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Redefining the TRIPS Agreement to Accommodate en masse Compulsory Licensing of Vaccines & Other Pharmaceuticals for the Treatment of Covid-19

Alexandra H. Farquhar

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**REDEFINING THE TRIPS AGREEMENT TO ACCOMMODATE EN
MASSE COMPULSORY LICENSING OF VACCINES & OTHER
PHARMACEUTICALS FOR THE TREATMENT OF COVID-19**

*Alexandra H. Farquhar**

Globally, over 48 million cases and over one million deaths have resulted from the COVID-19 pandemic at the time of this publication. Governments and pharmaceutical companies are simultaneously racing for effective treatments and vaccines against the deadly virus, giving rise to a vaccine nationalism in effort to claim a global monopoly on recovery. This Article analyzes the possible compulsory licensing fallout over COVID-19 vaccines and pharmaceuticals under the current terms of the TRIPS Agreement, advocating for clarifying the ambiguous language of TRIPS, creating a standardized compensation scheme to patent holders, and developing a third-party arbitration mechanism to specifically address compulsory licensing disputes over COVID-19 pharmaceuticals and vaccines. These proposed solutions aim to balance the interests of patent holders with the interests of the global population.

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I. INTRODUCTION

The current COVID-19 crisis is the most widespread *global* pandemic of this generation.¹ Both developed and developing countries *en masse* are desperately seeking pharmaceuticals and vaccines to fight the virus.² There are a number of antivirals and vaccines in development for treatment of COVID-19 in the United States alone,³ and several more abroad.⁴ This situation presents an opportunity to better define the terms of the international agreement on Trade-Related Aspects of Intellectual Property Rights

¹ Other than HIV/AIDS, which has killed a sobering 35 million people, only the Asian Flu and Hong Kong Flu in the 1950s and 1970s had approached the current 1 million death toll of COVID-19. See Michael S. Rosenwald, *History's Deadliest Pandemics, from Ancient Rome to Modern America*, WASH. POST (Apr. 7, 2020), <https://www.washingtonpost.com/graphics/2020/local/retropolis/coronavirus-deadliest-pandemics/> [https://perma.cc/ZH2H-CUPV]; see WHO Coronavirus Disease (COVID-19) Dashboard, WORLD HEALTH ORG. (2020), <https://covid19.who.int/> [https://perma.cc/5EK8-NG69].

² See Saeed Shah, *In Race to Secure Covid-19 Vaccines, World's Poorest Countries Lag Behind*, WALL ST. J. (Sept. 1, 2020), <https://www.wsj.com/article/s/in-race-to-secure-covid-19-vaccines-worlds-poorest-countries-lag-behind-11598998776> [https://perma.cc/RG2S-H664].

³ Al Root, *Here are the Covid-19 Vaccines and Antivirals Being Worked on Right Now*, BARRON'S, https://www.barrons.com/articles/a-field-guide-to-covid-19-vaccines-and-antivirals-51597352125?adobe_mc=MCMID%3D38365370633112365923991533347248315051%7CMCORGID%3DCB68E4BA55144CA0A4C98A5%2540AdobeOrg%7CTS%3D1598203825 [https://perma.cc/5L9F-QANN] (Aug. 14, 2020, 7:59 AM).

⁴ See *172 Countries and Multiple Candidate Vaccines Engaged in COVID-19 Vaccine Global Access Facility*, WORLD HEALTH ORG. (Aug. 24, 2020), <https://www.who.int/news-room/detail/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility> [https://perma.cc/CA3U-V9HE].

(“TRIPS”).⁵ TRIPS provisions providing for compulsory licensing⁶ were originally included to accommodate epidemics plaguing least-developed countries⁷ in need of life-saving therapeutics. However, these overly broad provisions meant to provide individual least-developed countries with flexibility in accessing medicines during public health crises are ill-suited to accommodate a pandemic of scale like COVID-19. Therefore, it is necessary to rework the compulsory licensing provisions within TRIPS to develop a solution that would balance the costs of developing an effective vaccine or treatment with the benefits of efficiently disseminating those pharmaceuticals to all countries in need. This Article explores how tighter definitions, standardized compensation schemes, and third-party arbitration mechanisms could improve TRIPS and craft a more practical and workable framework to disseminate curative medicines worldwide.

Part II of this Article examines the compulsory licensing provisions of the TRIPS Agreement. Part III examines the rise of vaccine nationalism against the backdrop of World Health Organization’s (“WHO”) “Solidarity Call to Action” in the current pandemic. Part IV analyzes the consequences and deficiencies of current TRIPS compulsory licensing provisions in disseminating a vaccine quickly and efficiently on an international scale. Finally, Part V suggests possible improvements to the TRIPS Agreement to promote greater patent protection and international cooperativity, including tighter definitions within the agreement, standardized compensation schemes, and third-party arbitration mechanisms.

⁵ Agreement on Trade-Related Aspects of Intellectual Property, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1191 (1994) [hereinafter TRIPS].

⁶ *Id.* at art. 31.

⁷ “The WTO recognizes as least-developed countries (LDCs) those countries which have been designated as such by the United Nations. There are currently 47 least-developed countries on the UN list, 36 of which to date have become WTO members.” *Least-developed Countries*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm [https://perma.cc/UFU9-5PMF] (last visited Oct. 8, 2020). Additionally, “[t]here are no WTO definitions of ‘developed’ or ‘developing’ countries,” and these designations are self-defined. These Members all benefit from TRIPS. *Id.*

II. TRIPS AGREEMENT – COMPULSORY LICENSING

TRIPS⁸ is an international trade agreement between all members of the World Trade Organization (“WTO”), effective since January 1, 1995, that sets minimum standards for regulation of intellectual property (“IP”) rights, including patents on pharmaceuticals and vaccines.⁹ TRIPS broadly defines intellectual property to include copyright, trademarks, and patents.¹⁰ While typical patent coverage under TRIPS provides for a twenty-year monopoly,¹¹ mirroring the U.S. patent system, the drafters also included Article 31 to address the humanitarian concerns of accessing technology through compulsory licenses¹² issued by countries experiencing a “national emergency” or other “extreme urgency.”¹³ Although member countries (“Members”) are normally required to first negotiate for a voluntary license with a patent holder prior to issuing a compulsory license, this requirement may be bypassed by a Member experiencing a “national emergency,” such as a public health crisis, and instead automatically issue its own compulsory license for the needed drug without the permission of the patent holder.¹⁴ This compulsory license enables the Member licensee to manufacture or produce the licensed drug within its borders for use in addressing its public health crisis and to determine “adequate remuneration” for the patent-holder.¹⁵

⁸ TRIPS, *supra* note 5.

⁹ *Overview: the TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm [<https://perma.cc/C4KY-DFA6>] (last visited Sept. 6, 2020).

¹⁰ TRIPS, *supra* note 5, at art. 1.2.

¹¹ *Id.* at art. 33.

¹² A compulsory license is “when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.” *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm [<https://perma.cc/D2KU-6NBQ>] (last visited Sept. 20, 2020). In the TRIPS Agreement, the country that “issues” or “grants” a compulsory license is the country using that patented product without the patent holder’s consent. *See id.*

¹³ TRIPS, *supra* note 5, at art. 31(b).

¹⁴ *See id.*

¹⁵ *See id.* at art. 31(h).

However, developing countries have often found Article 31 well-intentioned but impractical in use.¹⁶ In particular, countries with little or no resources to manufacture products remained unable to access the technology even though they held a compulsory license, due to the requirement that the drug be manufactured within its borders.¹⁷ In response, the WTO TRIPS council in 2003 adopted the amendment Article 31*bis* to allow exporting Member countries to manufacture pharmaceutical products under a compulsory license for an “eligible importing Member” experiencing a “national emergency” or “extreme urgency” in public health crises.¹⁸ Although all countries under Article 31*bis* may export generic pharmaceuticals under a compulsory license, Members could opt out of qualifying as an “eligible importing Member” that may receive pharmaceuticals manufactured under a compulsory license.¹⁹ Notably, the United States, as well as Canada, the United Kingdom, and many countries in the European Union, have opted out of qualifying as an “eligible importing Member,” meaning that they cannot receive generic pharmaceuticals from another exporting Member under a compulsory license pursuant to Article 31*bis*.²⁰ The United States’ decision to opt out as an eligible importing Member has been highly criticized as “shortsighted,” especially in the context

¹⁶ World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration] (acknowledging aspects of TRIPS that serve as roadblocks to equitable access to medicines, and reaffirming that TRIPS should “promote access to medicines for all”).

¹⁷ See *id.*; see TRIPS, *supra* note 5, at art 31(f).

¹⁸ See Amendment of the TRIPS Agreement, WTO Doc. WT/L/641 (Dec. 8 2005) [hereinafter TRIPS, art. 31*bis*]; see Dawn Dziuba, *TRIPS Article 31bis and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection?*, 20 IND. INT’L & COMP. L. REV. 195, 196–97 (2011).

¹⁹ See TRIPS, art. 31*bis*, *supra* note 18.

²⁰ Currently, thirty-seven Members of the WTO have opted out of participating as “eligible importing Members,” meaning that they cannot receive generic pharmaceuticals from eligible exporting Members. See *Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured under Compulsory License in Another Country, under 31bis of TRIPS Agreement*, KNOWLEDGE ECOLOGY INT’L (Apr. 7, 2020) [hereinafter *Open Letter*], <https://www.keionline.org/32707> [<https://perma.cc/HW4E-VR3W>].

of the COVID-19 pandemic where manufacturing capacity may fall short of the current crisis.²¹

Despite its intended purpose to aid developing countries in their ability to access life-saving medicines, compulsory licenses issued under Article 31 or the amended Article 31*bis* continue to face significant roadblocks and international red tape since the adoption of TRIPS.²² In particular, it took nearly four years to provide Rwanda, an eligible importing Member, with generic AIDS pharmaceuticals via Article 31*bis*.²³ Delays included a nearly two-year negotiation process between the generic manufacturer and patent holders, and over a year delay from when Rwanda's compulsory license was issued to the delivery of the first shipment.²⁴

Besides the practical limitations in effectively negotiating compulsory licenses, some countries utilize strong-arm tactics and attempt to abuse the system under Article 31 and Article 31*bis*.²⁵ For example, Brazil has issued, and threatened to issue, a compulsory license per Article 31 of TRIPS as a bargaining chip to lower prices of eligible pharmaceuticals from “Big Pharma” patent holders in the United States.²⁶ The United States has also accused Thailand of failing to enforce intellectual property rights when the country applied to extend compulsory licenses of antiretroviral drug²⁷

²¹ See *id.*

²² See Donald Harris, *TRIPS After Fifteen Years: Success or Failure as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 387–91 (2011); Tanya Talaga, *AIDS Drugs Fiasco a Tale of Red Tape*, STAR (Aug. 9, 2007), https://www.thestar.com/news/canada/2007/08/09/aids_drugs_fiasco_a_tale_of_red_tape.html [<https://perma.cc/8N2W-FHPM>].

²³ Harris, *supra* note 22, at 387–91.

²⁴ *Id.* The entire process was so expensive and slow that the Canadian generic drug manufacturer, Apotex, stated that it would not participate in another TRIPS compulsory licensing deal without future change in the legislation.

²⁵ See *id.* at 387–88.

²⁶ See *id.*

²⁷ “Antiretroviral medications are a group of drugs that inhibit different steps in the HIV replication process.” *Antiretroviral Therapy (anti-HIV drugs)*, HEALTHENGINE, <https://healthengine.com.au/info/antiretroviral-therapy-anti-hiv-drugs#c2> (last visited Oct. 9, 2020).

produced by Abbot and Merck after the patents for those drugs expired.²⁸

The name-brand pharmaceuticals currently under trial and any future vaccine for COVID-19²⁹ will likely face these same compulsory licensing issues. Strong-arm bargaining techniques threatening compulsory licensing may be used to drive down the price of potential COVID-19 treatments. For example, if a pharmaceutical company patented a vaccine or pharmaceutical shown to be efficacious in treating or preventing COVID-19, any country, including middle-income countries like Brazil, could utilize Article 31 to issue a compulsory license without any prior attempts to negotiate for a voluntary license.³⁰ Thus, the patent holder would receive no immediate compensation for its innovation, and it would also be at the mercy of the issuing Member to decide what constitutes “adequate remuneration” for the compulsory license, completely removing the patent holder’s ability to negotiate price.³¹ Often, the patent holder’s only recourse would be to seek review in the issuing Member’s jurisdiction.³² Moreover, the flexibility of Article 31 in allowing Members to issue compulsory licenses could expose this patent holder to multiple compulsory licenses issued by multiple Members without any sort of prior negotiation for voluntary licensing, possibly necessitating litigation in multiple forums.³³

Unlike prior epidemics and fatal diseases, such as SARS and Ebola, the current COVID-19 pandemic, with over 48 million cases worldwide and over one million deaths, has brought the entire globe

²⁸ *Id.*; Harris, *supra* note 22, at 387.

²⁹ *See* Root, *supra* note 3.

³⁰ The requirement for negotiating a voluntary license “may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” TRIPS, *supra* note 5, at art. 31(b).

³¹ *See id.* at art. 31(h).

³² *See id.* at art. 31(i), (j). Member countries may bring disputes to the Dispute Settlement Body of the WTO, but private entities (i.e., pharmaceutical companies) cannot. *See Introduction to the WTO Dispute Settlement System*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c1s4p1_e.htm#parties [<https://perma.cc/225P-Z9UH>] (last visited Oct. 9, 2020).

³³ *See* TRIPS, *supra* note 5, at art. 31.

to its knees in a desperate search for an effective treatment or vaccine.³⁴ Contrary to prior uses of Article 31 and Article 31*bis* of TRIPS,³⁵ both developing countries and developed countries are likely to make use of compulsory licensing provisions, highlighting the need to reform the compulsory licensing provisions of the TRIPS Agreement to include more specific definitions and mechanisms for third-party arbitration to navigate the likely complex political web of COVID-19 vaccine licensing requests.

III. VACCINE NATIONALISM IN THE FACE OF COVID-19

Despite idealistic notions that a global pandemic might inspire international cooperation in tandem with vaccine development, world superpowers such as the United States, Russia, and China, have stubbornly dug their heels into “vaccine nationalism.”³⁶ Each nation is in the race to patent the first vaccine for COVID-19, driving a deeper wedge into an already deep political divide centered around economic dominance.³⁷ Indeed, the anticipated life-saving vaccine has been dubbed “a monumental first prize for the first country able to manufacture it at scale,” not because of any humanitarian implications, but because it would grant a monopoly that “would allow the winner to . . . [center] the global recovery on its medical output.”³⁸

In contrast, WHO has issued a “Solidarity Call to Action” for countries and companies to contribute their research and data about the new virus to create a COVID-19 Technology Access Pool (“C-TAP”).³⁹ Patent pooling typically “aggregate[s] patent rights]

³⁴ Statistics current as of November 7, 2020. *WHO Coronavirus Disease (COVID-19) Dashboard*, *supra* note 1.

³⁵ See Harris, *supra* note 22, at 387.

³⁶ “Vaccine nationalism” is a term coined by public health experts for the “contest of which world power can immunize its population first.” Peter Loftus & Drew Hinshaw, *Vaccine Nationalism: A New Dynamic in the Race to Quash Coronavirus*, WALL ST. J. (May 27, 2020), <https://www.wsj.com/articles/geopolitical-power-play-over-coronavirus-vaccine-leaves-drugmakers-in-the-middle-11590577849?st=s1z2sed8l3lzi5> [<https://perma.cc/J8LG-KSKT>].

³⁷ *Id.*

³⁸ *Id.*

³⁹ See *Solidarity Call to Action*, WORLD HEALTH ORG. (June 2020), <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research->

amongst multiple patent holders” so that licensing fees can be charged for the pooled technologies, and the patent holders can be compensated proportionally to their contributions to the pool.⁴⁰ However, WHO’s patent pool encourages “open licenses that allow access [to COVID-19 IP] free of charge, use, adaptation and redistribution by others with no or limited restrictions.”⁴¹ Notably, the United States, China, and Russia have not signed this WHO-endorsed pledge for “voluntary licensing,” reflecting the stubborn vaccine nationalism exhibited by each of these countries.⁴²

Increased tension arose in May and July of 2020, when the United States accused China and Russia, respectively, of stealing COVID-19-related research.⁴³ These current piracy attempts highlight the grim reality that vaccine nationalism will likely complicate any potential cooperation between these countries in developing a vaccine, or perhaps even in negotiating cross-licensing arrangements if one of the above-mentioned countries develops the vaccine first. Thus, it seems reasonable that these countries might resort to retaliatory use of Article 31 in an international powerplay, making it imperative to ameliorate the current weaknesses in TRIPS to safeguard against its use as political capital.⁴⁴

on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/solidarity-call-to-action [https://perma.cc/2XBUC7K3]; see *COVID-19 Technology Access Pool*, WORLD HEALTH ORG. (2020), https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool [https://perma.cc/34AZ-VNLS].

⁴⁰ World Intell. Prop. Org., *Note by the Secretariat: Patent Pools and Antitrust – A Comparative Analysis*, at 3 (Mar. 2014), https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf [https://perma.cc/GVW3-SZ6K].

⁴¹ *Solidarity Call to Action*, supra note 39.

⁴² *Endorsements of the Solidarity Call to Action*, WORLD HEALTH ORG. (2020), https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action [https://perma.cc/J39C-SWP3].

⁴³ Jenny Strasburg & Dustin Volz, *Russian Hackers Blamed for Attacks on Coronavirus Vaccine-Related Targets*, WALL ST. J. (July 16, 2020), https://www.wsj.com/articles/russian-hackers-blamed-for-attacks-on-coronavirus-vaccine-related-targets-11594906060?st=t4553hn796rx86s [https://perma.cc/R86Q-P8MJ].

⁴⁴ For example, Brazil used the ambiguous terms of TRIPS to issue a compulsory license for Merck’s HIV/AIDS drug, even though Merck had offered

Regardless of respective nations' commitment to WHO open-licensing or, alternatively, vaccine nationalism, licensing issues will inevitably come to a head once a viable and marketable vaccine is patented. Assuming that the vaccine emerges from a country that has held its research close while fueled by vaccine nationalism,⁴⁵ the international bartering scheme will likely be even more complex and contentious. Notably, although some companies have freely released licensing of their drugs of interest for use during the COVID-19 pandemic,⁴⁶ others have doubled-down on protecting their rights,⁴⁷ perhaps forecasting bitter compulsory licensing battles ahead should those drugs prove effective in treating COVID-19.

IV. ANALYSIS OF TRIPS DEFICIENCIES AND THE CONSEQUENCES OF THOSE DEFICIENCIES

Article 31 and the amended Article 31*bis* of TRIPS remain deficient in three key areas that will hinder its effective use in the current pandemic: (1) the vague terms in the agreement that have yet

a voluntary license for the drug at a 30% reduced price. Given the current climate of vaccine nationalism, it is not hard to imagine a retaliatory use of TRIPS for COVID-19 pharmaceuticals or vaccines, regardless of any voluntary license that may be on the table. See Jamie Feldman, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT'L. BUS. L. 137, 154 (2009).

⁴⁵ Ana Rivas, Peter Loftus, & Alberto Cervantes, *Covid-19 Vaccines: What's Coming and When?*, WALL ST. J. (Sept. 1, 2020, 1:20 PM), https://www.wsj.com/articles/covid-19-vaccines-whats-coming-and-when-11598882964?cx_testId=3&cx_testVariant=cx_2&cx_artPos=0#cxrecs_s [<https://perma.cc/Q8FZ-NHHN>].

⁴⁶ AbbVie will not enforce patent rights of HIV drug Kaletra, a drug shown to be promising in the treatment of COVID-19. See Ben Adams, *After Kaletra Setback, AbbVie Joins Forces with Biotech, Academia for Experimental COVID-19 Hopeful*, FIERCE BIOTECH (June 5, 2020), <https://www.fiercebiotech.com/biotech/after-kaletra-setback-abbvie-joins-forces-biotech-academia-for-experimental-covid-hopeful> [<https://perma.cc/YV75-4ZYG>].

⁴⁷ Gilead has applied for orphan drug designation of Remdesivir to bolster IP protection. See Christopher Garrison, *Never Say Never – Why the High Income Countries that Opted-out from the Art. 31bis WTO TRIPS System Must Urgently Reconsider Their Decision in the Face of the Covid-19 Pandemic*, MED. L. & POL'Y (Apr. 8, 2020), <https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that-opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-covid-19-pandemic/> [<https://perma.cc/M4Q8-AR5H>].

to be uniformly defined;⁴⁸ (2) the lack of provisions that would meaningfully prevent or discourage threatening compulsory licensing to circumvent patent laws;⁴⁹ and (3) non-uniform and ineffective procedures for streamlining compulsory licensing under Article 31*bis* by countries requesting generics in good faith.⁵⁰

A. *Vague Definitions*

The terms of TRIPS under Article 31 and amended Article 31*bis* provide a major roadblock in efficient enforcement of the agreement because these provisions lack precise definitions, leaving much to debate.⁵¹ For example, Article 31(b) provides that an importing Member may bypass any attempt to negotiate terms of a licensing agreement for pharmaceuticals if the Member is in a state of “national emergency” or “other circumstances of urgency.”⁵² While it seems obvious that a global pandemic would qualify under either of those terms,⁵³ more problematic is the undefined “scope and duration of such use” with respect to the emergency or urgency.⁵⁴ Although the agreement provides that the license is “liable . . . to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur,” Article 31 provides no guidance in defining this amorphous timeframe.⁵⁵

⁴⁸ See TRIPS, *supra* note 5, at art. 31(b) (failing to define “national emergency” and “other circumstances of extreme urgency”); *id.* at art. 31(c) (stating that the “scope and duration of such use shall be limited for the purpose for which it was authorized”); *id.* at art. 31(g) (stating that “authorization for such use shall be liable . . . to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur”); *id.* at art. 31(h) (stating that “adequate remuneration in the circumstances of each case, taking into account the economic value” should be paid to the patent holders).

⁴⁹ See *generally id.* at art. 31 (allowing Members to license a patented technology without a patent holder’s permission, but also failing to define a standard of “adequate remuneration” to be paid to the patent holder).

⁵⁰ See Harris, *supra* note 22, at 390–91.

⁵¹ See Peter K. Yu, *TRIPS and its Contents*, 60 IDEA: L. REV. FRANKLIN PIERCE CTR. FOR INTELL. PROP. 149, 207 (2019).

⁵² See Dziuba, *supra* note 18, at 196–97.

⁵³ See Doha Declaration, *supra* note 16, ¶ 1.

⁵⁴ See TRIPS, *supra* note 5, at art. 31(c).

⁵⁵ See *id.* at art. 31(g).

This lack of guidance for determining the end of an “emergency” creates essentially open-ended compulsory licenses.⁵⁶ Considering that public health experts predict, even with an effective vaccine on hand, that the disruptive “new normal” of the COVID-19 pandemic will likely last for at least two years, *en masse* compulsory licensing of a patented vaccine could last for at least that long, if not longer.⁵⁷ Compulsory licensing terms for “emergencies” issued by individual countries with undetermined end-dates have caused political turmoil in the past,⁵⁸ but such licensing in response to COVID-19 stands to have a devastating economic impact,⁵⁹ considering that virtually every country on the globe is battling the virus simultaneously.⁶⁰

Thus, in an extreme scenario, the ultimate patent holder of a viable vaccine could face a globe’s worth of individual countries’ compulsory licensing agreements defined by vague terms. While pharmaceutical companies’ prior disdain for compulsory licensing procedures that put them at a disadvantage typically grew out of disputes with *one* country in the past, the sheer scale of this pandemic would likely compound those frustrations because companies would be simultaneously juggling compulsory licenses from potentially *hundreds* of countries.⁶¹

⁵⁶ See Doha Declaration, *supra* note 16.

⁵⁷ Epidemiologists predict that the pandemic will persist until two-thirds of the world’s population has developed immunity, which could take two years. Localized *epidemics* could last longer. See Jonathan Lauerman, *Covid-19 Pandemic Likely to Last Two Years, Report Says*, BLOOMBERG (May 1, 2020), <https://www.bloomberg.com/news/articles/2020-05-01/covid-19-pandemic-likely-to-last-two-years-report-says> [<https://perma.cc/2X6D-STPT>].

⁵⁸ For example, the United States put Thailand on its IP watch list for Thailand’s use of compulsory licensing for drugs meant to treat chronic illnesses such as cancer and heart disease, rather than drugs for treating acute illnesses associated with epidemics, such as Ebola or malaria. See Harris, *supra* note 22, at 387.

⁵⁹ See John LaMattina, *Large R&D Investments by Big Pharma Crucial in Fighting Covid-19, but Can it Last?*, FORBES (June 16, 2020), <https://www.forbes.com/sites/johnlamattina/2020/06/16/large-rd-investments-by-big-pharma-crucial-in-fighting-covid-19-but-can-it-last/#7c97594b24df> [<https://perma.cc/SV4G-LDHB>].

⁶⁰ See WHO Coronavirus Disease (COVID-19) Dashboard, *supra* note 1.

⁶¹ See Harris, *supra* note 22, at 387.

This possibility for chaos is further amplified by the ambiguous compensation to patent holders under a compulsory license.⁶² Article 31 provides that patent holders will be “paid adequate remuneration in the circumstances of each case, taking into account the economic value.”⁶³ Under normal patenting circumstances unaffected by compulsory licensing, pharmaceutical patent holders stand to gain a twenty-year monopoly of their technology pursuant to TRIPS.⁶⁴ However, that sanctioned monopoly loses value in a scenario where multiple countries issue compulsory licenses for the drug at its conception. The widespread need for a COVID-19 vaccine,⁶⁵ coupled with a possible widespread demand of compulsory licenses with undefined compensation schemes,⁶⁶ could threaten a patent holder’s investment in the vaccine, which could cost nearly four billion dollars from research and development (R&D) to approval and market.⁶⁷

B. Nefarious Use of Compulsory Licensing

The vague definitions in Article 31 that could lead to fuzzy compulsory licensing time frames and compensation schemes will likely compound any threatened use of Article 31 in bad faith to drive down the price of COVID-19 pharmaceuticals. While it should be a goal to make curative medicines accessible to countries with a true need, manipulative bargaining incorporating a threatened or actual use of Article 31(b), like that employed by Brazil and Thailand in the past,⁶⁸ could leave patent holders with little recourse in enforcing their IP rights.

⁶² See TRIPS, *supra* note 5, at art. 31(h).

⁶³ See *id.*

⁶⁴ *Id.* at art. 33.

⁶⁵ George Brumfiel, *Without a Vaccine, Researchers Say, Herd Immunity may Never be Achieved*, NPR (July 24, 2020), <https://www.npr.org/sections/health-shots/2020/07/24/894148860/without-a-vaccine-researchers-say-herd-immunity-may-never-be-achieved> [<https://perma.cc/L284-V7BR>].

⁶⁶ See TRIPS, *supra* note 5, at art. 31(h).

⁶⁷ See Dimitrios Gouglas et al., *Estimating the Cost of Vaccine Development Against Epidemic Infectious Diseases: A Cost Minimization Study*, 6 LANCET GLOB. HEALTH e1386, e1386 (2018).

⁶⁸ See Harris, *supra* note 22, at 387–89.

For example, when Thailand issued a compulsory license under Article 31(b) for a drug to treat an illness that most would not consider a “national emergency,”⁶⁹ the patent holder, Merck, was forced to argue the issue under Thai law with the Thailand Department of Intellectual Property pursuant to Article 31(i).⁷⁰ Article 31(i) provides that the “legal validity” of compulsory licenses is subject to judicial review of the Member issuing the license; thus, patent holders that protest compulsory licenses they believe to be obtained in bad faith are likely to be forced to litigate the issues in the Member forum exercising the threat.⁷¹ Therefore, patent holders may be subject to the whims of multiple countries choosing to wield the threat of compulsory licensing where their only remedy lies in the effective *ad hoc* adjudication by each Member’s interpretation of Article 31(b).

C. Ineffective Procedures Under Article 31bis

Finally, Article 31bis remains ineffective,⁷² a problem that will only be exacerbated by potentially multiple importing Members lacking the infrastructure to manufacture COVID-19 pharmaceuticals issuing compulsory licenses from qualifying exporting Members for generics. Past uses of Article 31bis have resulted in two-year timeframes from compulsory license issuance to shipment to the importing Member.⁷³ Clearly, two years to deliver a COVID-19 vaccine or other pharmaceutical to any country would be unacceptable, and the entire world economy benefits the faster global immunity can be imparted.⁷⁴

⁶⁹ See Lisa Peets & Mark Young, *Is the Exception Becoming the Rule?*, 195 PATENT WORLD 21, 24 (2007), <https://www.cov.com/-/media/files/corporate/publications/2007/09/is-the-exception-becoming-the-rule.pdf> [https://perma.cc/33SH-XAKD].

⁷⁰ See *id.*; see TRIPS, *supra* note 5, at art. 31(i).

⁷¹ See TRIPS, *supra* note 5, at art. 31(i).

⁷² See Harris, *supra* note 22, at 389-90.

⁷³ Only Canada and Rwanda have utilized Article 31bis compulsory licensing. Carlos M. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*, S.C.T.R. POL’Y BRIEF, at 5 (Jan. 2019) https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf [https://perma.cc/7K8X-HSR5].

⁷⁴ See Brumfiel, *supra* note 65.

Furthermore, the United States, and other countries such as the United Kingdom and Australia, who are not importing Members pursuant to Article 31*bis*, are ineligible to receive generic drugs manufactured in exporting Members under a compulsory license should they find themselves unable to meet manufacturing capacity within their own borders.⁷⁵ The United States and other countries' abstention from this provision has met international criticism culminating in an open letter, published by Knowledge Ecology International in April 2020 and signed by dozens of global health and nonprofit organizations, requesting that the United States and others opt in to become an eligible importing Member.⁷⁶ Although the United States is still eligible to export generic drugs to other countries,⁷⁷ the letter reprimands the United States' shortsightedness in assuming that importing generics from another country via Article 31*bis* would never be a necessity, regardless of the United States' manufacturing capacity.⁷⁸

Effective use of Article 31*bis*, coupled with wealthier developed countries opting into importing Member-eligibility, would serve to expedite COVID-19 vaccine access. However, neither of these conditions have been met, and thus massive roadblocks may prevent access to vital medicines in a timely fashion.

V. SOLUTIONS

There are three key areas in the TRIPS Agreement that could be improved to enhance the treaty's effectiveness in protecting patent holders' rights and providing a workable international mechanism for countries to gain access to vital pharmaceuticals in pandemics like the current COVID-19 outbreak. These suggested implementations include: (1) defining terms in the TRIPS Agreement, specifically the scope and duration of the "emergency," as well as the "adequate remuneration" to be paid to patent holders; (2) creating and implementing a compensation scheme whereby "adequate remuneration" is codified and regulated and thereby not

⁷⁵ See *Open Letter*, *supra* note 20; see TRIPS, art. 31*bis*, *supra* note 18.

⁷⁶ See *Open Letter*, *supra* note 20.

⁷⁷ See *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 12.

⁷⁸ See *Open Letter*, *supra* note 20.

subject to *ad hoc* estimations; and (3) developing a third-party arbitration mechanism where compulsory licensing disputes may be settled outside of potentially biased importing Members' adjudicatory systems. While none of these suggested implementations are mutually exclusive, developing a third-party arbitration mechanism would aid uniform adherence to any of the suggested amendments to the terms in TRIPS.

A. Defining the Emergency and Adequate Remuneration

Defining both the scope and duration of the “emergency” and setting standards for “adequate remuneration” in Article 31 will be tantamount to streamlining the cooperation of patent holders when executing compulsory licenses, as well as staying potential abuses of TRIPS by countries simply utilizing it as a bargaining chip.⁷⁹ According to the Doha Declaration issued by the WTO in 2001 prior to the amendment Article 31*bis*, “[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency.”⁸⁰ While the global pandemic will surely qualify as an “emergency”⁸¹ per Article 31 and Article 31*bis*,⁸² specific definitions outlining what factors determine the duration of an “emergency,” and what pharmaceutical products fall under the scope of the “emergency” are essential to ensuring long-term cooperation with pharma-patent holders.

First, the current system allowing Members to self-define both the scope and duration of their respective “emergencies” during the COVID-19 pandemic could render thousands of pharmaceuticals vulnerable to compulsory licensing on an unprecedented scale than in any previous epidemic since the adoption of TRIPS.⁸³ Now, not

⁷⁹ For example, Thailand's issuance of a compulsory license for “lifestyle” medications. *See* Peets & Young, *supra* note 69.

⁸⁰ *See* Doha Declaration, *supra* note 16.

⁸¹ *See id.* (“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.”).

⁸² *See id.*

⁸³ *See WHO Coronavirus Disease (COVID-19) Dashboard*, *supra* note 1.

just one, but thousands of antiviral and other pharmaceutical patents may be subject to global compulsory licensing.⁸⁴ The WTO asserted countries' "right to determine what constitutes a national emergency"⁸⁵ in response to localized epidemics affecting least-developed nations, such as HIV/AIDS and malaria, but not with a globalized pandemic of the current scale in mind.⁸⁶ While flexible definitions of an "emergency" may aid greater access to medicine for a few nations struggling with localized epidemics, this flexibility could subvert fair distribution of critical vaccines during a pandemic when the number of compulsory licensing requests for a vaccine could exceed the global supply.⁸⁷ Further, without definition as to what qualifies under its scope, failing to limit Members' ability to broadly self-define "emergency" could lend itself to nefarious compulsory licensing of several drugs for purposes unrelated to COVID-19, considering that many current pharmaceuticals under COVID-19 trials also have patented uses in treating other diseases.⁸⁸

On the other hand, one could argue that narrowly defining what constitutes the scope and duration of an "emergency" unnecessarily and paternalistically limits the very flexibility of TRIPS that safeguards less-developed countries' ability to access medicines.⁸⁹ For example, replacing a Member's ability to self-define "emergency" with a one-size-fits-all definition could fail to recognize individualized local concerns within that country.

⁸⁴ See Aude S. Peden & Antoinette F. Konski, *Coronavirus Innovation Guideposts on the Eve of the COVID-19 Pandemic*, 10 NAT. L. REV. (July 30, 2020), <https://www.natlawreview.com/article/coronavirus-innovation-guideposts-eve-covid-19-pandemic> [<https://perma.cc/GL86-5MA3>].

⁸⁵ See Doha Declaration, *supra* note 16.

⁸⁶ See *id.*

⁸⁷ Production of COVID-19 vaccines will result in heightened competition for resources that also manufacture other vaccines, such as those for influenza. See Roxanne Khamsi, *If a Coronavirus Vaccine Arrives, Can the World Make Enough?*, NATURE (Apr. 9, 2020), <https://www.nature.com/articles/d41586-020-01063-8> [<https://perma.cc/YQ8S-LJKG>].

⁸⁸ Some antivirals manufactured to treat HIV show promise in treating COVID-19. See Root, *supra* note 3.

⁸⁹ See Doha Declaration, *supra* note 16; TRIPS, at art. 31, *supra* note 5; TRIPS, art. 31*bis*, *supra* note 18.

Further, narrowing the definition of “emergency” in the context of a public health crisis to meet a well-defined standard is arguably technically difficult with several factors at play. For example, whether “emergency” should be defined purely numerically, considering a Member’s total number of cases, death rates, infection rates, or by some other statistic or combination of statistics. Narrowing the definition of the “scope of the emergency” would also be technically difficult, inherently requiring some judgment as to what treatments fall within the scope of the emergency.⁹⁰ For example, in the context of COVID-19, whether all antivirals and vaccines proven remotely efficacious in treating the virus would fall within the scope, or whether only the most efficacious treatments would qualify, would have to be decided. Even deciding whether only vaccines should qualify, or vaccines *and* other pharmaceuticals, would also have to be decided.⁹¹ Some Members may prefer certain treatments over others if those treatments are cheaper to manufacture, or more easily disseminated to that Member’s population.⁹²

Regardless of the understandable benefits that flexible self-definitions of “emergency” confer onto a Member country, the reality in the COVID-19 pandemic is that not just one Member, but all Members are experiencing an “emergency” simultaneously.⁹³

⁹⁰ See Cynthia M. Ho, *Patent Breaking or Balancing: Separating Strands of Fact from Fiction Under Trips*, 34 N.C. J. INT’L L. & COM. REG. 371, 405 (2009) (discussing the various complexities in defining the “scope” of the authorized purpose for a compulsory license, “[s]hould any scope that is rationally related to the purpose suffice?”).

⁹¹ See *id.* Article 31 as drafted does not define what drugs or other technologies would fall within the “scope” of an “emergency.” See TRIPS, *supra* note 5, at art. 31.

⁹² Many factors influence the cost to manufacture vaccines and other pharmaceuticals, including access to active pharmaceutical ingredients, supply of consumables and trained technicians, and even individual countries’ regulatory schemes. Wayne Winegarden, *The Economics of Pharmaceutical Pricing*, PAC. RES. INST. (June 2014); see generally Stanley Plotkin et al., *The Complexity and Cost of Vaccine Manufacturing – An Overview*, 35 VACCINE 4064, 4064 (2017) (detailing the costs associated with vaccine production).

⁹³ There are currently over 48 million cases worldwide (as of Nov. 7, 2020). See WHO Coronavirus Disease (COVID-19) Dashboard, *supra* note 1.

Given limited global pharmaceutical manufacturing capacity,⁹⁴ allowing any one Member to individually self-define what pharmaceuticals and treatments fall within the scope of its compulsory license for its respective “emergency” necessarily affects the access of those same pharmaceuticals and treatments to all Members, since each Member’s compulsory license is limited to domestic use within its own borders.⁹⁵ Thus, even if it would prove too difficult to draft a catch-all definition of “emergency,” it certainly should not be left to individual Members to self-define in the context of a pandemic affecting substantially all, if not all, Members.⁹⁶ Thus, at least during a globalized pandemic, it may be useful to reserve defining the size and scope of any particular Member’s “emergency” to an arbitration mechanism, although it may be challenging to find a disinterested third party when every Member has an interest in COVID-19 IP.⁹⁷

Additionally, while gating the use of compulsory licensing by defining “emergency” may prove too challenging, creating a standard definition for “adequate remuneration” to be paid to patent holders should at least cull any potentially nefarious uses of TRIPS.⁹⁸ Further, a standardized definition for “adequate remuneration” beyond its current amorphous “economic value” language⁹⁹ should be easier to craft than a standard definition for “emergency,” and is also critical to disincentivize and stymie countries’ illegitimate use of TRIPS to drive down pharmaceutical pricing.¹⁰⁰ If “adequate remuneration” is defined and assigned a

⁹⁴ See Elaine Chen, *Drugmakers Race to Build Covid-19 Vaccine Supply Chains*, WALL ST. J., <https://www.wsj.com/articles/drugmakers-race-to-build-covid-19-vaccine-supply-chains-11596101586> [<https://perma.cc/9C64-3QQE>], (last visited Oct. 9, 2020) (“Supply shortages, specialized handling and tight transportation capacity will make it harder to distribute hundreds of millions of vaccine doses.”).

⁹⁵ See TRIPS, *supra* note 5, at art. 31(f) (“[A]ny such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”).

⁹⁶ See WHO *Coronavirus Disease (COVID-19) Dashboard*, *supra* note 1.

⁹⁷ See *id.*

⁹⁸ See Harris, *supra* note 22, at 387–88.

⁹⁹ See TRIPS, *supra* note 5, at art. 31(h).

¹⁰⁰ See Harris, *supra* note 22, at 387–88.

baseline monetary value,¹⁰¹ Member countries simply looking to bypass normal contracting agreements may think twice before threatening compulsory licensing.

One could imagine standardizing the value of “adequate remuneration” based on a Member’s Gross Domestic Product (“GDP”), or other measurable economic standard.¹⁰² For example, Brazil is the world’s ninth largest global economy in terms of GDP,¹⁰³ yet it has threatened the use of compulsory licenses in the past to drive down “Big Pharma” prices in licensing negotiations.¹⁰⁴ Thus, if “adequate remuneration” were defined with respect to a country’s GDP, Brazil, for instance, may be deterred from threatening the use of compulsory licensing, as it would not provide an appreciable cost advantage. Basing a definition of “adequate remuneration” off of a standard like GDP may also help spread the cost of vital medicines and vaccines during a pandemic, where wealthier Members with higher GDPs would be expected to pay more than least-developed Members with lower GDPs. Thus, a standardized definition of “adequate remuneration” with respect to a Member’s economic ability to pay for pharmaceuticals might go further in ameliorating potential misuses of TRIPS in bad faith bargaining than an individualized review of each Members’ self-definitions of an “emergency” and its scope.

However, standardizing “adequate remuneration,” even with respect to a Member’s individual GDP or other measurable standard, could fall short in reflecting a Member’s ability to pay a patent holder in the wake of an “emergency.”¹⁰⁵ In other words, measuring

¹⁰¹ See *The Top 20 Economies in the World*, <https://www.investopedia.com/insights/worlds-top-economies/#9-brazil> [<https://perma.cc/U8J9-CC2L>] (last visited Sept. 20, 2020).

¹⁰² Arguably, there are other statistics that better gauge overall well-being of a country, taking into account health statistics and income disparities. See Steward Wallis, *Five Measures of Growth that are Better than GDP*, WORLD ECON. FORUM, <https://www.weforum.org/agenda/2016/04/five-measures-of-growth-that-are-better-than-gdp/> [<https://perma.cc/EU5C-BKSN>] (last visited Oct. 9, 2020).

¹⁰³ See *The Top 20 Economies in the World*, *supra* note 101.

¹⁰⁴ See Feldman, *supra* note 44.

¹⁰⁵ A “baseline forecast envisions a 5.2 percent contraction in global GDP in 2020” due to the COVID-19 pandemic. *The Global Economic Outlook During the COVID-19 Pandemic: A Changed World*, WORLD BANK (June 8, 2020),

a Member's "adequate remuneration" with respect to its economy before the emergency—like a measure of GDP likely would—might be unfair if that Member's economy changed drastically in the wake of its current crisis.¹⁰⁶ Further, regardless of what standard is used to measure a Member's expected "adequate remuneration" to the patent holder, the base price, or "economic value," of the pharmaceutical under license would still have to be determined.¹⁰⁷ One could certainly speculate that a patent holder's idea of the fair "economic value" of a license to its pharmaceutical would be inflated compared to a disinterested third party.

While it is important to consider individualized concerns that may not be reflected in numerical standards, measuring "adequate remuneration" with respect to a Member's GDP would likely be the fairest estimation of any given Member's ability to compensate the patent holder for their costly investment. Measuring a Member's ability to adequately compensate a patent holder against an objective economic standard ideally would balance promoting patent holders to continue to invest in costly pharmaceutical research against individual Members' interests and financial constraints. Investment in developing a treatment for any disease is a huge cost;¹⁰⁸ thus, measuring "adequate remuneration" against an objective standard would ideally provide more protection for least-developed countries with weaker economies by setting a low-bar for what those Members would be expected to pay in terms of their actual ability to contribute. On the other hand, Members with strong economies utilizing compulsory licensing would be expected to contribute "adequate remuneration" closer to, or at, the sticker price in order to appease patent holders.

B. Creating and Implementing a Compensation Scheme

There must also be a well-defined compensation scheme to pay patent holders an "adequate remuneration" incorporated into Article

<https://www.worldbank.org/en/news/feature/2020/06/08/the-global-economic-outlook-during-the-covid-19-pandemic-a-changed-world> [<https://perma.cc/9F2A-ZGH4>].

¹⁰⁶ *See id.*

¹⁰⁷ *See* TRIPS, *supra* note 5, at art. 31(h).

¹⁰⁸ Large companies such as Pfizer and Gilead have already invested upwards of \$1 billion in COVID-19 research. LaMattina, *supra* note 59.

31, safeguarding patent holders' costly investments in their products. As mentioned above, Article 31 currently provides that patent holders shall be paid "adequate remuneration" subsequent to the end of an emergency, but there is no official mechanism or plan whereby patent holders may seek that compensation.¹⁰⁹ Establishing a uniform method of compensation would help streamline compulsory licensing by removing uncertainty and *ad hoc* "economic value" calculations that currently take place each time a country invokes a compulsory license.¹¹⁰ This compensation scheme would simultaneously provide stability for the patent holder and a concrete expectation of payment from the issuing country.

While it is understandable that the WTO purposely left compensation mechanisms out of the agreement to serve humanitarian goals as flexibly as possible,¹¹¹ failure to set any standards for compensation mechanisms ultimately burdens the countries this "flexibility" aspires to protect.¹¹² In effect, failing to provide a compensation scheme puts the onus of navigating financial disputes on the countries with the least political power, subjecting them to political backlash and potentially less access to medicine in the future.¹¹³ Ideally, a compensation scheme would balance patent holders' interests in maintaining profits, with compulsory licensees' interests in gaining and maintaining access to vital medicines.

One possible solution would be to set a standard payment mechanism wherein a compulsory licensee makes payments to the patent holder with respect to its measured "adequate remuneration" for that pharmaceutical. Both the determination of what the Member's "adequate remuneration" to the patent holder is, and its payment mechanism, would likely need to be determined in some

¹⁰⁹ See TRIPS, *supra* note 5, at art. 31(h).

¹¹⁰ See *id.*

¹¹¹ See Doha Declaration, *supra* note 16, ¶ 4.

¹¹² For example, in response to Thailand's use of compulsory licensing, Abbott halted "introducing new [pharmaceuticals] to the Thai market." See Peets & Young, *supra* note 69.

¹¹³ See *id.*

sort of arbitration through a third-party or the WTO.¹¹⁴ Ideally, this payment mechanism would consider the duration of the “emergency,” and set an appropriate timeline for installments against the “adequate remuneration” for that Member’s compulsory license. Thus, if the “adequate remuneration” is measured against a Member’s actual ability to compensate the patent holder, as discussed above,¹¹⁵ such a payment mechanism could actually aid least-developed countries by setting the license cost at a reasonable limit to be paid over time, while simultaneously discouraging nefarious uses by wealthier countries because their “adequate remuneration” would be higher and paid accordingly.

Another possible solution would be to extend the lifetime of the patent term beyond the typical term of twenty years.¹¹⁶ Extending the patent term—and thus the patent holder’s monopoly—would allow the patent holder to recuperate any costs incurred under the compulsory license by sale of its name-brand product in other countries, while also serving to alleviate the financial burden on the compulsory licensee. However, this method of international cost-spreading assumes that the patent holder could recuperate its costs under a patent term extension, and that there would be no significant pushback from other countries forced to effectively finance the compulsory licensees’ cost by accepting a longer patent term and thus paying name-brand prices for longer than they would otherwise be obligated.¹¹⁷

Finally, another option for a compensation scheme, that might be particularly salient in the context of a pandemic, would be to allow the patent holder to pool compulsory licenses under a common agreement and designate a generic manufacturer of the patent holder’s choosing to make the drug. This option diverges from current compulsory licensing practices under both Article 31 or Article 31*bis*, where individual compulsory licensees determine whether to manufacture the pharmaceutical themselves or to receive

¹¹⁴ In contrast, TRIPS currently provides that the issuing Member review “any decision relating” to the adequate remuneration. *See* TRIPS, *supra* note 5, at art. 31(j).

¹¹⁵ *See* discussion *supra* Part V, subsection 2.

¹¹⁶ TRIPS, *supra* note 5, at art. 33.

¹¹⁷ TRIPS provides for a twenty-year patent term. *Id.* at art. 33.

generics from an exporting Member.¹¹⁸ Instead, this proposed compensation scheme acknowledges that there will likely be several compulsory licenses issued simultaneously for a given pharmaceutical effective in treating COVID-19, and would give the patent holder more control in determining the manufacture of its pharmaceuticals.¹¹⁹ While patent holders are never obligated to provide manufacturing to compulsory licensees under TRIPS,¹²⁰ allowing the patent holder to pool compulsory licenses could give the patent holder the most free-market flexibility in contracting with generic drug manufacturers, while also encouraging the patent holder to actively license its patent to other manufacturers, increasing the capacity and world supply of COVID-19 treatments or vaccines.¹²¹

Manufacturing costs of pharmaceuticals are marginal compared to initial R&D investments;¹²² thus, if patent holders contract with other drug manufacturers to make their product for both free-market consumers and compulsory licensees, the costs could be recuperated in the pricing of the products for the free-market consumers.¹²³ If given the option to pool compulsory licenses in this way, the patent holder might have an incentive to seek out large-scale manufacturing in order to control production costs of the compulsory-licensed pharmaceutical. Otherwise, compulsory licensees that incur their own manufacturing costs may factor those costs into the “economic value” of the license, and pay lower “adequate remuneration” to the patent holder to cover those expenses that were beyond the patent holder’s control.¹²⁴ Thus,

¹¹⁸ *Id.* at art. 31(f); TRIPS, art. 31*bis*, *supra* note 18, ¶ 1.

¹¹⁹ Currently, Member licensees manufacture compulsory licensed pharmaceuticals without any input from the patent holder. *See* TRIPS, art. 31*bis*, *supra* note 18, ¶ 1.

¹²⁰ *See id.*

¹²¹ *See generally* Eileen M. Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137, 1144 (2009) (stating that “[c]apacity precedes access” in a pandemic, where the “[e]ffective management of infectious disease is a race against time”).

¹²² *See* Winegarden, *supra* note 92, at 13.

¹²³ *See id.*

¹²⁴ *See* TRIPS, *supra* note 5, at art. 31(h)–(j). Notably, “adequate remuneration” is not synonymous with monetary payment. If the licensee incurs its own

pooling compulsory licenses might be attractive to patent holders that have already invested sunk costs into manufacturing pharmaceuticals for free-market consumers, because they could simply manufacture more pharmaceuticals and ideally recuperate the extra cost in pricing the drugs to their free-market consumers.¹²⁵ This method of cost spreading would put the onus of covering costs on the patent holder; however, giving patent holders the freedom to contract with generic providers of their choosing should enable them to serve their best interests while providing equitable distribution of needed medicines.

These three proposed compensation schemes—setting a standard payback mechanism, extending the lifetime of the patent, or allowing the patent holder to pool compulsory licenses—could be viewed as unfairly removing negotiating power from compulsory licensees during an emergency, thereby effectively working against equitable access to needed COVID-19 pharmaceuticals. For example, the standard payback mechanism might discourage Members with few resources from issuing compulsory licenses if that standardized “adequate remuneration” proves to be too steep a price. Additionally, opting to extend patent terms instead of setting a standardized payback mechanism could also effectively result in less worldwide access to vital pharmaceuticals by maintaining premium prices under a longer patent monopoly. Finally, the third option of allowing patent holders to pool compulsory licenses might not be utilized by patent holders if the burden of assuming production of compulsory licensed pharmaceuticals outweighs any economic benefit of controlling the production of those pharmaceuticals. Further, allowing patent holders to have more control in the distribution of their patented pharmaceuticals could inhibit global access to the drugs if the patent holder chooses

manufacturing costs, those costs would likely be taken into account when calculating the “adequate remuneration” owed to the patent holder. *The Process – Stages in a Typical WTO Dispute Settlement Case*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/dispu_settlement_cbt_e/c6s9p1_e.htm [<https://perma.cc/WH4W-STGX>] (last visited Oct. 9, 2020).

¹²⁵ See Winegarden, *supra* note 92, at 13.

manufacturers that cannot reasonably produce enough drugs to meet the global demand.¹²⁶

The concern for matching the global demand of vital COVID-19 pharmaceuticals has grown so much that some have argued for completely bypassing direct compensation to patent holders of COVID-19 pharmaceuticals altogether.¹²⁷ Instead, governments would require patent holders to place their COVID-19 IP into mandatory patent pools (or “licensing facilities”) for any Member to freely access “in return for specified compensation [to the patent holder’s government].”¹²⁸ Patent holders’ governments would then be paid in those patent holders’ stead, wherein royalties would be distributed by those governments to the patent holders.¹²⁹ Additionally, any patent holders that dispute their compensation through these mandatory patent pools would bring their claims in their own jurisdiction, wherein “compensation might be based on the cost to the patent owners of developing the new drugs or vaccines, plus a fair profit under the circumstances.”¹³⁰ Proponents of this plan argue that mandatory patent pooling would allow for global equitable access to COVID-19 pharmaceuticals, enable mass production of those vital drugs, and still compensate patent holders the aforementioned royalties distributed by the patent holders’ governments.¹³¹

Although mandatory patent pooling seems to balance the need for equitable distribution of COVID-19 pharmaceuticals while ideally also providing some compensation to the patent holders, the creation of those patent pools is entirely predicated on the utmost cooperation of Members to freely establish them.¹³² Unfortunately,

¹²⁶ Manufacturing capacity will already be in short supply and competing with resources for manufacturing other needed pharmaceuticals and vaccines. See Khamsi, *supra* note 87.

¹²⁷ See Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT’L ECON. L. 1, 9 (2020).

¹²⁸ See *id.*

¹²⁹ See *id.* at 11.

¹³⁰ See *id.* at 11 n.50.

¹³¹ See *id.* at 9.

¹³² “Nevertheless, there are reasonable grounds for concern that, in the midst of a pandemic, national governments will hoard medical supplies in defense of the

rampant nationalism, particularly vaccine nationalism, displayed by the United States, Russia, and China, does not forecast such broad-reaching global cooperativity.¹³³ Accordingly, proponents of this plan realistically acknowledge that such mandatory patent pools might only be established “simply by groups of like-minded countries.”¹³⁴ While establishing such patent pools amongst cooperating countries might enable greater access to COVID-19 pharmaceuticals to Members friendly with the patent holder’s government, the utility of TRIPS Article 31 and Article 31*bis* is to provide access to pharmaceuticals to Members who are unable to establish such friendly arrangements.¹³⁵ The very purpose of Article 31 and Article 31*bis* is to fill the gap in protecting countries that are not necessarily “like-minded” to those holding the patents.¹³⁶

Further, setting up mandatory patent pools subverts patent protection even more than individually issuing of compulsory licenses per Article 31 and Article 31*bis* by completely removing any sort of bargaining power from the patent holders at the outset.¹³⁷ Moreover, creating these mandatory patent pools only transfers compensation pricing power from the patent holders to the governments, assuming that governments will more altruistically negotiate compensation than the patent holders themselves.¹³⁸ The assumption that governments would provide more equitable access to COVID-19 pharmaceuticals than pharmaceutical companies is baseless, especially considering that the United States, home to several front-runner COVID-19 treatments,¹³⁹ has openly displayed

local population, and there is reason to believe this will prove to be the case in the current pandemic.” *Id.* at 9.

¹³³ See Loftus & Hinshaw, *supra* note 36.

¹³⁴ Abbott & Reichman, *supra* note 127, at 10.

¹³⁵ See TRIPS, *supra* note 5, at art. 31(b); TRIPS art. 31*bis*, *supra* note 18.

¹³⁶ See Doha Declaration, *supra* note 16, ¶ 4 (“We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health . . . we affirm that the Agreement can and should be interpreted and implemented . . . to promote access to medicines for all.”); TRIPS, art. 31*bis*, *supra* note 18.

¹³⁷ See Abbott & Reichman, *supra* note 127, at 9–10.

¹³⁸ See *id.* at 11–12.

¹³⁹ See Root, *supra* note 3.

vaccine nationalism,¹⁴⁰ threatened to remove funding from WHO,¹⁴¹ and refused to join WHO's open access patent pool.¹⁴²

While it would be a wonderful collaboration if all the world's countries freely and openly shared COVID-19 resources and established these sharing facilities, it seems more practical to leave this distribution to the free market attenuated by the compulsory licensing provisions of TRIPS. Given the worldwide demand for COVID-19 pharmaceuticals, patent holders of efficacious treatments already have an incentive to contract with manufacturers to produce their products on a mass scale.¹⁴³

Further, establishing some sort of compensation scheme should help put both patent holders and potential compulsory licensees on notice as to what to expect financially and to plan accordingly, thereby helping to streamline all Members' access to COVID-19 pharmaceuticals. For example, without establishing some sort of standard compensation scheme, patent holders could likely instigate multiple lawsuits against Members issuing compulsory licenses if the patent holder objects to that Member's chosen method of compensation.¹⁴⁴ Such litigation would likely increase the price of COVID-19 pharmaceuticals manufactured by that patent holder, and divert their financial resources away from more productive uses like additional R&D.¹⁴⁵ Since the COVID-19 pandemic is greatly

¹⁴⁰ See Loftus & Hinshaw, *supra* note 36.

¹⁴¹ "The U.S. has formally notified the World Health Organization it will withdraw from the United Nations agency over President Trump's criticism of its ties to China . . ." Drew Hinshaw & Stephanie Armour, *Trump Moves to Pull U.S. Out of World Health Organization in Midst of Covid-19 Pandemic*, WALL ST. J. (July 7, 2020, 7:46 PM), <https://www.wsj.com/articles/white-house-says-u-s-has-pulled-out-of-the-world-health-organization-11594150928?st=dwtglcikzhrdm8o> [<https://perma.cc/D7N6-UQ6X>].

¹⁴² See *Endorsements of the Solidarity Call to Action*, *supra* note 42.

¹⁴³ See Loftus & Hinshaw, *supra* note 36.

¹⁴⁴ For example, thirty-nine pharmaceutical companies sued South Africa over its issuance of a compulsory license for drugs to treat AIDS. Rachel L. Swarns, *Drug Makers Drop South Africa Suit Over AIDS Medicine*, N.Y. TIMES (Apr. 20, 2001), <https://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html> [<https://perma.cc/M3JQ-KHG8>].

¹⁴⁵ Domestic pharmaceutical patent litigation in the United States alone has a median cost of \$2.5 million per case. Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BLOOMBERG L. (Sept. 10, 2019, 8:01

affecting all countries, and not merely a handful,¹⁴⁶ increased organization through a mechanized compensation scheme should help streamline access to these pharmaceuticals by removing some of the financial uncertainty.

C. Third-Party Arbitration of Compulsory Licensing Disputes

Finally, at least in the context of a global pandemic, a third-party arbitration process to hear compulsory licensing disputes should be incorporated into Article 31 in order to (1) determine the validity of an issued compulsory license, and (2) to determine the “adequate remuneration” to be paid to the patent holder. Currently, Article 31(i) and (j) respectively provide that any decision relating to the “legal validity” of a compulsory license, or dispute regarding remuneration issued under Article 31, shall be subject to judicial review in the compulsory licensee’s Member jurisdiction.¹⁴⁷ However, such judicial review processes carried out in the compulsory licensing Member jurisdiction, although litigated in their home court, have often resulted in other political consequences, such as trade sanctions imposed upon them by the unhappy patent holder’s government, thereby blocking that Member’s access to other medicines.¹⁴⁸ Instead, establishing a third-party arbitration committee to review the validity of compulsory licenses and to determine “adequate remuneration” should serve to both discourage nefarious uses of compulsory licenses, as well as protect the interests of compulsory licensees by settling disputes on neutral grounds.

Moreover, in the context of a global pandemic where more is at stake than the rights of either the patent holder or any individual compulsory licensee, providing a third-party arbitration committee, outside either Member’s jurisdiction, would streamline compulsory license disputes more predictably and with global interests in mind. Establishing a third-party arbitration committee would avoid countries’ idiosyncratic procedural requirements and red-tape,

AM) <https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds> [<https://perma.cc/F4TV-DBS6>].

¹⁴⁶ See *WHO Coronavirus Disease (COVID-19) Dashboard*, *supra* note 1.

¹⁴⁷ TRIPS, *supra* note 5, at art. 31(i), (j); see Loftus & Hinshaw, *supra* note 36.

¹⁴⁸ See Harris, *supra* note 22, at 387.

ideally deciding disputes more efficiently.¹⁴⁹ Since all Members of the WTO are affected by this pandemic, a third-party arbitration would likely produce more equitable solutions for the collective world populace, compared to an individual country's judicial review deciding disputes solely from that country's perspective.

On the other hand, taking judicial review out of the compulsory licensee Member's jurisdiction could also effectively remove any bargaining power that a less-developed country might have in acquiring a license from an unwilling patent holder. Moreover, moving dispute settlement outside of a compulsory licensee's jurisdiction could unfairly remove an individual Member's right to negotiate its own rights in its own forum,¹⁵⁰ as well as slow down a compulsory licensee's access to the pharmaceuticals in dispute. As seen in past disputes, forcing patent holders to publicly litigate in the midst of a public health crisis in the licensee Member's jurisdiction can create intense international pressure for that patent holder to drop the suit.¹⁵¹

However, the issue at hand in the COVID-19 pandemic is not simply a collective of big-bully pharmaceutical companies hounding one developing country's request for a compulsory license during a local epidemic.¹⁵² The COVID-19 pandemic has the potential to generate multiple such licenses to be litigated in multiple international venues simultaneously. Although one should rightly

¹⁴⁹ See Lucas Volman, *The TRIPS Article 31 Tug of War: Developing Country Compulsory Licensing of Pharmaceutical Patents and Developed Country Retaliation*, 39–45 (2018) (LL.M. thesis, University of Dublin, Trinity College) (on file with author) (comparing past compulsory licensing disputes brought by both private pharmaceutical companies and Member governments, highlighting those disputes' disparate resolutions).

¹⁵⁰ For example, during the late 1990's AIDS epidemic in South Africa, thirty-nine pharmaceutical companies dropped their highly provocative suit against the South African government for issuing a compulsory license for antiretrovirals amidst mass protests and demonstrations. *See id.*; see Swarns, *supra* note 144. Arguably, removing the possibility of dispute settlement in a licensee Member's jurisdiction could sanitize the process of its current heightened controversy—certainly the optics of suing a country within its borders, currently suffering a health crisis, is quite different than a cleaner process of arbitration on neutral international grounds. *See* Volman, *supra* note 149; *see* Swarns, *supra* note 144.

¹⁵¹ *See* Swarns, *supra* note 144.

¹⁵² *See* WHO *Coronavirus Disease (COVID-19) Dashboard*, *supra* note 1.

argue in favor of aiding least-developed countries with little bargaining power, the current ambiguities in the TRIPS Agreement and lack of official arbitration scheme tailored to compulsory licensing disputes make patent holders vulnerable to *en masse*, nefarious uses of compulsory licensing provisions by countries other than those most vulnerable.¹⁵³

One previously suggested solution advocated for utilizing the WTO's Dispute Settlement Body ("DSB")¹⁵⁴ to convene a committee to hear individual compulsory licensing disputes.¹⁵⁵ The DSB allows complaining Members to challenge intellectual property policies instituted by another Member that are allegedly inconsistent with the WTO Agreement.¹⁵⁶ The dispute settlement process consists of a reviewing Appellate Body that decides the matter, and if the Body decides the policy is inconsistent with WTO principles, it orders that Member to remove its inconsistent policy.¹⁵⁷ Further, remedies such as compensation and other sanctions are issued only secondarily.¹⁵⁸

While it is certainly possible for Member governments to bring disputes regarding compulsory licensing before the DSB, private entities (i.e., pharmaceutical companies) are precluded from doing so, leaving those companies with no recourse but to sue in the adversary Member's jurisdiction.¹⁵⁹ Moreover, any "compensation"

¹⁵³ For example, Brazil issued a compulsory license of a drug despite its own strong economy and favorable negotiations for a voluntary license with Merck, who offered a 30% discount. See Feldman, *supra* note 44. One could imagine similar nefarious uses during the current pandemic.

¹⁵⁴ *WTO Bodies Involved in the Dispute Settlement Process*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/dispu_settlement_cbt_e/c3s1p1_e.htm [<https://perma.cc/PU7C-JXVF>] (last visited Oct. 9, 2020) ("The DSB has the authority to establish panels, adopt panel and Appellate Body reports, maintain surveillance of implementation of rulings and recommendations and authorize the suspension of obligations under the covered agreements [including TRIPS].").

¹⁵⁵ See Ann Marie Effingham, *TRIPS Agreement Article 31(b): The Need for Revision*, 46 SETON HALL L. REV. 883, 907 (2016).

¹⁵⁶ See *WTO Bodies Involved in the Dispute Settlement Process*, *supra* note 154.

¹⁵⁷ See *id.*

¹⁵⁸ See *id.*

¹⁵⁹ *Introduction to the WTO Dispute Settlement System*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/dispu_settlement_cbt_e/c1s4p1_e.htm#parties [<https://perma.cc/889C-AMML>] (last visited Oct. 9, 2020) ("Since

ordered by the WTO to the complaining party does not come in the form of monetary payment, but instead as a “benefit” such as tariff reduction by the respondent to nullify its ill use of WTO measures.¹⁶⁰ Thus, pharmaceutical companies holding patents to COVID-19 vaccines or pharmaceuticals currently cannot obtain remedies from the WTO.¹⁶¹

Thus, one possible solution to balance the needs of least-developed countries with those of patent holders, combined with an initiative to deter nefarious uses of TRIPS Article 31, requires creating a specialized arbitration committee to process compulsory licenses from issue to manufacture. Especially in light of the foreseeability of compulsory licensing disputes over COVID-19 pharmaceuticals, it seems pivotal to create an arbitration mechanism within the WTO DSB to exclusively address these claims and streamline resolution.

Although Article 31 currently allows Members to issue compulsory licenses without any initial third-party review,¹⁶² it seems warranted in a pandemic to require Members to submit a report detailing their need for compulsory licenses of COVID-19 pharmaceuticals to this specialized arbitration committee. This proposed committee could hear answers from private patent holders disputing the compulsory licenses, and then issue an opinion on the fairness of the compulsory license and what “adequate remuneration” would be in that case.¹⁶³ If the committee determined

only WTO Member governments can bring disputes, it follows that private individuals or companies do not have direct access to the dispute settlement system, even if they may often be the ones (as exporters or importers) most directly and adversely affected by the measures allegedly violating the WTO Agreement.”).

¹⁶⁰ *The Process – Stages in a Typical WTO Dispute Settlement Case*, *supra* note 124 (“This compensation does not mean monetary payment; rather, the respondent is supposed to offer a benefit, for example a tariff reduction, which is equivalent to the benefit which the respondent has nullified or impaired by applying its measure.”).

¹⁶¹ *See id.*

¹⁶² *See* TRIPS, *supra* note 5, at art. 31(b).

¹⁶³ *Introduction to the WTO Dispute Settlement System*, *supra* note 159 (“According to WTO jurisprudence, panels and the Appellate Body [of the DSB] have the discretion to accept or reject these submissions [of *amicus curiae* from

the compulsory license to be nefarious, it could ask the issuing Member to revoke the license and resume negotiating for a voluntary license.

Although requiring a committee to review a compulsory license prior to its issue would necessarily slow down the process by which any one Member accesses vital COVID-19 pharmaceuticals, it would also serve to protect the interests of all Members that will need the same pharmaceuticals in the wake of this pandemic.¹⁶⁴ Again, and especially in the context of already-displayed vaccine nationalism, it is critical to have a process streamlining global disputes related to COVID-19 pharmaceuticals to encourage both legitimate uses of compulsory licensing and discourage any potentially nefarious uses in response to vaccine nationalism. Overall, such an arbitration mechanism might balance the needs of legitimate uses of TRIPS by least-developed Members with the needs of patent holders, while simultaneously weeding out nefarious uses of the treaty.

VI. CONCLUSION

The COVID-19 pandemic presents the international community with an opportunity to address longstanding deficiencies in TRIPS to provide more efficient and equitable distribution of life-saving pharmaceuticals. Although flexibility was intentionally conferred to individual Members in their use of the compulsory licensing provisions of TRIPS, these goals were initially framed in the context of localized epidemics. While flexibility in issuing compulsory licenses for pharmaceuticals may arguably best serve the needs of individual Members, the potential for *en masse* compulsory licensing in a globalized pandemic threatens the collective needs of all Members.

non-governmental organizations], but are not obliged to consider them.”). This Article advocates for private patent holders’ submissions on the fairness of any given compulsory license for COVID-19 pharmaceuticals to be considered in WTO dispute settlement proceedings. *See id.*

¹⁶⁴ The widespread nature of COVID-19 still persists as of November 2020. *See WHO Coronavirus Disease (COVID-19) Dashboard*, *supra* note 1.

As such, this Article has identified three key areas in which TRIPS can be refined to address the current global needs: (1) incorporating more specific definitions and standards with respect to compulsory licensing; (2) implementing a standard compensation scheme to pay patent holders “adequate remuneration;” and (3) employing a third-party arbitration mechanism to streamline global disputes relating to COVID-19 pharmaceuticals and compulsory licensing. Although each of these three proposed solutions would serve to initially restrict individual Members’ flexibility to issue compulsory licenses, each of these proposed solutions should help guard the interests of all TRIPS Members while simultaneously serving the goals of TRIPS: encouraging patent holders’ costly investments into life-saving treatments while providing for their fair and equitable global distribution.