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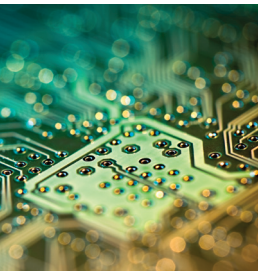



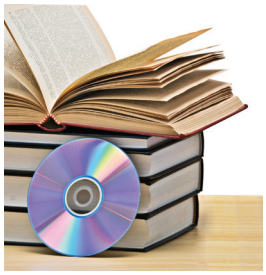

The TRIPS Waiver for COVID-19 Vaccines, and Its Potential Expansion:

Assessing the Impact on Global IP Protection and Public Health

Eric M. Solovy

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ERIC M. SOLOVY*

I. Introduction and Executive Summary

On June 17, 2022, in the early morning hours of the final day of the World Trade Organization's ("WTO") 12th Ministerial Conference, the Members of the WTO adopted a waiver of the Agreement on Trade Related Aspects of Intellectual Property Rights ("the TRIPS Agreement"), commonly known as the "TRIPS Waiver for COVID-19 Vaccines" or the "TRIPS Waiver."[1] The TRIPS Waiver, with its primary focus on compulsory licensing of patents (i.e., licensing without the authorization of the patent owner) that are "required for the production and supply of COVID-19 vaccines," reflected a compromise position among WTO Members.[2] The initial proposal advanced by India and South Africa, on October 2, 2020, would have gone much further, authorizing WTO Members to waive the substantive and enforcement-related provisions of the TRIPS Agreement not only for patents but also for copyrights, industrial designs, trade secrets, and test data protection; moreover, the original proposal would have gone far beyond COVID-19 vaccines, to cover intellectual property ("IP") "in relation to prevention, containment or treatment of COVID-19."[3]

The debate over the TRIPS Waiver began at a time when the development of the first COVID-19 vaccines was already nearing completion. To wit, the Pfizer-BioNTech COVID-19 Vaccine received emergency use authorization from the U.S. Food & Drug Administration ("FDA") on December 11, 2020—i.e., just two months after India and South Africa had submitted their original TRIPS waiver proposal.[4] Yet, at the same time that certain countries began attacking IP rights as an obstacle to addressing the pandemic, it was already well understood that the rapid development of COVID-19 vaccines, therapeutics, and diagnostics would not have been possible but for the billions of dollars in private investments, over the course of many years, in technologies that were incentivized by strong IP protection.[5] It is no coincidence that the first COVID-19 vaccines were developed in industrialized countries that offer strong IP protection—protection that provided the incentives necessary for private investors to take the huge risks required when researching revolutionary technologies.[6]

For example, although mRNA was discovered in 1961, it took many years of research, at huge expense and great risk, to create the mRNA-based technology used in COVID-19 vaccines.[7] BioNTech's Dr. Sahin and Dr. Tureci, a married couple, had been working on mRNA technology for more than 25 years, without any successful commercial applications prior to developing their COVID-19 vaccine.[8] To take another example, before going public in 2018 with its mRNA technology, Moderna had raised USD 2.6 billion in investments and partnership funding, along with USD 600 million raised in an IPO.[9] 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."[10] This scale of private investment in a venture as risky as these ground-breaking new technologies would simply have been impossible but for the upside potential offered by the promise of IP rights over any resulting therapeutics or vaccines and, in turn, the potential to recoup returns on those investments. Further, the assurance that IP rights would be honored and, where necessary, enforced, in multiple countries enabled the creators of vaccines to

* Partner, Global Arbitration, Trade and Advocacy, Sidley Austin, LLP. George Mason University Center for Intellectual Property x Innovation Policy Practitioner in Residence. B.A. 1996, Duke University; J.D. 1999, Harvard Law School. From 2001-2002, Mr. Solovy served as law clerk to the Honorable Pauline Newman, Circuit Judge, U.S. Court of Appeals for the Federal Circuit.

Any expansion of the waiver could deal an additional blow to incentives to biopharmaceutical innovation, which would, in turn, compromise our ability to deal with future public health emergencies (as well as possible future variants of COVID-19).

enter into voluntary licensing agreements with enterprises around the world for the manufacture and distribution of the vaccines, making them rapidly available throughout the world.[11]

Since the inception of the TRIPS Agreement nearly thirty years ago, there have been voices calling for its dilution. The ongoing COVID-19 pandemic amplified some of these voices. Ignoring the role of IP in the creation of COVID-19 vaccines (and diagnostic and therapeutic products), many governments bought into the narrative claims that protection of IP rights obstructs access to important vaccines and therapeutic products. In making this argument, they conveniently put to the side the multitude of trade, regulatory and logistical barriers that clearly prevented vaccines from quickly going into arms in a number of developing countries.[12] At the same time, some have argued that certain countries viewed the pandemic, and a TRIPS waiver in particular, as a strategic opportunity to get access to next generation technologies that would provide benefits to their domestic economies long after the COVID-19 pandemic ends.[13]

Upon the announcement and public release of the terms of the TRIPS Waiver, the reactions were, not surprisingly, mixed. They were generally aligned with the long-term views of international IP rights that had been consistently expressed by countries, activists, and industry since the inception of the TRIPS Agreement.

For those countries and activists that have long advocated against IP protection for pharmaceutical products, they characterized the TRIPS Waiver as a compromise that did not go far enough but that nevertheless served to validate (in their view) that they had been right all along about the relationship between IP protection and global health. For example, Médecins Sans Frontières ("MSF") expressed disappointment that the scope of the TRIPS Waiver was not as broad as the original proposal but then went on to question whether patent protection is ever appropriate for pharmaceutical products, calling "on governments to take concrete steps to rethink and reform the biomedical innovation system to ensure that lifesaving medical tools are developed, produced and supplied equitably where monopoly-based and market-driven principles are not a barrier to access."[14]

For those who, in record time, created and produced the revolutionary vaccines, diagnostics, and therapeutics that have enabled families and businesses around the world to begin returning to normal, the TRIPS Waiver was understood as a threat to IP rights, to the incentives they create, and ultimately, to innovation itself. As the U.S. Chamber of Commerce stated in advocating against a TRIPS waiver:

> Waiving intellectual property rights would only hobble the innovation that is critical to improving lives and raising living standards globally. If enacted, this move would set an unfortunate precedent and may limit innovative companies' ability to devote unprecedented resources to quickly discover and deliver solutions for the next global crisis, be it pandemic, food security, or climate-related.[15]

There are currently calls for a further expansion of this waiver, both in terms of duration and product scope. As explained below, any expansion of the waiver could deal an additional blow to incentives to biopharmaceutical innovation, which would, in turn, compromise our ability to deal with future public health emergencies (as well as possible future variants of COVID-19).

When WTO Members gather in Geneva, Switzerland, to decide, pursuant to the direction in paragraph 8 of the TRIPS Waiver, whether the waiver should be "extend[ed] to cover the production and supply of COVID-19 diagnostics and therapeutics," it is important to take a step back from the public rhetoric and evaluate the TRIPS Waiver in view of its actual text, as well as the text of the provisions of the TRIPS Agreement that it waives and/or purports to "clarify."

In Part II, below, this paper briefly discusses the evolution of global IP protection and why a multilateral treaty such as the TRIPS Agreement is absolutely essential to incentivizing R&D in an increasingly globalized economy. Part III then offers a summary of the legal content of the

TRIPS Waiver. Part IV places the TRIPS Waiver into its proper context in the WTO system, explaining the legal nature of a waiver as a matter of WTO law.

Next, in Part V, I turn to the potential impact of the TRIPS Waiver. After first noting that no WTO Member has given notice of an intent to make use of the TRIPS Waiver since its inception over five months ago, I explain (in Part V(A)) that, by creating uncertainty as to the value of pharmaceutical patents, the TRIPS Waiver may serve to decrease the incentives to innovation created by the patent system, to the detriment of global public health. Part V(B) highlights how, in contrast to the mechanism set out in Article 31*bis* of the TRIPS Agreement, the failure to include tracking, tracing, and detailed transparency requirements in the TRIPS Waiver could lead to diversion of vaccines, which would be counterproductive to the stated intent of the TRIPS Waiver.

Part V(C) considers the potential harm that may arise if WTO Members rely on one of the so-called "existing good practices," as referenced by the TRIPS Waiver, for determining remuneration to a patent owner whose patent is compulsorily licensed. In Part V(D), I consider the potential impact of the provision of the TRIPS Waiver addressing regulatory data protection, a type of IP right distinct from patents which provides important incentives to bring new pharmaceutical technologies to market. Part V(E) considers the public debate, particularly in the United States, surrounding the possible impact of the TRIPS Waiver on the global competitiveness of certain WTO Members.

Finally, Part VI considers how the proposed expansion of the product scope of the TRIPS Waiver to COVID-19 diagnostics and therapeutics (as not yet defined) could serve to create uncertainty for a much larger group of patent owners and, in turn, further reduce incentives for innovation, to the detriment of global public health. It would do so at a time when R&D is rapidly progressing in preparation for new variants of COVID-19 and ultimately for the next pandemic.

II. Background on the Evolution of International IP Protection

For centuries, States have protected, under their domestic law, various forms of IP rights as a way to promote innovation and creative endeavors.[16] The basic rationale for protecting IP is a simple one—originality takes risky investment in terms of work and resources, while copying an existing work is far easier.[17] In a world where everyone were at liberty to copy everything, there would be few incentives to invest in innovation. Instead, rational actors would await investments in innovation by others, and then, where possible, simply copy the fruits of those investments at a much lower cost. Protecting IP—*i.e.*, providing creators certain exclusive rights over their creation—switches this incentive in favor of innovation rather than copying.

The role of IP is particularly significant in research-intensive industries, such as the pharmaceutical industry.[18] Every successful product in the pharmaceutical industry needs to recover not only the cost of the raw material and labor involved in making that product, but also the much larger cost of R&D that went into creating that product, as well as the cost of many unsuccessful R&D endeavors that preceded it; without exclusive rights over the successful products, this would simply not be possible.

Since IP rights were traditionally a matter for only domestic law, they evolved differently in different countries. Countries differed in terms of the forms of IP rights they protected, the subject matter eligible for each form of protection, the range of exclusive rights conferred by each form of protection, the term for which protection was granted, and the means to enforce the IP rights that they did provide. As international trade grew, and it became more common for goods produced in one country to be imported into, sold in, and consumed in another country, there was a need to achieve some uniformity in the domestic law rules concerning IP rights. Although not requiring harmonization among WTO Members, the TRIPS Agreement was a significant milestone in achieving at least a minimum standard that all WTO Members must follow. This is subject to a transition period for least developed countries ("LDCs"), which do not need to apply the provisions of the TRIPS Agreement (other than Articles 3, 4, and 5) until July 1, 2034 (or until the date that they are no longer an LDC, whichever occurs first).[19]

The TRIPS Agreement is part of the "single undertaking" to which Members agree when they join the WTO.[20] Legally, the TRIPS Agreement is one of the several annexes to the Marrakesh Agreement Establishing the WTO ("Marrakesh Agreement").[21] The TRIPS Agreement does not usurp the role of domestic law in protecting IP rights; WTO Members continue to protect IP rights within

their territories through domestic law. Instead, the TRIPS Agreement places Members under an international legal obligation to abide by certain minimum standards in the protection of IP rights.

Members are under an obligation to protect certain stipulated forms of IP, make such protection available when certain stipulated conditions are met, ensure that each form of protection includes certain stipulated exclusive rights, make such protections available at least for a certain stipulated period of time, and ensure that their domestic law provides adequate means of enforcing these rights.[22] Subject to these requirements, Members remain at liberty to make their own choices (including through "TRIPS-plus" agreements beyond what is required by the TRIPS Agreement) in their domestic law on IP rights.[23]

Since its entry into force in 1995, the TRIPS Agreement has induced WTO Members to play by these common rules on IP rights. Where Members fell short, other Members have called for compliance, leveraging the WTO's dispute settlement rules.[24] The multilateralization of IP rules through this framework has ensured that innovators can participate in international trade with important safeguards against the risk of their IP being impermissibly copied by competitors.

III. The COVID-19 TRIPS Waiver: Legal Text

As noted above, on October 2, 2020, India and South Africa submitted the original proposal that ultimately led, after a number of important compromises, to the TRIPS Waiver. After more than one and a half years of debate, the final version of the TRIPS Waiver was agreed upon on June 17, 2022.

The October 2, 2020 proposal would have waived "implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19."[25] That is, had this proposal been accepted, the entirety of the TRIPS Agreement's obligations in respect of copyrights, industrial designs, patents and undisclosed information (including trade secrets and test data protection) would have been suspended "in relation to prevention, containment or treatment of COVID-19."[26] In May 2021, India and South Africa, along with sixty other co-sponsors, submitted a revised proposal, responding to the "concern that the original decision text was too broad."[27] While this communication retained the original demand to suspend entire chapters of the TRIPS Agreement, it claimed to have limited the breadth of the original proposal by focusing the product scope of the waiver on "health products and technologies."[28] This was followed by several rounds of counter-proposals advanced by the European Union ("EU").[29] Each of the EU proposals attempted to focus on clarifying the existing rules, and on offering limited waivers to individual provisions of the TRIPS Agreement laying down conditions for compulsory licensing, instead of a wholesale removal of protection of certain IP rights as had been originally proposed.

The TRIPS Waiver ultimately agreed upon "clarifies" and "waives" certain aspects of the existing rules related to the ability of certain eligible WTO Members to issue compulsory licenses over patents necessary for production and supply of COVID-19 vaccines without violating the TRIPS Agreement. It does so by dispensing with some of the obligations that otherwise apply, thereby giving those eligible Members the option of changing their domestic laws and/or practices when it comes to compulsory licensing. The current scope of the waiver includes patents claiming inventions necessary for production and supply of COVID-19 vaccines, as well as the ingredients and processes necessary for the manufacture of those vaccines.[30]

The TRIPS Waiver identifies all developing countries as its beneficiaries ("Eligible Members").[31] However, by the terms of the TRIPS Waiver, developing country Members with existing manufacturing capacity for COVID-19 vaccines "are encouraged to make a binding commitment" that they will not avail themselves of the flexibility under the waiver.[32] China made such a commitment at the meeting of the WTO General Council on May 10, 2022,[33] and appears to be the only developing country WTO Member to have done so to date.

To understand the terms of the TRIPS Waiver, one must first consider the provisions of the TRIPS Agreement directly impacted by the TRIPS Waiver. In particular, the waiver focuses on Article 31 of the TRIPS Agreement, which provides a list of conditions that a WTO Member must satisfy before issuing a compulsory license on a patent (which would otherwise be inconsistent with Article 28 of the TRIPS Agreement, i.e., the provision setting out the exclusive rights to be accorded to patent owners).

First, Article 31(b) of the TRIPS Agreement provides that a compulsory license may be issued only after "the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions" but where "such efforts have not been successful within a reasonable period of time."[34] The TRIPS Waiver removes this requirement, such that an Eligible Member may issue a compulsory license consistent with the waiver without any prior attempts to secure a voluntary license.[35] That said, Article 31(b), itself, already permitted Members to waive this requirement in "the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."[36] The TRIPS Waiver essentially deems the COVID-19 pandemic to be such a situation of urgency during the term of the waiver.

Second, Article 31(f) of the TRIPS Agreement requires that any compulsory license be authorized predominantly for the domestic market of the country issuing it. The TRIPS Waiver releases Eligible Members from this requirement, and allows "any proportion of the products manufactured" under a compulsory license pursuant to the waiver to be exported.[37] The requirement in Article 31(f) is already somewhat relaxed under certain conditions due to Article 31*bis* of the TRIPS Agreement, which itself evolved from paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 2001 ("Doha Declaration"),[38] and the WTO General Council's August 2003 Decision on the Implementation of Paragraph 6 of the Doha Declaration.[39]

While Article 31*bis* allows the exportation of products manufactured pursuant to a compulsory license under certain circumstances, these provisions still seek to ensure that such exports are exclusively destined for a set of "eligible" countries. As discussed below, there are extensive anti-diversion and notification requirements to prevent diversion. While the TRIPS Waiver also permits exportation only to certain eligible Members, it dilutes the anti-diversion requirements. The TRIPS Waiver requires Eligible Members merely to take "all reasonable efforts to prevent [] re-exportation," and all Members to "ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured" under the waiver that have been diverted to their markets.[40] However, an Eligible Member that has imported vaccines manufactured under a compulsory license pursuant to the waiver may permit their re-exportation to another Eligible Member, in "exceptional circumstances" "for humanitarian and not-for-profit purposes."[41] These "reasonable efforts"-style requirements are a far cry from the detailed anti-diversion and notification requirements in TRIPS Article 31*bis*, as discussed in Section V(B), below.[42]

Third, Article 31(h) of the TRIPS Agreement requires that a Member issuing a compulsory license provide "adequate remuneration" to the patent owner, and includes high level guidance on how to determine such remuneration.[43] Specifically, Article 31(h) provides that the remuneration shall be adequate "in the circumstances of each case, taking into account the economic value of the authorization."[44] While the TRIPS Waiver does not release Eligible Members from this requirement, it provides that determination of such remuneration "may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs."[45] In setting the remuneration in these cases, the TRIPS Waiver provides that Eligible Members may take into consideration certain so-called "good practices," citing two publications sponsored by the World Health Organization ("WHO"), World Intellectual Property Organization ("WIPO"), and the WTO.[46] As discussed below in Section V(C), the expressed judgment that the examples in the cited publication qualify as "good practices" may be highly problematic.

In addition, while the chapeau to Article 31 includes language that may be interpreted as requiring a WTO Member to have a formal compulsory licensing regime in place prior to issuing any such license (i.e., "where the law of a Member allows"), the TRIPS Waiver clarifies that an Eligible Member may issue a compulsory license through any means available under its domestic law, whether or not there is a formal regime in place.[47]

Beyond the provisions focused on compulsory licensing of patents, the TRIPS Waiver also addresses one other type of IP right—i.e., the protection of test and other regulatory data under Article 39.3. Article 39.3 appears in Part II, Section 7 of the TRIPS Agreement, which is a section titled "Protection of Undisclosed Information," and addresses a form of IP right distinct from patent rights (which appears in Part II, Section 5 of the TRIPS Agreement). Article 39.3 requires WTO Members to protect, against unfair commercial use, certain undisclosed test and other data submitted to governments for the purposes of regulatory approval of pharmaceutical products that utilize new chemical entities.[48] The TRIPS Waiver does not explicitly

release Eligible Members from the obligations of Article 39.3 or purport to modify that provision. Paragraph 4 states only that "it is understood that Article 39.3 of the Agreement does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision."[49] There is, however, no clarity on why or how that would be the case. As discussed in Section V(D), below, there is a risk that such uncertainty may be exploited by certain countries and activists in an effort to support their longstanding, erroneous interpretations and inadequate application of Article 39.3.

Pursuant to paragraph 6, the TRIPS Waiver will lapse, and any compulsory license issued pursuant to the waiver must lapse, within five years from the date of the waiver decision (June 17, 2022), barring an extension of the term of the waiver.[50] No later than six months from the date of the waiver, Members are directed to consider whether to expand its scope to cover "the production and supply of COVID-19 diagnostics and therapeutics,"[51] a topic to be addressed in Section VI, below.

Finally, it is important to highlight that the TRIPS Waiver refers to its substantive provisions as serving to clarify and waive the provisions of the TRIPS Agreement.[52] Yet, other than paragraph 3(b), which specifically uses the term "waiver," it is not clear which provisions constitute a waiver, which constitute a clarification, and which (if any) could potentially qualify as both. Consequently, any long-term implications of the TRIPS Waiver on the interpretation of the referenced provisions of the TRIPS Agreement likewise remain unclear.

Importantly, in providing that Eligible Members "may apply the provisions of this Decision until 5 years from the date of this Decision," subject to possible extension by the General Council, the TRIPS Waiver makes no distinction among any of the provisions.[53] This supports the proposition that WTO Members intended that the full extent of the TRIPS Waiver's impact would expire at that time.

IV. The Legal Nature of the TRIPS Waiver

As discussed above, the TRIPS Agreement is one of the annexes to the Marrakesh Agreement Establishing the WTO. WTO Members have undertaken substantive and procedural obligations under a number of agreements annexed to the Marrakesh Agreement, including the TRIPS Agreement. They have also created decision-making bodies and processes under the Marrakesh Agreement. The highest governing body of the WTO is the Ministerial Conference, established under the Marrakesh Agreement.[54]

Under the Marrakesh Agreement, the Ministerial Conference has the power to temporarily release WTO Members from performing certain obligations under a specific agreement. An instrument granting such temporary relief is called a "waiver."[55] During the period when the waiver remains in place, Members benefitting from it have the option to disregard the obligations from which they have been released. No dispute can be fruitfully brought, and no retaliatory steps may be taken, on account of such action to the extent it is consistent with the terms of the waiver.

A waiver remains in force for a period determined by the Ministerial Conference.[56] After the waiver expires, Members must resume their performance of the relevant obligations. This distinguishes a waiver from an amendment to a WTO agreement; an amendment is permanent, while a waiver is temporary.

V. Possible Impact of the TRIPS Waiver

In considering the impact of the TRIPS Waiver, the natural first question that arises is whether, after more than five months have passed since the June 17, 2022 Ministerial Decision, any WTO Member has actually taken advantage of the Waiver (or notified the WTO of its intent to do so in the future). Pursuant to paragraph 5 of the TRIPS Waiver, Eligible Members are required to inform the TRIPS Council of "any measure related to the implementation of this Decision, including the granting of an authorization."[57]

To date, there do not appear to have been any such notifications. This may not come as a surprise to those who focus on COVID-19-related statistics, as there is currently a global *surplus* of COVID-19 vaccines—something that was actually well known even before WTO Members agreed to the COVID-19 Waiver.[58]

As the TRIPS Waiver does not appear to have had any immediate impact on the production and distribution

of COVID-19 vaccines (at a time when the world has a surplus of vaccines), I now turn to consider the potential longer-term impacts of the TRIPS Waiver.

A. Potential to Decrease the Value of Patents on Pharmaceutical Products, Along with the Resulting Incentives to Innovation

The TRIPS Waiver does not change the domestic law or practices of WTO Members. Nor does the waiver *require* any WTO Member to effect such a change domestically. Instead, if Members opt to make certain changes in domestic law or practice, the TRIPS Waiver allows them to do so without violating their obligations under the TRIPS Agreement. That is, Members can engage in conduct that could otherwise have violated the TRIPS Agreement, so long as they do so within the scope of the waiver. This additional flexibility, even before it is ever exercised, creates uncertainty in the minds of patent owners, those working on the next generation of vaccines, and investors and commercial partners whose financial backing is essential to the success of the efforts of innovators.

Should Members choose to make use of the flexibility afforded by the TRIPS Waiver, the protection of IP in the territory of those Members would be significantly diluted. Specifically, pharmaceutical companies placing (or intending to place) COVID-19 vaccines on the market in these countries face the risks that: (i) the government may issue a compulsory license on the vaccine without any effort to obtain a voluntary license over it;[59] (ii) the government may issue compulsory licenses over the vaccine not only to supply the domestic market of that Member, but also for exportation to other markets (with fewer safeguards than provided for in Article 31*bis* of the TRIPS Agreement);[60] and (iii) the government may issue a compulsory license without providing adequate remuneration to the right holder.[61] These risks significantly detract from the ability of the patent owner to enjoy the rights conferred by the patent, and to derive economic value from the patent. In turn, they decrease the incentives for innovation generated by the availability of global IP protection.

Adding to the uncertainty, paragraph 2 of the TRIPS Waiver clarifies that a compulsory license may be issued through "any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place."[62] This provision provides greater comfort to Members who seek to issue compulsory licenses on an *ad hoc*, selective, and even discriminatory basis, without a general legal framework in place. Absent a general domestic law framework for compulsory licensing, patent owners enjoy a lower degree of predictability and security in matters of compulsory licensing, and face the risk that their rights may be taken away abruptly by an unpredictable government decision lacking any procedural safeguards.

All of these risks will also have consequences for the ability of patent owners, with rights over technologies necessary to COVID-19 vaccine production or supply, to license their patents to partners in the territories of WTO Members that may use the flexibilities under the waiver. *First,* since the risks created by the TRIPS Waiver will affect not only patent owners, but also licensees deriving their rights from licenses granted by the patent owners, potential licensees in certain Eligible Members may demand reduced fees to reflect the enhanced risks. *Second,* certain licensees may find it more attractive to lean on their governments to secure compulsory licenses than to negotiate voluntary licenses on commercial terms, particularly given that failed attempts at obtaining voluntary licenses are not a precondition to compulsory licensing in reliance on the TRIPS Waiver. *Third,* patent owners may consider these risks too high, and the rewards offered by the reduced license fees too low, and may consequently choose not to enter a particular market or exit an existing market. This would seriously compromise vaccine manufacturing capabilities, technology transfer, and ultimately, access to vaccines, in those markets.

B. Increased Risks of Diversion of Vaccines Produced and Exported Pursuant to the TRIPS Waiver

Pursuant to Article 28.1 of the TRIPS Agreement, the core rights conferred on a patent owner include the right to prevent all third parties from "making, using, offering for sale, selling, or importing" a product covered by a patent.[63] The exclusive rights to make and sell include the right to prohibit third parties, without authorization, from manufacturing a patented product for export, or selling the patented product for export. Article 28.1 also extends these exclusive rights to products that are obtained directly from a patented process.[64]

While the negotiators of Article 31 of the TRIPS Agreement had originally determined that compulsory licensing should not go so far as to permit the recipient

of the license to supply export markets, this position was ultimately moderated under certain limited circumstances through Paragraph 6 of the Doha Declaration, the WTO General Council's August 2003 Decision on the Implementation thereof, and, ultimately, Article 31*bis* of the TRIPS Agreement. This regime, however, was accompanied by detailed notification and concrete anti-diversion requirements. These requirements are an integral part of the mechanism, and essential for the objectives thereof. Absent the safeguards in these requirements, it is unlikely that WTO Members would have achieved consensus to amend the TRIPS Agreement to allow, under specified circumstances, export of products manufactured under a compulsory license.

The TRIPS Waiver allows compulsory licensing for export, but replaces these requirements with a post-shipment notification obligation and certain ambiguous "best efforts" obligations on anti-diversion efforts. This creates an enhanced risk that vaccines manufactured under a compulsory license, purportedly for export to a country facing a genuine vaccine shortage, will be diverted to more lucrative markets. Such diversion would, simultaneously, (1) reduce the economic opportunity for the patent owner in these lucrative markets, without any public health justification; and (2) deprive the most needy markets of COVID-19 vaccine, ultimately running counter to the purported rationale for the waiver—i.e., improved access to vaccines.

Curiously, those that advocate for maximum flexibility when it comes to compulsory licensing of pharmaceutical patents have argued that even the minimum notification requirement in the TRIPS Waiver may be unnecessary.[65] Yet, WTO Members have long understood the importance of transparency for measures providing for and affecting IP rights. Indeed, the TRIPS Agreement, itself, includes detailed transparency requirements in Article 63, as does Article 31*bis* and its predecessor. It is important for Members to be able to track the use and impact of waivers to core protections in the TRIPS Agreement, so that they may evaluate the impact and functioning of such waivers.

C. Impact on Remuneration to Patent Owners Affected by Compulsory Licensing

Compulsorily licensing a patent obviously has negative economic consequences to the patent owner, which loses the ability to negotiate the value of the patented product or process in the marketplace. As the WTO panel found in *Canada – Patent Protection of Pharmaceutical Products*, when interpreting the phrase "normal exploitation of [a] patent" in Article 30 of the TRIPS Agreement:

> "exploitation" refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent. The term "normal" defines the kind of commercial activity Article 30 seeks to protect.
>
> . . .
>
> The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. . . . Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws. Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the *policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined*.[66]

Thus, the ability to receive a premium price for a patented product or process is fundamental to patent protection, and the incentives to innovation that such protection generates. Recognising this fact, and aiming to preserve a balance between the rights of patent owners and the public interest underlying a compulsory license, Article 31(h) of the TRIPS Agreement provides that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."[67]

The TRIPS Waiver does not release Members from the obligation under Article 31(h). However, paragraph 3(d) identifies certain conditions that Members may take into account in determining adequate remuneration, stating that such determination:

> may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members. In setting the adequate remuneration

> in these cases, eligible Members may take into consideration existing good practices in instances of national emergencies, pandemics, or similar circumstances.[68]

Footnote 4, attached to this paragraph, identifies two examples of such "existing good practices"—"the remuneration aspects of the WHO-WIPO-WTO Study on Promoting Access to Medical Technologies and Innovation (2020), and the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1)."[69] Both of these documents reference, among other possibilities, the "tiered-royalty method" ("TRM") for determining remuneration, which may perhaps be understood as the type of practice referenced in paragraph 3(d) of the TRIPS Waiver.[70]

The starting point of calculations in the TRM is the price of the patented product in a high-income country, and four percent of that price is considered as the "base-royalty."[71] This "base-royalty" is treated as a proxy for the therapeutic value of the product, and is then adjusted by another proxy for the capacity of potential buyers to pay.[72] These adjustments are to be made generally on the basis of the relative per capita income of the country issuing the compulsory license, in comparison to the high-income country used for the calculation of the base royalty.[73] For countries with a high burden of the disease that is sought to be addressed through compulsory licensing, the adjustment is made on the basis of relative income per person with the disease.[74] Consequently, royalties are driven by two variables—the price in a high-income country, and the capacity of potential buyers to pay.

In a paper published in the Journal of Intellectual Property Law & Practice in 2021, I (and my co-author) previously argued that TRM is inconsistent with Article 31(h) of the TRIPS Agreement.[75] While Article 31(h) offers limited guidance on how remuneration is to be calculated, it clearly requires that remuneration be "adequate," "in the circumstances of each case, taking into account *the economic value of the authorization*."[76] As explained in that law journal article, the language of Article 31(h), properly interpreted in light of the context offered by other provisions of the TRIPS Agreement, requires: (i) the determination of remuneration to be a case-by-case exercise, and (ii) that remuneration reflect the full market value of the license from the perspective of the right holder (as required by the words "economic value of the authorization.")[77] TRM fails on both counts, as it uses a rigid formula that does not entail consideration of individual circumstances of each compulsory license, and neither of the two variables used reflects the market value of the license.

In possibly endorsing TRM as a "good practice," the TRIPS Waiver unfortunately is already being exploited by those who hope to legitimize a royalty method that falls short of the requirements of Article 31(h).[78] Inadequate royalties yielded by the TRM disturb the balance created by Article 31 of the TRIPS Agreement, and the TRIPS Agreement, more generally.

D. Impact on Regulatory Data Protection, and the Global Incentives to Invest in Bringing New Pharmaceutical Products to Market

As noted above, paragraph 4 of the TRIPS Waiver is the only provision that directly addresses a form of IP protection other than patents. In particular, paragraph 4 relates to regulatory data protection in accordance with Article 39.3 of the TRIPS Agreement.

Pursuant to Article 39.3, WTO Members must protect certain test and other data submitted "as a condition of approving the marketing of pharmaceutical or of agricultural chemical products."[79] Such protection provides the incentives necessary to conduct the expensive multi-phased clinical testing that is required to demonstrate the safety and effectiveness of a new drug or vaccine. Importantly, many such clinical trials result in failure, such that the actual cost of developing the data from both successful and unsuccessful products must be recouped from sales of those medicines and vaccines that are actually approved.

Pursuant to Article 39.3 of the TRIPS Agreement, WTO Members must protect such test and other data if the following conditions are met:

- The Member must require that the data be submitted as a condition for obtaining marketing approval for a product in that Member;
- The product for which marketing approval is sought is a pharmaceutical or agricultural chemical product;
- The product for which marketing approval is sought utilizes a new chemical entity;

• The data is undisclosed at the time of submission; and

• The generation of the data required considerable effort.[80]

Where these conditions are met, Article 39.3 entitles the data to (1) protection against "unfair commercial use;" and (2) protection against "disclosure," "except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

Properly interpreted, Article 39.3 requires WTO Members to prevent, for a limited period of time, third parties (including producers of generic drugs and biosimilars) from referencing or otherwise relying on the undisclosed data submitted by an originator to a governmental authority in order to demonstrate the safety and efficacy of their own competing product.[81] In other words, Article 39.3 effectively requires governments to treat the data developed to demonstrate safety and efficacy of the pharmaceutical product as exclusive to the party that developed it, for a limited period of time. Unlike with respect to patents, there is no provision permitting compulsory licensing of this type of IP right.

Allowing third parties to rely on the data generated by the originator in order to receive approval of their own competing pharmaceutical product, at a time before the originator could have been expected to recoup their investment, would provide competitors with an unfair commercial advantage. The competitor would avoid the cost of conducting its own tests or of licensing the data from the originator who spent resources in generating that data, and could use these (sometimes tremendous) cost savings to undercut the prices of the originator and gain market share. Without adequate protection, the high cost of developing test data (and the risk of its non-recuperation) may prevent market entry of innovative products.

Returning to the relevant portion of the TRIPS Waiver, paragraph 4 reads: "Recognizing the importance of the timely availability of and access to COVID-19 vaccines, it is understood that Article 39.3 of the Agreement does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision."[82] The language, "it is understood," does not purport to modify Article 39.3, or release Members from their obligations under that provision. However, those activists and WTO Members who have long advocated for diluting the obligation in Article 39.3 (by arguing, e.g., that Article 39.3 permits generic competitors to rely on data submitted by originators immediately after submission) may attempt to find support for their position in this portion of the TRIPS Waiver.

Indeed, this is precisely what Correa and Syam do in their South Centre "Research Paper" on the TRIPS Waiver, when they state: "The wording chosen in this paragraph is important, as it shows the understanding that the protection of test data as required under the TRIPS Agreement is not based on the grant of exclusive rights ('data exclusivity')."[83] They appear to go on to argue that the fact that the European Union and the United States signed on to this aspect of the TRIPS Waiver "suggest[s] a requirement of exclusivity has never been confirmed in the context of the WTO."[84] The vague language used in paragraph 4 of the TRIPS Waiver, of course, provides no support for such a bold proposition.

If the reference in the TRIPS Waiver to Article 39.3 were read as opening the door for governments to effectively forgo regulatory data protection, this would increase the harm to pharmaceutical companies that invest tremendous resources in preparing data for regulatory approval (including for products that are not protected by patents), and at significant risk that the pharmaceutical product will not ultimately be approved. The better reading of the provision would be one that harmonizes the protection in Article 39.3 with the possibility of speedy regulatory approvals.

This could be achieved, for example, by ensuring that regulatory data is adequately protected, while simultaneously creating conditions that enable originators of the data to readily cooperate with the beneficiaries of compulsory patent licenses granted pursuant to the TRIPS Waiver. These conditions could include the creation of well-defined rights for the creators of the protected data, ensuring certainty of enforcement of licensing contracts, and speedy and fair dispute settlement mechanisms.

It may also be the case that the reference to "rapid approval for use of a COVID-19 vaccine" in paragraph 4 is simply an acknowledgement of the fact that approval of COVID-19 vaccines, whether for originators or those producing under compulsory license, can in fact be expedited during health emergencies.[85] In the United States, for example, the FDA has made use of an expedited route known as Emergency Use Authorization ("EUA") that allowed distribution of COVID-19 vaccines before they were formally approved by the FDA. As the FDA explains,

EUA "is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, the FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives."[86] An EUA allows the sale of vaccines even before phase 3 clinical trials have been completed, and with less data about a "vaccine-maker's processes and facilities, including inspection of manufacturing plants," than would otherwise be required.[87]

E. Possible Impact on Global Competitiveness of Certain WTO Members

As explained above, by the terms of the TRIPS Waiver, developing country Members with existing manufacturing capacity for COVID-19 vaccines "are encouraged to make a binding commitment" that they will not avail of the flexibility under the waiver.[88] As noted above, China, in particular, made such a commitment at the meeting of the WTO General Council on May 10, 2022.[89] China's commitment was reportedly made at the behest of the United States, which has for several years alleged that China's policies require or pressure the transfer of U.S. IP rights and technology in China.[90] Understanding the importance of U.S.-owned IP rights to the U.S. economy, several Members of the U.S. Congress have repeatedly expressed concern about the impact of the COVID-19 Waiver on U.S. competitiveness.[91]

Ultimately, there is, and has always been, fierce competition among countries for the top spots in international trade and investment. As discussed in the beginning of this paper, the ability of the Western nations to rise to the top in this competition was enabled, in no small part, due to their robust systems of IP protection and the innovation they have fueled. If the COVID-19 pandemic leads Western nations to abandon their commitment to IP protection, innovation in these nations will slow, and that may, in the medium to long term, translate into loss of global competitiveness in the arena of international commerce. At the same time, other countries will naturally take the top spots that are left vacant. It would be myopic for Western nations to abandon the IP-engine powering their innovation and success at a time when they are worried about the growing economic threat from other countries.

VI. Possible Expansion of the TRIPS Waiver

As explained above, while the scope of the TRIPS Waiver currently covers COVID-19 vaccines and "ingredients and processes necessary for the manufacture of the COVID-19 vaccine," no later than six months from the date of its adoption (i.e., by 17 December 2022), Members "will decide" on the extension of the waiver "to cover the production and supply of COVID-19 diagnostics and therapeutics."[92] Any such extension of the substantive reach of the TRIPS Waiver would serve to further increase the harm to the global IP system, and decrease the incentives for innovation of products necessary to improve global public health.

As an initial matter, there is no indication of any existing global shortage of COVID-19 therapeutics or diagnostics, nor is there any evidence that particular localized instances of diagnostic or therapeutic shortages can somehow be blamed on IP protection.[93] As Mexico and Switzerland explained in a joint communication to the WTO TRIPS Council on November 1, 2022:

> Available information shows that no shortage of therapeutics exists. Instead, large parts of innovators' production capacity remain idle due to a lack of demand. According to Airfinity data, Pfizer would be able to produce 120 million doses of its Paxlovid therapeutic in 2022. The contracted supply stood in August 2022 at only 41.5 million doses, i.e. at 35% of the production capacity. The situation is similar with MSD's Molnupiravir, where

It would be myopic for Western nations to abandon the IP-engine powering their innovation and success at a time when they are worried about the growing economic threat from other countries.

> demand amounted to a mere 45% of the company's production capacity. Governments and NGOs have purchased 35 million COVID-19 treatments for LMIC for 2022 but have only been able to administer 10 million as of September this year.
>
> Global demand for tests has reduced and there is no evidence to suggest that supply is constrained relative to actual demand. Diagnostics companies working closely with WHO, and providing them with sample collection kits, have reported there is a high level of product surplus to order. This involves issues with logistics and distribution, which are not IP-related, but that need to be addressed.[94]

This communication by Mexico and Switzerland went on to highlight that, as of October 11, 2022, "138 bilateral or Medicines Patents Pool-based voluntary licensing agreements comprising some of the most highly demanded treatments, have been signed between innovators and companies all over the world enabling them to join this fight by producing therapeutics," covering more than 127 countries.[95] These agreements demonstrate that compulsory licensing is unnecessary and that existing TRIPS Agreement provisions already foster voluntary licensing of technologies, often on a royalty-free basis.

Further, the TRIPS Waiver provides no clarity of what the terms "COVID-19 diagnostics and therapeutics" refer to, and no guidance on how they should be defined. For example, there are a variety of ways to treat the symptoms of COVID-19, some of which overlap with treatments for other common conditions (such as steroid nasal sprays, which are also used for seasonal allergies).[96] That said, to the extent Members were to define the term "COVID-19 therapeutics" to cover those treatments targeted specifically for COVID-19 by the health authorities of governments like the United States, the focus would appear to be on certain antivirals (oral and intravenous) and monoclonal antibodies.[97]

The lack of any definition of perhaps the two most important terms in any TRIPS Waiver extension (i.e., "COVID-19 diagnostics" and "COVID-19 therapeutics") highlights the fact that any such extension would require more than just a one-line Ministerial statement providing that WTO Members have agreed to a subject matter extension. Rather, they would need to negotiate new legal text.

Among other aspects that would need to be negotiated is the definition of Eligible Members, as footnote 1 of the TRIPS Waiver is currently focused on the COVID-19 vaccine context. Those negotiating the TRIPS Waiver extension would also need to determine whether certain otherwise Eligible Members would be excluded from the scope. It does not automatically follow that countries that have made a "binding commitment not to avail themselves of" the TRIPS Waiver, such as China, would likewise do the same for a TRIPS Waiver extension.

The negotiators of any TRIPS Waiver extension would also need to consider the fact that diagnostics and therapeutics used for COVID-19 (such as test kits) may build upon platform technologies with actual and potential applications that go far beyond the COVID-19 context. Those Members advocating for strong IP protection would need to propose legal text which, *inter alia*, limits the impact on the future development of revolutionary technologies such as the CRISPR ("clustered regularly interspaced short palindromic repeats") gene editing process,[98] which is being used for COVID-19 diagnostics. CRISPR has "countless applications," with researchers working to apply it to "alter human genes to eliminate diseases; create hardier plants; wipe out pathogens and more."[99]

In May of 2020, Sherlock Biosciences, Inc. received FDA EUA for a COVID-19 testing kit that uses a CRISPR gene editing process to detect the virus in respiratory fluid samples.[100] Since then, other labs have developed CRISPR-based COVID-19 testing processes that are even more sensitive and can identify the virus even more quickly than the Sherlock Biosciences test.[101] For example, in January 2022, the FDA authorized Mammoth Bio's rapid CRISPR test for COVID-19, which "aims to process thousands of samples per day."[102]

Adding COVID-19 diagnostics to the product scope of the waiver could lead to the increased compulsory licensing of patents covering test kits and associated processes, such as CRISPR gene editing methods. It would be difficult to ensure that diagnostics manufactured pursuant to a compulsory license of patents claiming aspects of the CRISPR gene editing technology are used exclusively for the purpose of combating COVID-19. This possibility highlights the problems inherent with compulsory licensing of technologies with uses far beyond COVID-19, whether it be CRISPR or mRNA technologies, and the impact

that such compulsory licensing could have on slowing or eliminating a wide range of future global innovation.

It follows that any extension of the TRIPS Waiver to COVID-19 diagnostics and therapeutics could, by undermining global IP protection and norms, jeopardize the development of not only the 1,800 COVID-19 therapeutics that are currently in the R&D pipeline,[103] but also innovation going far beyond COVID-19.

ENDNOTES

1 *See Ministerial Decision on the TRIPS Agreement*, WTO Doc. WT/MIN(22)/30 (Jun. 22, 2022), available at: **https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True** ("TRIPS Waiver").

2 *Id.* at ¶ 1.

3 TRIPS Council, *Communication to the TRIPS Council from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, Annex at ¶ 1, WTO Doc. IP/C/W/669 (October 2, 2020).

4 Press Release, U.S. Food & Drug Admin., FDA Approves First COVID-19 Vaccine (Aug. 23, 2021), available at: **https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine#:~:text=The%20first%20EUA%2C%20issued%20Dec,trial%20of%20thousands%20of%20individuals**.

5 Eric M. Solovy, *The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health*, 42 Nw J. Int'l L. & Bus. 253, 289-296 (2022), available at: **https://jilb.law.northwestern.edu/issues/?vol=vol%2042%20-%20issue%202**.

6 *See* Bojan Pancevski & Jared Hopkins, *How Pfizer Partner BioNTech Became a Leader in Coronavirus Vaccine Race*, Wall Street Journal (Oct. 22, 2020), **https://www.wsj.com/articles/how-pfizer-partner-biontech-became-a-leader-in-coronavirus-vaccine-race-11603359015**.

7 *See* Elie Dolgin, *The Tangled History of mRNA Vaccines*, Nature (Sept. 14, 2021), **https://www.nature.com/articles/d41586-021-02483-w**.

8 *See* Pancevski & Hopkins, *supra* note 6; *see also* David Gelles, *The Husband-and-Wife Team Behind the Leading Vaccine to Solve Covid-19*, New York Times (Nov. 10, 2020), **https://www.nytimes.com/2020/11/10/business/biontech-covid-vaccine.html**.

9 *See* Moderna, Inc., U.S. Securities and Exchange Commission filing (Amendment No. 1 to Form S-1 Registration Statement), November 28, 2018, at i, 1.

10 *Id.* at 20.

11 *See, e.g.,* Guilherme Cintra, *Is an extension of the TRIPS waiver needed for COVID-19 tools?*, Global Health Matters, IFPMA (Oct. 15, 2022), available at: **https://www.ifpma.org/global-health-matters/is-an-extension-of-the-trips-waiver-needed-for-covid-19-tools/**; *see also COVID-19 vaccines and treatments output continues apace*, IFPMA (Apr. 13, 2022), available at: **https://www.ifpma.org/resource-centre/covid-19-vaccines-and-treatments-output-continues-apace-as-health-systems-and-last-mile-hurdles-remain-collective-stumbling-blocks/** ("The COVID-19 vaccine manufacturing scale-up has seen 372 partnerships forged, of which 88% (329) include technology transfer or fill & finish. 51 manufacturing and production agreements were made in developing countries (LICs and LMICs).").

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

13 *See* Shayerah I. Akhtar, Cong. Rsch. Serv., R47231, World Trade Organization: "TRIPS Waiver" for COVID-19 Vaccines (2022), at 13.

14 *Lack of a real IP waiver on COVID-19 tools is a disappointing failure for people,* Médecins Sans Frontières (Jun. 17, 2022), available at: **https://www.msf.org/lack-real-ip-waiver-covid-19-tools-disappointing-failure-people** (asserting that "we are disappointed that a true intellectual property waiver, proposed in October 2020 covering all COVID-19 medical tools and including all countries, could not be agreed upon, even during a pandemic that has claimed more than 15 million people's lives.").

15 Press Release, U.S. Chamber of Commerce, Proposal at WTO to Waive Intellectual Property Would Set Harmful Precedent (Jun. 15, 2022), available at: **https://www.uschamber.com/intellectual-property/proposal-at-wto-to-waive-intellectual-property-would-set-harmful-precedent**; *see also, e.g.*, Press Release, PhRMA, PhRMA Statement on the TRIPS Waiver Agreement (Jun. 17, 2022), available at: **https://phrma.org/resource-center/Topics/Trade/PhRMA-Statement-on-the-TRIPS-Waiver-Agreement** (stating that the COVID-19 TRIPS Waiver "undermine[s] the very intellectual property rights that enabled hundreds of collaborations to produce the COVID-19 vaccines on a global scale.").

16 *See generally, e.g.,* Pamela O. Long, *Invention, Authorship, "Intellectual Property," and the Origin of Patents: Notes toward a Conceptual History*, 32 Technology & Culture 864-884 (1991) (Special Issue: Patents and Invention); Joanna Kostylo, *From Gunpowder to Print: The Common Origins of Copyright and Patent*, in Ronan Deazley et al., Privilege and Property: Essays on the History of Copyright Law 23-50 (Cambridge: Open Book Publishers, 2010); Joanna Kostylo, *Venetian Statute on Industrial Brevets, Venice (1474)*, in Primary Sources on Copyright (1450-1900) (L. Bently & M. Kretschmer, eds., 2008); Carlo Marco Belfanti, *Between mercantilism and market: Privileges for invention in early modern Europe*, 2 J. Inst. Econ. 319-338 (2006); William W. Fisher III, "The Growth of Intellectual Property: A History of the Ownership of Ideas in the United States," available at: **https://cyber.harvard.edu/people/tfisher/iphistory.pdf**.

17 *See generally, e.g.,* David M Gould & William C Gruben, The *Role of Intellectual Property Rights in Economic Growth,* in Dynamics of Globalization and Development 369-405 (Satya Dev Gupta & Nanda K. Choudhry, eds., Springer, 1997).

18 *See generally, e.g.,* The Role of Intellectual Property Rights in Biotechnology Innovation (David Castle, ed., Edward Elgar Publishing, 2009); Eric Solovy & Deepak Raju, *The UNDP/WHO Remuneration Guidelines: A Proposed Formula for Inadequate Remuneration for Compulsory Licencing in Violation of the TRIPS Agreement,* 16 J. Intel. Prop. L. & Prac. 1192-1202 (2021); Harvey E. Bale Jr., *Patent protection and pharmaceutical innovation,* 29 NYU J. Int'l L. & Pol. 95 (1996).

19 *See* WTO, *WTO Members Agree to Extend TRIPS Transition Period for LDCs until 1 July 2034* (June 29, 2021), available at: **https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm**; TRIPS Council, Extension of the Transition Period Under Article 66.1 for Least Developed Country Members, Decision of the Council for TRIPS of 29 June 2021, WTO Doc. IP/C/88 (June 29, 2021). There is also a longstanding transition period, also for LDCs, for certain obligations with respect to pharmaceutical products, which currently extends through January 1, 2033. *See* 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, IP/C/73 (Nov. 6, 2015). The WTO recognizes as LDCs those 49 countries designated as such by the United Nations, 30 of which are WTO Members. *See* WTO, Towards Free Market Access for Least-Developed Countries, available at: **https://www.wto.org/english/thewto_e/minist_e/min01_e/brief_e/brief03_e.htm** (last visited Nov. 28, 2022).

20 Appellate Body Report, *Brazil – Measures Affecting Desiccated Coconut*, p. 12, WTO Doc. WT/DS22/AB/R (adopted Mar. 20, 1997).

21 *See* Agreement Establishing the World Trade Organization, Annex 1.C.

22 *See generally*, TRIPS Agreement, Parts II and III.

23 *See* TRIPS Agreement, Art. 1.1.

24 *See, e.g.,* Panel Report, *Saudi Arabia — Measures concerning the Protection of Intellectual Property Rights*, WTO Doc. WT/DS567/R (circulated Jun, 16, 2020); *see also* Panel Report, *China — Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WTO Doc. WT/DS362/R (adopted Mar. 20, 2009).

25 TRIPS Council, *Communication to the TRIPS Council from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, ¶ 12, WTO Doc. IP/C/W/669 (October 2, 2020).

26 *Id.*

27 TRIPS Council, *Communication to the TRIPS Council by the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, The LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, The Bolivarian Republic of Venezuela, and Zimbabwe, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text,* ¶ 4, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021).

28 *Id.*

29 *See* TRIPS Council, *Communication from the European Union to the TRIPS Council, Urgent Trade Policy Response to the COVID-19 Crisis: Intellectual Property*, WTO Doc. IP/C/W/680 (Jun. 4, 2021); *see also* TRIPS Council, *Communication from the European Union to the TRIPS Council, Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic,* WTO Doc. IP/C/W/681 (Jun. 18, 2021).

30 TRIPS Waiver, ¶ 1 and footnote 2.

31 *Id.* at footnote 1.

32 *Id.*

33 WTO General Council, *Minutes of the Meeting* (May 9-10, 2022), ¶ 5.9, WTO Doc. WT/GC/M/198 (July 21, 2022), available at: **https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/M198.pdf&Open=True** ("To further demonstrate our pragmatism and constructiveness and to better facilitate the negotiation, China hereby announces that, if our concern on the footnote is addressed, we will not seek to use the flexibility provided by this decision.").

34 TRIPS Agreement, Art. 31(b).

35 TRIPS Waiver, ¶ 3(a).

36 TRIPS Agreement, Art. 31(b).

37 TRIPS Waiver, ¶ 3(b).

38 *Declaration on the TRIPS Agreement and Public Health,* WTO Doc. WT/MIN(01)/Dec/2 (Nov. 20, 2001) (adopted Nov. 14, 2001).

39 *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the General Council of August 30, 2003, WTO Doc. WT/L/540 and Corr.1 (Sept. 1, 2003); see also generally,* Eric M. Solovy, *The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health*, 42 Nw. J. Int'l L. & Bus. 253, 258-277 (2022), available at: **https://jilb.law.northwestern.edu/issues/?vol=vol%2042%20-%20issue%202**.

40 TRIPS Waiver, ¶ 3(c).

41 *Id.* at footnote 3.

42 A summary of the anti-diversion and notification requirements can be found in WTO, WIPO and WHO, COVID-19 Update to Promoting Access to Medical Technologies and Innovation 304-309 (2nd ed., as updated on Aug. 30, 2021), available at: **https://www.wipo.int/edocs/pubdocs/en/wipo-pub-628e-insert-en-an-integrated-health-trade-and-ip-approach-to-respond-to-the-covid-19-pandemic-update-august-30-2021.pdf**.

43 TRIPS Agreement, Art. 31(h).

44 *Id.*

45 TRIPS Waiver, ¶ 3(d).

46 *Id.* at ¶ 3(d) and footnote 4.

47 *Id.* at ¶ 2.

48 *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, 20-22 (2003).

49 TRIPS Waiver, ¶ 4.

50 *Id.* at ¶ 6.

51 *Id.* at ¶ 8.

52 *Id.* at ¶¶ 1 ("in accordance with the provisions of Article 31 of the Agreement, as clarified and waived") and 3 ("Members agree on the following clarifications and waiver . . .").

53 *Id.* at ¶ 6.

54 Marrakesh Agreement, Art. IV:1.

55 *Id.* at Art. IX:3.

56 *Id.* at Art. IX:4.

57 TRIPS Waiver, ¶ 5.

58 Josh Wingrove et al., *Failure to address a global surplus of COVID vaccines raises the risk of new variants emerging, health experts warn*, Fortune (May 11, 2022), available at: **https://fortune.com/2022/05/11/covid-19-vaccines-global-surplus-new-variants/** ("The world finds itself awash in COVID-19 vaccines, but governments can't get them into arms fast enough, as hesitancy and logistical hurdles threaten to indefinitely extend the pandemic.").

59 TRIPS Waiver, ¶ 3(a).

60 *Id.* at ¶ 3(b).

61 *Id.* at ¶ 3(d). For a discussion on why this provision may result in inadequate remuneration, *see* part V(C), *infra*.

62 TRIPS Waiver, ¶ 2.

63 TRIPS Agreement, Art. 28.1(a).

64 *Id.* at Art. 28.1(b).

65 Carlos M. Correa & Nirmalya Syam, "The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?", South Centre Research Paper 169 (Nov. 8, 2022), at 14, available at: **https://www.southcentre.int/wp-content/uploads/2022/11/RP169_The-WTO-TRIPS-Decision-on-COVID-19-Vaccines_EN.pdf**.

66 Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, ¶¶ 7.54-7.55, WTO Doc. WT/DS114/R (adopted April 7, 2000) (emphasis added).

67 TRIPS Agreement, Art. 31(h).

68 TRIPS Waiver, ¶ 3(d).

69 *Id.* at footnote 4.

70 *See* James Love, *Remuneration Guidelines for Non-Voluntary Use of A Patent on Medical Technologies*, Health Economics and Drugs TCM Series No. 18, Pub. No. WHO/TCM/2005.1 (2005), at 85. TRM was featured in this report, commissioned by the United Nations Development Programme and the WHO, and referenced in subsequent reports by the WTO and other international organizations. *See also* WTO, WIPO, and WHO, Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade (2nd ed., 2020), at 231 (Table 4.1) and Section IV, endnote 241, available at: **https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf**.

71 *See* Love, *supra* note 70, at 85.

72 *Id.* at 73-74.

73 *Id.*

74 *Id.*

75 *See generally* Eric M. Solovy & Deepak Raju, *The UNDP/WHO remuneration guidelines: a proposed formula for inadequate remuneration for compulsory licencing in violation of the TRIPS agreement*, 16 J. Intell. Prop. L. & Prac. 1192-1202 (2021).

76 TRIPS Agreement, Art. 31(h) (emphasis added).

77 Solovy & Raju, *supra* note 75, at 1194.

78 *See* Correa & Syam, *supra* note 65, at 12 (asserting that "[t]he option spelled out in paragraph 3 (d) of the Decision with regard to determining the level of adequate remuneration for a compulsory license *is also a flexibility already allowed under article 31 (h). This is hence another clarification and not a waiver.* Members can currently use—and in fact, some have done so—the WHO "Remunerations Guidelines" mentioned in footnote 4.") (emphasis added).

79 TRIPS Agreement, Art. 39.3.

80 *See* Skillington & Solovy, *supra* note 48, at 23.

81 *Id.* at 51.

82 TRIPS Waiver, ¶ 4.

83 Correa & Syam, *supra* note 65, at 13.

84 *Id.*

85 To be clear, pursuant to Article 39.3 of the TRIPS Agreement, undisclosed test or other data submitted in the context of an expedited procedure during a public health emergency must be protected in the same way as the more comprehensive set of data required for full approval. When data is submitted "as a condition of approving the marketing of pharmaceutical" products, whether for emergency use approval or full approval, Article 39.3 applies. Developing such data in each situation "involves a considerable effort" within the meaning of the provision. Thus, for both the originator of test data and any authorized generic competitors *that choose to prepare and develop their own test data* regarding the safety and efficacy of a pharmaceutical product, the approval can be "rapid" relative to the process under normal circumstances.

86 U.S. Food & Drug Admin, Emergency Use Authorization for Vaccines Explained, available at: **https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained** (last visited Nov. 28, 2022).

87 *Id.; see also* Carrie MacMillan, *Emergency Use Authorization Vs. Full FDA Approval: What's the Difference?*, Yale Medicine (Mar. 7, 2022), **https://www.yalemedicine.org/news/what-does-eua-mean#:~:text=For%20an%20EUA%20for%20a,for%20at%20least%20six%20months**.

88 TRIPS Waiver, footnote 1.

89 WTO General Council, *Minutes of the Meeting* (May 9-10, 2022), ¶ 5.9, WTO Doc. WT/GC/M/198 (July 21, 2022), available at: **https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/GC/M198.pdf&Open=True** ("China hereby announces that, if our concern on the footnote is addressed, we will not seek to use the flexibility provided by this decision").

90 *See* Bryce Baschuk, *US-China Fight May Spoil Global Deal for a Covid Vaccine-Patent Waiver*, Bloomberg (May 16, 2022), **https://www.bloomberg.com/news/articles/2022-05-16/us-china-spat-may-spoil-global-deal-for-a-vaccine-patent-waiver?leadSource=uverify%20wall**; *see also* Office of the US Trade Representative, Findings of the Investigation into China's Acts, Policies and Practices Related to Technology Transfer, Intellectual Property, and Innovation Under Section 301 of the Trade Act of 1974 (March 22, 2018), available at: **https://ustr.gov/sites/default/files/Section%20301%20FINAL.PDF**.

91 *See* Shayerah I. Akhtar, Cong. Rsch. Serv., R47231, World Trade Organization: "TRIPS Waiver" for COVID-19 Vaccines (2022), at 13 (noting that "[s]ome Members of Congress and business groups argue that [the TRIPS Waiver] could compromise U.S. competitiveness internationally and pose major national security threats . . . ."); *see also* Press Release, United States Senate Committee on Finance, Crapo, Brady: President Biden Set America's Interests Back at WTO -- No Dispute Reform, Surrendered Crucial Medical Patents, Failed to Protect U.S. e-Commerce, Fishing Interests (June 17, 2022), available at: **https://www.finance.senate.gov/ranking-members-news/crapo-brady-president-biden-set-americas-interests-back-at-wto_--no-dispute-reform-surrendered-crucial-medical-patents-failed-to-protect-us-e-commerce-fishing-interests**; Letter to Secretary Gina Raimundo and Ambassador Katherine Tai (May 19, 2021), available at: **https://www.cotton.senate.gov/imo/media/doc/trips.pdf**.

92 TRIPS Waiver, ¶ 8.

93 *See, e.g.,* Guilherme Cintra, *Is an extension of the TRIPS waiver needed for COVID-19 tools?,* Global Health Matters, IFPMA (Oct. 15, 2022), **https://www.ifpma.org/global-health-matters/is-an-extension-of-the-trips-waiver-needed-for-covid-19-tools/**.

94 TRIPS Council, *Communication from Mexico and Switzerland, TRIPS Council Discussion on COVID-19 Therapeutics and Diagnostics: Evidence and Questions on Intellectual Property Challenges Experienced by Members*, ¶¶ 2-3, WTO Doc. IP/C/W/693 (Nov. 1, 2022) (internal citations omitted).

95 *Id.* at ¶ 4.

96 Press Release, Cleveland Clinic, Cleveland Clinic Study Suggests Steroid Nasal Spray May Help Improve Outcomes in Severe COVID-19 Disease (Sept. 28, 2021), available at: **https://newsroom.clevelandclinic.org/2021/09/28/cleveland-clinic-study-suggests-steroid-nasal-sprays-may-help-improve-outcomes-in-severe-covid-19-disease/**.

97 *See, e.g.,* U.S. Dep't Of Health & Human Servs. Admin. for Strategic Preparedness and Response, What Are the Possible Treatment Options for COVID-19, available at: **https://aspr.hhs.gov/COVID-19/Treatments/Pages/Possible-Treatment-Options-for-COVID19.aspx** (last visited Nov. 28, 2022) (listing Paxlovid®, Lagevrio® (molnupiravir), Veklury® (remdesivir), bebetlovimab, and Evusheld®).

98 *See* Heidi Ledford & Ewen Callaway, *Pioneers of revolutionary CRISPR gene editing win chemistry Nobel*, Nature (Oct. 7, 2020), available at: **https://www.nature.com/articles/d41586-020-02765-9**; *see also* Oliver Whang, *The Many Uses of CRISPR: Scientists Tell All*, New York Times (Jun. 27, 2022), **https://www.nytimes.com/2022/06/27/science/crispr-science-medical-research.html**; Syed Shan-e-Ali Zaidi et al., *Engineering crops of the future: CRISPR approaches to develop climate-resilient and disease-resilient plants*, 21 Genome Biology 289 (2020).

99 Ledford & Callaway, *supra* note 98.

100 Giorgia Guglielmi, *First CRISPR test approved for coronavirus approved in the United States*, Nature (May 8, 2020), **https://www.nature.com/articles/d41586-020-01402-9**; *see also* U.S. Food & Drug Admin., Instructions for Use: Sherlock CRISPR SARS-CoV-2 Kit (2022), **https://www.fda.gov/media/137746/download**.

101 *See* Robert F. Service, *New test detects coronavirus in just 5 minutes*, Science (Oct. 8, 2020), **https://www.science.org/content/article/new-test-detects-coronavirus-just-5-minutes**.

102 Conor Hale, *FDA authorizes Mammoth Bio's high-thoroughput CRISPR test for COVID-19*, Fierce Biotech (Jan. 24, 2022), **https://www.fiercebiotech.com/medtech/fda-authorizes-mammoth-bio-s-high-throughput-crispr-test-for-covid-19**.

103 TRIPS Council, *Communication from Mexico and Switzerland, TRIPS Council Discussion on COVID-19 Therapeutics and Diagnostics: Evidence and Questions on Intellectual Property Challenges Experienced by Members*, ¶ 10, WTO Doc. IP/C/W/693 (Nov. 1, 2022) (internal citation omitted) (citing EFPIA, Factsheet On COVID-19 Therapeutics (September 2022)).

ABOUT THE AUTHOR

Eric M. Solovy is Partner, Global Arbitration, Trade and Advocacy at Sidley Austin, LLP. Mr. Solovy is a Practitioner in Residence at the Center for Intellectual Property x Innovation Policy. He received his B.A. in 1996 from Duke University and his J.D. from Harvard Law School in 1999 (where he served as Executive Editor of the *Harvard International Law Journal*). From 2001-2002, Mr. Solovy served as law clerk to the Honorable Pauline Newman, Circuit Judge, U.S. Court of Appeals for the Federal Circuit.

The arguments and views in this policy brief are the author's and do not necessarily reflect those of the Center for Intellectual Property x Innovation Policy.

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Center for Intellectual Property x Innovation Policy
George Mason University Antonin Scalia Law School
3301 Fairfax Drive
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