

# **A TRIP AROUND THE WORLD: HOW THE TRIPS AGREEMENT RESOLVES THE INTELLECTUAL PROPERTY WAIVER DISPUTE AND FACILITATES GLOBAL ACCESS TO MEDICINES**

WHITNEY SMELLY\*

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\* J.D. Candidate, 2023, The Ohio State University Moritz College of Law; Source Editor, 2022-2023, *Ohio State Journal on Dispute Resolution*. Special thank you to Professor Bryan Choi for his thoughtful suggestions and guidance in selecting this topic, as well as the *Ohio State Journal on Dispute Resolution* team for their hard work preparing this Note for publication. I would also like to thank my husband, Nicholas Heppner, for his constant support and encouragement throughout law school and the Note writing process.

## I. INTRODUCTION

While the incentive-based intellectual property system actively encourages and rewards the creation of vital medicines, the exclusivity aspect of patent protection allows pharmaceutical companies to prevent others from manufacturing their patented vaccines.<sup>1</sup> As a result, intellectual property protections, established to promote the progress of science and useful arts, can negatively impact lower- and middle-income countries (LMICs), especially during times of crisis.<sup>2</sup> Contrary to public interest, patent protection can ultimately thwart the international sharing of vaccines and other life-saving drugs while impeding efforts to provide access to medicine for LMICs.<sup>3</sup> Amid the numerous advantages of issuing patents, there remains concerns regarding the effects patent monopolies have on the social welfare of the public.<sup>4</sup> For LMICs, patents can act as a barrier to essential medicines, which, in some cases, is a matter of life or death for individuals in those countries.<sup>5</sup> This naturally leads to a question of whether certain intellectual property rights, such as patents, are an unfair exercise of monopoly power.

Absent trade agreements governing international intellectual property rights, LMICs are left to their own accord to develop, manufacture,

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<sup>1</sup> See generally *Patent Essentials*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents/basics/essentials> [<https://perma.cc/A6D7-MARS>], (last visited Oct. 12, 2023). In exchange for developing a vaccine and securing a patent through the United States Patent and Trademark Office (USPTO), a patentee is granted “the right to exclude others from making, using, offering for sale, or selling” the vaccine. *Id.*

<sup>2</sup> See generally Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, 11 GLOB. POL’Y, 46, 51 (2020) (discussing how the commercialization of biotechnical patents can lead to fewer useful products for improving human health and a limited scope for accessible treatment and future research).

<sup>3</sup> See *id.* at 51.

<sup>4</sup> *Id.* at 53.

<sup>5</sup> *Id.* at 46.

and supply vaccines to citizens of their countries.<sup>6</sup> When LMICs cannot do this, their citizens are ultimately subjected to increased risk of mortality and morbidity from diseases easily treated (or, in the case of malaria, eradicated) in certain high-income or developed countries.<sup>7</sup> To fight against access-to-medicine issues facing LMICs, international trade agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), help to ensure that intellectual property rights do not become barriers to international trade.<sup>8</sup>

The unexpected emergence of the coronavirus (Covid-19)<sup>9</sup> drew worldwide attention to the general aims and provisions established by the TRIPS Agreement, as it has been identified as one of the most significant barriers to vaccine and medicine affordability, especially for LMICs.<sup>10</sup> Its adoption prompted concerns from local and international health activists, such as Ellen ‘t Hoen, long-time leader of the Access to Medicines

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<sup>6</sup> See generally OECD Secretary-General, *Using Trade to Fight COVID-19: Manufacturing and Distributing Vaccines*, ORGANISATION FOR ECON. CO-OPERATION AND DEV. (Feb. 11, 2021), <https://www.oecd.org/coronavirus/policy-responses/using-trade-to-fight-covid-19-manufacturing-and-distributing-vaccines-dc0d37fc/> (discussing how trade plays a key role in enabling the mass production and distribution of vital Covid-19 vaccines across the globe); PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION - INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE 21 (2d ed. 2020) [hereinafter PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION] (“International trade is vital for access to medicines and other medical technologies, markedly so for smaller and less-resourced countries.”).

<sup>7</sup> See Matthew M. Coates et al., Burden of Disease Among the World’s Poorest Billion People: An Expert-Informed Secondary Analysis of Global Burden of Disease Estimates, PLoS ONE 17 (Aug. 16, 2021), <https://doi.org/10.1371/journal.pone.0253073> (“Among studies using verbal autopsy at health and demographic surveillance sites in low and lower-middle-income countries, higher death rates have been documented in the poor from malaria, communicable disease generally, HIV, TB, and childhood illness such as diarrhea and acute respiratory infection, though there has been some variation.”).

<sup>8</sup> See generally *Introduction to the TRIPS Agreement*, in A HANDBOOK ON THE WTO TRIPS AGREEMENT 1 (Antony Taubman et al. eds., 2d ed. 2020).

<sup>9</sup> See generally Ben Hu et al., *Characteristics of SARS-CoV-2 and COVID-19*, 19 NATURE REV. MICROBIOLOGY 141, 141 (2021) (discussing the novel strain of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-Cov-2), a highly transmissible and pathogenic coronavirus that causes Covid-19).

<sup>10</sup> Chattu, Vijay Kumar et al., COVID-19 Vaccine, TRIPS, and Global Health Diplomacy: India’s Role at the WTO Platform, BIOMED RSCH. INT’L 1, 2 (2021); see generally Cucinotta D & Vanelli M., WHO Declares COVID-19 a Pandemic, 91 ACTA BIOMED 157, 157 (2020) (explaining how, on March 11, 2020, the World Health Organization declared the Covid-19 outbreak a global pandemic).

Campaign at Médecins Sans Frontières (Doctors Without Borders).<sup>11</sup> After the signing of the TRIPS Agreement, Ellen noted that an international meeting in 1995 was “the first time public health advocates raised the concern that the globalization of new international trade rules and the harmonization of regulatory requirements would restrict countries’ ability to implement drug policies that would ensure access to medicines for all.”<sup>12</sup>

The steady rise in deaths resulting from Covid-19, which currently sits at more than 6.19 million individuals globally,<sup>13</sup> and the economic impact of Covid-19, calls for a reexamination of the provisions negotiated under the TRIPS Agreement to determine its effect on access to medicine for LMICs. An examination of the TRIPS Agreement, its amendment, and the Doha Ministerial Declaration on TRIPS and Public Health (the Doha Declaration), which provides the mandate for negotiations on a range of subjects, including issues concerning the implementation of current World Trade Organization (WTO) agreements,<sup>14</sup> is necessary. A comprehensive look into the provisions of these agreements can potentially aid in halting the monopolization of Covid-19 vaccine patents at the expense of individuals from LMICs.

This Note analyzes the impact of the Doha Declaration, which was enacted during the Fourth Session of the Ministerial Conference as a response to the issues and concerns raised by many developing-country members regarding the implementation of several WTO agreements and decisions,<sup>15</sup> on the compulsory licensing provisions of the TRIPS Agreement. The current dispute over the potential waiver of intellectual property rights for the Covid-19 vaccine, amid claims of impractical compulsory licensing provisions, is needless given the amended TRIPS

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<sup>11</sup> Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1584 (2009).

<sup>12</sup> Id. at 1584–85 (quoting Ellen ‘t Hoen, *The Revised Drug Strategy: Access to Essential Medicines, Intellectual Property and the World Health Organization*, in *ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY* (2010)).

<sup>13</sup> Since the writing of this note in early 2022, the number of deaths resulting from Covid-19 has increased. *Cumulative Confirmed Covid-19 Deaths*, OUR WORLD IN DATA, <https://ourworldindata.org/covid-deaths> [<https://perma.cc/ZEE2-5Z6Y>], (choose “cumulative” from “interval” dropdown, then search and check “world”, then uncheck the “relative to population” box) (last visited Apr. 14, 2022).

<sup>14</sup> *The Doha Declaration Explained*, WORLD TRADE ORG. [WTO], [https://www.wto.org/english/tratop\\_e/dda\\_e/dohaexplained\\_e.htm](https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm) [<https://perma.cc/JQ6F-HEFX>] (last visited Apr. 14, 2022).

<sup>15</sup> *Doha WTO Ministerial 2001: Ministerial Declarations and Decisions, Implementation-Related Issues and Concerns*, WTO, [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_implementation\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_implementation_e.htm) [<https://perma.cc/LA5V-MKWT>] (last visited Apr. 17, 2022).

#### A TRIP AROUND THE WORLD

Agreement in conjunction with the Doha Declaration. This Note argues that despite the weaknesses of its compulsory licensing provisions in Article 31, the TRIPS Agreement provides a method for LMICs to access Covid-19 vaccines and, therefore, should not be subject to an intellectual property waiver. Formally, the TRIPS Agreement provides developing countries with more flexibility regarding access to medicines than generally recognized.<sup>16</sup> Additionally, this Note argues that any changes to or suspension of provisions in Article 31 of the TRIPS Agreement shall only occur as a result of concessions during the next round of WTO negotiations at the WTO Ministerial Conference. Finally, this Note offers suggested topics for negotiation during the next Conference, in Geneva, Switzerland, to

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<sup>16</sup> Kapczynski, *supra* note 11, at 1589.