing a compulsory license) that the recipient of the license “has made efforts to obtain authorization from the right holder on reasonable commercial terms and condition,” and that such efforts “have not been successful within a reasonable period of time.”⁴⁴

Subparagraph 5(d) provides that the effect of the TRIPS Agreement is that each WTO Member is “free to establish its own regime for . . . exhaustion [of IP rights] without challenge, subject to the MFN and national treatment provisions of Article 3 and 4 [of the TRIPS Agreement].”⁴⁵ This is essentially a restatement of Article 6 of the TRIPS Agreement, which provides that WTO dispute settlement shall not be “used to address the issue of the exhaustion of intellectual property rights” other than Articles 3 and 4 thereof.⁴⁶ IP exhaustion is a term used to address the question of when, after a patented product has first been lawfully sold, the patent holder’s rights to

³⁹ *Id.* art. 31(h).

⁴⁰ *Id.* arts. 31(a), (d), (e).

⁴¹ Doha Declaration, *supra* note 1, ¶ 5(b).

⁴² *Id.*

⁴³ *Id.* ¶ 5(c).

⁴⁴ TRIPS Agreement, *supra* note 14, art. 31(b).

⁴⁵ Doha Declaration, *supra* note 1, ¶ 5(d).

⁴⁶ See Solovy & Krishnamurthy, *supra* note 19, at 115-16.

prevent further sale of that product expire.⁴⁷ Exhaustion can be delimited at the national, international, or regional level, or a combination thereof.⁴⁸ If a given country adopts a policy of international exhaustion, for example, it may consider that the first sale of a product by a patent owner (or a person authorized by the patent owner) anywhere in the world terminates the patent owner's rights over the patented product in that country, such that the patent owner could not stop the import of that product into that country (known as "parallel imports").⁴⁹ A system of domestic exhaustion (which lacks international exhaustion), however, would provide a patent owner the right to prevent such parallel imports as part of the core patent right required under Article 28.1 of the TRIPS Agreement (which specifically requires that Members provide the right to prevent unauthorized third parties from "importing" a patented product).

Importantly, all of the flexibilities described above are subject to the caveat, included in the chapeau to Paragraph 5, that they can be applied only "*while maintaining our commitments in the TRIPS Agreement.*"⁵⁰ Consistent with this interpretation, the Trilateral Study refers to each of the subparagraphs of Paragraph 5 as providing either "clarifications" or "confirm[ations]."⁵¹

6. Paragraph 6

Turning now to the specific instructions provided to WTO Members in the Doha Declaration, Paragraph 6 "recognize[s] that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement" and instructs the TRIPS Council to find "an expeditious solution to this problem."⁵² This paragraph implicitly refers to the requirement in TRIPS Article 31(f) that any compulsory licensing "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."⁵³ As detailed in Section III, below, this directive led to the August 2003 WTO General Council Decision and

⁴⁷ WTO Fact Sheet: TRIPS and Pharmaceutical Patents, Obligations and exceptions, https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited July 17, 2022); WIPO Secretariat, Interface Between Exhaustion of Intellectual Property Rights and Competition Law, CDIP/4/4 Rev./Sutdy/Inf/2, at 4-5 (June 1, 2001), https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4rev_study_inf_2.pdf (last visited July 17, 2022).

⁴⁸ WIPO Secretariat, Interface Between Exhaustion of Intellectual Property Rights and Competition Law, CDIP/4/4 Rev./Sutdy/Inf/2, at 4-5 (June 1, 2001), https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4rev_study_inf_2.pdf (last visited July 17, 2022).

⁴⁹ *Parallel imports*, WTO.ORG, https://www.wto.org/english/thewto_e/glossary_e/parallel_imports_e.htm (last visited July 17, 2022).

⁵⁰ Doha Declaration, *supra* note 1, ¶ 5 (emphasis added).

⁵¹ Trilateral Study, *supra* note 21, at 93.

⁵² Doha Declaration, *supra* note 1, ¶ 6.

⁵³ TRIPS Agreement, *supra* note 14, art. 31(f).

eventually the amendment to the TRIPS Agreement, i.e., Article 31*bis*.

7. Paragraph 7

Through Paragraph 7, the Doha Declaration directed the TRIPS Council to extend the transition period that LDC WTO Members were initially provided to “implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement” (i.e., covering patents and undisclosed information) with respect to pharmaceutical products, or to enforce the rights provided for under those Sections.⁵⁴ In doing so, Paragraph 7 referenced the transition period for LDCs originally included in Article 66.1 of the TRIPS Agreement (which had begun with a 10 year transition period).

In fact, WTO Members followed the instruction to extend this transition period, with the most recent extension available for LDCs through “1 January 2033, or until such a date on which they cease to be a least developed country Member, whichever date is earlier.”⁵⁵

Importantly, Paragraph 7 also refers back to another provision in the TRIPS Agreement specifically focused on LDCs, i.e., Article 66.2. Article 66.2 provides that developed-country WTO Members “shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer” to LDCs, with the aim of enabling them to “create a sound and viable technological base.”⁵⁶ This provision in the TRIPS Agreement, and its reaffirmation in the Doha Declaration, is an important reminder of the potential for IP protection to enable LDCs to grow their own technology bases and, in turn, their economies.

Before enterprises and institutions in developed countries can be comfortable transferring such technology to developing countries, however, they must be provided some assurance that the technology covered by IP rights will be protected. In a June 2002 communication discussing the relationship between trade and technology transfer (pursuant to paragraph 37 of the Doha Ministerial Declaration⁵⁷), the European Union emphasized this point, stating:

Where the technology in question is subject to intellectual property rights, the transfer of this technology implies transfer of the legal rights to the technology in question by selling patent rights or

⁵⁴ Doha Declaration, *supra* note 1, ¶ 7.

⁵⁵ See Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article: 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. No. IP/C/73 (Nov. 6, 2015).

⁵⁶ TRIPS Agreement, *supra* note 14, art. 66.2.

⁵⁷ World Trade Organization, Ministerial Declaration, Doha WTO Ministerial 2001, ¶ 37, WT/MIN(01)/DEC/1 (Nov. 20, 2001), https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

licensing the right to make use of the right. Know-how and skills linked to the licensed technology will normally become available through the learning process of the licensee country, and might be facilitated where the licensing is linked to investment, e.g. in the form of a joint venture.

The decision to license in a given country is that of the right-holder and forms part of the right-holder's business strategy or, in the event of a non-profit organisation holding the right, its objectives. *The existence and enforcement of an IPR system in the recipient country is often a prerequisite and the confidence of the right-owner in that system is a key element.*⁵⁸

Likewise, in negotiating Article 39 of the TRIPS Agreement (covering protection of undisclosed information, including trade secrets) back in 1989, the United States made this same point, with the U.S. representative to the negotiations stating that trade secret protection is “important for developing countries since there was no better way of encouraging the transfer of technology to developing countries than to provide protection to trade secrets and proprietary information which constituted the very essence of the transfer of technology.”⁵⁹

B. Legal Status

As explained by Solovy and Krishnamurthy, the text and negotiating history of the Doha Declaration indicate that it was intended to be a legally non-binding statement of intent.⁶⁰ In the WTO system, this type of declaration is not considered an authoritative interpretation, within the meaning of Article IX:2 of the Marrakesh Agreement Establishing the WTO (“the Marrakesh Agreement”), which provides a particular method for establishing such an interpretation.⁶¹

⁵⁸ Communication from the European Communities, Trade and Transfer of Technology, *Work of the Working Group Under the Auspices of the General Council Pursuant to Paragraph 37 of the Doha Ministerial Declaration*, WT/WGTTT/1 (Jun. 10, 2002), https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=97491,70866,2909,1541,15753,42543,24924,102138,47494,32863&CurrentCatalogueIdIndex=8&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True (emphasis added).

⁵⁹ Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Meeting of Negotiating Group of 30 October—2 November 1989*, 22, MTN.GNG/NG11/16 (Dec. 4, 1989).

⁶⁰ See Solovy & Krishnamurthy, *supra* note 19, at 92.

⁶¹ See Thomas Cottier, *The Agreement on Trade-Related Aspects of Intellectual Property Rights*, in *THE WORLD TRADE ORGANIZATION: LEGAL ECONOMIC AND POLITICAL ANALYSIS* 1041, 1077 (Patrick F. J. Macrory, Arthur E. Appleton & Michael G. Plummer eds. 2005). See also Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* 44, Health Economics and Drugs EDM Series, No. 12, WHO/EDM/PAR/2002.3 (June 2002) (noting that the Doha Declaration “has no specific legal status in the framework of WTO Law; it is not strictly an authoritative interpretation in terms of Article

In 2018, for the first time, a WTO dispute settlement panel interpreted an aspect of the Doha Declaration. Specifically, the WTO panel in *Australia—Tobacco Plain Packaging* considered Paragraph 5 of the Doha Declaration (i.e., recognizing the “flexibilities” in the TRIPS Agreement) to be a “‘subsequent agreement’ of WTO Members, within the meaning of Article 31(3)(a) of the Vienna Convention.”⁶² In interpreting a treaty, Article 31(3) of the Vienna Convention allows for consideration of, along with context, inter alia: “any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions.”⁶³ As noted by the *Australia—Tobacco Plain Packaging* panel, the WTO Appellate Body had previously clarified 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 Members on the *interpretation* or *application* of a provision of WTO law.⁶⁴

On appeal of the *Australia—Tobacco Plain Packaging* panel report, the Appellate Body avoided endorsing that panel’s observations regarding Paragraph 5 (or any other aspect) of the Doha Declaration. With particular respect to Paragraph 5(a), the Appellate Body (like the panel before it) noted that the statement, “each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles” “reflects” the applicable rules of interpretation under customary international law.⁶⁵ The Appellate Body merely (and unsurprisingly) agreed with the panel’s recourse to the “general principle of treaty interpretation” when interpreting the TRIPS Agreement,

IX:2 of the Marrakesh Agreement Establishing the WTO”).

⁶² 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/DS441/R (adopted June 29, 2020) [hereinafter Panel Report, *Australia—Tobacco Plain Packaging*] (as upheld by Appellate Body Report, *Australia—Certain Measures Concerning Appellate Body Report, Australia—Tobacco Plain Packaging Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS441/AB/R (adopted June 29, 2020) [hereinafter Appellate Body Report, *Australia—Tobacco Plain Packaging*]).

⁶³ Vienna Convention on the Law of Treaties, *supra* note 27, art. 31(3)(a); *see also* International Law Commission, *Commentary on the Draft Vienna Convention*, in Y.B. OF THE INT’L L. COMM’N Vol. II 118 (1966).

⁶⁴ Panel Report, *Australia—Tobacco Plain Packaging*, *supra* note 62, ¶ 7.2409 (quoting Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, ¶ 262, WT/DS406/AB/R (adopted Apr. 24, 2012)).

⁶⁵ Appellate Body Report, *Australia—Tobacco Plain Packaging*, *supra* note 62, ¶ 6.657.

“regardless of the legal status of the Doha Declaration.”⁶⁶ Thus, the Appellate Body did not express any opinion on whether Paragraph 5 of the Doha Declaration was a “subsequent agreement.”⁶⁷ Rather, the Appellate Body minimized the panel’s reliance on (and, by implication, statement about the legal status of) the Doha Declaration, stating that “the reliance on the Doha Declaration was not of decisive importance for the Panel’s reasoning” and highlighted that the “Panel relied on the Doha Declaration simply to reconfirm its previous conclusions.”⁶⁸

The correctness of the panel’s characterization is not without doubt. According to the panel in *Australia—Tobacco Plain Packaging*, rather than being an agreement on the meaning of any particular provision of the TRIPS Agreement, Paragraph 5 of the Doha Declaration is an agreement on “the approach to be followed in interpreting the provisions of the TRIPS Agreement.”⁶⁹ As for that approach, the Doha Declaration provides (pursuant to Paragraph 5(a)) that the TRIPS Agreement shall be interpreted in light of its object and purpose, including as reflected in Articles 7 and 8 of the TRIPS Agreement. According to Gathii, this “sets an interpretive baseline that requires balancing the interests of producers and consumers of intellectual property rights.”⁷⁰ In this regard, the “approach” set out by the Doha Declaration is not any different from the approach that would be applied in its absence.

The panel explained that “guidance provided by the Doha Declaration is consistent . . . with the applicable rules of interpretation, which require a treaty interpreter to take account of the context and object and purpose of the treaty being interpreted.”⁷¹ Thus, it is doubtful whether the Members did make, through the Doha Declaration, any new “agreement” concerning the “interpretation or application” of the TRIPS Agreement, or what practical purpose any such agreement would serve in the course of interpreting the TRIPS Agreement.

Notably, in amending the TRIPS Agreement in accordance with the instruction in Paragraph 6 of the Doha Declaration, Article 31*bis* of the TRIPS Agreement now includes a specific reference back to the Doha Declaration. It provides in relevant part, at paragraph 5, that Article 31*bis* is “without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS

⁶⁶ *Id.* (emphasis added).

⁶⁷ *Id.*

⁶⁸ *Id.* ¶ 6.658.

⁶⁹ Panel Report, *Australia—Tobacco Plain Packaging*, *supra* note 62, ¶ 7.2410.

⁷⁰ James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 292, 316 (2002).

⁷¹ Panel Report, *Australia—Tobacco Plain Packaging*, *supra* note 62, ¶ 7.2411.

Agreement and Public Health.”⁷² The key phrase here is “reaffirmed by,” a phrase that clarifies the limited legal nature and impact of the Doha Declaration (beyond the instruction that led to the amendment, and the instruction to extend the transition period for LDCs).

Further, based on the statements made by certain WTO Members contemporaneous with the negotiation of the Doha Declaration, it likewise does not appear that the Members intended it to be a “subsequent agreement” of the parties, under Article 31(3)(a) of the Vienna Convention, or a document that would otherwise add any substantive value to the TRIPS Agreement. In this case, several WTO Members, including the United States, European Communities (now the European Union) and Switzerland, objected to the idea of the Doha Declaration having the status of something that could alter the TRIPS Agreement.⁷³ For example, in its “Fact Sheet Summarizing Results from WTO Doha Meeting,” the Office of the United States Trade Representative (USTR) referred to the Doha Declaration as a “*political* Declaration regarding patent rules and public health” that “highlights provisions in the TRIPS agreement that provide Members with the flexibility to address public health emergencies” and expresses “strong support for the TRIPS agreement and the importance of Intellectual Property Protection for the development of life saving drugs.”⁷⁴

On November 10, 2001, just four days before the adoption of the Doha Declaration, the United States issued a background paper on “TRIPs and Health Emergencies” that made the following points:

- We support clarifying the flexibility in the TRIPs Agreement. . . .
- The United States opposes a declaration that creates a broad carve-out to TRIPs ostensibly to ‘protect public health.’ Instead of permitting targeted exceptions to TRIPs, [the pending] open-ended language would result in commonplace erosion of patent protections—from pharmaceuticals to medical software—and thwart research into medicines to treat life-threatening diseases.

⁷² World Trade Organization, *Article 31bis of the Agreement on Trade-Related Aspects of Intellectual Property Rights*, art. 1.1, ¶ 5 (emphasis added), https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf.

⁷³ See, e.g., Gathii, *supra* note 70, at 315 (“The United States has maintained that Doha was a political declaration with no legal authority. The United States Trade Representative’s Fact Sheet summarizing the results of the Doha meeting refers to the Doha Declaration on TRIPS and Public Health as a political declaration. From this perspective, the Declaration is not a *fait accompli* for countries seeking to facilitate access to essential medicines. Rather, it is an implicit reciprocation by the West to developing countries for their implementation of the TRIPS Agreement and their acquiescence to a new round of WTO talks.”).

⁷⁴ Office of the United States Trade Representative, Fact Sheet Summarizing Results from WTO Doha Meeting (Nov. 14, 2001) (emphasis added). See also Press Release, Office of the United States Trade Representative, USTR Zoellick Says World Has Chosen Path of Hope, Openness, Development and Growth (Nov. 14, 2001).

Indeed, it could subvert the entire TRIPs Agreement.⁷⁵

Thus, there was certainly no common view among WTO Members that the Doha Declaration was, itself, doing anything more than clarifying what was already in the TRIPs Agreement. While the Doha Declaration also included an agreed future work plan for the WTO TRIPs Council (through paragraphs 6 and 7), those provisions do not “express an agreement between Members on the interpretation or application of a provision of WTO law,” and thus would not be considered a “subsequent agreement” within the meaning of Article 31(3)(a) the Vienna Convention.⁷⁶ To the extent other aspects of the Doha Declaration are considered a “subsequent agreement” with respect to the obligations in the TRIPs Agreement, it is one that simply confirms what could already be deduced from a proper interpretation of the treaty text, consistent with the rules of treaty interpretation in the Vienna Convention.

In the U.S. Government’s Special 301 Reports published subsequent to the Doha Declaration, through which the United States reviews on an annual basis the global state of IP protection and enforcement, the United States reasserts its continuing understanding that WTO Members are obligated to abide by the requirements in the TRIPs Agreement, including those regarding issuance of compulsory licenses (as modified by the August 2003 Decision and TRIPs Article 31*bis*). In 2011, for example, the United States clarified that it “respects its trading partners’ rights to grant compulsory licenses, *in a manner consistent with the provisions of the TRIPs Agreement*” and strongly supported the August 2003 Decision and Article 31*bis*.⁷⁷

In its 2018 Special 301 Report, the United States criticized several countries for overuse of compulsory licensing (or the threat thereof), and recalled the conditions for compulsory licensing required by the TRIPs Agreement:

[A]ctions by trading partners to unfairly issue, threaten to issue, or encourage others to issue, compulsory licenses raise serious concerns. Such actions can undermine a patent holder’s IP, reduce incentives to invest in research and development for new treatments and cures, unfairly shift the burden for funding such research and development to American patients and those in other markets that properly respect IP, and discourage the introduction of important new medicines into affected markets. To maintain the integrity and predictability of IP systems, governments should use compulsory licenses only in

⁷⁵ Press Release, United States Trade Representative, TRIPs and Health Emergencies, USTR Background Paper (Nov. 10, 2001).

⁷⁶ Panel Report, *Australia—Tobacco Plain Packaging*, *supra* note 62, ¶ 7.2409 (emphasis omitted) (quoting Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, *supra* note 64, ¶ 262).

⁷⁷ OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2011 SPECIAL 301 REPORT 13 (2011) (emphasis added).

extremely limited circumstances and after making every effort to obtain authorization from the patent owner on reasonable commercial terms and conditions. Such licenses should not be used as a tool to implement industrial policy, including providing advantages to domestic companies, or as undue leverage in pricing negotiations between governments and right holders.⁷⁸

Similarly, the European Commission's periodic Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries has highlighted the need for any compulsory licensing to be consistent with the TRIPS Agreement, pointing out concerns about Thailand's use of compulsory licenses for medicines.⁷⁹

III. IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION

On August 30, 2003—almost two years after adoption of the Doha Declaration, and in line with the instruction in Paragraph 6—the WTO General Council adopted the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.⁸⁰ Through this August 2003 Decision, WTO Members created a “waiver” to certain existing obligations under the TRIPS Agreement, removing the limitation on compulsory licensing for exports to countries that cannot manufacture the necessary pharmaceutical products themselves (subject to fulfilment of several conditions).⁸¹

Upon issuing the decision, the then-Chairperson of the WTO General Council, Carlos Pérez del Castillo, issued a separate statement that was, as summarized by the WTO Secretariat, “designed to provide comfort to those who feared that the decision might be abused and undermine patent

⁷⁸ OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2018 SPECIAL 301 REPORT 14 (2018); *see also* OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2019 SPECIAL 301 REPORT 14, 49-51, 60, 65, 76 (2019); OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2020 SPECIAL 301 REPORT 14, 48, 50, 52, 57, 62, 75 (2020).

⁷⁹ European Commission Staff Working Document, *Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries*, at 23 (July 1, 2015). Considering such statements by the United States and the European Union, together with the actions by the WTO Members being criticized, may demonstrate a lack of relevant “subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation” with respect to compulsory licensing, within the meaning of Article 31(3)(b) of the Vienna Convention.

⁸⁰ August 2003 Decision, *supra* note 5. *See* DANIEL J. GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS*, 134-40, (5th ed. 2021).

⁸¹ A “waiver” is a decision adopted by WTO Members to release all or some WTO Members from certain substantive WTO obligations which would otherwise apply, usually for a limited period of time and subject to certain conditions. The power to grant a waiver is vested in the Ministerial Conference of the WTO, and when the Ministerial Conference is not meeting, in the General Council of the WTO. *See* Marrakesh Agreement Establishing the World Trade Organization arts. IX:3, IX:4, IV:2, Apr. 15 1994, 1867 U.N.T.S. 154.

protection.”⁸² Mr. Pérez del Castillo characterized his statement about the August 2003 Decision as representing “several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented.”⁸³ Among those shared understandings, according to Mr. Castillo, was the following:

Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, *not be an instrument to pursue industrial or commercial policy objectives*.⁸⁴

In other words, the August 2003 Decision should not be used as a means to broadly limit patent protection (and the benefits that naturally flow from such protection), or of subverting the disciplines of the TRIPS Agreement, when evaluated in view of the object and purpose of the Agreement.

The August 2003 Decision refers to the powers of the Ministerial Conference under Article IX of the Marrakesh Agreement, and recalls the “instruction . . . contained in paragraph 6 of the [Doha] Declaration.”⁸⁵ It states that “exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products.”⁸⁶ The August 2003 Decision then releases Members from certain substantive obligations under those paragraphs, and sets forth the detailed conditions and safeguards with which actions benefitting from the waiver must comply.

With respect to the waiver of the requirement in Article 31(f) of the TRIPS Agreement, the August 2003 Decision provides for the ability of an exporting Member to grant a compulsory license “to the extent necessary for the purpose of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)” in accordance with the terms specified in the Decision.⁸⁷ Such terms require the eligible importing Member to (i) notify names and expected quantities of the products needed; (ii) confirm that the eligible importing Member has established insufficient or no manufacturing capacities for the product in question (or that it is an LDC), consistent with the Annex to the August 2003 Decision; and (iii) confirm that a compulsory

⁸² World Trade Organization, *The General Council Chairperson’s Statement*, WTO: 2003 NEWS ITEMS (Aug. 30, 2003), https://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm [hereinafter *The General Council Chairperson’s Statement*].

⁸³ *Id.*

⁸⁴ *Id.* (emphasis added).

⁸⁵ August 2003 Decision, *supra* note 5, at Preamble.

⁸⁶ *Id.* For purposes of the August 2003 Decision, a pharmaceutical product is defined as “any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.” *Id.* ¶ 1.

⁸⁷ *Id.* ¶ 2.

license has been granted where the product is patented in its territory.⁸⁸

Further, the compulsory license issued by the exporting Member must (i) be limited to the amount “necessary to meet the needs of the eligible importing Member(s)” and be for export to that Member; and (ii) be clearly identified as being produced under the scope of the August 2003 Decision through “specific labelling or marking,” and “special packaging and/or special colouring/shaping of the products themselves.”⁸⁹

As explained in the General Council Chairperson’s statement accompanying the August 2003 Decision, “Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision[s] are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision.”⁹⁰

In addition, the exporting Member must provide information about the compulsory license on a website, and shall notify the TRIPS Council of the details of the license.⁹¹

With respect to regional trade agreements (“RTAs”) in which at least half of the membership is made up of LDCs, paragraph 6 of the August 2003 Decision provides for a waiver of the obligations in Article 31(f) with respect to developing-country or LDC members of such RTAs “to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question.”⁹² To date, it does not appear that any country has taken advantage of this RTA-focused aspect of the August 2003 Decision (or of Article 31*bis* of the TRIPS Agreement).

Turning to the partial waiver of the requirement under TRIPS Article 31(h), the key point is that a patent holder need not be compensated by *both* the exporting and importing Members, even when they each issue a compulsory license on patents covering the product at issue. Pursuant to the August 2003 Decision, adequate remuneration must be paid only in the exporting Member, and in that case such remuneration shall take “into account the economic value to the importing Member of the use that has been authorized in the exporting Member.”⁹³ In other words, this aspect of the “waiver” applies only to the importing Member, as the right holder must still be compensated in the exporting Member.

As noted, the August 2003 Decision includes several provisions aimed at preventing trade diversion of the products exported pursuant to the system,

⁸⁸ *Id.* ¶ 2(a).

⁸⁹ *Id.* ¶ 2(b).

⁹⁰ The General Council Chairperson’s Statement, *supra* note 82.

⁹¹ August 2003 Decision, *supra* note 5, ¶ 2.

⁹² *See also* TRIPS Agreement, *supra* note 14, art. 31*bis*(3).

⁹³ August 2003 Decision, *supra* note 5, ¶ 3.

so that they ultimately are used by the people in the importing Member.⁹⁴

Two years later, on December 6, 2005, WTO Members agreed that the key aspects of the August 2003 Decision should be permanently incorporated into an amendment to the TRIPS Agreement, upon acceptance of two-thirds of WTO Members. While several developing country Members had proposed removing certain aspects of the August 2003 Decision from the TRIPS amendment, particularly those directed at preventing trade diversion and certain notification requirements, they did not succeed.⁹⁵ The amendment was formally accepted in January 2017, making permanent the flexibilities that had been first provided in August 2003, along with the associated safeguards and notification requirements.⁹⁶

The amendment is currently found at Article 31*bis* of the TRIPS Agreement, which also incorporated by reference an associated Annex and Appendix to the TRIPS Agreement. Pursuant to its own terms, the August 2003 Decision terminates “for each Member on the date on which an amendment to the TRIPS Agreement replacing its provision takes effect for that Member.”⁹⁷ According to the WTO Secretariat, the waiver provided pursuant to the August 2003 Decision remains in effect for the minority of WTO Members yet to accept Article 31*bis*.⁹⁸ As of September 1, 2020, Article 31*bis* applied to 131 WTO Members, with only 33 WTO Members not yet having accepted the amendment.⁹⁹

It is important to point out that WTO obligations are not self-executing in most domestic legal systems, and that Article 31*bis* (and the August 2003 Decision before it) provides only the *discretion* to establish a system that would enable compulsory licensing for export, in line with the conditions set out therein. Thus, WTO Members that intend to participate as exporters must amend their domestic law and/or regulations before making use of this class of compulsory license. Many countries have done so, with Norway and Canada being among the first to notify the WTO General Council that they had implemented the August 2003 Decision in their domestic legal systems.¹⁰⁰

⁹⁴ *Id.* ¶¶ 4-5.

⁹⁵ See GERVAIS, *supra* note 80, at 141.

⁹⁶ See WTO, *Amendment of the TRIPS Agreement*, https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited May 19, 2022). For details on the negotiations of the amendment, see GERVAIS, *supra* note 80, at 140-46.

⁹⁷ August 2013 Decision, *supra* note 5, ¶ 11.

⁹⁸ TRIPS and Public Health, WTO, https://www.wto.org/english/tratop_e/trips_e/pharmapatent_e.htm.

⁹⁹ Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Special Compulsory Licensing System, Report to the General Council*, ¶ 11, WTO Doc. IP/C/86 (Nov. 11, 2020) [hereinafter *2020 Annual Review of the Special Compulsory Licensing System*].

¹⁰⁰ See GERVAIS, *supra* note 80, at 140 (citing World Trade Organization, Communication from Norway, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/427 (Sept. 17, 2004)); *Annual Review of the Decision*

To be clear, implementing such domestic legislation was not required in order to sign onto the amendment to the TRIPS Agreement in the first place. The WTO Secretariat clarified the relationship between the Protocol amending the TRIPS Agreement and domestic law implementation, explaining as follows:

[I]f a Member does accept the Protocol, it does not assume any legal obligation to have in place or to put in place implementing legislation. Effectively, the step of accepting the Protocol means that a Member is confirming its agreement that other Members are entitled to use the System if they so wish. Of course, it is an important step to accept the Protocol, but essentially because it will mainly give other Members legal certainty and confidence to use the System. If they do choose to use the new flexibility to obtain affordable medicines, their access to medicines by these means will thus be on a legal parity with any other health-related flexibility in the TRIPS Agreement. Therefore, it is clear that many Members—in fact the overwhelming majority of acceptances of the Protocol from a wide range of legal, economic, geographic backgrounds—have accepted the Protocol without first putting implementing legislation in place.¹⁰¹

According to a WTO press release issued at the time that Article 31*bis* of the TRIPS Agreement entered into force (January 2017): “The bulk of global medicine exports is covered by laws enabling exports under this system, opening up new options for potential beneficiaries to access a wide range of potential suppliers and enabling new, innovative procurement strategies.”¹⁰²

As detailed further below in Section IV.B, Canada was the first country to take advantage of the August 2003 Decision, when it issued a compulsory license in 2007 for HIV/AIDS medicines for export to Rwanda.¹⁰³

It is important to note that a number of developed countries have formally notified the WTO that they will not use the system established by Article 31*bis* to import pharmaceutical products. This notification is recorded in the Annex to the TRIPS Agreement, and includes: Australia, Canada, the

on the Implementation of Paragraph 6, supra note 25, at 80-117 (including descriptions of implementation under domestic law by Canada, China, the European Union, Hong Kong (China), India, Korea, Switzerland, Croatia, Japan); *2020 Annual Review of the Special Compulsory Licensing System, supra* note 99, app. I, ¶ 8.

¹⁰¹ World Trade Organization, Report to the General Council, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, app. 1, ¶ 4, IP/C/72 (Nov. 9, 2015).

¹⁰² World Trade Organization, *WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines*, WTO: 2017 NEWS ITEMS (Jan. 23, 2017), https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm.

¹⁰³ See World Trade Organization, *Canada is First to Notify Compulsory License to Export Generic Drug*, WTO: 2007 NEWS ITEMS (Oct. 4, 2007), https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm.

European Union (including its member States), Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.¹⁰⁴ Other countries have stated that they would use the system as importers only in cases of national emergency or other circumstances of extreme urgency, namely Hong Kong, China; Israel; Korea; Kuwait; Macao; China; Mexico; Qatar; Singapore; the Separate Customs Territory of Taiwan, Penghu, Kinmen, and Matsu; Turkey; and the United Arab Emirates.¹⁰⁵

IV. USE OF TRIPS AGREEMENT “FLEXIBILITIES,” AS EXPANDED PURSUANT TO THE DOHA DECLARATION, TO ISSUE COMPULSORY LICENSES, AND IMPLICATIONS THEREOF

This section examines the recent use of the “flexibility” in the TRIPS Agreement to issue compulsory licenses on patents covering biopharmaceutical products—including the expanded flexibility established in line with Paragraph 6 of the Doha Declaration—and the implications of such use. As a preliminary matter, subsection A explains why the Doha Declaration, followed by the amendment to the TRIPS Agreement, demonstrates the finite and limited nature of establishing exceptions to WTO agreements, and the formal process that is required for an amendment. Subsection B reviews the efforts to compulsory license patents for export pursuant to the August 2003 Decision and Article 31*bis* of the TRIPS Agreement, and the perceptions of these efforts as expressed by WTO Members. Subsection C then briefly looks at the role and impact of compulsory licensing, more generally (beyond compulsory licensing under the Article 31*bis* system), focusing on the experiences and lessons learned over the twenty years since adoption of the Doha Declaration.

A. *Limited and Finite Nature of Exceptions*

As explained above, the TRIPS Agreement reflects a careful balance that protects both IP rights and other public policy objectives. An integral component of maintaining this balance is the existence of exceptions and flexibilities within the TRIPS Agreement. Each of the existing exceptions was the result of extensive negotiation, and is accommodated in specific treaty language.

Presently, there is a tendency among certain academics and NGOs to simply imagine exceptions into existence. Where they would like the balance in the TRIPS Agreement to be different from the one actually negotiated by the WTO Members, they simply argue that an exception exists, without identifying the exception in the treaty text. For example, as noted above, a South Centre Policy Brief has stated that, in view of the Doha Declaration (which did not, itself, amend the TRIPS Agreement), “any measure that is

¹⁰⁴ World Trade Organization, *Annex to the TRIPS Agreement*, n.3 (2018).

¹⁰⁵ GERVAIS, *supra* note 80, at 134.

necessary to protect public health cannot be held to violate the provisions of TRIPS.”¹⁰⁶ In extreme cases, some even argue that exceptions of their choice exist simply because “the TRIPS Agreement remains silent” on the lack of such an exception.¹⁰⁷

As Solovy and Raju explain:

If silences in the TRIPS Agreement were to be interpreted as providing for exceptions, one could invent any number of exceptions, and bring down the entire TRIPS Agreement with those exceptions. For example, are the general exceptions in Article XX of the General Agreement on Tariff and Trade 1994 (“GATT 1994”) applicable to the TRIPS Agreement, despite that exception describing its scope as “this agreement” (i.e., the GATT 1994), and the TRIPS Agreement not having an analogue? Is there an exception permitting the denial of patents when applications are filed on a rainy day? Is there an exception to protection of undisclosed information where the lawful owner of that information is a person with blond hair? If one fills the silences with exceptions, one could simply keep going, and rewrite the entirety of the TRIPS Agreement to ridiculous effect.¹⁰⁸

The process followed in the Doha Declaration, and in the subsequent August 2003 Decision and the amendment to the TRIPS Agreement, exposes the fallacy in imagining exceptions into existence. If the TRIPS Agreement were full of infinite exceptions which could fill the silences, there would have been no need for an amendment. However, when the Members saw the need to alter the existing balance in the TRIPS Agreement to create a new exception, they found it necessary to do so through a process of negotiation, and then by the formal process set out in the Marrakesh Agreement for amendments to the WTO agreements. This underscores that the exceptions in the TRIPS Agreement (as in all WTO agreements, and indeed, in all treaties) are limited and finite, and the power to create new exceptions lies solely with WTO Members, and not in individual academic or NGO imaginations.

B. Compulsory Licensing Pursuant to TRIPS Article 31bis and the August 2003 Decision

While a number of WTO Members, academics, and NGOs have argued that the limited use of the system established by Article 31bis and the August 2003 Decision demonstrates the need for *additional flexibilities* to the TRIPS Agreement, there is no basis for such an assertion.

¹⁰⁶ SOUTH CENTRE POLICY BRIEF NO. 7, *supra* note 24, at 4.

¹⁰⁷ Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines Via Involuntary Technology Transfer*, 16 J. OF INTELL. PROP. L. & PRAC. 1242, 1251 (2021).

¹⁰⁸ Eric M. Solovy & Deepak Raju, *Compulsory Licensing of Trade Secrets: Illegality Under International and Domestic Laws*, 55 INT’L LAWYER (forthcoming 2022).

Instead, limited use of the system may constitute evidence that compulsory licensing of any kind is often a deeply flawed means to the critically important end of increasing access to medicines, even if such licenses are issued in accordance with the TRIPS Agreement. As the Swiss Government correctly pointed out in an annual review of implementation of Paragraph 6 of the Doha Declaration:

compulsory licences are as such not an easy and quick-fix solution to address the broader problem of sustainable access to affordable medicines—whether in developing countries or any other WTO Member. Implementing a compulsory licence, and again I refer to normal or special compulsory licences even once granted, pose their own challenges. A generic manufacturer needs to be found who is ready, willing and available to produce the medicine needed and the quantities needed within a short time-period at an affordable and competitive price and at the required quality and safety standards. This demonstrates that a compulsory licence is never a quick-fix solution and this cannot be remedied by the Paragraph 6 System or by revising it for that matter.¹⁰⁹

This section considers the practical experience with the system created by the August 2003 Decision (and continued with TRIPS Article 31*bis*) (subsection 1); the positions expressed by WTO Members about this experience (subsection 2); and the overall impact of compulsory licensing, generally (subsection 3).

1. Practical Experience with the System

As noted above, in 2007, Canada was the first country to take advantage of compulsory licensing for export as inspired by Paragraph 6 of the Doha Declaration when it issued a compulsory license for HIV/AIDS medicines for export to Rwanda.¹¹⁰ Canada had also been one of the first countries to implement into domestic law the type of system set out in the August 2003 Decision, through its Access to Medicines Regime (CAMR) in 2005.¹¹¹ Pursuant to CAMR, drugs that are produced under compulsory license for export must appropriately meet the same safety, efficacy and quality standards as any drug sold in Canada's domestic market.¹¹²

The process that led to the first (and, so far, only) use of the system began on July 17, 2007, when Rwanda notified the WTO TRIPS Council of

¹⁰⁹ Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, app. 1, ¶ 64, WTO Doc. IP/C/76 (Nov. 23, 2016).

¹¹⁰ See *Canada is First to Notify Compulsory License to Export Generic Drug*, WTO (Oct. 4, 2007), https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm.

¹¹¹ *Annual Review of the Decision on the Implementation of Paragraph 6*, *supra* note 25, ¶ 7.

¹¹² *Id.* ¶ 70.

its intention to import 260,000 packs of HIV/AIDS medicine (TriAvir) made by Apotex, a Canadian company.¹¹³ Two months later, on September 19, 2007, Canada granted an authorization to Apotex to manufacture for and export that drug to Rwanda under a compulsory license (only 15 days after receiving the application from Apotex).¹¹⁴ Canada formally notified the TRIPS Council of this compulsory license on October 4, 2007.¹¹⁵ The medicines (over 14 million tablets) were ultimately shipped to Rwanda in September 2008 and 2009.¹¹⁶ Beall et al. found that use of the process set out in the August 2003 Decision by Canada and Rwanda was ultimately of “negligible benefit” because Rwanda was able to purchase the same drug contemporaneously from Indian companies for almost the same price (US\$0.198-US\$0.210 per unit compared to US\$0.195 per unit from Apotex).¹¹⁷ In that case, according to Beall et al., “Apotex’s compulsory licensing pricing struggled to catch up with international procurement pricing, not the other way around.”¹¹⁸

More recently in the midst of the COVID-19 pandemic, in February 2021, Bolivia notified the TRIPS Council of its intention to make use of Article 31*bis* of the TRIPS Agreement as an importer.¹¹⁹ Bolivia clarified in May 2021, that it intends to import an estimated 15 million COVID-19 vaccines pursuant to Article 31*bis*.¹²⁰ Antigua and Barbuda followed suit in May 2021, also notifying the intention to use the system as an importer.¹²¹

¹¹³ Council for Trade-Related Aspects of Intellectual Property Rights, *Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/N/9/RWA/1 (July 19, 2007).

¹¹⁴ *Annual Review of the Decision on the Implementation of Paragraph 6*, *supra* note 25, ¶ 11.

¹¹⁵ Council for Trade-Related Aspects of Intellectual Property Rights, *Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/N/10/CAN/1 (Oct. 8, 2007).

¹¹⁶ *Annual Review of the Decision on the Implementation of Paragraph 6*, *supra* note 25, ¶¶ 7, 12.

¹¹⁷ Reed F. Beall, Randall Kuhn & Amir Attaran, *Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement*, 34 HEALTH AFFAIRS 493, 499 (2015).

¹¹⁸ *Id.*

¹¹⁹ Council for Trade-Related Aspects of Intellectual Property Rights, *Notification Under the Amended TRIPS Agreement, Notification of Intention to Use the Special Compulsory Licensing System as an Importing Member*, WTO Doc. IP/N/8/BOL/1 (Feb. 19, 2021).

¹²⁰ Council for Trade-Related Aspects of Intellectual Property Rights, *Bolivia’s Notification of Need to Import Pharmaceutical Products Under the Special Compulsory Licensing System*, WTO Doc. IP/N/9/BOL/1 (May 11, 2021); *Bolivia Outlines Vaccine Import Needs in Use of WTO Flexibilities to Tackle Pandemic*, WTO: 2021 NEWS ITEMS (May 12, 2021), https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm.

¹²¹ Council for Trade-Related Aspects of Intellectual Property Rights, *Antigua and Barbuda Notification of Intention to Use the Special Compulsory Licensing System as an Importing Member*, WTO Doc. IP/N/8/ATG/1 (May 12, 2021).

To date, no country has notified an intention to make use of Article 31*bis* to export to those Members, although there have been press reports indicating that Bolivia hopes to import from Canada.¹²²

The WTO Secretariat has pointed out that a notification “does not mean a commitment to procure medicines under this System” such that a Member may later opt to procure medicines through other means.¹²³ Indeed, given the fact that Bolivia and Antigua and Barbuda have ramped up their COVID-19 vaccinations throughout 2021 and 2022, they may ultimately determine that their needs can be fulfilled through voluntary arrangements. In particular, as of mid-July 2022, Bolivia has reportedly provided at least first doses to 63 percent of its population, while Antigua and Barbuda has provided at least first doses to 66 percent of its population.¹²⁴

2. WTO Members’ Review of the System

Pursuant to the August 2003 Decision (and in line with the general requirement in Article IX:4 of the Marrakesh Agreement for waivers), the TRIPS Council has been required to annually review and report on “the functioning of the System” set out in that decision.¹²⁵ These reports provide useful insight into the functioning of the Paragraph 6 System, and the WTO Members’ views.

During the 2010 review meeting, for example, Canada asserted (as summarized in the official report) that its use of the system to export HIV antiretroviral drugs to Rwanda “clearly showed that Canada’s regime and the System [set out in the August 2003 Decision] were efficient, effective and timely.”¹²⁶ In contrast, a number of WTO Members, including India, Indonesia, Egypt and Venezuela, have criticized the System, pointing to the fact that it has been used only once, and blaming the limited use on inter alia, the anti-diversion and notification requirements.¹²⁷

As stated by Abbott & Reichman, “there remains a widely held belief” that there has been insufficient use of the System “[d]espite the carefully

¹²² See *Canadian Company Wins COVID-19 Vaccine Deal With Bolivia—and WTO Support*, THE GLOBE AND MAIL (May 11, 2021), <https://www.theglobeandmail.com/world/article-canadian-company-wins-covid-19-vaccine-deal-with-bolivia-and-wto>.

¹²³ *2020 Annual Review of the Special Compulsory Licensing System*, *supra* note 99, app. I, ¶ 11; see also *id.* at 13.

¹²⁴ *Tracking Coronavirus Vaccinations Around the World*, Josh Holder, N.Y. TIMES (July 17, 2022), <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> (last visited July 17, 2022) (compiling data from Our World in Data project at the University of Oxford, and reporting Antigua and Barbuda with 66 percent vaccinated (defined to include at least one dose) and 64 percent fully vaccinated; and Bolivia with 63 percent vaccinated and 52 percent fully vaccinated).

¹²⁵ August 2003 Decision, *supra* note 5, ¶ 8.

¹²⁶ *Annual Review of the Decision on the Implementation of Paragraph 6*, *supra* note 25, Annex ¶ 7.

¹²⁷ *Id.* at Annex, ¶¶ 16-17 (India), 27 & 63 (Egypt), 32 (Indonesia), 62 (Venezuela).

elaborated terms of Article 31*bis*, or perhaps because of them.”¹²⁸ In 2012, Bhattacharya characterized the obstacles to use as the “formalistic nature and built-in administrative roadblocks” of the August 2003 Decision, as well as the concern by countries (and companies) about investing “scarce and lumpy resources under the additional flexibility due to lack of certainty about its continuation.”¹²⁹ With the adoption of Article 31*bis*, however, the latter concern no longer has any basis.

With respect to the anti-diversion and notification requirements, they are an integral part of the mechanism created by Article 31*bis* (and the August 2003 Decision before it), and indispensable for the achievement of its objectives.¹³⁰ When pharmaceutical products are manufactured pursuant to a compulsory license, with the express purpose that they provide further access to medicines in one or more particular countries which most need them, it is imperative to have safeguards to ensure that the products actually reach their target destinations, and are not diverted to the most profitable markets. Thus, the anti-diversion safeguards not only protect right holders that have IP rights in the markets to which the products may be diverted, but are also essential to furthering the objective of increasing access to medicines. Moreover, those who argue that the anti-diversion and notification requirements are burdensome ignore the reality that mechanisms to track origin and destination of goods, and the requirement that certain trade actions be notified, are already regular features of international trade, including various WTO agreements.¹³¹ Further, the WTO Secretariat has

¹²⁸ Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. OF INT’L ECON. L., 535, 552 (2020). Abbott and Reichman, themselves, have stated that “this belief in excessive complexity of the Article 31*bis* system is not well founded.” *Id.* (citing Frederick M. Abbott & Jerome H. Reichman, *The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. OF INT’L ECON. L. 921, 927-29 (2007)).

¹²⁹ Alexandra Bhattacharya, *The Use of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2001): A Review of Implementation Experiences in the Developing Countries*, 13 J. OF WORLD INV. & TRADE 186, 190 (2012).

¹³⁰ Trilateral Study, *supra* note 21, at 304-09 (providing a summary of the anti-diversion and notification requirements).

¹³¹ For example, the Generalized System of Preferences, maintained by Armenia, Australia, Belarus, Canada, the European Union, Iceland, Japan, Kazakhstan, New Zealand, Norway, the Russian Federation, Switzerland, Turkey, United Kingdom and the United States, granting LDCs preferential treatment in trade of goods requires that the origin of goods benefiting from the preference be evidenced through a “GSP Certificate of Origin.” This requirement, which is necessary to track the origin of goods and the destination in which they would enjoy the preference, has not prevented LDCs from benefiting from the GSP. *See Generalized System of Preferences*, UNCTAD, <https://unctad.org/topic/trade-agreements/generalized-system-of-preferences>. Rather than being dissuaded by this origin-tracking requirement, “[i]n 2019, products valued at about \$21.0 billion (imports for consumption) entered the United States duty-free under the program.” *See Vivian C. Johnes & Liana Wong*, CONG. RSCH. SERV., RL33663, GENERALIZED SYSTEM OF PREFERENCES (GSP): OVERVIEW AND ISSUES FOR CONGRESS 1, <https://sgp.fas.org/crs/misc/RL33663.pdf> (last updated Jan. 7, 2021).

been available to provide technical assistance relating to the effective use of the system.¹³²

In light of criticisms largely targeted at the anti-diversion and notification requirements, a number of WTO Members have strongly defended the system and provided alternative explanations for the limited use of the Article 31*bis* mechanism.

For example, in a 2011 intervention, the European Union expressed its strong disagreement with Members asserting that the limited use of the flexibility provided by the August 2003 Decision demonstrated that there were legal, procedural, commercial and other obstacles that were difficult to overcome.¹³³ The European Union set out several reasons that it believed could explain the limited use, namely (1) the vast majority of essential medicines are already in the public domain (i.e., not patented); (2) LDCs are still enjoying an extended transition period, such that they are not obligated to protect patents on pharmaceutical products; and (3) developing countries can acquire medicines through voluntary licenses or other means consistent with the TRIPS Agreement that do not require recourse to the system.¹³⁴

In also defending the system (and its limited use), Canada's representative to the TRIPS Council explained that a regime established to implement the August 2003 Decision:

could only assist in supplying low-cost drugs if a demand was notified to the WTO by an eligible importing Member for generic drug(s) that required use of the System. This was a demand-driven process by countries in need . . . He noted that, since the adoption of the Decision in 2003, many options had become available to importing countries. The international environment for procurement of drugs had changed significantly with the introduction of a variety of global mechanisms and alliances which offered greater choice to countries to obtain medicines. The role and effectiveness as well as the potential for broader use of the Waiver needed to be understood in this broad global

Similarly, several free trade agreements ("FTAs") require that the origin of goods be evidenced to benefit from the terms of the FTA. As for notification requirements, various WTO agreements require several forms of trade measures to be notified. These include: subsidies (GATT 1994, Article XVI:1), certain measures on agricultural products (Agreement on Agriculture, Article 18.2, 18.3), sanitary and phytosanitary measures (Agreement on Sanitary and Phytosanitary Measures, Article 7), technical regulations (Agreement on Technical Barriers to Trade, Articles 2.9.2, 2.10.1, 3.2), trade related investment measures (Agreement on Trade Related Investment Measures, Article 5), anti-dumping measures (Anti-dumping Agreement, Article 16.4), and safeguard measures (Agreement on Safeguards, Article 12).

¹³² 2020 *Annual Review of the Special Compulsory Licensing System*, *supra* note 99, ¶ 16.

¹³³ Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 64, WTO Doc. IP/C/61 (Nov. 18, 2011).

¹³⁴ *Id.* ¶ 65.

context.

. . . [T]he System had never been intended to solve the issue of access to medicines on its own, but was seen as part of a broader international strategy to combat diseases impacting the developing world. The System and CAMR functioned well. They played a supporting role and were not a panacea to the challenges faced on global access to medicines and were not designed to generate global supply.¹³⁵

The Swiss representative added that the countries criticizing the effectiveness of the August 2003 Decision may be misconstruing Paragraph 6 of the Doha Declaration, pointing out that the mandate “had not, and could not possibly have been, to solve the problem of affordable access to medicines for the poor in developing countries through such a solution, although some Members seemed to expect the System to achieve exactly that goal and measured its success by this standard.”¹³⁶ Switzerland has, in recent communications, emphasized that Article 31*bis* “has not been conceived for frequent use” but rather “applies to eligible beneficiary countries, in a specific case scenario and under particular circumstances.”¹³⁷ Switzerland has criticized as “misleading” any implication that “many casualties that today still—and tragically enough—result from insufficient and untimely access to medicines would be the result of IP or perceived deficiencies in the system provided by Art. 31*bis*.”¹³⁸

The United States has likewise emphasized that the Paragraph 6 system was “only one tool for addressing the larger issue of access to medicines,” and that this issue must also be addressed by a variety of other means; in that context, the United States emphasized that it had “been supporting the innovation and intellectual property protection that was vital to developing new medicines and achieving other medical breakthroughs.”¹³⁹

C. *Impact of Compulsory Licensing*

Despite studies finding that, in recent years, approximately 95 percent (or greater) of essential medicines were not protected by patents,¹⁴⁰ those that

¹³⁵ *Id.* ¶¶ 14-15.

¹³⁶ *Id.* ¶ 59.

¹³⁷ 2020 *Annual Review of the Special Compulsory Licensing System*, *supra* note 99, at app. I, ¶ 73.

¹³⁸ *Id.*

¹³⁹ Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 133, ¶ 65.

¹⁴⁰ *See, e.g.*, Reed F. Beall, *Patents and the WHO Model List of Essential Medicines (18th ed.): Clarifying the Debate on IP and Access*, WIPO GLOBAL CHALLENGES BRIEF 2 (“Of the 375 items on the 2013 WHO MLEM, 95% are off-patent, meaning that these medicines patents’ have expired and that generic equivalents are likely available. This result is consistent with previous studies, as the percentage of off-patent MLEM products has regularly been above 90%. Attaran found that 94% (300 of 319) of the 2003 MLEM items were likely to be

contend that IP rights are the greatest global barrier to access to medicines continue to place blame on the existence of patents and call for, inter alia, increased compulsory licensing.

Specifically, a WIPO-sponsored report authored by Beall and Attaran concluded in 2016 that, of the 375 medicines on the World Health Organization's Model List of Essential Medicines (MLEM), as of 2013, only seven were covered by patents on active compounds.¹⁴¹ This amounted to patents on just two percent of the MLEM medicines, which represented a decline since similar analyses were performed in 2004 and 2009.¹⁴²

With the MLEM expanding to include more treatments for non-communicable diseases, such as cancer, the number of patented medicines included on that list may ultimately increase. That said, according to Beall and Attaran, this will provide: "more opportunities to choose new collaborations over conflict (whether in the form of licensing agreements or more creative solutions not yet envisaged) and to avoid repeating past friction between advocates for essential medicines access and advocates for patent protection during the HIV/AIDS crisis."¹⁴³

Because there are so many barriers to access to pharmaceutical products that have nothing to do with IP rights, as discussed in Section V.B, below, it is not surprising that those countries that have issued compulsory licenses in line with their understanding of the metes and bounds of the TRIPS Agreement (whether or not that understanding was correct) have *not* found compulsory licensing to be the silver bullet for their problems. Further, empirical data collected on the impact of compulsory licensing demonstrate that compulsory licensing may, in fact, have the *opposite of the intended effect* on prices of medicines, relative to other possible options.

To wit, a 2015 study by Beall, Kuhn, and Attaran reported as follows:

Thirty compulsory license cases were analyzed with 673 comparable procurements from WHO and Global Fund data. *Compulsory license prices exceeded the median international procurement prices in nineteen of the thirty case studies*, often with a price gap of more than 25 percent. Compulsory licensing often delivered suboptimal value when compared to the alternative of international procurement,

off-patent, and Kowalski and Cavicchi found that 95% (333 of 350) were when using the 2009 MLEM. Our preliminary assessment of the recently published 2015 MLEM has this number at 92% (375 of 409).") (footnotes omitted); D. Wayne Taylor, *Pharmaceutical Access in Least Developed Countries: On-the-Ground Barriers and Industry Successes*, CAMERON INSTITUTE 5 (2010) ("WHO's list of essential medicines is comprised of over 95% off-patent products—the remainder being primarily second-line anti-AIDS medicines.").

¹⁴¹ Reed Beall & Amir Attaran, *Global Challenges Report: Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines* 25, WIPO (2016).

¹⁴² *Id.*

¹⁴³ *Id.* at 26.

especially when used by low-income countries to manufacture medicines locally. There is an ongoing need for multilateral and charitable actors to work collectively with governments and medicine suppliers on policy options.¹⁴⁴

Further, Beall, Kuhn, and Attaran explain that voluntary licenses provide a more successful route to increasing access to drugs at reasonable prices in developing countries; they point, by way of example, to Gilead's decision to grant Indian generic firms the right to manufacture and export generic versions of sofosbuvir and ledipasvir for hepatitis C to 91 countries, in exchange for a modest royalty.¹⁴⁵

Nevertheless, those who generally disfavor patents on pharmaceutical products persist in touting the benefits of compulsory licensing, and in advocating for other ways to limit IP protection on pharmaceutical products. In a recent South Centre policy brief, Gurgula asserts that “[t]here is no doubt that compulsory licensing can be an effective tool in facilitating access to affordable medicines, as can be evidenced by its use in relation to life-saving drugs by several countries in the past.”¹⁴⁶ In support, Gurgula refers only to a “TRIPS Flexibilities Database” published by the “Medicines Law & Policy” NGO (which, itself, advocates for expanded use of the flexibilities in the TRIPS Agreement).¹⁴⁷ While this database claims to list instances where countries have granted compulsory licenses, there is nothing in this database that “evidence[s]” (to use Gurgula’s term) that they were an “effective tool in facilitating access to affordable medicines” beyond what could have been accomplished through voluntary arrangements. Nor does Gurgula consider whether, in the long term, those compulsory licenses may have *negatively* impacted the pace of innovation or the willingness of companies to invest in, or share technology with, the countries that issued these licenses. Such factors must be part of any analysis of whether, particularly in the long term, compulsory licensing is an “effective tool in facilitating access to affordable medicines.”

Fundamentally, when a WTO Member abuses its power to compulsory license, or to threaten to issue compulsory licenses, such abuse serves to lower the overall credibility of that country’s patent system, and the incentives to develop new technologies that its system may create. This has long-term implications for access to medicines, and goes against the balance that the TRIPS Agreement intends to achieve, in line with the object and

¹⁴⁴ Reed F. Beall, Randall Kuhn & Amir Attaran, *supra* note 117, at 493 (Abstract) (emphasis added).

¹⁴⁵ *Id.* at 499.

¹⁴⁶ OLGA GURGULA, SOUTH CENTRE POLICY BRIEF NO. 104, COMPULSORY LICENSING VS. THE IP WAIVER: WHAT IS THE BEST WAY TO END THE COVID-19 PANDEMIC? 2 (2021), https://www.southcentre.int/wp-content/uploads/2021/10/PB104_Compulsory-licensing-vs.-the-IP-waiver_EN-2.pdf.

¹⁴⁷ Medicines Law & Policy, *TRIPS Flexibilities Database*, <http://tripsflexibilities.medicineslawandpolicy.org/>.

purpose set out in Articles 7 and 8 thereof. Indeed, several studies have found that patent protection in developing countries—rather than robust use of “flexibilities” that reduce or eliminate such protection—improves the availability of medicines in the long term.¹⁴⁸

Thus, compulsory licensing does not appear to be either an effective or sustainable manner to improve access to medicines, and in the long term would be expected to backfire by reducing incentives for innovation for new technologies that could improve public health. While the TRIPS Agreement makes them a viable option, WTO Members must carefully weigh the costs and benefits (both short-term and long-term) before deciding whether to exercise that option.

V. LESSONS LEARNED FROM THE DOHA DECLARATION, AND RELEVANCE TO THE DEBATE OVER PROTECTION OF IP RIGHTS COVERING COVID-19 VACCINES AND THERAPEUTICS

In the 2021 version of the Trilateral Study (as updated to cover issues related to the COVID-19 pandemic), the WTO, WIPO and WHO begin their joint report’s discussion of IP rights as they should—by focusing on the critical role of IP in innovation: “The global IP system provides an incentive framework in which urgently needed innovation in relation to COVID-19 can

¹⁴⁸ Cockburn, Lanjouw, and Schankerman conducted a study that found as follows:

Using new data on launches of 642 new molecules in 76 countries during 1983-2002, we show that, all else equal, *longer and more extensive patent protection accelerated diffusion*, while price regulation strongly delayed it. Health policy institutions, and economic factors that make markets more profitable, also sped up diffusion. These results hold *both for developing countries and high income countries*, and the results are robust to using instrumental variables to address the endogeneity of policy regimes.

Iain M. Cockburn, Jean O. Lanjouw & Mark Schankerman, *Patents and the Global Diffusion of New Drugs* 25 (Nat’l Bureau of Econ. Res. Working Paper No. 20492, 2014) (emphasis added). In considering whether a given country had strong patent protection, the study took into account, among other factors, the use of compulsory licenses. *See id.* at 33-34. *See also* Joan-Ramon Borrell, *Patents and the Faster Introduction of New Drugs in Developing Countries*, 12 *Applied Econ. Letters* 379, 379 (2005) (“This paper uses sales data on HIV/AIDS drugs in a sample of 34 low and middle-income countries between 1995 and 1999. It estimates a reduced-form probit model to assess empirically the impact of market exclusivity on introduction of new drug therapy. The main finding is that the *patent regime had a positive effect on the introduction of new HIV/AIDS drugs* in the subset of countries of the sample used with relatively equally distributed incomes.” (emphasis added)); Ernst R. Berndt & Iain M. Cockburn, *The Hidden Cost of Low Prices: Limited Access to New Drugs in India*, 33 *HEALTH AFF.* 1567 (2014) (“Launch lags could be reduced by implementing policies that encourage innovator companies to bring new products to the Indian market. These policies include bringing India’s patent law into closer conformity with laws in the United States and the European Union and delaying the onset of generic competition through regulatory means. Such changes would promote faster access to a wider range of new drugs for residents of India without affecting the pricing of currently available drugs, and there is little evidence that they would result in substantially higher prices for new drugs than can be expected under the current regime.”).

be encouraged. It covers the stages from invention to supply of a product or service.”¹⁴⁹ The Trilateral Study then turns its attention to the “flexibilities” that are “built into the international IP regime,” and how they can be used to promote access to those COVID-19-related innovations.¹⁵⁰ Among the flexibilities covered in the report is compulsory licensing (both pursuant to Article 31 as well as the Article 31*bis* system).¹⁵¹ As a matter of public policy, the 2021 Trilateral Study notes that several countries (i.e., Israel, Hungary, and Russia) have already issued compulsory licenses on COVID-19 treatments (without adjudging the TRIPS consistency of such actions).¹⁵² The study further recalls the notifications made by Bolivia in early 2021, as well as by Antigua and Bermuda, of an intent to import vaccines pursuant to Article 31*bis*.¹⁵³

The Trilateral Study also describes the use of “voluntary actions and initiatives” to further promote access to innovations needed to slow or end the COVID-19 pandemic, including voluntary actions to license vaccine technology globally, such as licenses from developed-country innovators to developing-country manufacturers.¹⁵⁴ The Study references, among other organizations and collaborations, the Coalition of Epidemic Preparedness Innovations (CEPI), which provides funding for the development of new vaccines in return for a commitment by innovators to provide “equitable access to any vaccine developed through its funding,” and to transfer technology to enable production by a global network of manufacturers.¹⁵⁵

With these COVID-19-related observations from the 2021 Trilateral Study in mind, the subsections that follow consider how the lessons learned since adoption of the Doha Declaration are relevant for understanding the market developments and policy debates related to the creation of, and access to, COVID-19 vaccines and treatments. In particular, Section A considers the benefits enjoyed as a result of the innovation supported, incentivized and licensed as a consequence of strong global IP protection, as reaffirmed by the Doha Declaration. Indeed, hundreds of partnerships and collaborations among manufacturers around the world have resulted in the provision of more than 12 billion doses of COVID-19 vaccines around the globe by mid-July 2022.¹⁵⁶ Section B highlights the barriers to access to COVID-19

¹⁴⁹ Trilateral Study, *supra* note 21, at 9.

¹⁵⁰ *Id.* at 21.

¹⁵¹ WTO, WIPO & WHO, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION UPDATED EXTRACT: INTEGRATED HEALTH, TRADE AND IP APPROACH TO RESPOND TO THE COVID-19 PANDEMIC, 30 AUGUST 2021 8-9 (2d ed., 2021), https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2021_e.pdf [hereinafter 2021 Updated Trilateral Study].

¹⁵² *Id.* at 8.

¹⁵³ *Id.* at 9.

¹⁵⁴ *Id.* at 10.

¹⁵⁵ *Id.* at 12.

¹⁵⁶ *More than 12.2 Billion Shots Given: COVID-19 Tracker*, BLOOMBERG, <https://www.>

therapeutics and vaccines that are not related to IP rights, but which were already recognized at the time of adoption of the Doha Declaration. Such barriers are often obscured during policy debates over IP rights. Section C then considers a misguided proposal by several academics to establish a global mass compulsory licensing mechanism covering all COVID-19-related technologies and related clinical test data.

A. Benefits During a Global Pandemic of Innovation and Collaboration Incentivized and Protected by IP Rights

Despite exhibiting numerous flaws in its discussion of the TRIPS Agreement and its “flexibilities,”¹⁵⁷ the Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines acknowledged in 2016 how far the world has come in terms of the availability of new medicines and vaccines, stating as follows:

Never in the past has our knowledge of science been so profound and the possibilities to treat all manner of diseases so great. Many sources of transmissible and non-transmissible diseases have been identified, and therefore prevention, including the fight against bacteria, viruses and parasites, has improved dramatically. New generations of medicines and their combinations are treating patients whose prognosis some years ago would have been fatal. . . . Progress in fundamental research is nourishing an exceptional phase of development of medicines, vaccines, diagnostics and medical devices.¹⁵⁸

The successful development of the COVID-19 vaccines (with more still being developed) is indeed a tribute to strong IP protection and the incentives that it creates in the WTO Members where those vaccines—which have saved millions of lives around the world—are being developed and manufactured.

After having first been discovered by French scientists in 1961, many years of research led to a realization that therapeutic use of mRNA technology would require overcoming difficult obstacles.¹⁵⁹ Researchers around the world worked to further understand and develop the mRNA technology, and protected their innovations with patents and trade secrets,

[bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/](https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/) (last visited July 17, 2022)

¹⁵⁷ See generally Solovy & Krishnamurthy, *supra* note 19.

¹⁵⁸ UN SECRETARY-GENERAL & CO-CHAIRS OF THE HIGH-LEVEL PANEL, REPORT OF THE UNITED NATIONS SECRETARY-GENERAL’S HIGH-LEVEL PANEL ON ACCESS TO MEDICINE: PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES 3 (2016), <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

¹⁵⁹ See JENNIFER BRANT & MARK F. SCHULTZ, UNPRECEDENTED: THE RAPID INNOVATION RESPONSE TO COVID-19 AND THE ROLE OF INTELLECTUAL PROPERTY 20 (2021).

including patents that have now been licensed to the companies that are producing and distributing billions of doses of their COVID-19 vaccines.¹⁶⁰ According to the Head of Patents at Merck KGaA, “IP enabled the early discussions for COVID-19 collaborations and exchanges.”¹⁶¹ The availability of IP protection also provided the incentives necessary to raise the private funds that moved the mRNA research from the laboratory to clinical application, even though such technology had never before led to a commercially successful product of any kind.

While the U.S. Government, through Operation Warp Speed, provided additional funding for design, testing and ultimately delivery of Moderna’s COVID-19 vaccine, such support came only *after* Moderna had been able to convince private funders that it could take an untested technology and bring it to market.¹⁶² Indeed, before going public in 2018, Moderna had raised over \$2 billion in investments and partnership funding, along with \$600 million for an IPO.¹⁶³ At the time of its IPO, Moderna was spending hundreds of millions of dollars a year, reporting in September 2018 that it “had an accumulated deficit of \$865.2 million.”¹⁶⁴ At that time, financial reporters noted that “[l]osses may never be recouped, as the company is years away from actual product sales.”¹⁶⁵ While the investment in Moderna turned out to be a great success, both for investors and for the world, other investments in related technology were not so successful. For example, Merck & Co. and CureVac each failed in their robust and costly attempts to create a COVID-19 vaccine.¹⁶⁶ This provides a helpful reminder that the incentives for innovation and investment fueled by IP protection must be sufficient to overcome the disincentives that arise from the very real possibility of failure, which can occur at any stage of development, testing, or commercialization.

As reported by the *New York Times*, in 2018, Dr. Ugur Sahin, the co-founder of BioNTech, predicted that his company might be able to use mRNA technology to quickly develop a vaccine in the event of a global pandemic.¹⁶⁷ Dr. Sahin and his wife, Dr. Tureci, had been working on mRNA technology for more than 25 years, without any successful commercial applications.¹⁶⁸ As of 2018, BioNTech had been investing time and money

¹⁶⁰ *Id.* at 20-21.

¹⁶¹ *See id.* at 26.

¹⁶² *See id.* at 28.

¹⁶³ *Id.* at 21; Sarah Toy, *Moderna: 5 Things to Know About the Largest Biotech to IPO*, MARKETWATCH (Dec. 7, 2018), <https://www.marketwatch.com/story/moderna-ipo-5-things-to-know-about-what-could-be-the-largest-biotech-ipo-in-history-2018-12-05>.

¹⁶⁴ Toy, *supra* note 163.

¹⁶⁵ *Id.*

¹⁶⁶ BRANT & SCHULTZ, *supra* note 159, at 32-33.

¹⁶⁷ David Gelles, *The Husband-and-Wife Team Behind the Leading Vaccine to Solve Covid-19*, N.Y. TIMES (Nov. 10, 2020), <https://www.nytimes.com/2020/11/10/business/biontech-covid-vaccine.html>.

¹⁶⁸ Bojan Pancevski & Jared S. Hopkins, *How Pfizer Partner BioNTech Became a Leader*

into using mRNA technology for cancer treatment, but without having yet brought any such treatment to market.¹⁶⁹

The *Wall Street Journal* reported that, when BioNTech and Pfizer scientists met in 2017 to discuss possible collaborations on treating infectious diseases with mRNA technology, Pfizer's head of vaccine R&D was initially skeptical about BioNTech's platform.¹⁷⁰ It was the prospect of strong protection for patentable inventions, valuable trade secrets and, eventually, costly test data required for regulatory approval, that enabled inventors (and investors) like Dr. Sahin and Dr. Tureci to take the huge risks necessary to invent these new technologies and bring them to market.¹⁷¹ While Pfizer's CEO has noted that Dr. Sahin "cares only about science" and that "[d]iscussing business is not his cup of tea," it must also be the case that without the prospect of receiving a return on a risky investment like that which Drs. Tureci and Sahin were making, BioNTech may very well not have been in a position to have the technology ready to begin working towards a vaccine so early in the pandemic.¹⁷² Dr. Sahin and his team reportedly got to work on using BioNTech's technology to create a COVID-19 vaccine in January 2020, after reading an article in the *Lancet* about the initial emergence of the virus in China.¹⁷³ Their staff cancelled their vacations and worked seven days a week, beginning with twenty vaccine candidates in late February, of which four were selected for a trial in Germany.¹⁷⁴

BioNTech's leaders knew early on that they were not in a position to produce the massive quantities of vaccine that would be necessary to vaccinate the world.¹⁷⁵ Thus, they entered into an agreement to license their IP rights to Pfizer, which had the capability and experience to enable mass production of a vaccine, and to receive regulatory approval around the world as quickly as possible.¹⁷⁶ As Pfizer explained in its press release announcing their co-development agreement, "by pairing Pfizer's development, regulatory and commercial capabilities with BioNTech's mRNA vaccine technology and expertise as one of the industry leaders, we are reinforcing our commitment to do everything we can to combat this escalating pandemic, as quickly as possible."¹⁷⁷

in Coronavirus Vaccine Race, WALL ST. J. (Oct. 22, 2020), <https://www.wsj.com/articles/how-pfizer-partner-biontech-became-a-leader-in-coronavirus-vaccine-race-11603359015>.

¹⁶⁹ Gelles, *supra* note 167.

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ *Id.*; Pancevski & Hopkins, *supra* note 168.

¹⁷⁵ Pancevski & Hopkins, *supra* note 168.

¹⁷⁶ *Id.*

¹⁷⁷ Press Release, Pfizer, Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine (Mar. 17, 2020), <https://investors.pfizer.com/investor-news/press-release-details/2020/Pfizer-and-BioNTech-to-Co-Develop-Potential-COVID-19-Vaccine/default.aspx>.

In addition to the formal agreements, the scientists and executives at BioNTech and Pfizer worked very closely together, *as a team*. Indeed, in explaining how the two companies moved forward even before they had finalized the financial terms of the partnership agreement, Dr. Sahin pointed out that “[t]rust and personal relationship is so important in such business, because everything is going so fast,”¹⁷⁸ emphasizing that “[it] was all about trust.”¹⁷⁹ Pfizer emphasized that it:

would add their considerable development expertise and infrastructure to help BioNTech realize the potential of their technology. It took some time to work through all the details, but we reached an agreement that leveraged both of our strengths in pursuit of doing something that many thought was impossible.¹⁸⁰

The *Wall Street Journal* reports that, at the outset of the collaboration, Dr. Sahin and Pfizer CEO Albert Bourla were speaking “several times a day,” as well as on the weekends.¹⁸¹

It is this type of voluntary collaboration, and the development of trust among the collaborators, that generated the rapid development and approval of the Pfizer-BioNTech vaccine. The same was true for other COVID-19 vaccine developers, including Johnson & Johnson, which collaborated with an immunologist and virologist at Beth Israel Deaconess Medical Center to develop its one-dose vaccine.¹⁸² Government intervention in the form of compulsory licensing of patents, and threatened compulsory licensing of trade secrets, does nothing to create this essential ingredient of trust and collaboration between innovator and licensee. Rather than leveraging strengths of two partners, a compulsory license can create, from the outset, a difficult and unwelcome relationship, to the extent the innovator and licensee develop any relationship at all.

The ability to ramp-up production through partnership between innovators and other companies is likewise made possible due to the confidence that companies around the globe can share information (including trade secrets) across borders, and license patent rights, in the expectation that those IP rights will be protected. In the case of the BioNTech-Pfizer relationship, it was BioNTech that owned the IP predominantly directed toward the vaccine.¹⁸³ According to a Pfizer executive, “IP protection was critical . . . I can’t speak for BioNTech, but I cannot imagine they would be

¹⁷⁸ Gelles, *supra* note 167.

¹⁷⁹ Pancevski & Hopkins, *supra* note 168.

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² See BRANT & SCHULTZ, *supra* note 159, at 28.

¹⁸³ It is possible, pursuant to their agreement, that new discoveries after the COVID-19 partnership might be jointly owned by BioNTech and Pfizer, depending on the nature of the discovery. Pancevski & Hopkins, *supra* note 168.

comfortable sharing their proprietary mRNA technology with a company like Pfizer without having IP protection.”¹⁸⁴

To take another example, UK-based AstraZeneca entered into voluntary license agreements with the Serum Institute of India pursuant to which they are working together to supply one billion doses, for low-and-middle-income countries, of the COVID-19 vaccine first developed by Oxford University, with support from CEPI and Gavi, the Vaccine Alliance.¹⁸⁵ As AstraZeneca announced: “The Company is building a number of supply chains in parallel *across the world* to support global access at no profit during the pandemic and has so far secured manufacturing capacity for two billion doses of the potential vaccine.”¹⁸⁶ Also with respect to AstraZeneca’s COVID-19 vaccine, CSL Behring has agreed to transition elements of its Australian manufacturing capacity to manufacture fifty million doses of that vaccine for local use in Australia and neighboring islands.¹⁸⁷

With respect to Johnson & Johnson’s COVID-19 vaccine, it has partnered with Merck & Co. to expand manufacturing capacity.¹⁸⁸ Similarly, Pfizer and BioNTech have entered into a license agreement with Novartis (which used to have its own vaccine business) that allows Novartis to use its facilities to help contribute to production of additional Pfizer-BioNTech COVID-19 vaccines in Switzerland.¹⁸⁹ Similarly, Sanofi has been supporting manufacture of three different vaccines (i.e., Pfizer-BioNTech, Johnson & Johnson, and Moderna), with the aim of providing half a billion doses of those vaccines throughout the world.¹⁹⁰ As explained by Pfizer, “IP facilitated these relationships” in the same way that it facilitated the relationship between Pfizer and BioNTech, pointing to patents and trade

¹⁸⁴ See BRANT & SCHULTZ, *supra* note 159, at 27.

¹⁸⁵ Press Release, AstraZeneca, *AstraZeneca Takes Next Steps Towards Broad and Equitable Access to Oxford University’s Potential COVID-19 Vaccine* (June 4, 2020), <https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html>.

¹⁸⁶ *Id.* (emphasis added).

¹⁸⁷ Press Release, CSL Behring, *COVID-19 Update, Continues to Provide Medicines to Patients Around the World* (June 2, 2021), <https://www.cslbehring.com/newsroom/2020/covid-19-update>.

¹⁸⁸ Press Release, Johnson & Johnson, *Johnson & Johnson Statement on Collaboration with Merck* (Mar. 20, 2021), <https://www.jnj.com/johnson-johnson-statement-on-collaboration-with-merck>.

¹⁸⁹ *Novartis Joins Pharma-wide Effort to Meet Global Demand for COVID-19 Vaccines*, NOVARTIS (Mar. 22, 2021), <https://www.novartis.com/stories/novartis-joins-pharma-wide-effort-meet-global-demand-covid-19-vaccines>; Press Release, Novartis, *Novartis Signs Initial Agreement to Provide Manufacturing Capacity for Pfizer-BioNTech COVID-19 Vaccine* (Jan. 29, 2021), <https://www.novartis.com/news/media-releases/novartis-signs-initial-agreement-provide-manufacturing-capacity-pfizer-biontech-covid-19-vaccine>.

¹⁹⁰ Press Release, Sanofi, *Our Commitment to Fighting COVID-19* (Sept. 28, 2021), <https://www.sanofi.com/en/about-us/our-stories/sanofi-s-response-in-the-fight-against-covid-19>.

secrets.¹⁹¹

With a particular focus on developing countries, Pfizer and BioNTech have entered into an agreement with South Africa-based Biovac to manufacture the Pfizer-BioNTech COVID-19 vaccine for distribution exclusively within the African Union.¹⁹² Beginning in 2022, they anticipate that this collaboration will result in production and distribution of over 100 million finished doses in Africa.¹⁹³

Beyond vaccines, innovators have likewise agreed to robust voluntary licensing arrangements for COVID-19 therapeutics. In October 2021, for example, the Medicines Patent Pool (MPP) and Merck & Co. announced that they entered into “a voluntary licensing agreement to facilitate affordable global access for molnupiravir, an investigational oral COVID-19 antiviral medicine for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization.”¹⁹⁴ According to Merck, this will help create access in 105 low- and middle-income countries.¹⁹⁵ The agreement allows the MPP, in turn, to further license to manufacturers so as to “diversify the manufacturing base for the supply” of the COVID-19 antiviral medicine.¹⁹⁶ Because molnupiravir is a small molecule drug (which would be easier to manufacture than a biologic, as a technical matter), it would appear to be particularly amenable to such a robust global voluntary licensing scheme.

A recent study published by *The Lancet Public Health* concluded that voluntary licenses through the MPP mechanisms, which allow for “broad access to quality-assured, affordable versions of high-volume, low cost, oral tablet drug formulations,” have led to “both economic and health benefits for people in [low and middle-income countries], saving money and lives.”¹⁹⁷ Such licenses constitute another *voluntary* tool in the toolkit for companies, governments, universities, non-profits, and international organizations

¹⁹¹ See BRANT & SCHULTZ, *supra* note 159, at 40.

¹⁹² Press Release, Pfizer, *Pfizer and BioNTech Announce Collaboration with Biovac to Manufacture and Distribute COVID-19 Vaccine Doses Within Africa* (July 21, 2021), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac>.

¹⁹³ *Id.*

¹⁹⁴ Press Release, Merck, *The Medicines Patent Pool (MPP) and Merck Enter into License Agreement for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine, to Increase Broad Access in Low- and Middle-Income Countries* (Oct. 27, 2021), <https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countries/>.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.* The license agreement is publicly available at <https://medicinespatentpool.org/licence-post/molnupiravir-mol/>.

¹⁹⁷ Sébastien Morin et. al., *The Economic and Public Health Impact of Intellectual Property Licensing of Medicines for Low-Income and Middle-Income Countries: A Modelling Study*, 7 *THE LANCET PUB. HEALTH* 169, 175 (2021).

looking for ways to expand access to medicines, particularly for developing countries, without recourse to compulsory licensing.

Another option for increasing access to patented medicines in developing countries is for patent owners to issue “non-assert declarations” or “non-assertion covenants,” pursuant to which they commit not to enforce certain patents in a defined group of countries.¹⁹⁸ Even before the authorization or launch of its revolutionary COVID-19 vaccine, Moderna declared that “while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic.”¹⁹⁹

With respect to trade secrets, as the United States emphasized in advocating for the inclusion of Article 39 of the TRIPS Agreement back in 1989, protection of trade secrets is “important for developing countries since there was no better way of encouraging the transfer of technology to developing countries than to provide protection to trade secrets and proprietary information which constituted the very essence of the transfer of technology.”²⁰⁰ In June 2021, the WHO announced the establishment of mRNA technology transfer hubs in Africa, beginning with the first one in South Africa led by a consortium comprising Biovac, Afrigen Biologics and Vaccines, a network of universities, and the Africa Centres for Disease Control and Prevention, and with the support of France.²⁰¹ The aim of these hubs is to allow mRNA technology to be established at industrial scale, and to provide training, necessary licenses, and share “the production know-how” (including trade secrets) with local manufacturers.²⁰² Here, again, IP protection is important to enable this type of voluntary collaboration that will make a big difference in improving access to COVID-19 vaccines.

Brant and Schultz have found that, as of August 1, 2020, there were over 40 different manufacturing partnerships to produce the main components of COVID-19 vaccines; 27 partnerships to place vaccines in vials, label and prepare them for distribution; and 6 distribution partnerships to provide

¹⁹⁸ See *Voluntary Licenses and Non-Assert Declarations: Actions by R&D Pharmaceutical Companies that Facilitate Access to Medicines*, IFPMA (July 28, 2010), https://www.ifpma.org/wp-content/uploads/2016/02/2010_07_28_IFPMA_Statement_VoluntaryLicensing_NonAssert_28Ju.pdf.

¹⁹⁹ See Press Release, Moderna, *Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic* (Oct. 8, 2020), <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19>.

²⁰⁰ Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *supra* note 59, ¶ 61.

²⁰¹ *WHO Supporting South African Consortium to Establish First COVID mRNA Vaccine Technology Transfer Hub*, WHO (June 21, 2021), <https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub>.

²⁰² *Id.*

regional capabilities in over 25 countries.²⁰³

B. Recognition of Multiple Non-IP-related Measures that Act as Barriers to Access to Vaccines and Medicines

While the debate over the relationship between IP and access to medicines often dominates the headlines, it is well accepted that numerous trade barriers exist that, if removed, would facilitate trade in products necessary to improve global health *without* impacting the IP rights that are essential to incentivizing development and availability of the products and technologies in the first place. Moreover, developed countries can take affirmative steps to improve access for the developing world, including through financial assistance, technical assistance, and donations of vaccines and therapeutics. For a global pandemic like COVID-19, where new variants evolve and spread back-and-forth across borders, it is indeed in the long-term self-interests of developed countries to take such actions.

As the United States, itself, explained just a few days before signing onto the Doha Declaration: “TRIPS is just one element of the needed global response to a pandemic such as HIV/AIDS. The United States is pursuing a comprehensive, integrated approach, stressing education, prevention, care, training and treatment.”²⁰⁴

As part of this comprehensive approach, the United States highlighted that, at the time of the Doha Declaration’s adoption, it was “the largest bilateral donor of funds for HIV/AIDS assistance, providing over \$2 billion per year on related research, much of which helps to address developing country problems.”²⁰⁵

In the course of the annual review meetings of the 2003 Decision, the European Union similarly explained that:

Other aspects had to be taken into account with regard to access to medicines, such as financing of medicine purchases, the setting-up and financing of health-care systems, the financing of research targeting neglected diseases and the development of appropriate pricing and reimbursement policies. *These issues went well beyond intellectual property and patent protection.*²⁰⁶

During those same regular annual review meetings, the United States emphasized other “tools” that can be used to improve access to medicines, including:

²⁰³ BRANT & SCHULTZ, *supra* note 159, at 39.

²⁰⁴ Press Release, USTR, *USTR Background Paper: TRIPS and Health Emergencies*, USTR Press Release 3 (Nov. 10, 2001).

²⁰⁵ *Id.*

²⁰⁶ *Annual Review of the Decision on the Implementation of Paragraph 6*, *supra* note 25, ¶ 78 (emphasis added).

(i) enhancing legal certainty for manufacturers of generic medicines; (ii) eliminating tariffs on medicines and medical devices, thereby decreasing costs for hospitals, clinics, aid organizations and consumers, among others; (iii) reducing customs obstacles to medicines by minimizing import barriers, such as discriminatory, burdensome, and unpredictable customs procedures, that impeded access to innovative and generic medicines; (iv) curbing trade in counterfeit medicines by making customs and criminal enforcement measures available to prevent medicines bearing counterfeit trademarks from entering national markets, and thus supporting efforts of countries to address the serious risks to patients posed by such counterfeits; (v) reducing internal barriers to distribution of medicines by guaranteeing importing, exporting, and distribution rights with respect to medicines and minimizing internal barriers that could stand in the way of efficiently distributing medicines to those in need; and (vi) minimizing unnecessary regulatory barriers by promoting transparent and nondiscriminatory regulatory structures to facilitate the availability of safe and efficacious medicines to the public.²⁰⁷

On the topic of tariffs and its impact on access to medicine, the United States elaborated in subsequent TRIPS Council meetings that such tariffs are “borne by consumers, and more specifically by patients.”²⁰⁸ While some countries have agreed to eliminate tariffs on medicines and active ingredients (the so-called “zero-for-zero” agreement), other countries continue to require high tariffs on those products. The European Union supported the United States on this point, stating as follows:

It is very difficult to understand how countries who have problems of access to medicines and who clearly point to intellectual property as the main culprit for this, can keep very high import tariffs on pharmaceuticals. I assume tha[sic] this can only be explained for reasons of protection of a domestic industry, but the fact is that this is an obstacle to access to medicines by the poorest layers of society.²⁰⁹

In July 2021, the WTO Secretariat prepared an “Information Note” that provides a long list of such trade barriers (as identified by speakers at a WTO webinar and symposium) in the context of providing access to “products to combat COVID-19.”²¹⁰ The Information Note highlighted one “common

²⁰⁷ Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 133, ¶ 66.

²⁰⁸ Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* 8, WTO Doc. IP/C/66 (Oct. 23, 2013).

²⁰⁹ *Id.* at 11.

²¹⁰ *Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19*, WTO (July 20, 2021), https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_report_e.pdf.

theme,” i.e., “essential goods and inputs need to flow efficiently and expeditiously to support the rapid scaling up of COVID-19 production capacity worldwide,” such that a delay of even a single component may slow everything down given the globally integrated supply chains.²¹¹

According to the Information Note, some of the “trade-related bottlenecks” in this context include: (i) absence of expedited procedures for import and export of vaccine inputs; (ii) difficulty in sending non-commercial samples for testing and quality control purposes to laboratories located across borders due to import/export procedures and restrictions; (iii) taxes and tariffs, or long exemption processes, imposed on products (including vaccines) intended for combatting COVID-19 (including even on donations); (iv) administrative difficulties of conducting cross-border business due to limited services in embassies and consulates; (v) difficult and time-consuming regulatory frameworks, procedures and timelines for acquiring regulatory approval in many countries; (vi) lengthy border clearance conditions for products ancillary to vaccines (e.g., syringes and refrigerators); and (vii) technical barriers to trade that differ across countries.²¹²

C. Evaluation of a Misguided Proposal to Expand the Permissible Scope of Compulsory Licensing During the COVID-19 Pandemic

Abbott and Reichman recently published an article proposing a type of mass compulsory licensing mechanism for all patents covering the treatment and prevention of COVID-19.²¹³ They do so after first setting the scene on their general views on IP rights, stating that it is an “open question” whether IP rights are “necessary or useful in the context of addressing the COVID-19 pandemic.”²¹⁴

Specifically, they propose that governments require that “owners of patents must place their patents into a ‘pool’ from which licenses must be freely taken and used by manufacturing companies in return for specified compensation.”²¹⁵ They indicate that such a pool of compulsory licensed patents should be managed by a global licensing facility established by “countries party to existing regional agreements, or simply by groups of like-minded countries.”²¹⁶ Further, Abbott and Reichman propose that there should be no marketing exclusivity linked to the data submitted for regulatory approval, based on, *inter alia*, the clinical testing that comes at great expense to the innovators.²¹⁷

²¹¹ *Id.* at 1.

²¹² *Id.* at 1-3.

²¹³ Abbott & Reichman, *supra* note 128, at 541, 543-45.

²¹⁴ *Id.*

²¹⁵ *Id.* at 543.

²¹⁶ *Id.* at 544.

²¹⁷ *Id.* at 543-44.

While the first part of their proposal would appear to potentially run afoul of multiple aspects of Articles 31 and 31*bis* of the TRIPS Agreement for failure to satisfy the requisite conditions for compulsory licensing (e.g., requirements to consider requests on their individual merits, limitations on scope and duration of individual compulsory licenses, and limitations on exports subject to meeting the conditions in Article 31*bis*), the second part would violate the obligations of WTO Members to protect test data pursuant to Article 39.3 of the TRIPS Agreement.²¹⁸

The fact that a subset of WTO Members might agree to work together to establish a compulsory licensing scheme that violates the TRIPS Agreement would not somehow render that scheme consistent with the WTO. Curiously, Abbott and Reichman made this proposal at a time *before* any vaccines or therapeutics for COVID-19 had been developed and/or authorized in any country²¹⁹—which was precisely the time when the incentives for innovation, and investment in testing the efficacy and safety of new products, *were most needed*. Had such a proposal been implemented, it may very well have diminished the resources and time invested when, as Abbott and Reichman admitted, the “ultimate degree of effectiveness [of any future vaccine or therapeutic] remain[ed] uncertain.”²²⁰ While Abbott and Reichman agree that “[c]learly, innovators should be paid well for their efforts,”²²¹ and also assert that “diverse contribution and royalty payment options are available,” they recognize that “a specific formula is not

²¹⁸ See generally G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Amendment*, 24 NW. J. INT’L L. & BUS. 1 (2003). Abbott and Reichman argue that the mechanism could be established in a manner that is compatible with the TRIPS Agreement, but rely in part on the possibility of Members agreeing to a waiver of TRIPS obligations, as well as possible recourse to the national security exception of the TRIPS Agreement (Article 73). See Abbott & Reichman, *supra* note 128, at 546-47. WTO adjudicators have recently confirmed that the exception in Article 73 does not allow for unlimited departures from WTO obligations. Panel Report, *Saudi Arabia—Measures Concerning the Protection of Intellectual Property Rights*, ¶¶ 7.241-7.255, add. 1, WTO Doc. WT/DS567/R (June 16, 2020). The right to take “any action which it considers necessary for the protection of its essential security interests” is conditioned by one of three exhaustively listed circumstances in paragraphs (i)-(iii) of Article 73(b): (1) measures relating to fissionable material, (2) supply of a military establishment, and (3) war or other emergency in international relations. While Members may depart from any TRIPS obligation where the conditions for an invocation of Article 73 are met, the meeting of such conditions cannot be assumed. Further, systemic implications arise from overreliance on the national security exceptions of the TRIPS Agreement or any of the WTO agreements.

²¹⁹ Abbott & Reichman, *supra* note 128, at 536 (indicating that the article was prepared at a time when “there were no vaccines available that appear capable of preventing the spread of COVID-19, although promising research results have been announced”). *Id.* at 538 (“We cannot accurately predict when a pharmaceutical company, academic researchers, a teaching hospital, or biotech startup will develop a successful treatment for COVID-19, or an efficacious vaccine.”).

²²⁰ *Id.* at 537.

²²¹ *Id.* at 539.

prescribed in [their] article.”²²² Yet, the incentives for innovation and investment created by IP protection derive from market expectations, and not from the untested possibility that governments may someday agree to band together to devise some functional and reasonable compensation scheme for all vaccines and therapeutics directed at ending the global pandemic.

This proposal would also result in practical obstacles given the difficulties that manufacturers would face in producing any vaccine or therapeutic based only on information found in patents and test data, without the guidance, direction, and cooperation from those who were first able to successfully develop the technology and produce those products. As explained above in Section V.A, beyond the technology and raw data, a key element to the successful launch and production of the COVID-19 vaccines, for example, has been the spirit of cooperation and collaboration between those who invented the underlying technology and those who attempted to build upon that technology and rapidly scale up mass production. To recall, in discussing the relationship between BioNTech and Pfizer, the co-founder of BioNTech pointed out that “[it] was all about trust.”²²³ This would not take place in the type of compulsory patent pool scenario proposed by Abbott and Reichman.

VI. CONCLUSION

In the twenty years since adoption of the Doha Declaration, it has become clear that WTO Members anticipated quite well the importance of continuing to provide incentives for innovation and ensuring access to the fruits of such innovation. When Members gathered together in Doha, Qatar in 2001 to consider the relationship between IP rights and the public health crises facing the world at that time, they reaffirmed the principles already set out in the TRIPS Agreement, and highlighted the permissible flexibilities. While the Doha Declaration included a call for action to modify the TRIPS Agreement in order to enable compulsory licensing for export and to extend some of the transition periods for LDCs, it did not itself result in any changes to the TRIPS Agreement.

Given that many WTO Members have opted to provide strong IP protection in line with their TRIPS Agreement obligations, innovators from around the world had already been developing new technologies, including mRNA technologies, that required many years and billions of dollars in investments before they could potentially bear fruit (in terms of benefits to patients, and revenue). They could do so with faith that the fruits of their labor, creativity and teamwork—in this case, IP rights—would be protected, and that they could license those rights to partners that would be obligated by law to protect them. The result was the remarkable ability to develop, and receive emergency approval for, COVID-19 vaccines in less than one year,

²²² *Id.* at 546.

²²³ Pancevski & Hopkins, *supra* note 168.

when the fastest that a vaccine had previously been developed (from viral sampling to approval) was four years (for mumps).²²⁴ Innovators and their partners were then able to create several vaccines, as a result of which over 12.2 billion shots were administered (as of mid-July 2022)—enough to fully vaccinate almost 75% of the global population—only 19 months after the first vaccine was authorized for emergency use.²²⁵

While there is still much to do in terms of improving distribution of COVID-19 vaccines and therapeutics in developing countries, and while more of such vaccines and therapeutics are in development, it is important to step back and appreciate the breathtaking technological developments that the world has seen, and the difference these developments have made in terms of saving lives and improving the quality of those lives as societies begin to get back to normal. As WTO Members did together twenty years ago when adopting the Doha Declaration, they must continue to acknowledge the benefits of IP protection for global health, while finding ways to maximize access to the technologies incentivized by such protection, without leaving the world unprepared for the next pandemic.

²²⁴ Philip Ball, *The Lightning-Fast Quest for COVID Vaccines—and What It Means for Other Diseases*, NATURE (Dec. 18, 2020), <https://www.nature.com/articles/d41586-020-03626-1>.

²²⁵ *More Than 12.2 Billion Shots Given: COVID-19 Tracker*, BLOOMBERG, <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/> (last visited July 17, 2022). See also Ball, *supra* note 224.