



Volume 37 No 3, September 2022

DOI: 10.20473/ydk.v37i3.37237

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Yuridika (ISSN: 0215-840X | e-ISSN: 2528-3103)

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FAKULTAS HUKUM UNIVERSITAS AIRLANGGA



Article history: Submitted 8 April 2022; Accepted 19 June 2022; Available Online 1 September 2022.

Reconciling the Global Public Health Interest with Intellectual Property Protection Through the Waiver of Certain Provisions of the WTO TRIPS Agreement

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Abstract

The rapid spread of the SARS-CoV-2 virus, which is responsible for the COVID-19 pandemic, has spawned an intense debate on the necessity of a waiver of some provisions of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to increase access to medicines and other medical technologies essential for combating the disease. Through a legal research method, this article explores the potential of the TRIPS waiver as a mechanism for reconciling the conflicting norms of public health with intellectual property rights protection by interpreting the TRIPS provisions backed by relevant legal theories. It argues that while the TRIPS waiver can be an effective legal instrument that accommodates public health concerns of increasing access to medicines and medical technologies, it has, in its current form and text, many flaws that militate against its effectiveness. These flaws are evident in how the TRIPS waiver is couched, notwithstanding that the waiver presents multiple benefits, including furthering re-humanisation, distributive justice and decolonisation goals. The article offers recommendations on how the TRIPS waiver adopted during the WTO's recently concluded 12th Ministerial Conference could be strengthened to eliminate some of its defects in expanding access to COVID-19 vaccines and other therapeutics products. The research methodology used in this article is the qualitative desktop doctrinal research method.

Keywords: Essential Medicines; Medical Technologies; Waiver; TRIPS Agreement; Re-Humanisation; Distributive Justice; Decolonisation.

Introduction

The global public health emergencies spawned by the rapid spread of the SARS-CoV-2 virus, which is behind the COVID-19 pandemic,¹ has birthed an intense debate on the need to waive some of the provisions of the World Trade

¹ WHO, 'Coronavirus Disease: Variants of the Severe Acute Respiratory Syndrome (COVID19)' (2019) <www.who.int/> accessed 2 February 2022.

Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to increase access to medicines and medical equipment essential for the fight against the disease.² Although there is a declining trend of infection cases in most regions to date,³ such discussion is still important to avert similar issues in the future.⁴ In this regard, proponents posit that the TRIPS waiver potentially provides the necessary mechanism for reconciling the tension between intellectual property (IP) rights protection and promoting the public health goals of increasing access to vaccines, diagnostic technologies and equipment.⁵ However, critics opine that using the TRIPS waiver may not have the desired outcome given, *inter alia*, that the current rules already allow states to override IP rights during a public health emergency by resorting to compulsory licensing.⁶ Compulsory licensing occurs when permission is given to a third party to use, sell, or manufacture a patented product or use a patented process without the explicit permission of the patent owner.⁷

This article examines the efficacy of the TRIPS waiver during the COVID-19 pandemic considering the aforementioned arguments. It begins by presenting the

² Ruth L Okediji, 'The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System' (2003) 7 *Singapore Journal of International Comparative Law* 315; UN General Assembly, 'Decrying Covid-19 Vaccine Inequity, Speakers in General Assembly Call for Rich Nations to Share Surplus Doses, Patent Waivers Allowing Production in Low-Income Countries 76th Session' (23 September 2021). <www.un.org/press/en/2021/ga12367.doc.htm> accessed 3 February 2022; Sangeeta Shashikant, 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines' (Research Paper 2014).

³ 'COVID: New Cases Decline by 19% Worldwide, Deaths Stabilise' *Al Jazeera* (16 February 2022) <www.aljazeera.com/news/2022/2/16/covid-new-cases-decline-by-19-worldwide-deaths-stabilise> accessed 5 February 2022.

⁴ Talat Chaudhary and Arshi Chaudhary, 'TRIPS Waiver of COVID-19 Vaccines: Impact on Pharmaceutical Industry and What It Means to Developing Countries' (2021) 24 *The Journal of World Intellectual Property*. [447].

⁵ OHCHR, 'Statement by UN Human Rights Experts Universal Access to Vaccines Is Essential for Prevention and Containment of COVID-19 around the World' (*Office of the United Nations High Commissioner for Human Rights*, 9 November 2020). <www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E> accessed 5 February 2022.

⁶ European Parliament, 'World Trade Organization TRIPS Waiver to Tackle Coronavirus' (2021) <[www.europarl.europa.eu/RegData/etudes/ATAG/2021/690649/EPRS_ATA\(2021\)690649_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/ATAG/2021/690649/EPRS_ATA(2021)690649_EN.pdf)> accessed 5 February 2022.

⁷ Yousuf A Vawda, 'Compulsory Licenses and Government Use: Challenges and Opportunities' in M Correa and Reto M Hilty (eds) *Access to Medicines and Vaccines* (Springer Cham 2022). [73].

contextual background to the debate about the effectiveness of the TRIPS waiver.⁸ Such an approach is necessary because no credible discourse on the effectiveness of the TRIPS waiver can be complete without the pertinent contextual background. Many of the arguments raised for and against the TRIPS waiver are grounded in the COVID-19 situation currently prevailing across the globe.

The article then offers an appraisal of arguments advanced for and against the TRIPS waiver. It is necessary to explore these arguments because they demonstrate the complexities of reconciling competing interests in the governance of IP and the promotion of public health objectives. Next, focus is placed on the TRIPS waiver, including the latest version adopted during the WTO's 12th Ministerial Conference (MC12) recently held in Geneva, to determine whether it is likely to achieve a balance between increasing access to medicines and medical equipment essential for combating COVID-19 and IP protection. The article also looks at other desirable goals, such as re-humanisation, distributive justice and decolonisation goals, which may have informed the adoption of the TRIPS waiver. The article concludes by offering solutions for strengthening the current version of the TRIPS waiver to reconcile the global public health interest of expanding access to essential medicines and medical equipment with effective global-scale IP protection.

Qualitative and Doctrinal Research Methodological Approach(es)

This article aims to explore the potential of the TRIPS waiver as a mechanism for reconciling the conflicting norms of public health with IP rights protection in the era of COVID-19 and beyond. To achieve this objective, the methodology used to assess the efficacy of the TRIPS waiver regarding expanding access to essential medicines should be reliable. Two types of research approaches in law may apply to this article: quantitative and qualitative.⁹ The former is predicated on utilising

⁸ Mochamad Kevin Romadhona, Bambang Sugeng Ariadi Subagyono and Dwi Agustin, 'Examining Sustainability Dimension in Corporate Social Responsibility of ExxonMobil Cepu: An Overview of Socio-Cultural and Economic Aspects' () 3 Journal of Social Development Studies.

⁹ Johnson R Burke and Larry B Christensen, *Educational Research: Quantitative, Qualitative, and Mixed Approaches* (SAGE Publishing 2012).[366].

empirical data such as statistics, surveys and questionnaires; the latter largely depends on doctrinal data that mainly focus on the analysis of legal rules and the content of the law in a ‘black letter’ manner.¹⁰ The qualitative approach may be used by means of several research methods with varying effectiveness and applicability depending on the nature of the subject matter.

For the preparatory work on this article, the qualitative approach was employed by means of a limited number of research techniques.¹¹ They include contextual and historical studies, critical analysis and comparative sectional analysis.¹² These research techniques are regarded as the most suitable for the subject of this article because they enable a credible discussion of the debate and contestations around the effectiveness of the TRIPS waiver in reconciling competing interests in the governance of IP and the promotion of public health objectives.¹³ Primary and secondary legal source analysis of the substantive provisions of the TRIPS Agreement, journal articles, internet sources and textbooks on IP law is relied upon throughout the article.¹⁴

TRIPS and the origin of the COVID-19 pandemic: A brief insight into the epidemiological and virological spread

The debate on the desirability of the TRIPS waiver is largely informed by the prevailing epidemiological spread of the SARS-CoV-2 virus, which is mutating into different variants as it drives a pandemic across the world.¹⁵ While there is no

¹⁰ Peter Clinch (ed), *Legal Research: A Practitioner’s Handbook* (Wildy, Simmonds & Hill Publishing 2013).[17].

¹¹ M McConville and WH Chui (eds), *Research Methods for Law* (Edinburgh University Press 2017).[9].

¹² Charles Kivunja, ‘Understanding and Applying Research Paradigms in Educational Contexts’ (2017) 5 *International Journal of Higher Education*.[35].

¹³ *ibid.*

¹⁴ EU, ‘Open Science and Intellectual Property Rights How Can They Better Interact? State of the Art and Reflections Report of Study’ (2022) <https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_open-science-and-ip-report.pdf> accessed 8 November 2022.

¹⁵ International Commission of Jurists, ‘Human Rights Obligations of States to Not Impede the Proposed COVID-19 TRIPS Waiver Expert Legal Opinion’ (2021) 1 <[www.wits.ac.za/media/witsuniversity/facultiesandschools/commercelawandmanagement/researchentities/cals/documents/Expert Legal Opinion 8 Nov .pdf](http://www.wits.ac.za/media/witsuniversity/facultiesandschools/commercelawandmanagement/researchentities/cals/documents/Expert%20Legal%20Opinion%208%20Nov.pdf)> accessed 6 February 2022.

agreed meaning of the term ‘pandemic’, virologists and other medical experts posit that COVID-19 qualifies as a pandemic because of its distinctive features, including novelty, severity, high attack rates, explosiveness, and how it is both infectious and contagious.¹⁶ After the pandemics caused by the Spanish flu in 1918, the Asian Flu of 1956 and subsequently HIV/AIDS of 2005–2012, it was not expected that another deadly pandemic, such as COVID-19, would develop within the same decade.¹⁷ COVID-19 is causing a massive epidemiological health crisis and far-reaching socio-economic and political devastation.¹⁸

As of 8 November 2022, the confirmed global cases of COVID-19 infections stood at 630,832,131, including 6,584,104 deaths, while a total of 12,885,748,541 vaccine doses have been administered.¹⁹ In South Africa, the pandemic has claimed the lives of over 102,371, with 4,030,563 infections and a total of 37,856,678 vaccines administered.²⁰ As of 19 March 2022, the confirmed global cases of COVID-19 infections stood at 523,786,368, with 6,279,667 deaths.²¹ In South Africa, the pandemic has claimed the lives of over 99,829, with 3,700,484 cases of infections.²² Whereas some countries are experiencing a sharp decline in infections that has enabled them to suspend some restrictive measures, such as lockdowns, China has re-imposed some hard measures because of a sudden resurgence of the disease in cities such as Wuhan, Yangzhou and Beijing.²³

While COVID-19 continues to cause an epidemiological health crisis, the

¹⁶ Shabir Ahmad Lone and Aijaz Ahmad, ‘COVID-19 Pandemic—An African Perspective’ (2020) 9 *Emerging Microbes & Infections*. [1300].

¹⁷ Akhilesh Agrawal and others, ‘A Comparative Analysis of the Spanish Flu 1918 and COVID-19 Pandemics’ (2021) 14 *The Open Public Health Journal*. [129].

¹⁸ *ibid.*

¹⁹ WHO, ‘WHO Coronavirus (COVID-19) Dashboard’ <<https://covid19.who.int/>> accessed 8 November 2022.

²⁰ South African Department of Health, ‘Updates on Covid-19’ (19 March 2020) <<https://sacoronavirus.co.za/2022/03/19/update-on-covid-19-saturday-19-march-2022/>> accessed 9 November 2022.

²¹ WHO, ‘WHO Coronavirus (COVID-19) Dashboard’ <<https://covid19.who.int/>> accessed 19 March 2022.

²² South African Department of Health (n 20).

²³ Zubaidah Abdul Jalil and Annabelle Liang, ‘China: Businesses Shut as Officials Widen Covid Lockdowns’ (*BBC News*, 15 March 2022) <www.bbc.com/news/world-asia-china-60703301> accessed 16 March 2022.

origin of the disease remains veiled in obscurity.²⁴ What is currently known is that the first case was reported in December 2019 when clinicians at a hospital in Wuhan City, Hubei Province, China, diagnosed the outbreak of novel pneumonia cases.²⁵ This novel virus has now been identified as the SARS-CoV-2 of zoonotic specie.²⁶ Thereafter, China only notified the World Health Organization (WHO) about the rapid spread of the disease on 31 December 2019. The delay in notification led to some countries condemning China despite the WHO praising it for transparency.²⁷ It led to then-US President Donald Trump concluding that the WHO had become China-centric to the detriment of global health security.²⁸ Whether the WHO has indeed become China-centric by relegating its responsibility to global health leadership remains a point of contestation.²⁹

Aside from the contestation surrounding the WHO response to the COVID-19 pandemic, there are three main schools of thought on the origins of the pandemic.³⁰ The first whose support has increased is the COVID-19 lab-leak theory.³¹ This theory is predicated on the belief that the SARS-CoV-2 coronavirus emerged from a laboratory, perhaps as a consequence of either human error or well-orchestrated genetic engineering and bio-weaponisation.³² However, the lab-leak theory

²⁴ Abdul Aleem, Abdul Bari Akbar Samad and Amy K Slenker, 'Emerging Variants of SARS-CoV-2 and Novel Therapeutics against Coronavirus (COVID-19)', in *StatPearls* (StatPearls Publishing 2022).[34].

²⁵ Hong-Ling Jia and others, 'Genomic Elucidation of a COVID-19 Resurgence and Local Transmission of SARS-CoV-2 in Guangzhou, China' (2021) 59 *Journal of Clinical Microbiology*. [2].

²⁶ *ibid.*

²⁷ OECD, 'The Case of the World Health Organization' (2016) <www.oecd.org/gov/regulatory-policy/WHO_Full-Report.pdf>; Michael Walsh, 'Australia Called for a COVID-19 Probe. China Responded with a Trade War' *ABC Network* (2021).

²⁸ Elisabeth Mahase, 'Covid-19: Trump Threatens to Stop Funding WHO amid "China-Centric" Claims' (British Medical Journal Publishing Group, 2020).[369].

²⁹ Germán Velásquez, 'The World Health Organization Reforms in the Time of COVID-19' (2020) <<https://www.southcentre.int/wp-content/uploads/2020/11/RP-121-rev2.pdf>>.

³⁰ Sara Platto and others, 'History of the COVID-19 Pandemic: Origin, Explosion, World-wide Spreading' (2021) 538 *Biochemical and Biophysical Research Communications*.[538].

³¹ Katherine Eban, 'The Lab-Leak Theory: Inside the Fight to Uncover COVID-19's Origins' *Vanity Fair* (3 June 2021) <www.vanityfair.com/news/2021/06/the-lab-leak-theory-inside-the-fight-to-uncover-covid-19s-origins> accessed 19 March 2022.

³² Dacre Knight, 'COVID-19 Pandemic Origins: Bioweapons and the History of Laboratory Leaks' (2021) 114 *Southern Medical Journal*.[465].

cannot be entirely dismissed given that China has rejected and even suppressed calls for further investigations into the origins of the COVID-19 virus through a comprehensive independent investigation into the activities of the Wuhan Institute of Virology located where the first cases were reported.³³

Currently, the majority of scientists have concluded that the genetic sequence and structure of COVID-19 make it difficult to replicate the virus in a way that makes it possible to infect humans.³⁴ They believe that COVID-19 emerged from wild animals and was then transposed to human beings.³⁵ This school of thought is supported by many epidemiologists whose studies show that many of the first COVID-19 patients in China were exposed to wildlife at the South China Seafood Market in Wuhan.³⁶ The market is the largest seafood market in central China, where different wild and domestic animal species are sold, including bats, minks, rats, snakes, porcupines and poultry.³⁷ Scientifically, the mixture of wild and domestic animals' species and unprotected contact with human beings present an opportunity for pathogen transmission and virology mutations.³⁸

COVID-19 is similar to, though distinct from, a group of viruses referred to as the Middle East Respiratory Syndrome (MERS) discovered in human beings in 2012.³⁹ In turn, coronaviruses are also viruses that cause flu in human beings.⁴⁰ According to the South African Disaster Management Act, COVID-19 is a highly

³³ *ibid.*

³⁴ Yen-Chin Liu, Rei-Lin Kuo and Shin-Ru Shih, 'COVID-19: The First Documented Coronavirus Pandemic in History' (2020) 43 *Biomedical Journal*. [328].

³⁵ Sara Platto and others, 'Biodiversity Loss and COVID-19 Pandemic: The Role of Bats in the Origin and the Spreading of the Disease' (2021) 538 *Biochemical and Biophysical Research Communications*. [2].

³⁶ Stefan Frey and Mirko Himmel, 'SARS-CoV-2: International Investigation under the WHO or BWC' [2021] *Frontiers in Public Health*. [2432].

³⁷ Jing-Bao Nie, 'In the Shadow of Biological Warfare: Conspiracy Theories on the Origins of COVID-19 and Enhancing Global Governance of Biosafety as a Matter of Urgency' (2020) 17 *Journal of Bioethical Inquiry*. [567].

³⁸ Ping Liu and others, 'Are Pangolins the Intermediate Host of the 2019 Novel Coronavirus (SARS-CoV-2)?' (2020) 16 *PLoS Pathogens* e1008421. [13].

³⁹ Angela D Luis and others, 'A Comparison of Bats and Rodents as Reservoirs of Zoonotic Viruses: Are Bats Special?' (2013) 280 *Proceedings of the Royal Society B: Biological Sciences*. [201].

⁴⁰ Aiping Wu and others, 'Genome Composition and Divergence of the Novel Coronavirus (2019-NCov) Originating in China' (2020) 27 *Cell Host & Microbe*. [325].

infectious disease caused by a virus that began to spread among human beings in 2019 and became a global pandemic. This pandemic has exposed the negative impact of TRIPS on equitable access to vaccines and other therapeutic instruments necessary to effectively combat the pandemic.⁴¹

The global call for a TRIPS waiver

Cognisant of the long-held view that the global IP rules under the auspices of the TRIPS Agreement exacerbate vaccines inequality by inhibiting access to essential medicines and other medical technologies, India and South Africa submitted the first proposal for adopting a TRIPS waiver in 2020 to the TRIPS Council of the WTO.⁴² The waiver calls for a temporary suspension of articles 1, 4, 5 and 7 of part II of the TRIPS to increase access to essential medicines and equipment necessary for combating the global pandemic.⁴³

The first version of the proposal stated that the TRIPS waiver would last for a period to be determined by the General Council.⁴⁴ The waiver would apply to patents and other forms of IP.⁴⁵ However, in 2021, proponents of the TRIPS waiver submitted a revised version that narrows the coverage only to COVID-19-related products and medical equipment and proposes the waiver's duration to be at least three years.⁴⁶ At the time of writing, the TRIPS Council was deliberating

⁴¹ WTO, 'World Trade Primed for Strong but Uneven Recovery after COVID-19 Pandemic Shock' (31 March 2021) <www.wto.org/english/news_e/pres21_e/pr876_e.htm> accessed 18 March 2022.

⁴² Gerhard Erasmus, 'The Proposed TRIPS Waiver to Respond to the COVID-19 Pandemic' (*Tralac*, 7 June 2021) <www.tralac.org/blog/article/15235-the-proposed-trips-waiver-to-respond-to-the-covid-19-pandemic.html> accessed 19 March 2022.

⁴³ WTO, 'Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19 Communication from India and South Africa' (2021) <<https://docs.wto.org>> accessed 18 March 2022.

⁴⁴ *ibid.*

⁴⁵ Henning Grosse Ruse-Khan, 'Proportionality and Balancing within the Objectives for Intellectual Property Protection', in *Intellectual Property Law and Human Rights* (Kluwer Law International 2020).[201].

⁴⁶ WTO, 'Waiver from Certain Provisions of the Trips Agreement for the Prevention Containment and Treatment of Covid-19 Revised Decision Text' (2021) <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>> accessed 18 March 2022.

on the 2021 version of the proposed waiver, aiming to either adopt it or subject it to further consideration.⁴⁷

Meanwhile, the 2021 version of the TRIPS waiver has been endorsed by more than 100 countries and supported by over 300 civil society organisations, the WHO, other international organisations, some academic commentators and various political leaders across the globe.⁴⁸ However, the proposed TRIPS waiver has received strong opposition from many WTO members, including the United States (US), Canada, Australia, Brazil, Japan, the European Union (EU), Norway, the United Kingdom (UK) and Switzerland.⁴⁹ Although the ascension to power of President Joseph Biden has resulted in the US abandoning its negative stance on the TRIPS waiver, with some developed countries following suit, their support is limited only to the adoption of a waiver covering vaccines and excludes other medical products and technologies needed to combat COVID-19.⁵⁰

Subsequently, the final version of the TRIPS waiver was adopted during the WTO's 12th Ministerial Conference (MC12) held from 12 to 16 June 2022 in Geneva. The merits and demerits of this latest version of the TRIPS waiver will be explored as the discussion unfolds below.

Theoretical, practical and policy implications of adopting a TRIPS waiver during the COVID-19 pandemic

Proponents of a TRIPS waiver have advanced various arguments. They argue

⁴⁷ Emmanuel Kolawole Oke, 'The TRIPS Waiver Compromise Draft Text: A Preliminary Assessment' (*Afronomics Law*, 18 March 2022) <www.afronomicslaw.org/category/analysis/trips-waiver-compromise-draft-text-preliminary-assessment> accessed 18 March 2022.

⁴⁸ Andrew Green, 'TRIPS Waiver Compromise Draws Mixed Response' (*Devex*, 17 March 2022) <www.devex.com/news/trips-waiver-compromise-draws-mixed-response-102860> accessed 18 March 2022.

⁴⁹ 'TRIPS Waiver Proposal: A Compilation of Statements and Reports' (*Third World Network*, 2021) <www.twn.my/title2/intellectual_property/trips_waiver_proposal.htm> accessed 18 March 2022.

⁵⁰ United States Congressional Research Service, 'The Biden Administration Announces Its Support for a WTO TRIPS Waiver' (*United States Congressional Research Service*, 2021) <https://www.everycrsreport.com/files/20210507_IN11662_af1721ffd72c022a804a086af504d9d5e90cb8e2.pdf> accessed 18 March 2022.

that the TRIPS waiver can be an effective legal instrument that reconciles the public health objective of increasing access to medicines and other medical technologies with the goal of IP protection.⁵¹ Moreover, the TRIPS Agreement in its current form does not adequately address access to essential medicines such as the vaccines and medical technologies required to combat the COVID-19 pandemic.⁵² While article 31 of TRIPS *prima facie* allows member states to issue compulsory licences that can positively affect efforts to fight the pandemic, such licensing option is only available to countries either without or with limited capacity to manufacture such essential medicines and medical equipment.⁵³

Additionally, the TRIPS Agreement restricts the issuing of compulsory licensing to specific products that each country should determine on a case-by-case basis.⁵⁴ The situation is worsened because many of the essential medicines and technologies needed to tackle the COVID-19 pandemic cover multiple forms of IP products and technologies, rendering the issuance of compulsory licensing either practically impossible or complex and strenuous.⁵⁵ Conversely, adopting the waiver would allow countries to bypass the bureaucratic processes in TRIPS by allowing them to issue a single waiver authorisation for many patents and even extend to ingredients and processes involved, thereby minimising the risk of expensive litigation by the patent holders.⁵⁶

In the same vein, the use of voluntary licensing flexibilities under the TRIPS Agreement has proven to be problematic, with efforts by pharmaceutical companies

⁵¹ Hans Morten Haugen, 'Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) Prevent COVID-19 Vaccines as a Global Public Good?' (2021) 24 *The Journal of World Intellectual Property*. [195].

⁵² *ibid.*

⁵³ MSF Access Campaign, 'Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies' [2021] Technical Brief. [26].

⁵⁴ KD Raju, 'Compulsory v Voluntary Licensing: A Legitimate Way to Enhance Access to Essential Medicines in Developing Countries' (2017) 22 *Journal of Intellectual Property Rights*. [23].

⁵⁵ Medecins Sans Frontieres, 'Overcoming Intellectual Property Monopolies in the COVID-19 Pandemic' (2020) <https://msfaccess.org/sites/default/files/2020-07/MSF-AC_COVID-19_IP-monopolies_briefing-doc_July2020.pdf>.

⁵⁶ Katrina Perekhodoff, Ellen't Hoen and Pascale Boulet, 'Overriding Drug and Medical Technology Patents for Pandemic Recovery: A Legitimate Move for High-Income Countries, Too' (2021) 6 *BMJ Global Health*. [518].

falling short of expanding access to essential medicines, including vaccines and other technologies.⁵⁷ Voluntary licensing is the process whereby developers of essential medicines and other technologies set terms and conditions as to whom the IP can be licensed to enable manufacturing.⁵⁸ Because voluntary licensing depends on pharmaceutical companies' and other developers' discretion to voluntarily increase the production of essential medicines, it is hardly capable of delivering enough health products at the pace needed to address the pandemic.⁵⁹ According to the WHO, voluntary licensing agreements 'tend to be exclusive and non-transparent, compromising equitable access'.⁶⁰ Further, few pharmaceutical companies have exercised voluntary corporate responsibility in the form of nonexclusive licensing, leaving a void which the TRIPS waiver can fill in pursuit of widening access to vaccines and medical equipment.⁶¹

It is noteworthy that other voluntary participation-based avenues to expand access to vaccines and other medical equipment have not had the desired outcome.⁶² For instance, few European-based pharmaceutical companies have joined the WHO's Covid-19 Technology Access Pool (C-TAP), a platform created to facilitate the voluntary sharing of IP, data, and knowledge between pharmaceutical companies and other medicines developers.⁶³ Other similar voluntary initiatives, such as the WHO COVID-19 mRNA Technology Transfer Hub, have been largely ineffective because they failed to attract vaccine manufacturers.⁶⁴

⁵⁷ Medecins Sans Frontieres, 'Voluntary Licenses and Access to Medicines. Médecins Sans Frontières Technical Briefing Document' (2020) <https://msfaccess.org/sites/default/files/202010/IP_VoluntaryLicenses_fullbrief_Oct2020_ENG.pdf> accessed 20 March 2022.

⁵⁸ *ibid.*

⁵⁹ Raju (n 54).

⁶⁰ 'Gilead Offers Voluntary Licenses for Manufacturing of Viread in Developing World' (*Gilead Creating Possible*, 2006) <www.gilead.com/news/press-releases/2006/5/gileadoffers-voluntary-licenses-for-manufacturing-of-viread-in-developing-world-#sthash.Gsw4dfGm.dpuf> accessed 20 March 2022.

⁶¹ Tahir Amin, 'Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines' (2007).

⁶² Sara Eve Crager, 'Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways' (2018) 108 *American Journal of Public Health*. [414].

⁶³ WHO, 'WHO COVID-19 Technology Access Pool' (2022) <www.who.int/initiatives/covid-19-technology-access-pool> accessed 20 March 2022.

⁶⁴ WHO, 'The mRNA Vaccine Technology Transfer Hub' (2022) <www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub> accessed 20 March 2022.

The problem is also worsened by the fact that many innovators have been disinterested in becoming a part of the Open COVID Pledge, which allows the issuing of non-exclusive licenses.⁶⁵ While the creation of the Open COVID Pledge is celebrated as the future open innovation model, lamentably, it is dominated by technology companies, with few pharmaceutical companies participating.⁶⁶ The TRIPS waiver, therefore, provides a credible alternative to the failure of voluntary initiatives in pursuit of access to vaccines and equipment.⁶⁷

Furthermore, many countries, including the US, India and some European countries, imposed export restrictions on raw materials essential for manufacturing vaccines and related products at the beginning of the COVID-19 pandemic.⁶⁸ Although these export restrictions impede global access to essential medicines, easing the restrictions does not exclude the urgent need to increase manufacturing capacity by adopting the TRIPS waiver that suspends certain IP rights.⁶⁹ The large-scale ill health and mortality caused by the pandemic and its uneven effect require a fuller response than easing export restrictions.⁷⁰ Imposing export restrictions would have less effect or damage when the TRIPS waiver is adopted because it will enable the development of diversified global vaccines manufacturing capacity.⁷¹

Another argument is that many developing countries support adopting a TRIPS waiver because it allows them to suspend IP rights without risking subjection to the

⁶⁵ Ginevra Assia Antonelli, Maria Isabella Leone and Riccardo Ricci, 'Exploring the Open COVID Pledge in the Fight against COVID-19: A Semantic Analysis of the Manifesto, the Pledgors and the Featured Patents' (2022) 52 R&D Management.[255].

⁶⁶ Jorge L Contreras, 'The Open COVID Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons' [2021] Utah Law Review.[833].

⁶⁷ Simon Lester and Huan Zhu, 'The International Trade Law Review: The TRIPS Waiver and Covid-19 Vaccine Production' (*The Law Reviews*, 2022) <<https://thelawreviews.co.uk/title/the-international-trade-law-review/the-trips-waiver-and-covid-19-vaccine-production>> accessed 20 March 2022.

⁶⁸ United States Congress Research Service, 'Export Restrictions in Response to the COVID-19 Pandemic' (*United States Congress Research Service*, 23 April 2021) <<https://crsreports.congress.gov/product/pdf/IF/IF11551>> accessed 20 March 2022.

⁶⁹ *ibid.*

⁷⁰ Ralf Peters and Divya Prabhakar, 'Export Restrictions Do Not Help Fight COVID-19' (2021) <<https://unctad.org/news/export-restrictions-do-not-help-fight-covid-19>> accessed 21 March 2022.

⁷¹ Imad Antoine Ibrahim, 'Overview of Export Restrictions on COVID-19 Vaccines and Their Components' (2021) 25 American Society of International Law Insights.[1].

challenging processes under the WTO dispute settlement system.⁷² The complexity and high costs of those WTO processes are making these countries compliance-driven in an attempt to avoid a proliferation of dispute settlement matters and the consequences of related reputational damage.⁷³ Concerns about infringing IP rules are not limited to the TRIPS Agreement; they include TRIPS-Plus standards agreed upon by the US and some developing countries under bilateral trade and investment agreements.⁷⁴ In this regard, the US Trade Act allows imposing trade sanctions against contracting parties who violate TRIPS-Plus standards agreed upon between the US and other countries, notwithstanding that they may be inconsistent with obligations imposed by the TRIPS.⁷⁵

One of the significant effects of the TRIPS waiver is that it will insulate member states against accountability for non-compliance with TRIPS-Plus standards.⁷⁶ To a large degree, the proposed TRIPS waiver will enable developing countries to promote equitable access to vaccines and medical technologies, thereby reconciling IP protection with public health goals.⁷⁷

Re-humanisation aspects of the TRIPS waiver

Notwithstanding the above, other arguments can be deployed in support

⁷² Kristin Bohl, 'Problems of Developing Country Access to WTO Dispute Settlement' (*Chicago-Kent | Journal of International and Comparative Law*, 2014) <<https://studentorgs.kentlaw.iit.edu/jicl/wpcontent/uploads/sites/5/2014/01/BohlSubmissionWTOFinal.pdf>> accessed 22 March 2022.

⁷³ Roderick Abbott, 'Are Developing Countries Deterred from Using the WTO Dispute Settlement System? Participation of Developing Countries in the DSM in the Years 1995-2005' (2007) No. 01/2007 <https://www.google.com/search?q=ecipe&rlz=1C5CHFA_enID1001ID1001&oq=ecipe&aqs=chrome..69i57j0i10i433i512j0i10i512j0i131i433j0i10i512l2j69i60l2.1710j0j7&sourceid=chrome&ie=UTF-8>.

⁷⁴ Medecins Sans Frontieres, 'Compulsory Licenses, The Trips Waiver and Access to Covid-19 Medical Technologies' (2021) <https://msfaccess.org/sites/default/files/202105/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf> accessed 23 March 2022.

⁷⁵ Mohammed K El Said, *Public Health Related TRIPS-plus Provisions in Bilateral Trade Agreements* (WHO Library Cataloguing in Publication Data 2010) <<https://applications.emro.who.int/dsaf/dsa1081.pdf>>.

⁷⁶ Beatrice Lindstrom, 'Scaling Back TRIPS-plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific' (2009) 42 *NYU Journal of International Law & Policy*. [917].

⁷⁷ *ibid.*

of the TRIPS waiver.⁷⁸ First, the TRIPS waiver can be viewed as a significant instrument for re-humanising the global IP protection regime.⁷⁹ The argument is that global IP protection under the auspices of TRIPS is based on three theoretical perspectives – particularly utilitarian economic efficiency, personality law theory and Lockean labour theory – with the humanisation theory neither being a substantial nor a major guide informing the development of IP rules.⁸⁰ International IP protection arrangements and governance mirror the three main theoretical goals advanced under TRIPS.⁸¹ In turn, the domestic IP laws entrench and institutionalise three theoretical justifications.⁸² This three-fold theoretical approach focuses on promoting an IP regime that encourages the production and distribution of products, including vaccines and equipment, via utilitarian IP laws and the personality law theory designed to promote economic efficiency, exclusive rights of inventors and allocation of private property rights.⁸³ Such an approach promotes the commercialisation of scientific goods and allows deviation from the grand norms only through compulsory and voluntary licensing in limited circumstances.⁸⁴ The domestic IP laws in developing and developed countries are at the least based on these three aforementioned theoretical foundations.⁸⁵

The substantive content of the three theoretical approaches to IP protection has been well explored over the years by many academic commentators, and repeating them would not be warranted.⁸⁶ However, in brief, the utilitarian economic efficiency approach protects IP assets as products of the mind that ‘free rider users’

⁷⁸ Human Rights Watch, ‘Seven Reasons the EU Is Wrong to Oppose the TRIPS Waiver’ (*Human Rights Watch*, 3 June 2021) <www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver> accessed 25 March 2022.

⁷⁹ J Janewa Osei-Tutu, ‘Humanizing Intellectual Property: Moving Beyond the Natural Rights Property Focus’ (2017) 20 *Vanderbilt Journal of Entertainment & Technology Law*. [207].

⁸⁰ *ibid.*

⁸¹ William Fisher, ‘Theories of Intellectual Property’ (2001) <www.law.harvard.edu/faculty/tfisher/iptheory.html>.

⁸² *ibid.*

⁸³ *ibid.*

⁸⁴ Mikhalien Du Bois, ‘Justificatory Theories for Intellectual Property Viewed through the Constitutional Prism’ (2018) 21 *Potchefstroom Electronic Law Journal*. [8].

⁸⁵ *ibid.*

⁸⁶ Peter Drahos, *A Philosophy of Intellectual Property* (Routledge 2016).

copy without permission from the inventors to the detriment of scientific innovation and development.⁸⁷ The objectives of IP laws should be to grant exclusive rights that exclude free riders from producing innovative products without permission and paying for them.⁸⁸ The personality theory is based on Hegelian philosophy, which proposes that inventors are autonomous and endowed with rights over their creations.⁸⁹ Consequently, IP products, including medicines and medical technologies, are a significant reflection of the originators' creation.⁹⁰ The Lockean labour theory is premised on the view that inventors have a natural right to their IP products because they are the fruit of their individual labour.⁹¹ The three theoretical approaches promote the commercialisation and commodification of IP products by creating and granting exclusionary rights that hinder access to essential medicines and other equipment, including during a pandemic.⁹²

At the behest of the aforementioned, the global IP regime, as represented by the TRIPS Agreement, overly promotes the objectives of three theoretical justifications and ignores an entirely different yet crucial theoretical underpinning of humanisation.⁹³ The humanisation approach is based on egalitarian values that should influence the development of law and policy.⁹⁴ Humanising values such as promoting human dignity, equality and freedom prohibit the enactment of IP laws that de-humanise poor people by inhibiting their access to essential medicines and medical equipment.⁹⁵ These values are the cornerstone of the human rights order

⁸⁷ Ole-Andreas Rognstad, *Property Aspects of Intellectual Property*, vol 46 (CUP 2018).

⁸⁸ Mark A Lemley, 'Property, Intellectual Property, and Free Riding' (2004) 83 *Texas Law Review*. [1031].

⁸⁹ Justin Hughes, 'The Philosophy of Intellectual Property' (1988) 77 *Georgetown Law Journal* 287; Jeanne L Schroeder, 'Unnatural Rights: Hegel and Intellectual Property' (2005) 60 *University of Miami Law Review*. [453].

⁹⁰ Schroeder (n 89).

⁹¹ John Locke, *Two Treatises of Government* (CUP 1967). [27].

⁹² Michael A Carrier, 'Cabining Intellectual Property through a Property Paradigm' (2004) 54 *Duke Law Journal*. [15].

⁹³ Laurence R Helfer, 'Toward a Human Rights Framework for Intellectual Property' (2006) 40 *UC Davis Law Review*. [971].

⁹⁴ *ibid.*

⁹⁵ UN, 'Access to Essential Medicines Is a Fundamental Element of the Right to Health' (*United Nations*, 24 March 2017) <www.ohchr.org/en/stories/2017/03/access-essential-medicines-fundamental-element-right-health> accessed 27 March 2022.

expressed under the international and regional human rights framework, including the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights.⁹⁶ Therefore, adopting a TRIPS waiver should be viewed as an avenue for re-humanising the global IP governance regime by aligning it with other important social values.⁹⁷

Distributive justice aspects of the TRIPS Waiver

Another argument closely linked to the re-humanising IP governance is the need to honour the distributive imperative.⁹⁸ It can be strongly argued that the TRIPS waiver would constitute an important mechanism that aligns the global IP regime with the demands of distributive justice spawned by international human rights treaties and statements.⁹⁹ In other words, the TRIPS waiver may reconcile public health goals of increasing access to medicines and medical equipment for combating the COVID-19 pandemic with IP rights protection through the waiver of prohibitive provisions.¹⁰⁰ Such a development, it is assumed, would reshape global IP law by making it more responsive to the demands of vaccine equality, egalitarianism and distributive justice.¹⁰¹ The proposed TRIPS waiver would constitute a commitment to increase access to essential medicines and medical equipment, which is effectively a pledge towards distributive justice.¹⁰² The argument is that the TRIPS should be

⁹⁶ Osei-Tutu (n 79).

⁹⁷ Centre for Applied Legal Studies, 'Expert Legal Opinion on COVID-19 TRIPS Waiver' (*Centre for Applied Legal Studies*, 24 March 2017) <www.ohchr.org/en/stories/2017/03/access-essential-medicines-fundamental-element-right-health> accessed 27 March 2022.

⁹⁸ WHO, 'Social Justice and Human Rights as a Framework for Addressing Social Determinants of Health Final Report of the Task Group on Equity' (*Equality and Human Rights*, 2016) <https://www.euro.who.int/__data/assets/pdf_file/0006/334356/HR-task-report.pdf> accessed 23 March 2022.

⁹⁹ *ibid.*

¹⁰⁰ Campaign (n 53).

¹⁰¹ Nancy S Jecker, Aaron G Wightman and Douglas S Diekema, 'Vaccine Ethics: An Ethical Framework for Global Distribution of COVID-19 Vaccines' (2021) 47 *Journal of Medical Ethics*. [308].

¹⁰² William W Fisher and Talha Syed, 'Global Justice in Healthcare: Developing Drugs for the Developing World' (2006) 40 *UC Davis Law Review*. [581].

infused with values such as distributive justice and egalitarianism with which the global IP rules should comply.¹⁰³

Nonetheless, in actuality, legal scholars and other theorists are yet to settle on a universal definition and mutually agreed modalities for achieving distributive justice and egalitarianism.¹⁰⁴ The meaning of justice and egalitarianism elusively differ subjectively depending on the socio-economic and legal factors existing in a particular arrangement.¹⁰⁵ Consequently, the conceptualisation of theories of justice differs significantly, subject to the values by which they are sustained, such as communitarianism and utilitarian theories of justice.¹⁰⁶ However, a reflective engagement with the pertinent international human rights instruments suggests that equality and egalitarianism should be the basis for re-configuring the global IP governance in pursuit of expanding access to essential medicines and medical equipment.¹⁰⁷

That the current global IP rules hinder access to essential medicines and other medical equipment is largely uncontentious.¹⁰⁸ This lack of fairness in the disparate impact of global IP arrangements implies that regulatory gains envisaged by TRIPS mainly accrue to pharmaceutical corporations largely owned by nationals of developed countries.¹⁰⁹ The situation contributes to the troubling vaccine inequality between developed and developing countries.¹¹⁰

¹⁰³ Bawa Singh and others, 'COVID-19 and Global Distributive Justice: 'Health Diplomacy' of India and South Africa for the TRIPS Waiver' [2022] *Journal of Asian and African Studies*. [2].

¹⁰⁴ Orsolya Salát, 'A Theoretical Review of the Conceptualisation and Articulation of Justice in Legal Theory Contributing to Task' (*Ethos-EU*, 2017) <https://www.ethoseurope.eu/sites/default/files/a_theoretical_review_of_the_conceptualization_and_articulation_of_justice_in_legal_theory_contributing_to_task_2.3.pdf> accessed 28 March 2022.

¹⁰⁵ Kristin Voigt and Gry Wester, 'Relational Equality and Health' (2015) 31 *Social Philosophy and Policy*. [204].

¹⁰⁶ Chi Carmody, Frank J Garcia and John Linarelli, *Global Justice and International Economic Law: Opportunities and Prospects* (CUP 2012). [7].

¹⁰⁷ Catharine A MacKinnon, 'Substantive Equality Revisited: A Reply to Sandra Fredman' (2016) 14 *International Journal of Constitutional Law*. [739].

¹⁰⁸ Frank J Garcia, 'Globalization, Inequality & International Economic Law' (2017) 8 *Religions*. [78].

¹⁰⁹ *ibid.*

¹¹⁰ Medecins Sans Frontieres, 'Compulsory Licenses, The Trips Waiver and Access to Covid-19 Medical Technologies' (n 74).

Certainly, the goal of distributive justice is to eradicate these social disparities through a fair allocation of regulatory benefits and responsibilities among member states.¹¹¹ That the TRIPS inevitably has distributional effects is not a novel claim.¹¹² Distributive justice can be employed as a plausible justification for suspending unjust IP rules by adopting a TRIPS waiver to address access to essential medicines and medical equipment.¹¹³ In explicating the meaning of justice, Campbell opines that the notion embodies the principle of distributing benefits and burdens to rectify an undesired outcome or experience emanating from certain injustices.¹¹⁴ Distributive justice, also dubbed ‘social justice’, generates legal obligations to achieve a just IP protection system.¹¹⁵ Given the utility of the distributive justice theory, it may provide compelling theoretical justification in support of the adoption of the TRIPS waiver to combat the COVID-19 pandemic.¹¹⁶

According to Rawls,¹¹⁷ distributive justice entails three major tenets.¹¹⁸ First, the attainment of freedom, subject only to limitations in defence of such freedom.¹¹⁹ Second, the triumph of equality for all mainly through the enjoyment of fundamental liberty of social life and egalitarian distribution of public goods in society, subject to the norm of variance, which is permitted only if it produces the highest benefit for people living on the peripheries of life.¹²⁰ Rawls argues that distributive justice is instrumental in combatting all uneven distribution of opportunities, including regulatory inequality resulting from arbitrary social stratifications based on birth, wealth and elitism.¹²¹ He further argues that distributive justice envisages a far-reaching goal of transforming the global regulatory architecture through a

¹¹¹ *ibid.*

¹¹² Darrel Moellendorf, ‘The World Trade Organization and Egalitarian Justice’ (2005) 36 *Metaphilosophy*. [146].

¹¹³ *ibid.*

¹¹⁴ Tom Campbell, *Justice* (CUP 1988). [19].

¹¹⁵ John Rawls, ‘The Priority of the Right and Ideas of the Good’ [1988] *Philosophy and Public Affairs*. [252]; John Rawls, *Theory of Justice* (Harvard University Press 1972). [291].

¹¹⁶ Brian Barry, *Treatise on Social Justice* (University of California Press 1989). [355].

¹¹⁷ Rawls, *Theory of Justice* (n 107). [356].

¹¹⁸ *ibid.*

¹¹⁹ *ibid.*

¹²⁰ *ibid.*

¹²¹ *ibid.*

fair allocation of rights and obligations.¹²² It is plausible to suggest that Rawls' conception of distributive justice recognises that states have an inalienable right to assert their public health goals in negotiating or implementing various IP protection arrangements.¹²³

Further, camouflaging vaccine inequality under the guise of obligatory compliance with the TRIPS governance framework to the detriment of the realisation of the human rights to health, life, equality and human dignity would be the opposite of Rawls' conception of distributive justice.¹²⁴ His distributive justice theory envisages the significant goal of re-configuring TRIPS in pursuit of a just IP regime.¹²⁵ However lyrical the ideas of Rawls' distributive theory may be, one should not conflate them with the goals advanced by utilitarian theory.¹²⁶ There is a difference between utilitarianism and distributive justice theory.¹²⁷ Utilitarianism accepts that some countries in a regulatory arrangement may derive benefits that exceed those of others, provided that such benefits do not amount to the winner takes all outcome.¹²⁸ Whatever the distinction between utilitarianism and Rawls' distributive justice theory, it is clear that both ideologies advance a model of justice that challenges IP rules reproducing vaccine inequality.¹²⁹

Notwithstanding the above, it is plausible to posit that in terms of the extant TRIPS rules, distributive justice may be unachievable as it is not one of the explicit

¹²² *ibid.*

¹²³ Frank J Garcia, 'Between Cosmopolis and Community: Globalization and the Emerging Basis for Global Justice' (2013) 298 *New York University Journal of International Law and Politics*. [3].

¹²⁴ David W Gunzburger, Daniel M Wegner and Linda Anooshian, 'Moral Judgement and Distributive Justice' (1977) 20 *Human Development*. [160].

¹²⁵ Dhawal Shankar, 'Rawls's Theory of Justice through Amartya Sen's Idea' (2016) 20 *Indian Law Institute Law Review*. [151].

¹²⁶ John Rawls, *The Law of Peoples: With the Idea of Public Reason Revisited* (Harvard University Press 1997). [12].

¹²⁷ Jeremy Bentham, *Introduction to the Principles of Morals and Legislation* (OUP 1970) 3.; Robert Cavalier, 'Utilitarian Theories' <<http://caae.phil.cmu.edu/Cavalier/80130/part2/sect9.html>> accessed 2 March 2022.

¹²⁸ Cynthia M Ho, 'Do Patents Promote the Progress of Justice? Reflections on Varied Visions of Justice' (2005) 36 *Loyola University Chicago Law Journal*. [469].

¹²⁹ Harry Jones, 'Equity in Development: Why It Is Important and How to Achieve It' (*DI*) <<https://www.odi.org/sites/odi.org.uk/files/odi-assets/publications-opinion-files/4577.pdf>> accessed 2 March 2022.

objectives of the Agreement. The highly diverse ways in which TRIPS promotes collective forms of economic power suggest a significant tension and even incompatibility with theories of justice.¹³⁰ In such a context, it is difficult to dismiss the demand to temper the application of TRIPS rules with norms of justice.¹³¹ However, the challenge of ascertaining the meaning of justice makes it difficult to reshape global IP protection in light of theories of justice.¹³²

Decolonial Aspects of the TRIPS Waiver

Adopting a TRIPS waiver can be viewed as a significant step towards the decolonisation of the global IP governance regime, which prioritises protecting patent-related rights at the expense of access to essential medicines, including vaccines and medical equipment.¹³³ It can be posited that current global IP governance reflects neo-colonial power asymmetry wielded by developed countries.¹³⁴ This asymmetry is evidenced by the fact that the distribution of essential medicines is largely determined by uneven power disparities and inequalities in financial resources steeped in colonial wealth deprivation, with rich countries individually procuring their vaccines and equipment from the manufacturers resulting in glaring inequitable access to such vaccines and equipment.¹³⁵ It can be argued that TRIPS facilitates access to essential medicines, including vaccines and medical equipment, for affluent countries, reinforcing the power structure at the expense of the developing countries and their populations.¹³⁶ Adopting a TRIPS waiver, therefore, provides an opportunity for centring the public health interests and goals

¹³⁰ *ibid.*[152].

¹³¹ *ibid.*

¹³² Jonathan Trejo-Mathys, 'Towards a Critical Theory of the World Trade Organization: Thinking with Rawls beyond Rawls' (2013) 20 *Constellations*. [464].

¹³³ Benjamin Mason Meier Lisa Forman, Timothy Hodgson, Moses Mulumba, Hadijah Namyalo-Ganafa, 'Decolonising Human Rights: How Intellectual Property Laws Result in Unequal Access to the COVID-19 Vaccine' (2021) 10 *BMJ Global Health*. [2].

¹³⁴ Yousuf Vawda, 'The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonising Intellectual Property Policy Brief 2021' (*South Centre*, August 2021) <www.southcentre.int/wp-content/uploads/2021/08/PB-99.pdf> accessed 10 March 2022.

¹³⁵ *ibid.*

¹³⁶ Caroline B Ncube, 'Decolonising Intellectual Property Law in Pursuit of Africa's Development' (2016) 8 *IPO Journal*. [36].

of developing countries through a radical rethinking of how the global IP rules are calibrated to expand access to vaccines and other therapeutics.¹³⁷

Exploring the 2022 Geneva Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics

Notwithstanding the above, the WTO's MC12, which took place from 12 to 17 June 2022 in Geneva, resulted in adopting a series of negotiated outcomes on key trade issues, including a Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics.¹³⁸ The declaration affirmed the need to use compulsory licences to boost the production of COVID-19 vaccines through the waiver of certain provisions of the TRIPS Agreement.¹³⁹ WTO members agreed to waive IP rights exclusively for COVID-19 vaccine production and called for members to decide on extending the waiver to include other COVID-19-related treatments and therapeutics after six months.¹⁴⁰ This TRIPS waiver, in its current form, has a life span of five years.¹⁴¹ One particular provision of the final draft, which sought to make members' eligibility for the TRIPS waiver dependent on the number of vaccines they have produced, was a key point of dispute between the US and China. That provision was eventually removed, paving the way for the waiver to apply to all COVID-19 vaccine production.¹⁴²

Potential Objections to the TRIPS Waiver

Aside from the strong theoretical and practical arguments above supporting

¹³⁷ Caroline B Ncube, 'Harnessing Intellectual Property for Development: Some Thoughts on an Appropriate Theoretical Framework' (2013) 16 Potchefstroom Electronic Law Journal.[369].

¹³⁸ WHO, 'Ministerial Declaration on the WTO Response to the Covid-19 Pandemic and Preparedness for Future Pandemic' (2022) <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True>>.

¹³⁹ *ibid.*

¹⁴⁰ WTO, 'WTO Members Secure Unprecedented Package of Trade Outcomes at MC12' (2022) <www.wto.org/english/news_e/news22_e/mc12_17jun22_e.htm> accessed 2 June 2022 .

¹⁴¹ *ibid.*

¹⁴² WTO, 'Ministerial Decision on the TRIPS Agreement Adopted on 17 June 2022' (2022)<<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True>> accessed 2 June 2022.

the TRIPS waiver, criticism of its effectiveness can be made.¹⁴³ While the adopted TRIPS waiver may be instrumental towards deconcentrating and diversifying vaccine manufacturing capacity across the world, some civil society organisations have noted that the EU, the US, the UK and Switzerland have been blocking a ‘meaningful IP waiver’ by supporting a watered-down version of the TRIPS waiver, which does not cover important non-vaccine treatments and therapeutic products.¹⁴⁴ The argument is that the version of the TRIPS waiver adopted in Geneva, though spearheaded by the WTO Director General, was largely based on problematic proposals sourced from the EU.¹⁴⁵ As a result, rather than comprehensively waiving IP protection, the waiver clarifies the utility of the current TRIPS flexibilities and provides a narrow exception to an export restriction on COVID-19 vaccines for five years.¹⁴⁶

Another criticism is that lack of access to essential medicines, including vaccines and medical equipment, is largely linked to a number of factors, including lack of manufacturing capacity, poor public health investments in vaccines and health infrastructure, logistical challenges, and other socio-economic and political factors.¹⁴⁷ These factors are directly linked to the successful management and combatting of the COVID-19 pandemic.¹⁴⁸ The *res deire* nature of the proposed TRIPS waiver limits it to issues pertaining to IP protection, which does not address other existing problems.¹⁴⁹ Therefore, it becomes sensible to question the logic of taking far-reaching measures of suspending IP rights when there are legitimate concerns as to whether such measures would effectively

¹⁴³ Scott Graham, ‘Should IP Rights Be Suspended for COVID Vaccines?’ *Law.com* (28 April 2021) <www.law.com/nationallawjournal/2021/04/28/should-ip-rights-be-suspended-for-covidvaccines-a-qa-with-university-of-houstons-sapna-kumar/> accessed 2 March 2022.

¹⁴⁴ Amnesty International, ‘Covid-19: WTO Ministerial Decision on TRIPS Agreement Fails to Set Rules That Could Save Lives’ (*Amnesty International*, 2022) <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=Tre>> accessed 2 July 2022.

¹⁴⁵ *ibid.*

¹⁴⁶ *ibid.*

¹⁴⁷ Alicia Bárcena and Carissa Etienne, ‘The Prolongation of the Health Crisis and Its Impact on Health, the Economy and Social Development’ (*Cepal*, 2021) <https://www.cepal.org/sites/default/files/events/files/s2100593_en.pdf> accessed 3 March 2022.

¹⁴⁸ *ibid.*

¹⁴⁹ Sarah Joseph, *TRIPS and the Right to Health in Sarah Joseph Blame It on the WTO? A Human Rights Critique* (OUP 2011).[217].

address many of the problems behind shortages of COVID-19-related vaccines and medicines.¹⁵⁰ However, arguments that minimise the potential role played by TRIPS in hindering access to essential medicines in favour of other factors should be dismissed.¹⁵¹ Empirical evidence during the HIV/AIDS pandemic has demonstrated that although other factors determine access to medicines, the role of IP rules cannot simply be minimised.¹⁵²

Another plausible argument against the TRIPS waiver is its duration, which renders it unsuitable for attaining meaningful re-humanisation, distributive justice and decolonial objectives.¹⁵³ The first proposed version of the TRIPS waiver has a three-year lifespan, while the latest one adopted during the WTO's MC12 has a five-year lifespan,¹⁵⁴ providing a temporal solution to the permanent problem of access to vaccines and medical technologies during the COVID-19 pandemic.¹⁵⁵ With the perpetual mutating of the COVID-19 virus, there is no guarantee that the proposed period of the TRIPS waiver would be enough for countries to quickly expand their capacity to produce vaccines and improve their access.¹⁵⁶

¹⁵⁰ Scott Graham, 'Should IP Rights Be Suspended for COVID Vaccines?' (*Sapna Kumar University of Houston*) <www.law.com/nationallawjournal/2021/04/28/should-ip-rights-be-suspended-for-covidvaccines-aqawithuniversityofhoustonssapnakumar/?slreturm=20220327132340> accessed 4 March 2022.

¹⁵¹ Joseph E. Stiglitz and Lori Wallach, 'Preserving Intellectual Property Barriers to Covid-19 Vaccines Is Morally Wrong and Foolish' *Washington Post* (26 April 2021) <www.washingtonpost.com/opinions/2021/04/26/preserving-intellectual-property-barriers-covid-19-vaccines-is-morally-wrong-foolish/> accessed 7 March 2022.

¹⁵² Ellen't Hoen, 'Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines' (*Haiweb*, 2021) <<https://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf>> accessed 8 March 2022.

¹⁵³ James Bacchus, 'An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines' (*CATO*) <<https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>> accessed 10 March 2022.

¹⁵⁴ Mochamad Kevin Romadhona, 'Does the Pandemic Affect Unemployment Rate in East Java? (A Study of Pre and Post COVID-19 Pandemic in 2016 to 2021)' (2022) 3 *The Journal of Indonesia Sustainable Development Planning* 164 <<http://journal.pusbindiklatren.bappenas.go.id/lib/jisdep/article/view/308>>.

¹⁵⁵ WTO, 'Waiver from Certain Provisions of the Trips Agreement for the Prevention Containment and Treatment of Covid-19 Revised Decision Text' (n 46); Hannah Monicken, 'U.S. Seeks to Narrow IP Waiver Scope as WTO Members Agree to Text Talks' *Inside Trade* (9 June 2021) <<https://insidetrade.com/daily-news/us-seeks-narrow-ip-waiver-scope-wto-members-agree-text-talks>> accessed 11 March 2022.

¹⁵⁶ WTO, 'Waiver from Certain Provisions of the Trips Agreement for the Prevention Containment and Treatment of Covid-19 Revised Decision Text' (n 46); Monicken (n 155).

Furthermore, adopting a TRIPS waiver also harms innovation.¹⁵⁷ The drastic approach of suspending IP rights removes the incentives needed for developing new COVID-19 vaccines and diminishes the financial returns that innovators may derive from their inventions.¹⁵⁸

Critics also argue that the prolonged consensus-based process which occurred before the adoption of the TRIPS waiver was time-consuming and made it an inappropriate instrument for responding to the COVID-19 pandemic.¹⁵⁹ The TRIPS waiver negotiations took more than two years without its adoption, so the waiver will likely not have the desired effect on the COVID-19 pandemic.¹⁶⁰ This argument is based on the view that while the WTO members adopted the Doha Declaration in 2001 and a protocol to amend the TRIPS Agreement to enable countries with limited or no manufacturing capacity to import HIV/AIDS generic medicines, the Doha Declaration only entered into effect in January 2017, after two-thirds of the contracting parties ratified the amendment.¹⁶¹ Even though the TRIPS waiver has been adopted, WTO members need to systematically incorporate it into their domestic laws and regulations before commencing implementation.¹⁶² Given that many WTO members grapple with implementing their international agreements due to a lack of political will, inadequate expertise and corruption, there is no guarantee that the waiver will be effective.¹⁶³

¹⁵⁷ Dalindyabo Shabalala, 'How to Get COVID-19 Vaccines to Poor Countries – and Still Keep Patent Benefits for Drugmakers' (*The Conversation*, 2022) <<https://theconversation.com/how-to-get-covid-19-vaccines-to-poor-countries-and-still-keep-patent-benefits-for-drugmakers-158384>> accessed 12 March 2022.

¹⁵⁸ Bacchus (n 154).

¹⁵⁹ Bryan Mercurio, 'The IP Waiver for COVID-19: Bad Policy, Bad Precedent' [2021] *International Review of Industrial Property and Copyright Law*. [983].

¹⁶⁰ Oke (n 47).

¹⁶¹ UNAIDS, 'Doha+10 Trips Flexibilities And Access To Antiretroviral Therapy: Lessons From The Past, Opportunities For The Future' (*UNAIDS Technical Brief*, 2011) <https://www.unaids.org/sites/default/files/media_asset/JC2260_DOHA+10TRIPS_en_0.pdf> accessed 15 March 2022.

¹⁶² Priti Patnaik, 'Efforts to Limit the Implementation of the TRIPS Waiver, Proposals to Exclude India and China' (*Geneva Health*, 4 February 2022) <<https://genevahealthfiles.substack.com/p/exclusive-efforts-to-limit-the-implementation?s=r>> accessed 16 March 2022.

¹⁶³ Simon Lester, 'The EU's Counterproposal on COVID-19 Vaccines and Treatments' (*International Economic Law and Policy Blog*, 4 June 2021) <<https://ielp.worldtradelaw.net/2021/06/the-eus-counterproposal-on-covid-19-vaccines-and-treatments.html>> accessed 17 March 2022.

Besides the fact that the current TRIPS waiver is insufficient and constitutes an inadequate response to the problem of access to essential medicines during the COVID-19 pandemic and beyond, it worsens the situation by excluding the COVID-19 diagnostics and therapeutics and narrowly focusing only on COVID-19 vaccines. Furthermore, given the resurgence of COVID-19 in China and some developing countries, the failure of the TRIPS waiver to address the issue of transferring knowledge and its exclusion of other IP rights means it has a minimal effect on the fight against the pandemic. It sets a defective precedent for combating pandemics and dealing with the question of access to medicines in future.¹⁶⁴

Addressing the Shortcomings of the TRIPS Waiver

Given the aforementioned, WTO members should strive to address the shortcomings of the current version of the TRIPS waiver to make it fit to effectively increase access to essential medicines, including vaccines and medical technologies.¹⁶⁵ To that end, the scope of coverage of the TRIPS waiver should be extended not only to vaccines and medical equipment required to tackle the COVID-19 disease but also to other essential medicines used in treating secondary diseases emanating from the pandemic.¹⁶⁶ However, the enlargement of the TRIPS waiver's coverage without adopting ancillary measures to safeguard the economic interest of innovators may undermine the further development of COVID-19 vaccines and medical products.¹⁶⁷

To address that unintended outcome, a global COVID-19 fund should be created to cushion innovators from the economic losses they may suffer due to

¹⁶⁴ WTO, 'Ministerial Decision on the TRIPS Agreement, MC12 Outcomes' (*World Trade Organisation*) <www.wto.org/english/thewto_e/minist_e/mc12_e/mc12_e.htm#outcom> accessed 10 November 2022.

¹⁶⁵ WTO, 'Okonjo-Iweala Underlines Urgent Need to Address Equitable Access to Vaccines' <https://www.wto.org/english/news_e/news21_e/gc_05may21_e.htm> accessed 19 March 2022.

¹⁶⁶ Khorsed Zaman, 'The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence' (2022) 10 *European Journal of Risk Regulation*. [10].

¹⁶⁷ Oke (n 160).

the suspension of their IP rights.¹⁶⁸ Consistent with the essence of distributive justice, the proposed global COVID-19 fund would be largely sustained by the financial contributions of developed countries because they are better positioned economically.¹⁶⁹ Accompanying the TRIPS waiver should be a push for pharmaceutical companies to voluntarily participate in the COVID-19 Tools Accelerator and its twin instrument, the COVID-19 Vaccines Global Access (COVAX).¹⁷⁰ WTO members may offer incentives to encourage pharmaceutical companies to participate in voluntary schemes established to enable access to essential medicines, including COVID-19-related vaccines and equipment.¹⁷¹

Conclusion

This article has demonstrated that adopting a TRIPS waiver suspending IP rights to increase access to COVID-19-related vaccines and medical equipment remains a contentious issue.¹⁷² The current version of the TRIPS waiver adopted during the WTO's MC12 has many cracks, including the five-year lifespan and limited coverage that excludes other medical products and technologies needed to combat COVID-19.¹⁷³ To address these shortcomings, the longevity and coverage of the proposed TRIPS waiver should be extended to at least eighty years, covering a wider range of essential medicines, including COVID-19-related vaccines and medical equipment.¹⁷⁴

Furthermore, the TRIPS waiver should not be regarded as the only solution to the problem of inequitable access to COVID-19 vaccines and medical equipment.¹⁷⁵

¹⁶⁸ Karen Hussmann, 'Global Access to Covid-19 vaccines: Lifting the Veil of Opacity' (*Relief Web*, 2021) <<https://reliefweb.int/sites/reliefweb.int/files/resources/lifting-the-veil-of-opacity-in-covid-19-vaccines-to-combat-the-pandemic.pdf>> accessed 20 March 2022.

¹⁶⁹ Dube (n 137).

¹⁷⁰ WHO, 'COVAX Working for Global Equitable Access to COVID-19 Vaccines' (2022) <www.who.int/initiatives/act-accelerator/covax> accessed 21 March 2022.

¹⁷¹ *ibid.*

¹⁷² European Parliament (n 6).

¹⁷³ WTO, 'WTO Members Secure Unprecedented Package of Trade Outcomes at MC12' (17 June 2022) <www.wto.org/english/news_e/news22_e/mc12_17jun22_e.htm>.

¹⁷⁴ WTO, 'Members Discuss TRIPS Waiver, LDC Transition Period and Green Tech Role for Small Business' (11 March 2021) <www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm> accessed 25 March 2022.

¹⁷⁵ Monicken (n 155).

Instead, countries should push pharmaceutical companies to participate in voluntary arrangements under the COVAX, and the global COVID-19 fund should be established in tandem with the TRIPS waiver.¹⁷⁶ However, notwithstanding its limitations, the TRIPS waiver has the potential to become an effective legal instrument for increasing access to medicines and medical technologies.¹⁷⁷ It, therefore, advances the goals of distributive justice, re-humanisation and decolonisation of the global rules governing IP.¹⁷⁸

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¹⁷⁶ Shabalala (n 157).

¹⁷⁷ Jecker, Wightman and Diekema (n 92).[310].

¹⁷⁸ Ncube (n 128).[39].

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HOW TO CITE: Shelton T Mota Makore, Patrick C. Osode and Nombulelo Lubisi, ‘Reconciling the Global Public Health Interest with Intellectual Property Protection Through the Waiver of Certain Provisions of the WTO TRIPS Agreement’ (2022) 37 *Yuridika*.

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