2022

Stumbling Over Trips: The International Intellectual Property Waiver Petition and The U.S. Executive

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STUMBLING OVER TRIPS: THE INTERNATIONAL INTELLECTUAL PROPERTY WAIVER PETITION AND THE U.S. EXECUTIVE

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This article examines the relationship among intellectual property (IP) law protections; United States (U.S.) and international law and policy; and the actualization of diagnostics, drugs, and vaccines in the time of the COVID-19 coronavirus. Two key international treaties that relate to IP law – The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) – establish international norms for the protection of IP. Core aspects of each of these treaties are described along with the role of the World Trade Organization (WTO) and concepts of compulsory licensing. As a result of COVID-19, there have been recent calls for an international IP waiver to TRIPS to address disparities in access to health and medical products during the pandemic. The article traces the timeline of the waiver petition, beginning with its initiation by South Africa and India in October 2020, through the emergence of the omicron variant in November 2021. The waiver continues to generate significant controversy, with staunch opposition from the European Union and several other developed countries, including early opposition from the U.S. The Biden Administration has signaled support for the waiver, although the extent of that support has not been fully demarcated. Several alternative models have arisen, which are also discussed in connection with the general lack of progress of the WTO to implement any such waiver as of early 2022.

I. INTRODUCTION

As the COVID-19 pandemic has unfolded, widespread acts of vaccine and patent nationalism have fostered significant vaccine inequity. The World Health Organization (WHO) reports that as of July 2021, just ten countries account for seventy-five percent of vaccine administrations, with only one percent of low-income country populations having received a single dose of the vaccine.[1] In the United States (U.S.), drug and vaccine incentives are driven largely through intellectual property protections granted by the Patent and Trademark Office and product exclusivity periods issued by the Food and Drug Administration.[2] Longstanding alternative, non-exclusionary models supporting access to medical innovations include compulsory licensing;[3] exercise of governmental march-in rights;[4] patent pooling; open source collaborations and platforms; and voluntary industry pledges not to enforce particular patents or to provide access to materials, methods, or products.[5]

In the face of such extreme vaccine inequity, another access model has emerged: a petition for the implementation of a waiver to the international World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This article examines the history and development of the petition for waiver of intellectual property (IP) protections, the changing position of the U.S. Executive branch, and proposed alternative models for access and distribution during the pandemic. Part II identifies international entities, treaties, and processes related to IP rights and explores the development of the current

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1. Bruce Baschuk, *WTO Holiday From Vaccine Equity Talks Draws Calls for Action,* BLOOMBERG NEWS, July 27, 2021, https://www.bloomberg.com/news/articles/2021-07-26/wto-s-holiday-from-vaccine-equity-talks-draws-calls-for-action?utm_campaign=pharmalittle&utm_medium=email&_hsmi=143777081&_hsenc=p2ANqtz-9tIeIr6qvvPgAJrvE6gmzfMgFZIQYTgaVnvx3tUoOm4rbe5BB4dEM4rIjph8oaDVJG5b54HDbW1XFQhaj8CFPwaLPpVA&utm_content=143777081&utm_source=hs_email.

2. *See* Jordan Paradise, *Information Opacity in Biopharmaceutical Innovation Through the Lens of COVID-19,* 47 AM. J. L. & MED. 157 (2021) (discussing the intertwining roles of each agency).

3. *See, e.g.*, Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV (forthcoming).

4. Jordan Paradise, *COVID-IP: Staring Down the Bayh-Dole Act with 2020 Vision,* 7 J. L. & THE BIOSCIENCES 1 (2020).

5. *See* Jorge Contrearas et al., *Pledging Intellectual Property for COVID-19*, 38 NAT'L BIOTECHNOLOGY 1146 (2020).

international IP paradigm structured through TRIPS and the Doha Declaration. Part III traces the history of the IP waiver petition as a response to the COVID-19 pandemic, including support and opposition, scope of the waiver, and the relationship to the existing IP paradigms. Part IV turns to the evolution of the position of the U.S. regarding the waiver, comparing the Trump Administration and the Biden Administration's statements and representations. Part V examines alternative models for access and distribution and the explores the feasibility of each approach in the face of the pandemic. The article then concludes, acknowledging international uncertainty and a lack of resolution regarding the waiver.

II. PANDEMIC ACRONYMS AND AUTHORITIES: WHO, WTO, TRIPS, AND DOHA

At the global scale, the WHO is the world's lead actor in pandemic response efforts. The WHO declared the novel coronavirus outbreak a pandemic in March 2020 following several cases of the disease reported outside of the outbreak epicenter.[6] The WHO initiated a three-part Access to COVID-19 Tools (ACT) initiative in April 2020,[7] which includes the COVID-19 Vaccines Global Access (COVAX) collaboration to ensure global access to COVID-19 vaccines.[8] Along with the WHO, the Coalition for Epidemic Preparedness Innovations and the Gavi Vaccine Alliance lead the COVAX collaboration.[9] By August 2020, 172 countries were engaged in the Global Access Facility within COVAX responsible for the distribution of vaccines.[10] Initially the U.S. (under President Trump) and a small number of other countries refused to join the COVAX effort.[11]

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6. *Listings of WHO's Response to COVID-19*, WORLD HEALTH ORGANIZATION, Jan. 29, 2021, https://www.who.int/news/item/29-06-2020-covidtimeline.

7. World Health Organization, *Access to COVID-19 Tools (ACT) Accelerator,* Apr. 24, 2020, https://www.who.int/initiatives/act-accelerator.

8. *172 Countries and Multiple Candidate Vaccines Engaged in COVID-19 Vaccine Global Access Facility*, WORLD HEALTH ORGANIZATION, Aug. 24, 2020, https://www.who.int/news/item/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility.

9. *Id.*

10. *Id.*

11. Emily Rauhala & Yasmeen Abutaleb, *U.S. Says It Won't Join WHO-Linked Effort to Develop, Distribute Coronavirus Vaccine,* WASHINGTON POST, Sept. 1, 2020, https://www.washingtonpost.com/world/coronavirus-vaccine-trump/2020/09/01/b44b42be-e965-11ea-bf44-0d31c85838a5_story.html.

President Trump also withdrew the U.S. from the WHO in July 2020 despite vocal opposition from public health experts.[12]

Within weeks of taking office, President Biden reversed the course of the Trump administration and joined the international pandemic response and vaccine development efforts.[13] President Biden has since pledged the distribution of 25 million doses of COVID vaccines from the United States stockpile to countries around the world.[14] Roughly seventy-five percent of those doses would be channeled through COVAX, the international effort to disseminate medical products during the pandemic.[15] The U.S. has earmarked $2 billion to Gavi to provide vaccines for ninety-two low- and middle-income economies.[16]

Alongside the international collaborative efforts of the WHO and other entities are legal frameworks to adjust the status of IP protections to respond to crises. The WTO, another key actor, is responsible for the implementation of international agreements regarding IP protections during a global pandemic. Complex procedural and logistic challenges exist at the crossroads of IP protections and the need for rapid, widespread production and distribution of vaccines, and pharmaceutical and medical device products. The WTO, via the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration, recognizes that public health crises will sometimes require special attention or compel different obligations on WTO member states.[17] TRIPS is an agreement, binding on WTO member countries, that provides minimum standards, not uniform laws, for intellectual property rights.

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12. Janice Hopkins Tanne, *COVID-19: U.S. Will Not Join WHO in Developing Vaccine*, 370 BMJ m3396 (2020).

13. The White House, *Fact Sheet: President Biden to Take Action on Global Health through Support of COVAX and Calling for Health Security Financing*, Feb. 18, 2021, https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/18/fact-sheet-president-biden-to-take-action-on-global-health-through-support-of-covax-and-calling-for-health-security-financing/.

14. Stephen Wertheim, *America Pursues Vaccine Internationalism - but What Kind?*, The Nation, June 7, 2021, https://www.thenation.com/article/politics/vaccine-covax-internationalism/.

15. *Id.*

16. The White House, *supra* note 13.

17. World Trade Organization, Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)(DEC/2, 41 I.L.M. 755 (2001).

The WHO and WTO Secretariat jointly recognize that patent protections are important and influential in the pharmaceutical industry and medical equipment industry given high research and development costs, length of clinical trials, and regulatory review and approval.[18] Vaccine research is fueled by the protections and financial incentives afforded by patents due to the characteristics of vaccines, as complex biological rather than relatively-simple chemical products, which makes their development and manufacturing extremely costly. Compared to pharmaceutical companies, there are relatively fewer vaccine manufacturers globally because vaccines are sensitive biological products that require strict control for safety, quality, procurement, and distribution. Manufacturers must possess sophisticated technical knowledge to produce vaccines; often, such knowledge is not readily available or accessible because of patents, trade secrets, or other IP protections.[19] Patents, trade secrets, and technological knowledge assigned to large companies with licensing schemes have created a web of intellectual property that is not easily navigated.[20] Notably, thirteen European Union (E.U.) member states possess over sixty percent of the world's major facilities for vaccine production and ninety percent of global vaccine production.[21]

Since the inception of TRIPS, and the subsequent creation of the Doha Declaration resulting in Article 31*bis* of TRIPS, several international public health emergencies have provided the need for utilization of the IP adaptation mechanisms. One prime example is the AIDS crisis. In the late 1990s, TRIPS flexibilities and individual countries' compulsory licensing frameworks became a method to deal with HIV/AIDS epidemics and the high cost of Gilead's approved AIDS drug.[22] Many developing countries were concerned that TRIPS was restricting access to HIV/AIDS drugs, and important tuberculosis and malaria drugs, which eventually led

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18. World Health Organization & World Trade Organization Secretariat, WTO Agreements and Public Health, at 92 (2002), https://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf.

19. *Id.* at 97.

20. Mario Gaviria & Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NATURE BIOTECH. 546, 546 (2021), https://www.nature.com/articles/s41587-021-00912-9.

21. Kayvan Bozorgmehr et al., *Free Licensing of Vaccines to End the COVID-19 Crisis*, U.S. NAT. LIBR. MED., 1261, 1262, Mar. 18, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7972308/.

22. Jacqui Wise, *Access to AIDS Medicines Stumbles on Trade Rules*, BULL. WTO 342, 342 (May 2006), https://apps.who.int/iris/handle/10665/269649.

to the Doha Declaration in 2001.[23] The Doha Declaration set out a compulsory licensing scheme within TRIPS, in a new Article 31*bis*.[24] A compulsory license allows a country or authorized third party to use a patented invention without the patent owner's permission, in exchange for a government-determined royalty.[25] TRIPS outlines the requirements for countries seeking to grant a compulsory license. Members must evaluate patents on individual bases to determine whether a license is appropriate, and if so, the proper amount of royalty. To procure a compulsory license, the party seeking licensure must attempt and fail to get a voluntary license from the patent owner first via "prior negotiations," a process that is not well-defined. Waiver of the prior negotiation requirement is acceptable in cases of: (1) national emergency, (2) circumstances of extreme urgency, or (3) public non-commercial use, so long as the patent owner is notified as soon as is practicable.

Compulsory licensing via TRIPS is currently disfavored among many countries, and very few countries issue them. Countries who are opposed to compulsory licensing often pressure other countries to not issue them. Furthermore, the TRIPS requirements are procedurally difficult for many countries to follow, making compulsory licenses impractical. Between 1995-2011, twenty-four TRIPS-Doha attempts to procure compulsory licenses for pharmaceutical products were issued.[26] The highest period of activity in compulsory licensing occurred right after the Doha Declaration was passed.[27] The diseases dealt with included HIV/AIDS, anthrax,

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23. *Id.*

24. WTO Analytical Index, TRIPS Agreement – Article 31bis (Practice), Mar. 2021, https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf. Article 31*bis* provides, in part: "The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement." *Id.*

25. Sapna Kumar, *supra* note 3, at 6.

26. Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9(1) PLOS MED. 1 (2012), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001154.

27. *Id,* at 1.

pandemic influenza, cancer, cardiovascular disease, and noncommunicable disease.[28]

The first country to procure a framework for compulsory licensing amidst COVID was Brazil.[29] Subsequently, Israel, Hungary, and Russia issued compulsory licenses for COVID therapeutics, while Chile, Colombia, and Indonesia made proposals for new laws increasing barriers to compulsory licenses.[30] In early 2021, Biolyse Pharma Corp., a company with the manufacturing capacity to make 20 million vaccine doses annually, threatened to apply for a compulsory license for the Johnson &

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28. *Id,* at 4. (following the first decade of the 2000s, Thailand dominated the compulsory license scene. Thailand used licenses for twenty drugs, including those for HIV/AIDS, cancer, and cardiovascular disease. Brazil followed and issued a compulsory license for antiretroviral drug (ARV) Nelfinavir, and then another drug in 2007. Rwanda used the provisions of the Doha Declaration to request manufacturing of a Canadian drug, and Canada became the first country to issue a compulsory license for exporting a generic drug to a third country. Following the Rwanda-Canada success, several developed countries used compulsory licensing to provide ARVs to poorer countries and to halt anticompetitive actions. In 2006, the WTO made a landmark decision to allow a generic copy made under a compulsory license to be exported to developing countries. Zimbabwe declared its 2002 AIDS epidemic a period of emergency and authorized the government to override patents to permit the local production or import of ARVs. In 2003, Malaysia allowed the import of certain medicines from India. In 2004, Mozambique and Zambia issued compulsory licenses for local production of ARVs, while Indonesia authorized government use of patents to enable local production of two drugs. Some LDCs, as of 2006, allowed the import of generics and refused to issue patents, which is proper under the TRIPS exemption for LDCs. Both South Africa and Kenya obtained voluntary licenses for local ARVs, though with a great deal of pressure and difficulty. A great number of solutions sought in the early 2000s to deal with HIV/AIDS epidemics related to compulsory licensing and the import and export of generics, refusal to patent certain drugs in LDCs, and some rare instances of voluntary licensing. There was no global instance of a waiver of IP requirements under TRIPS or broadening of the exemption from TRIPS requirements for LDCs); *See also* Charitini Stavropoulou & Tommaso Valletti, *Compulsory Licensing and Access to Drugs*, 16 EUR. J. HEALTH ECON. 84 (2015).

29. Britain Eakin, *IP Waiver Talks Hinge on Use of Big Pharma's Trade Secrets*, LAW360, May 25, 2021, https://www.law360.com/lifesciences/articles/1388176/ip-waiver-talks-hinge-on-use-of-big-pharma-s-trade-secrets?nl_pk=10d3b1b5-5f83-4189-938a-df7f5d9ca046&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences.

30. Tiffany Hu, *US Ranks 2nd in Global Patent Protection for 3rd Year*, Law360, Mar. 25, 2021, https://www.law360.com/lifesciences/articles/1368344/us-ranks-2nd-in-global-patent-protection-for-3rd-year?nl_pk=10d3b1b5-5f83-4189-938a-df7f5d9ca046&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences.

Johnson vaccine through the Canadian Access to Medicines Regime, after failing to receive a voluntary license upon its first request.[31] The World Intellectual Property Organization has published a COVID IP Policy Tracker to keep up with the function of member state intellectual property offices and supporting regulatory agencies amidst COVID-19.[32]

III. THE HISTORY OF THE IP WAIVER PETITION

South Africa and India led the global effort to propose a waiver of intellectual property rights when they jointly proposed an exemption to specific articles of the TRIPS amidst the COVID-19 pandemic. On October 2, 2020, South Africa and India proposed that the WTO waive or adjust intellectual property requirements on copyrights, industrial designs, patents, protection of undisclosed information, and compulsory licenses.[33] The proposal cites more than one million COVID-related deaths and more than three hundred million confirmed global cases of COVID as an extreme and unique circumstance. South Africa and India noted that the WTO member countries, not only least-developed countries, were struggling to access COVID-19 treatments in a timely fashion and in the volume necessary to deal with the ongoing and growing pandemic.

The South Africa-India proposal goes further in saying that the shortage of treatments has the power to exacerbate both the short and long-term negative consequences of the pandemic.[34] The proposal urges the WTO to waive TRIPS requirements in the COVID context until there is widespread vaccination on the global scale and the majority of the world's population has developed immunity.[35] The waiver would be renewed each year until the General Council of the WTO determined that it was no longer

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31. Mari Serebrov, *Canadian Company to J&J: License, or Else . . .*, BIOWORLD, Mar. 15, 2021, https://www.bioworld.com/articles/504737-canadian-company-to-jj-license-or-else?v=preview.

32. World Intellectual Property Organization, *COVID-19 IP Policy Tracker*, https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/ipo-operations (visited Jan. 18, 2022).

33. Communication to the TRIPS Council of the WTO by South Africa and India, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020) (noting that the respective provisions of TRIPS are Section 1, Section 4, Section 5, Section 7, and Article 31*bis*).

34. *Id.* at 1.

35. *Id.*

necessary. There is no further clarification in the original proposal regarding when either of those events are triggered, how they will be measured, and what mechanisms will be used to effectuate them. South Africa, India, and their supporters are pushing for the WTO to waive a number of intellectual property requirements that are binding via TRIPS. In addition, the proposal that Article 31*bis* on compulsory licenses would greatly hinder countries lacking sophisticated and sufficient manufacturing capacity in being able to access COVID vaccines and treatments under the regular TRIPS structure, and that its provisions should thus also be waived.

Immediately following the October 2020 proposal by India and South Africa, the WTO members met to discuss the waiver and other related proposals.[36] WTO member states discussed the possibility of extending the grace period offered to less-developed countries in implementing the TRIPS agreement after Chad, on behalf of the LDC WTO member group, made such a proposal to the TRIPS Council.[37] Members also discussed competitiveness issues for micro, small, and medium enterprises (MSMEs) through the protection of IP rights. The TRIPS Council suspended the proposal and planned to reconvene in December 2020, following the first WTO conference on the South Africa-India waiver proposal. In general, member states expressed support for some version of an IP waiver via TRIPS pursuant to the proposal.

The December 2020 meeting of the WTO members included further discussion of the South Africa-India proposal.[38] The TRIPS Council did not rule on the waiver request prior to the meeting and extended their 90-day period to do so.[39] The WTO members met subsequently in March 2021.[40] By the March 2021 meeting, the proposal had been co-sponsored

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36. World Trade Organization, Press Release, *Members Discuss Intellectual Property Response to the COVID-19 Pandemic*, October 20, 2020, https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm.

37. Communication to the TRIPS Council of the WTO by Chad on behalf of the LDC Group, *Extension of the Transition Period under TRIPS Article 66.1 for Least Developed Country Members*, WTO Doc. IP/C/W/668 (Oct. 1, 2020).

38. World Trade Organization, *Members to Continue Discussion on Proposal for Temporary IP Waiver in Response to COVID-19*, May 10, 2020, https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm.

39. *Id.*

40. World Trade Organization, *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business*, Mar. 11, 2021, https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm.

by nine countries, the African Group, and the LDCs group.[41] On May 25, 2021, several WTO member states, the African Group, and the LDCs group submitted a revised version of the original South Africa-India proposal.[42] As of May 26, 2021, Jordan requested to officially join in its support of the waiver, increasing the number of signed supporters to thirteen countries and two WTO groups.[43] The TRIPS Council had not yet ruled on the proposals, and no decision was made regarding extension of the LDC transition period, which was set to expire on July 1, 2021.[44] The WTO members met again in April 2021 and held that the General Council had to make a decision on the waiver proposal by May 5th or 6th, 2021.[45] Note that the holding of the WTO members was merely a decision to schedule a discussion, and that there is no formal recourse in the event that the meeting fails to happen. Sixty WTO member countries supported the waiver proposal.[46] There was no decision by the TRIPS Council on the proposal at that time.[47] Despite the meetings of the WTO members

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41. *Id.* Bolivia, Egypt, Eswatini, Kenya, Mongolia, Mozambique, Pakistan, Venezuela, and Zimbabwe co-sponsored the South Africa-India proposal as of March 2021. Council for Trade-Related Aspects of Intellectual Prop. Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, The LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe*, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021) [hereinafter WTO Waiver, May 25, 2021].

42. Communication to the TRIPS Council of the WTO by South Africa and India, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-1 9, supra* note 33.

43. Addendum, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of COVID-19: Communication from India and South Africa*, (visited January 3, 2022), https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=274473,274404,274395,274268,274269,274271,274186,273996,273770,273787&CurrentCatalogueIdIndex=3&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True.

44. Communication to the TRIPS Council of the WTO by Chad on behalf of the LCD Group, *Extension of the Transition Period under TRIPS Article 66.1 for Least Developed Country Members, supra* note 37.

45. *TRIPS Council to Continue to Discuss Temporary IP Waiver, Revised Proposal Expected in May*, WTO, April 30, 2021, https://www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm.

46. *Id.*

47. *Id.*

following the South Africa-India proposal, there has not been a decision on the waiver by the TRIPS Council and the proposal is still pending.

The TRIPS Council met on June 8-9, 2021 to discuss the proposed waiver and decided to proceed to text-based negotiations regarding the proposal.[48] The text-based negotiation is to take place via a WTO General Council meeting.[49] A draft of the negotiations, which aims to satisfy every member state in order to reach consensus, will be presented at the upcoming meeting on July 21-22.[50] Negotiations in this format allow dissenters or opponents to negotiate specific provisions of the proposed waiver, seek compromises, or make changes to the proposal.[51] The EU has put forth its own alternative proposal to the existing proposal and revision before the WTO, and despite growing international support, several EU countries still oppose the waiver.[52]

On June 24, 2021, the TRIPS committee met to discuss the EU's plan for increasing vaccine access during the pandemic.[53] The EU proposal is an alternative to the proposed waiver by WTO member states.[54] The proposal suggests the safeguarding of IP protections and the utilization of TRIPS flexibilities to increase vaccine access, rather than waiving the provisions.[55] The main call of action of the EU's plan is to members, asking them to "ensure that vaccine and treatment products can cross borders freely, to avoid disruptions to global supply chains and to not restrict supplies to COVID-19 Vaccines Global Access, the WTO body designed to provide vaccines to poorer countries."[56] Supporters of the E.U. plan argue that it will be implemented quickly and will neither require negotiation of patent rights nor require the length of time attributed to

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48. Andrew Green, *WTO Council Offers Hope for TRIPS Vaccine Proposal*, DEVEX, June 10, 2021, https://www.devex.com/news/wto-council-offers-hope-for-trips-vaccine-proposal-100125.

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

53. Tiffany Hu, *WTO Panel Debates EU's Alternative to IP Waiver Proposal*, LAW360, June 24, 2021, https://www.law360.com/lifesciences/articles/1397412/wto-panel-debates-eu-s-alternative-to-ip-waiver-proposal?nl_pk=10d3b1b5-5f83-4189-938a-df7f5d9ca046&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences.

54. *Id.*

55. *Id.*

56. *Id.*

compulsory licensing.[57] Some supporters of the TRIPS waiver, like South Africa and India, opposed the E.U.'s plan, stating that it was an unnecessary repetition of flexibilities that already exist under TRIPS.[58] The US, UK, and other members entertained the idea of the E.U.'s plan but "asked for more clarification."[59]

On July 20, 2021, the TRIPS Council again met to consider the language and scope of the proposed waiver.[60] The members approved a status report on waiver negotiations to be presented at the July 27-28 meeting of the General Council.[61] At the time of the late-July TRIPS Council meeting, two divergent opinions generally remained throughout the members of the WTO regarding whether the waiver should be implemented.[62] The meeting closed without any resolution on the matter, despite outcry from public health officials and member countries.[63]

At the July 27-28 General Council meeting of the WTO, the chair of the TRIPS Council reported that the TRIPS Council had engaged in further discussions of the proposed waiver, as initiated by South Africa and India and revised and endorsed by several other countries.[64] The TRIPS Council has also been considering a proposal from the E.U. for a draft General Council declaration on TRIPS and public health issues despite the pandemic.[65] The fundamental disagreement between whether there should be a waiver of intellectual property rights at all and how that waiver should come to light has caused a delay in coming to a conclusion on the proposed waiver, especially where the E.U.'s proposal is logically at-odds with the waiver proposal.[66] The chair suggested that the meetings and negotiations will likely continue in both formal and informal contexts.[67] The WTO

57. *Id.*
58. *Id.*
59. *Id.*
60. World Trade Organization, *TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19*, July 20, 2021, https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm.
61. *Id.*
62. *Id.*
63. *Id.*
64. World Trade Organization, *Chair Urges Members to Focus on Priorities, Outcome for MC12*, July 28, 2021, https://www.wto.org/english/news_e/news21_e/gc_28jul21_e.htm.
65. *Id.*
66. *Id.*
67. *Id.*

General Council has not discussed the TRIPS waiver on the official agenda since July 28, 2021. The WTO General Council reconvened in September 2021, taking no further action on the waiver petition.[68] In November 2021, as the omicron variant emerged as a virulent and predominant strain of the virus, President Biden reiterated support for the waiver, yet without articulating the extent of that support or what form the waiver should be adopted.[69] A White House statement dated November 26, 2021, provides:

> I call on the nations gathering next week for the World Trade Organization ministerial meeting to meet the U.S. challenge to waive intellectual property protections for COVID vaccines, so these vaccines can be manufactured globally. I endorsed this position in April; this news today reiterates the importance of moving on this quickly.[70]

Despite the strong sentiment to the U.S. public, the Biden administration has been criticized for failing to engage in productive conversation with countries currently opposing the IP waiver.[71] The same day Biden issued his statement, the WTO ministerial conference of the General Council was postponed indefinitely because of the risks posed by the omicron variant.[72] Figure 1 depicts key dates and actors involved in the waiver petition spanning October 2020 through November 2021.

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68. Baschuk, *supra* note 1.

69. Walker Bragman, *Where Is Biden In the Global War on Omicron?*, The Daily Poster, Dec. 7, 2021, https://www.dailyposter.com/where-is-biden-in-the-global-war-on-omicron/.

70. The White House, *Statement from President Joe Biden on the Omicron COVID-19 Variant*, Nov. 26, 2021, https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/26/statement-by-president-joe-biden-on-the-omicron-covid-19-variant/

71. Bragman, *supra* note 69; Sarah Lazare, *Documents Reveal Biden Admin Not Fighting for a COVID Vaccine Patent Waiver, Despite Public Statements*, In These Times, Nov. 29, 2021, https://inthesetimes.com/article/biden-omicron-wto-trips-waiver-intellectual-property-patents.

72. World Trade Organization, *General Council Decides to Postpone MC12 Indefinitely*, Nov. 26, 2021, https://www.wto.org/english/news_e/news21_e/mc12_26nov21_e.htm.

Figure 1: Waiver Petition Timeline

Date	*Description*	*Actors*
10/2/20	South Africa and India propose the waiver of certain TRIPS provisions for COVID.[73]	South Africa and India
10/15/20; 10/26/20	WTO member states met to discuss the proposal and planned to reconvene in December 2020. Some members suggested that the TRIPS Council extend the grace period (period of exemption from TRIPS) for LDCs beyond July 1, 2021. [74]	WTO General Council, TRIPS Council
11/20/20; 12/3/20	Informal TRIPS Council meetings were held to discuss the lack of consensus on the waiver. The Chair referred the TRIPS Council as the body to hold a meeting and report to the General Council on the status of discussions re: the waiver. The TRIPS Council would have 90 days to report to the General Council. The 90 days would expire on December 31, 2020. [75]	TRIPS Council (informal meetings)
12/10/20	WTO members attended the TRIPS Council meeting. The TRIPS Council planned to provide its status report to the General Council on December 16-17, 2020. The TRIPS Council and General Council extended the 90-day period for the upcoming	TRIPS Council

73. Council for Trade-Related Aspects of Intellectual Prop. Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa*, WTO doc. IP/C/W/669 (Oct. 2, 2020) [hereinafter WTO Waiver, Oct. 2, 2020].

74. World Trade Organization, *Members Discuss Intellectual Property Response to the COVID-19 Pandemic*, Oct. 20, 2020, https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm.

75. World Trade Organization, *Members to Continue Discussion on Proposal for Temporary IP Waiver in Response to COVID-19*, Dec. 10, 2020, https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm.

	status report and planned to continue negotiations. [76]	
3/10/21; 3/11/21	Nine countries, the African Group, and the LDCs Group joined to co-sponsor the South Africa-India proposal. The TRIPS Council discussed the waiver and the possible extension of the LDC grace period past July 1, 2021. [77]	TRIPS Council Bolivia, Egypt, Eswatini, Kenya, Mongolia, Mozambique, Pakistan, Venezuela, Zimbabwe, the African Group, and LDCs Group
4/30/21	The TRIPS Council agreed that the report to the General Council on the waiver will be submitted by May 5-6, 2021.Co-sponsors of the waiver proposal announced that they would submit a revised proposal at the next General Council meeting. The proposal was supported by 60 WTO members.[78]	TRIPS Council
5/5/21	U.S. Trade Representative Katherine Tai announced that the U.S. supports the waiver in-part.[79]	United States
5/25/21	A revised version of the proposal was	WTO General Council,

76. *Id.*

77. World Trade Organization, *Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business*, *supra* note 40.

78. World Trade Organization, *TRIPS Council to Continue to Discuss Temporary IP Waiver, Revised Proposal Expected in May*, Apr. 30, 2021, https://www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm.

79. Office of the United States Trade Representative, *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, May 5, 2021, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver [hereinafter Statement from Ambassador Tai.]

	submitted to the General Council.[80]	TRIPS Council
6/4/21	The European Union proposed an alternative plan to the proposed TRIPS waiver.[81]	European Union
6/8/21; 6/9/21	The TRIPS Council decided that text-based negotiations should take place forthcoming.[82]	TRIPS Council
6/24/21	The TRIPS Council met to discuss increased access to vaccines, as proposed by the European Union.[83]	TRIPS Council (informal meeting)
7/1/21	Grace period for LDC implementation of TRIPS is set to expire. When the period expires, LDCs must adhere to TRIPS provisions, with an exception for drug patents. LDCs do not have to adhere to TRIPS for drug patents until January 2033.[84]	TRIPS Agreement
7/21/21; 7/22/21	The General Council met to negotiate the proposal[85] and adopt a report on the status of the negotiations.[86]	WTO General Council
Week of 9/6/21	The General Council reconvened following summer break.[87]	WTO General Council
11/26/21	The General Council indefinitely postponed upcoming conference meeting because of omicron variant.[88]	WTO General Council

80. WTO Waiver, May 25, 2021, *supra* note 41.
81. Hu, *supra* note 53.
82. Green, *supra* note 48.
83. Hu, *supra* note 53.
84. World Trade Organization, *WTO Members Agree to Extend Drug Patent Exemption for Poorest Members*, Nov. 6, 2015, https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm.
85. Green, *supra* note 48.
86. Baschuk, *supra* note 1.
87. *Id.*
88. World Trade Organization, *General Council Decides to Postpone MC12 Indefinitely*, *supra* note 72.

Countries may "officially" or "formally" support the waiver by signing the proposal before the WTO, which sixty countries had done for the original proposal by late April 2021.[89] Countries might also show public support for or opposition to the waiver or parts of the waiver. According to the WTO, there are several countries who support some type of waiver but take issue with the ambiguity of the South Africa and India waiver proposal or some other facet of that proposal.[90]

The revised waiver to waive TRIPS amidst COVID-19 provides some new clarity to the proposed terms. The working version of the document as of now, IP/C/W/669/Rev. 1, clarifies that the waiver should continue for a minimum of three years after the General Council decides to implement the waiver.[91] For the years following, the General Council is to review the circumstances relevant to the waiver and determine whether: (1) those circumstances no longer exist and (2) the waiver should be terminated.[92] In addition, the General Council, within one year of granting the proposal, must review the waiver and continue to do so annually in accordance with paragraph 4 of Article IX of the Marrakesh Agreement.[93] Article IX, paragraph 4 states that waivers granted: (1) for more than one year and (2) under exceptional circumstances must be reviewed by the overseeing body within one year of their implementation and annually until they no longer apply.[94] Upon such review, the overseeing body must ascertain whether the exceptional circumstances allowing the waiver still exist, and whether the terms and conditions of the waiver have been met. Finally, Marrakesh Agreement, Article IX, paragraph 4 states that the overseeing body, upon annual review of the waiver, has the power to extend, modify, or terminate it.[95]

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89. World Trade Organization, *TRIPS Council to Continue to Discuss Temporary IP Waiver, Revised Proposal Expected in May*, *supra* note 78.

90. D. Ravi Kanth, *Developed Countries Continue to Block TRIPS Waiver Proposal*, THIRD WORLD NETWORK, Nov. 23, 2020, https://www.twn.my/title2/intellectual_property/info.service/2020/ip201108.htm.

91. WTO Waiver, May 25, 2021, *supra* note 41, at 3.

92. *Id.*

93. *Id.*

94. Marrakesh Agreement Establishing the WTO art. 9 ¶4, Apr. 15, 1994, 1867 U.N.T.S. 154.

95. *Id.*

The proposed waiver has, in both drafts, outlined several TRIPS requirements to be abandoned considering the COVID-19 pandemic. The first version of the proposal urges the waiver of TRIPS protections (contained in Sections 1, 4, 5, and 7 of Part II) for essential medical products that create barriers to access, such as patents, industrial designs, copyrights, and protection of undisclosed information.[96] The first version also cited Article 31*bis* requirements on compulsory licenses as problematic for countries with poor manufacturing capacity, but did not explicitly or unambiguously request the General Council to waive the requirements of TRIPS Article 31*bis*.[97] The revision narrows and clarifies that such waiver shall apply to Sections 1, 4, 5, and 7 of Part II of TRIPS for "health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19."[98] The revision abandons any mention of Article 31*bis*, compulsory licenses.[99]

Due to the change in the proposal, Article 31*bis* on compulsory licenses is no longer being discussed as a waived provision of TRIPS under this schema for curbing COVID. Article 31*bis* waives the domestic use requirement for compulsory licensing, which previously required products to be used mostly in the domestic market in order to qualify for a compulsory license under TRIPS.[100] Under the waiver, a country can issue a compulsory license that is primarily for export to another country; however, the other Article 31 requirements still require a lot of heavy lifting for both the importing and exporting country, and compulsory licenses are somewhat difficult to procure even with the Article 31*bis* waiver in place.[101] South Africa and India initially brought up this issue in

96. WTO Waiver, Oct. 2, 2020, *supra* note 73, at 1.

97. *Id*, at 2.

98. WTO Waiver, May 25, 2021, *supra* note 41, at 1.

99. WTO Waiver, May 25, 2021, *supra* note 41; *see also Part II – Standards Concerning the Availability, Scope and Use of Intellectual Property Rights*, WORLD TRADE ORG., https://www.wto.org/english/docs_e/legal_e/27-trips_04_e.htm (visited Oct. 20, 2021). Under TRIPS, Part II, Section 1 discusses copyrights, Section 4 discusses industrial designs, Section 5 discusses patents, and Section 7 discusses protection of undisclosed information. *Id.*

100. CYNTHIA M. HO, *Complicated Compulsory Licenses: The Waiver/Article31bis 'Solution', in* ACCESS TO MEDICINE IN THE GLOBAL ECONOMY 196, 197 (2011); Kumar, *supra* note 3.

101. *Id.* at 198.

the proposal for the TRIPS waiver, but it has been abandoned and is not even mentioned in the revised version.[102] This suggests that if the waiver of TRIPS requirements for certain types of intellectual property during COVID-19 goes through, a revision or exemption of requirements for compulsory licenses will have to come from another proposal or source.

Certain TRIPS exemptions and provisions related to pharmaceutical products already exist outside of the proposed exemptions.[103] For example, governments can refuse to grant patents for "diagnostic, therapeutic, and surgical methods" for treating humans and animals.[104] Several additional waivers of compulsory licensing requirements also exist under Article 31*bis* and binding WTO decisions, and they apply to pharmaceutical products.[105] Despite their existence, about 50 of the WTO members do not use or very seldom use these TRIPS provisions and WTO-approved waivers for pharmaceutical products.[106]

There are a variety of procedural issues facing the proposed waiver. The procedural aspects most pertinent to the TRIPS waiver are the procedures of the WTO and the TRIPS Council, the procedural history of the WTO and similar entities regarding emergency use and prior waivers or proposals, and the possible future consequences of allowing such waivers during emergencies, like the pandemic. The WTO and its subsidiary TRIPS Council have not done anything substantive with the waiver—the original waiver was proposed in October 2020, but the WTO has not made a decision that binds the members. The WTO is a rules-based, member-driven organization that makes most of its decisions based on consensus, which is established when no member state formally objects to a decision made by the General Council.[107] Formal objection is not well-

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102. WTO Waiver, May 25, 2021, *supra* note 41.

103. *Fact Sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions*, WORLD TRADE ORG. (Sept. 2006), https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm [hereinafter Pharmaceutical Patents].

104. *Part II – Standards Concerning the Availability, Scope and Use of Intellectual Property Rights*, WORLD TRADE ORG., https://www.wto.org/english/docs_e/legal_e/27-trips_04_e.htm (visited Oct. 20, 2021) (referring to Art. 27(3)(a)).

105. Pharmaceutical Patents, *supra* note 103.

106. *Id.*

107. Georgetown Law Library, *International Trade Law Research Guide: WTO Organizational Structure & Decision Making*, https://guides.ll.georgetown.edu/c.php?g=363556&p=4154931 (last updated Dec. 2, 2021).

defined, and consensus is generally inferred where there is no writing or other suggestion that a member state is vehemently opposed to a decision.[108] Consensus requires all 164 member states to agree on a proposal.[109] If a period of time— undefined—passes and the members fail to reach consensus, the General Council will vote on the proposal, and a two thirds vote is required for the proposal to pass.[110]

On May 25, 2021, the TRIPS Council recommended, following several prior recommendations, that the General Council should formally discuss and rule on the revised proposal for the TRIPS waiver.[111] The proposed waiver was the only working document within the TRIPS Council docket as of June 2021, and the General Council had planned to discuss the TRIPS waiver as a formal matter of business for its next meeting.[112] Generally, issues that are outside of the mandatory agenda for the TRIPS Council are discussed *ad hoc*, which leaves room for the WTO to ignore, postpone, or change agendas regarding proposals such as the TRIPS waiver and the revision.[113]

The TRIPS Council has previously made rulings via the member states that are enforced by the WTO and binding on the member states. Most notably, in 2015, the TRIPS Council, without opposition from member states, waived TRIPS requirements for least-developed countries (LDCs) for pharmaceutical products.[114] The exemption for LDCs already was in place, but the 2015 decision by the TRIPS Council extended that exemption to January 2033— because of this extension of the exemption period, LDC member countries are exempt from TRIPS requirements for pharmaceutical products at present.[115] The implication of the extension of the LDC exemption period is twofold: first, it shows that the TRIPS Council has made unanimous decisions that were accepted as binding on

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108. *Id.*

109. *Id.*

110. World Trade Organization, *Whose WTO Is It Anyway?*, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm (visited Jan. 7, 2022).

111. WTO Waiver, May 21, 2021, *supra* note 41.

112. *Id.*

113. World Trade Organization, *Module XI: Current TRIPS Issues*, https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/modules11_e.pdf (visited Jan. 7, 2022).

114. World Trade Organization, *WTO Members Agree to Extend Drug Patent Exemption for Poorest Members*, Nov. 6, 2015, https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm.

115. *Id.*

WTO members, and second that LDCs are not bound by TRIPS requirements for pharmaceutical products, which applies to the question about COVID vaccines. At present, there are thirty-five LDC members of the WTO.[116]

IV. THE EVOLUTION OF THE U.S. POSITION ON THE WAIVER

The U.S. and some European countries have been staunch opponents of the waiver.[117] The U.S. only changed its critical position in May 2021, when the Biden administration backed the waiver and proclaimed its public support for the waiver of certain IP requirements under TRIPS.[118] According to Reuters, the Biden administration changed the U.S. position on the waiver following pressure from democratic lawmakers in the U.S. and more than one hundred countries who are in support of the waiver.[119] The Biden-Harris administration issued a statement supporting the TRIPS waiver to international intellectual property rights,[120] an about-face from the prior administration's staunch opposition to any effort to support global access and distribution. U.S. Trade Representative Katherine Tai made the statement on May 6, 2021, announcing that the U.S. had changed its stance and was now in support of the proposed IP waiver for COVID vaccines.[121] The statement issued by Tai carefully limited support of the waiver to vaccines, a narrower segment of medical products and

116. World Trade Organization, *Least-Developed Countries*, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm#:~:text=Eight%20more%20least-developed%20countries%20are%20negotiating%20to%20join,no%20WTO%20definitions%20of%20%E2%80%9Cdeveloped%E2%80%9D%20or%20%E2%80%9Cdeveloping%E2%80%9D%20countries (visited Jan. 18, 2022).

117. Sidhant Sibal, *WTO to Take Up India-SAfrica Proposal for Waiver on IP Rights for COVID Vaccines on Feb 23*, WION, Feb. 5, 2021, https://www.wionews.com/india-news/wto-to-take-up-india-safrica-proposal-for-waiver-on-ip-rights-for-covid-vaccines-on-feb-23-361554.

118. Shalal et al., *U.S. Reverses Stance, Backs Giving Poorer Countries Access to COVID Vaccine Patents*, REUTERS, May 5, 2021, https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/.

119. *Id.*

120. Statement from Ambassador Tai, *supra* note 79: Shalal et al, *supra* note 118.

121. Statement from Ambassador Tai, *supra* note 79.

information than contemplated in the most recent version of the petition for waiver.[122]

The current proposed waiver at the WTO seeks to waive TRIPS requirements for "health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment, or containment of COVID-19."[123] The U.S. did not sign the original or revised proposal, but instead publicly expressed its support through the Trade Representative's statement.[124] Representative Tai stated in the "official" statement from the U.S., "The [Biden] Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines."[125] Representative Tai went further to say,

> "The Administration's aim is to get as many safe and effective vaccines to as many people as fast as possible. As our vaccine supply for the American people is secured, the Administration will continue to ramp up its efforts – working with the private sector and all possible partners – to expand vaccine manufacturing and distribution. It will also work to increase the raw materials needed to produce those vaccines."[126]

Representative Tai's choice wording that the U.S. supports the proposed waiver of TRIPS requirements, under the first proposal at the WTO by South Africa and India, applies to vaccines, but there is not an explicit indication that: (1) the U.S. fully supports the waiver for the proposed items in the first version of the proposal; (2) the U.S. fully supports the waiver for the proposed items in the revised version of the proposal: or (3) the U.S. only supports either version of the waiver with respect to vaccines. There is, however, some indication that the U.S. Trade Representative's phrasing indeed only applies U.S. support to waiver of TRIPS requirements despite COVID-19 for vaccines, because some

122. *Id.*
123. WTO Waiver, May 25, 2021, *supra* note 41.
124. Statement from Ambassador Tai, *supra* note 79.
125. *Id.*
126. *Id.*

stakeholders have urged the Biden Administration to also consider the waiver for other COVID-relevant items.[127]

In May 2021, Senator Warren expressly asked Representative Tai whether the U.S. supports the waiver for vaccines only, or if it also applies to diagnostics, therapeutics, and PPE.[128] Representative Tai responded that the U.S. will focus on vaccines, in an effort to answer the time-sensitive vaccine crisis.[129] When asked again, Representative Tai reiterated that vaccines are the priority and that the U.S. supports the waiver of TRIPS for vaccines and raw materials, but that the U.S. recognizes the need for diagnostic testing and PPE.[130] It remains unclear whether Representative Tai is suggesting that the U.S. supports the waiver of TRIPS requirements for PPE and diagnostic testing, even after the exchange with Senator Warren.

Leading up to and before this shift in support of the waiver, the Trump administration supported the general trend of the U.S. upholding strong intellectual property rights. The U.S. has historically maintained very strong IP rights, with the annual number of issued patents having quintupled since several pieces of important legislation in the 1980s.[131] In 2021, the U.S. was ranked second in global patent protection, for the third year in a row.[132] The U.S. is the global leader in copyright and trademark protections, amidst a general global trend toward stronger IP rights.[133] During the Trump administration, the U.S. Patent Office was headed by those in strong support of strong intellectual property rights, who consequently also opposed the proposal by South Africa and India.[134] In contrast, however, the Biden administration has made some indications

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127. Green, *supra* note 48.

128. Press Release, Elizabeth Warren, Warren to Tai at Hearing: Our Trade Negotiations Must Put Patients Over Big Pharma Profits, May 12, 2021, https://www.warren.senate.gov/newsroom/press-releases/warren-to-tai-at-hearing-our-trade-negotiations-must-put-patients-over-big-pharma-profits.

129. *Id.*

130. *Id.*

131. Brink Lindsey, *Why Intellectual Property and Pandemics Don't Mix*, BROOKINGS, June 3, 2021, https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/.

132. Tiffany Hu, *supra* note 30.

133. *Id.*

134. Ian Lopez, *Biden Vaccine IP Waiver Stance Offers Clue on Patent Office Pick*, BLOOMBERG LAW, May 17, 2021, https://news.bloomberglaw.com/coronavirus/biden-vaccine-ip-waiver-stance-offers-clue-on-patent-office-pick.

that the Patent Office will spearhead support of strong intellectual property rights and simultaneously uphold the new and current U.S. stance in support of a TRIPS waiver.[135]

Early in the Biden administration, Democratic lawmakers urged the President to support the IP waiver. Around March 2021, pressure from developing countries and support from progressive lawmakers pushed the White House to consider the IP waiver.[136] Senator Pelosi and several Democratic colleagues issued a letter to urge the Biden administration to further study the waiver issue.[137] U.S. Representatives DeLauro, Schakowsky, Blumenauer, Dogget, Espaillat, and Levin urged President Biden to support a temporary TRIPS waiver in March 2021.[138] They argued that the U.S. had lost its position and status as a global health leader and that COVID is a crisis requiring global collaboration.[139] More than sixty U.S. Representatives joined to urge President Biden to support the South Africa-India proposal at the WTO.[140] In early April 2021, Senators Baldwin, Blumenthal, Brown, Markley, Merkley, Murphy, Sanders, Van Hollen, Warnock, and Warren wrote a letter to President Biden urging him to support the IP waiver for COVID vaccines.[141] Lawmakers cited damage done during former President Trump's tenure as the president.[142] A Data for Progress and Progressive International poll showed that sixty percent of U.S. voters supported the waiver, including fifty percent of registered Republicans.[143] Democratic lawmakers were largely supportive of a temporary IP waiver, especially following strong lobbies from Senators

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135. *See Id.*

136. Tausche et al., *White House Weighs Temporarily Lifting Intellectual Property Shield on COVID-19 Vaccines*, CNBC, Mar. 26, 2021, https://www.cnbc.com/2021/03/26/covid-vaccine-updates-white-house-mulls-lifting-intellectual-property-shield.html.

137. *Id.*

138. Press Release, DeLauro, Schakowsky, Blumenauer, Doggett, Espaillat, Urge Biden Administration to Support COVID-19 Waiver to Boost Global Distribution of Vaccines and Therapeutics, Mar. 17, 2021, https://delauro.house.gov/media-center/press-releases/delauro-schakowsky-blumenauer-doggett-espaillat-levin-urge-biden.

139. *Id.*

140. *Id.*

141. *Colleagues Urge Biden to Approve Vaccine Patent Waiver to Boost Production and End Pandemic*, Apr. 16, 2021, https://www.warren.senate.gov/newsroom/press-releases/ warren-colleagues-urge-biden-to-approve-vaccine-patent-waiver-to-boost-production-and-end-pandemic.

142. *Id.*

143. *Id.*

Warren and Biden.[144] At the time the U.S. announced its support for the waiver, more than one hundred House Democrats supported the TRIPS waiver for vaccines and treatments.[145]

Despite a general trend in progressive U.S. legislators supporting the waiver, a number of Democrats refused to back the COVID vaccine patent waiver, even before President Biden expressed U.S. support via Ambassador Tai.[146] Of the top twenty-five members of the House who received money from the pharmaceutical industry, nine are Democrats.[147] None of those Democrats have signed the letter from other House members urging the President to support the waiver.[148] Democratic opponents of the waiver cite harm to the global competitiveness of the U.S., the inability of the waiver to solve a shortage issue, and manufacturing capacity issues that would stunt the effectiveness of the waiver.[149]

The general U.S. trend toward strong protection of intellectual property rights is evidenced by pushback to the Biden administration's change of position regarding the TRIPS waiver proposal. PhRMA and pharmaceutical companies strongly opposed the U.S. decision to reverse its prior stance on the TRIPS waiver. Following U.S. Trade Representative Katherine Tai's statement that the U.S. supports the proposal for the waiver of TRIPS requirements during the pandemic, the pharmaceutical industry voiced collective frustration.[150] Moderna and several other pharma superpowers argue that there is insufficient manufacturing capacity to supply the rapid or even near-term deployment of widespread mRNA vaccines, even if there were to be a patent or IP

144. *Id.*

145. Hannah Monicken, *House Democrats Push Biden to Support, Negotiate on IP Waiver at WTO*, INSIDEHEALTHPOLICY, May 5, 2021, https://insidehealthpolicy.com/daily-news/house-democrats-push-biden-support-negotiate-ip-waiver-wto.

146. Jake Johnson, *Democrats Funded by Big Pharma Refuse to Back COVID Vaccine Patent Waiver*, TRUTHOUT, May 4, 2021, https://truthout.org/articles/democrats-funded-by-big-pharma-refuse-to- back-covid-vaccine-patent-waiver/.

147. *Id.*

148. *Id.*

149. *Id.*

150. Jonathan Gardner & Ned Pagliarulo *Pharma Erupts as Biden Administration Backs Waiver of Vaccine Patent Rights*, BIOPHARMADIVE, May 6, 2021, https://www.biopharmadive.com/news/biden-vaccine-patent-waiver-pharma-opposition/599704/.

waiver.[151] U.S. industry and trade organizations opposed to the waiver claim that it is broad and sweeping, vague, and undermines well-established IP rights.[152] Some pharmaceutical companies purport that the waiver undermines pharmaceutical investment and intellectual property assets worth tens of billions of U.S. dollars.[153] The Wall Street Journal reflected these concerns, while also expressing concern that the U.S. has given up its stronghold on innovation via intellectual property, especially in the patent space.[154] Pfizer, Moderna, Johnson & Johnson, and the U.S. Chamber of Commerce have consistently opposed democratic lobbies to support the waiver, including for vaccines, personal protective equipment, diagnostics, and treatments for COVID-19.[155]

Both up to and following Ambassador Tai's announcement, a handful of U.S. lawmakers and activist groups have pushed the President to expand U.S. support of the waiver beyond application solely to vaccines.[156] These groups seek to expand U.S. support not only to include vaccines, but also critical treatments and diagnostics.[157] In addition, activists have urged Dr. Anthony Fauci and other federal officials to use a government-owned patent to make Moderna's COVID vaccine more widely available.[158]

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151. Noah Higgins-Dunn, *Moderna CEO Says He's Not Losing Any Sleep over Biden's Support for COVID-19 Vaccine Waiver*, FIERCE PHARMA, May 6, 2021, https://www.fiercepharma.com/pharma/moderna-ceo-says-he-s-not-losing-any-sleep-over-biden-s-endorsement-for-covid-19-ip-waiver; Lewis Krauskopf, Julien Ponthus, & Ankur Banerjee, *COVID-19 Vaccine Maker Shares Sink as Governments Mull Patent Waiver*, REUTERS, May 6, 2021, COVID-19 vaccine maker shares sink as governments mull patent waiver | Reuters.

152. Mari Serebrov, *Debate Continues to Boil over Pandemic-Related IP*, BIOWORLD, Mar. 30, 2021, https://www.bioworld.com/articles/505358-debate-continues-to-boil-over-pandemic-related-ip.

153. Editorial Board, *Biden's Vaccine IP Debacle*, WALL STREET JOURNAL, May 6, 2021, https://www.wsj.com/articles/bidens-vaccine-ip-debacle-11620341686.

154. *Id.*

155. Connor Perrett, *Sen. Bernie Sanders Says U.S. Drug Companies Should Relinquish... 'Millions of Lives are at Stake Around the World'*, BUSINESS INSIDER, May 2, 2021, https://www.businessinsider.com/sanders-drug-companies-should-relinquish-ip-rights-to-covid-19-vaccines-2021-5.

156. *See* Andrew Green, *U.S. Backs Waiver for Intellectual Property Rights for COVID-19 Vaccines*, DEVEX, May 6, 2021, https://www.devex.com/news/us-backs-waiver-for-intellectual-property-rights-for-covid-19-vaccines-99847.

157. *Id.*

158. Tiffany Hu, *Feds Urged to Use Moderna Vaccine Patent to Expand Access*, LAW360, March 25, 2021, https://www.law360.com/lifesciences/articles/1368802/feds-

Moderna has contracted with a manufacturer to produce the drug substance for the vaccine, but has failed to provide the technology to developing countries.[159] In a letter to Secretary Becerra and others on the use of the patent, proponents suggested that the agreement would: (1) empower the U.S. to authorize production of the mRNA strand necessary for the vaccine, (2) require technology sharing with the WHO to expedite global production, and (3) include requirements for accessible pricing universally.[160]

Until the switch in the U.S. position, the U.S., E.U., Australia, Brazil, Canada, Japan, Norway, Singapore, Switzerland, Taiwan, and the U.K. had all opposed the joint proposal for the TRIPS waiver.[161] China and Russia both support the waiver.[162] Germany has consistently opposed the waiver.[163] Switzerland, South Korea, and Japan are expected to continually oppose the waiver due to the influence of wealthy pharmaceutical companies.[164] Some of the waiver's opponents say that the waiver will not solve vaccine nationalism, hoarding of supplies, and poor sharing of COVID vaccines.[165] Many wealthy countries were adverse to the IP waiver before the U.S. expressed its position in support— once the U.S. expressed support, a number of developing countries expressed support for the revised proposal.[166] Supporters claim that the waiver will boost vaccine production, that it is more desirable and efficient than compulsory licenses, and that public health is to be prioritized over profits.[167] Supporters look to a bottlenecking effect, claiming that

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urged-to-use-moderna-vaccine-patent-to-expand-access?nl_pk=10d3b1b5-5f83-4189-938a-df7f5d9ca046&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences.

159. *Id.*

160. Letter from PrEp4All et al., Various Health Organizations, to Xavier Becerra et al, United States Secretary of Health, Mar. 24, 2021.

161. John Zarocostas, *What Next for a COVID-19 Intellectual Property Waiver?*, THE LANCET, May 22, 2021, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01151-X/fulltext.

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. Anshu Siripurapu, *The Debate Over a Patent Waiver for COVID-19 Vaccines: What to Know*, COUNCIL ON FOREIGN RELATIONS, May 26, 2021, https://www.cfr.org/in-brief/debate-over-patent-waiver-covid-19-vaccines-what-know.

167. *Id.*

intellectual property protections on patents, copyrights, trade secrets, and industrial designs greatly hinder production of critical medical products.[168] Opponents say that the waiver is a red herring, that it will stunt innovation, and that there is insufficient manufacturing capacity even with the waiver in place.[169]

V. ALTERNATIVE MODELS FOR ACCESS AND DISTRIBUTION

There is intense disagreement on whether the waiver is an effective and appropriate way to address the vaccine shortage. The director-general of the WTO, Ngozi Okonjo-Iwela, made a statement in late May that the waiver is insufficient as a method to expedite the provision of vaccines in countries that are behind and many legal commentators agree.[170] There is no evidence, as argued by those agreeing with Okonjo-Iweala, that there is an international mechanism or system whereby IP laws protected and required by TRIPS impede the "development, production, or distribution of vaccines and treatments for COVID."[171] They further argue that generic companies who already have begun production have not cited IP as the issue that needs to be solved at the global scale for faster production and increased volume of COVID vaccines and treatments.[172]

There is an additional group of countries and companies that support the waiver in general but have issues with the specific proposal and revision put forth to the WTO.[173] The ambiguity in the first proposal and the unresolved lack of clarity in the revision leaves some entities unclear on whether the specific method of the waiver should be supported or not.[174] One existing obstacle to the waiver of TRIPS requirements, despite the pandemic, is a lack of consensus on whether compulsory licenses will

168. *Id.*

169. *Id.*

170. David J. Kappos, *Waiving COVID-19 Vaccine Patents Won't Get Shots in Arms Faster...*, NBC NEWS OPINION, May 25, 2021, https://www.nbcnews.com/think/opinion/waiving-covid-19-vaccine-patents-won-t-get-shots-arms-ncna1268099.

171. *Id.*

172. *Id.*

173. *Developed Countries Continue to Block TRIPS Waiver Proposal*, THIRD WORLD NETWORK, Nov. 24, 2020, https://www.twn.my/title2/intellectual_property/info.service/2020/ip201108.htm.

174. *Id.*

require the compulsion of pharma's trade secrets.[175] In the past, compulsory licenses have not required the divulsion of trade secrets, so it is unclear where the suspicion comes from beyond speculation.[176] Law360 goes further to say that critics of the waiver claim that it will impede speedy and equitable vaccine distribution and weaken IP rights globally.[177] The waiver was blocked by the E.U., U.K., Switzerland, Japan, and some other countries. Despite heavy lobbying of Congress by pharmaceutical companies to deny the waiver, the U.S. has expressed support, though has also been criticized for a lack of movement with that support or follow up on questions of scope of that support.[178] At present, Medecins Sans Frontieres (Doctors Without Borders) has a map of countries that support or oppose the waiver.[179]

One controversial issue regarding the waiver of certain TRIPS provisions is whether it would require disclosure of certain information that is considered trade secrets by big pharma companies.[180] The TRIPS provision of concern is Part II, Section 7 on protection of undisclosed information. Section 7, Article 39, paragraph 1 states that members shall protect against unfair competition in accordance with Article 10*bis* of the Paris Convention for the Protection of Industrial Property.[181] Article 39, paragraph 2 outlines that natural and legal persons have the possibility to prevent others from acquiring information that is: (1) secret, (2) has commercial value because it is secret, and (3) has been subject to

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175. Eakin, *supra* note 29.

176. *Id.*

177. *Id.*

178. *Id.*

179. Press Release, *Countries Obstructing COVID-19 Patent Waiver Must Allow Negotiations to Start*, MÉDECINS SANS FRONTIÈRES, Mar. 9, 2021, https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations.

180. A trade secret is "a formula, process, device, or other business information that is kept confidential to maintain an advantage over competitors; information — including a formula, pattern, compilation, program, device, method, technique, or process — that (1) derives independent economic value, actual or potential, from not being generally known or readily ascertainable by others who can. obtain economic value from its disclosure or use, and (2) is the subject of reasonable efforts, under the circumstances, to maintain its secrecy." *Trade Secret*, BLACK'S LAW DICTIONARY, 789 (7th ed. 1996).

181. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, I.L.M. (1994).

reasonable measures to be kept a secret.[182] Finally, Article 39, paragraph 3 states that members, as a condition of approving marketing of pharmaceutical products, should protect clinical data against unfair commercial use.[183] Article 39, paragraph 3 provides that members should protect clinical data against disclosure, except where necessary to protect the public or steps are taken to ensure that the data are protected against unfair commercial use.[184]

The TRIPS provisions regarding undisclosed information are somewhat ambiguous. The ambiguity in the treaty leaves pharmaceutical companies' ample opportunity to argue that trade secrets are protected and defined in Article 39, and that disclosure of trade secrets via the proposed waiver further interferes with companies' monopolistic IP rights and threatens their profits.

An alternative approach based on international organization and cooperation has also been proffered: a joint effort by the WTO and WHO, wherein public health issues are governed with special attention to TRIPS and the Doha Declaration.[185] The proposed effort would include a committee for emergency preparedness and response, a specific dispute settlement mechanism that is separate from the general quasi-judicial method of the WTO, incentives for members to report public health issues, and permissions for member states to take actions, otherwise forbidden, during disease outbreaks with high risk and virulence with clear, unilateral trade restrictions that would cause a large, unjustified burden on a member country.[186]

The WHO and WTO Secretariat have offered some opinions on how to deal with public health crises and balance the interests of the public with the interests of intellectual property owners. The WHO and WTO Secretariat have suggested solutions and measures outside of intellectual property, including: (1) price and reimbursement controls; (2) tiered or equity pricing; (3) bilateral negotiation of price discounts between companies and governments, use of bulk purchasing power, voluntary licensing, and compulsory licensing; (4) voluntary price cuts that are

182. *Id.*

183. *Id.*

184. *Id.*

185. Mackey et al., *Lessons from SARS and H1N1/A: Employing a WHO-WTO Forum to Promote Optimal Economic-Public Health Pandemic Response*, 33 J. PUB. HEALTH POL'Y, 119 (2012).

186. *Id.*

accessible to all, not only some, countries; and (5) donation of drugs or treatments during global public health emergencies.[187]

A shared opinion by some proponents on both sides of the aisle of the TRIPS waiver debate is that waiving patents, on its own, is not enough to end the pandemic.[188] Some have suggested that the waiver of IP protections during COVID is necessary, but it is not sufficient to solve the pandemic.[189] A primary logistical barrier, even with the imposition of a waiver, is the inability of manufacturers to produce and distribute vaccines.[190] In addition, pharma companies are reluctant or averse to sharing their technological experience and knowledge, and governments back those companies by refusing to compel that transfer.[191] Big corporations report that mRNA vaccines are especially difficult to distribute and manufacture on a large scale, because they are complex and relatively new— the same argument is made about adenovirus vaccines, but to a lesser extent.[192] Pharmaceutical companies also hold on to their technology and knowledge, because they consider them indispensable trade secrets.[193]

Those in support of the waiver plus additional efforts claim that windfall profits have already gone to pharma companies, and significant public funding is available to support institutions that otherwise would not have been able to meet the current demand for production and distribution of vaccines.[194] One Indian company already produces a large amount of the AstraZeneca vaccine for Europe, and supporters of technology transfer plus the TRIPS waiver argue that there is no reason to believe that this particular Indian company and others do not have the ability to meet the manufacturing and production needs once the technology becomes available.[195] Supporters further argue that the U.S. is in a position where

187. World Health Organization & World Trade Organization, *WTO Agreements & Public Health: A Joint Study by the WHO and the WTO Secretariat*, 101 (2002), https://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf.

188. Kay et al., *Waiving Patents Isn't Enough— We Need Technology Transfer to Defeat COVID*, The Hill, May 13, 2021, https://thehill.com/opinion/healthcare/553368-waiving-patents-isnt-enough-we-need-technology-transfer-to-defeat-covid?rl=1.

189. *Id.*

190. *Id.*

191. *Id.*

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.*

the government can: (1) supply multinationals with ample financial incentives to build capacity to vaccine production and (2) apply pressure on companies by threatening to sequester existing patents if the company fails to adhere to compulsory technology transfers.[196]

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) joins many opponents of the TRIPS waiver, stating that it is not a worthy solution, either on its own or in conjunction with another.[197] IFPMA suggests that, instead of a waiver, trade barriers, bottlenecks in supply chains, and shortages of raw materials must be eliminated to fix the production and distribution challenges amidst the pandemic.[198] The IFPMA Chief cited 275 ongoing manufacturing deals, including technology transfer, which helped the industry grow from zero to one billion COVID vaccine doses, looking toward ten billion doses by the end of 2021.[199] Some pharma industry actors oppose technology transfer, because they are unsure about the safety and quality standards of the recipient manufacturers.[200] Moderna, for example, has argued that technology transfer will take away raw materials from the companies that have the capacity to meet the global production and distribution demand and erroneously give them to those that do not have that capacity.[201] However, firms in Bangladesh, Canada, South Korea, and Pakistan have expressed their interest and ability to make vaccines once the waiver is approved and implemented, which suggests that there is not a uniform issue in manufacturing problems across the nations that are relying on the possibility of an IP waiver.[202]

A final consideration regarding the issues with the proposed waiver of TRIPS requirements related to COVID is whether a cooperative global effort or a national effort is more effective. A late 2020 projection used a public health epidemiology model to predict whether, for a vaccine with sixty-five to eighty percent efficacy, the overall effect of global

196. *Id.*

197. *Pharma Federation IFPMA Says U.S. Support for Patent Waiver 'Disappointing'*, MEDICAL XPRESS, May 6, 2021, https://medicalxpress.com/news/2021-05-pharma-federation-ifpma-patent-waiver.html.

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.*

202. Johnson, *supra* note 146.

cooperation versus non-cooperation would be best.[203] Using the Global Epidemic and Mobility Model (GLEAM), the authors found that the cooperative model averted the most COVID-related deaths for a hypothetical vaccine with sixty-five percent efficacy and another hypothetical vaccine with eighty percent efficacy.[204] The study does not provide details on how the vaccines would be acquired, manufactured, or allocated, but provides insight that, epidemiologically, a global collaborative effort to eradicate COVID-19 via vaccination is more likely than isolated efforts to succeed.[205]

VI. CONCLUSION

The implications of the controversy surrounding the petition for waiver of IP rights under TRIPS will be felt for decades. The limitations of procedures without meaningful resolution mechanisms, reluctance of international bodies to make determinative decisions, and intense disagreements over the purpose of IP and the importance of global health and safety will be one resounding legacy of the COVID-19 pandemic. The process for reaching consensus or taking votes on passing proposals is undefined. Many countries still express at least partial opposition to the waiver, further delaying consensus or a situation where a vote may bring the proposal to action. As of November 2021, there have not been any major updates in the progress of the proposed waiver from the WTO given the requirement of consensus from the General Council and the controversy surrounding the scope of the waiver itself.

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203. Matteo Chinazzi et al., *Estimating the Effect of Cooperative Versus Uncooperative Strategies of COVID-19 Vaccine Allocation: A Modeling Study*, NETWORK SCIENCE INSTITUTE, Sept. 14, 2020, https://www.networksciencinstitute.org/publications/estimating-the-effect-of-cooperative-versus-uncooperative-strategies-of-covid-19-vaccine-allocation-a-modeling-study.

204. *Id.*

205. *See Id.*