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

Patrick Osode
posode@ufh.ac.za
University of Fort Hare, South Africa

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

---

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


\(^7\) 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.\textsuperscript{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 12\textsuperscript{th} 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.\textsuperscript{9} The former is predicated on utilising

\textsuperscript{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.

\textsuperscript{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. 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. They include contextual and historical studies, critical analysis and comparative sectional analysis. 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. 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.

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. While there is no

---

11 M McConville and WH Chui (eds), Research Methods for Law (Edinburgh University Press 2017).[9].
13 ibid.
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. 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. COVID-19 is causing a massive epidemiological health crisis and far-reaching socio-economic and political devastation.

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. 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. As of 19 March 2022, the confirmed global cases of COVID-19 infections stood at 523,786,368, with 6,279,667 deaths. In South Africa, the pandemic has claimed the lives of over 99,829, with 3,700,484 cases of infections. 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.

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

18 ibid.
22 South African Department of Health (n 20).
origin of the disease remains veiled in obscurity. 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. This novel virus has now been identified as the SARS-CoV-2 of zoonotic specie. 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. It led to then-US President Donald Trump concluding that the WHO had become China-centric to the detriment of global health security. Whether the WHO has indeed become China-centric by relegating its responsibility to global health leadership remains a point of contestation.

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. The first whose support has increased is the COVID-19 lab-leak theory. 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. However, the lab-leak theory

---

26 ibid.
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.
\(^{35}\) 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].
\(^{40}\) Aiping Wu and others, ‘Genome Composition and Divergence of the Novel Coronavirus (2019-NCoV) Originating in China’ (2020) 27 Cell Host & Microbe.[325].
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. 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.

The first version of the proposal stated that the TRIPS waiver would last for a period to be determined by the General Council. The waiver would apply to patents and other forms of IP. 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. At the time of writing, the TRIPS Council was deliberating...

---


44 ibid.


on the 2021 version of the proposed waiver, aiming to either adopt it or subject it to further consideration.\footnote{Emmanuel Kolawole Oke, ‘The TRIPS Waiver Compromise Draft Text: A Preliminary Assessment’ (\textit{Afronomics Law}, 18 March 2022) <www.afronomicslaw.org/category/analysis/trips-waiver-compromise-draft-text-preliminary-assessment> accessed 18 March 2022.}

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.\footnote{Andrew Green, ‘TRIPS Waiver Compromise Draws Mixed Response’ (\textit{Devex}, 17 March 2022) <www.devex.com/news/trips-waiver-compromise-draws-mixed-response-102860> accessed 18 March 2022.} 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.\footnote{‘TRIPS Waiver Proposal: A Compilation of Statements and Reports’ (\textit{Third World Network}, 2021) <www.twn.my/title2/intellectual_property/trips_waiver_proposal.htm> accessed 18 March 2022.} 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.\footnote{United States Congressional Research Service, ‘The Biden Administration Announces Its Support for a WTO TRIPS Waiver’(\textit{United States Congressional Research Service}, 2021) <https://www.everycrsreport.com/files/20210507_IN11662_af1721f6d72c022a804a0866af504d9d5e90cb8e2.pdf> accessed 18 March 2022.}

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.

\section*{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
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.\(^5\) 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.\(^2\) 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.\(^3\)

Additionally, the TRIPS Agreement restricts the issuing of compulsory licensing to specific products that each country should determine on a case-by-case basis.\(^4\) 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.\(^5\) 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.\(^6\)

In the same vein, the use of voluntary licensing flexibilities under the TRIPS Agreement has proven to be problematic, with efforts by pharmaceutical companies...
falling short of expanding access to essential medicines, including vaccines and other technologies.\textsuperscript{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.\textsuperscript{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.\textsuperscript{59} According to the WHO, voluntary licensing agreements ‘tend to be exclusive and non-transparent, compromising equitable access’.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{64}

\textsuperscript{58} ibid.
\textsuperscript{59} Raju (n 54).
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. 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. The TRIPS waiver, therefore, provides a credible alternative to the failure of voluntary initiatives in pursuit of access to vaccines and equipment.

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. 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. The large-scale ill health and mortality caused by the pandemic and its uneven effect require a fuller response than easing export restrictions. 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.

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].
69 ibid.
challenging processes under the WTO dispute settlement system.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{77}

\textbf{Re-humanisation aspects of the TRIPS waiver}

Notwithstanding the above, other arguments can be deployed in support


\textsuperscript{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..69i57j0i10i433i512j0i10i512j0i131i433j0i10i512j69i6o12.1710j0j7&sourceid=chrome&ie=UTF-8>.


\textsuperscript{77} \textit{ibid.}
of the TRIPS waiver. First, the TRIPS waiver can be viewed as a significant instrument for re-humanising the global IP protection regime. 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. International IP protection arrangements and governance mirror the three main theoretical goals advanced under TRIPS. In turn, the domestic IP laws entrench and institutionalise three theoretical justifications. 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. 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. The domestic IP laws in developing and developed countries are at the least based on these three aforementioned theoretical foundations.

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. However, in brief, the utilitarian economic efficiency approach protects IP assets as products of the mind that ‘free rider users’
copy without permission from the inventors to the detriment of scientific innovation and development. 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. The personality theory is based on Hegelian philosophy, which proposes that inventors are autonomous and endowed with rights over their creations. Consequently, IP products, including medicines and medical technologies, are a significant reflection of the originators’ creation. 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. 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.

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. The humanisation approach is based on egalitarian values that should influence the development of law and policy. 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. These values are the cornerstone of the human rights order

---

90 Schroeder (n 89).
91 John Locke, *Two Treatises of Government* (CUP 1967).[27].
94 ibid.
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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{102} The argument is that the TRIPS should be

\textsuperscript{96} Osei-Tutu (n 79).


\textsuperscript{99} ibid.

\textsuperscript{100} Campaign (n 53).


infused with values such as distributive justice and egalitarianism with which the global IP rules should comply.\textsuperscript{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.\textsuperscript{104} The meaning of justice and egalitarianism elusively differ subjectively depending on the socio-economic and legal factors existing in a particular arrangement.\textsuperscript{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.\textsuperscript{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.\textsuperscript{107}

That the current global IP rules hinder access to essential medicines and other medical equipment is largely uncontroversial.\textsuperscript{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.\textsuperscript{109} The situation contributes to the troubling vaccine inequality between developed and developing countries.\textsuperscript{110}

\textsuperscript{105} Kristin Voigt and Gry Wester, ‘Relational Equality and Health’ (2015) 31 Social Philosophy and Policy.[204].
\textsuperscript{106} Chi Carmody, Frank J Garcia and John Linarelli, Global Justice and International Economic Law: Opportunities and Prospects (CUP 2012).[7].
\textsuperscript{108} Frank J Garcia, ‘Globalization, Inequality & International Economic Law’ (2017) 8 Religions.[78].
\textsuperscript{109} ibid.
\textsuperscript{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.\textsuperscript{111} That the TRIPS inevitably has distributional effects is not a novel claim.\textsuperscript{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.\textsuperscript{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.\textsuperscript{114} Distributive justice, also dubbed ‘social justice’, generates legal obligations to achieve a just IP protection system.\textsuperscript{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.\textsuperscript{116}

According to Rawls,\textsuperscript{117} distributive justice entails three major tenets.\textsuperscript{118} First, the attainment of freedom, subject only to limitations in defence of such freedom.\textsuperscript{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.\textsuperscript{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.\textsuperscript{121} He further argues that distributive justice envisages a far-reaching goal of transforming the global regulatory architecture through a

\begin{itemize}
\item \textsuperscript{111} ibid.
\item \textsuperscript{112} Darrel Moellendorf, ‘The World Trade Organization and Egalitarian Justice’ (2005) 36 Metaphilosophy.[146].
\item \textsuperscript{113} ibid.
\item \textsuperscript{114} Tom Campbell, \textit{Justice} (CUP 1988).[19].
\item \textsuperscript{116} Brian Barry, \textit{Treatise on Social Justice} (University of California Press 1989).[355].
\item \textsuperscript{117} Rawls, \textit{Theory of Justice} (n 107).[356].
\item \textsuperscript{118} ibid.
\item \textsuperscript{119} ibid.
\item \textsuperscript{120} ibid.
\item \textsuperscript{121} ibid.
\end{itemize}
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. 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. His distributive justice theory envisages the significant goal of re-configuring TRIPS in pursuit of a just IP regime. However lyrical the ideas of Rawls’ distributive theory may be, one should not conflate them with the goals advanced by utilitarian theory. There is a difference between utilitarianism and distributive justice theory. 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. 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.

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.
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.


\(^{135}\) ibid.

of developing countries through a radical rethinking of how the global IP rules are calibrated to expand access to vaccines and other therapeutics.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{140} This TRIPS waiver, in its current form, has a life span of five years.\textsuperscript{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.\textsuperscript{142}

**Potential Objections to the TRIPS Waiver**

Aside from the strong theoretical and practical arguments above supporting


\textsuperscript{139} ibid.


\textsuperscript{141} ibid.

the TRIPS waiver, criticism of its effectiveness can be made. 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. 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. 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.

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. These factors are directly linked to the successful management and combatting of the COVID-19 pandemic. The res deire nature of the proposed TRIPS waiver limits it to issues pertaining to IP protection, which does not address other existing problems. 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

---


145 ibid.

146 ibid.


148 ibid.


Another plausible argument against the TRIPS waiver is its duration, which renders it unsuitable for attaining meaningful re-humanisation, distributive justice and decolonial objectives.\footnote{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.} 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,\footnote{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.pushindiklatren.bappenas.go.id/lib/jisdep/article/view/308> accessed 11 March 2022.} providing a temporal solution to the permanent problem of access to vaccines and medical technologies during the COVID-19 pandemic.\footnote{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).} 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.\footnote{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{163}


\textsuperscript{158} Bacchus (n 154).

\textsuperscript{159} Bryan Mercurio, ‘The IP Waiver for COVID-19: Bad Policy, Bad Precedent’ [2021] International Review of Industrial Property and Copyright Law.[983].

\textsuperscript{160} Oke (n 47).


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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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

\footnotesize{\textsuperscript{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.}

\footnotesize{\textsuperscript{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.}


\footnotesize{\textsuperscript{167} Oke (n 160).}
the suspension of their IP rights.\textsuperscript{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.\textsuperscript{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).\textsuperscript{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.\textsuperscript{171}

\section*{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{175}

\begin{footnotesize}
\begin{enumerate}
\item[169] Dube (n 137).
\item[171] ibid.
\item[172] European Parliament (n 6).
\item[175] Monicken (n 155).
\end{enumerate}
\end{footnotesize}
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.\textsuperscript{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.\textsuperscript{177} It, therefore, advances
the goals of distributive justice, re-humanisation and decolonisation of the global
rules governing IP.\textsuperscript{178}

\textbf{Bibliography}

Abbott R, ‘Are Developing Countries Deterred from Using the WTO Dispute
Settlement System? Participation of Developing Countries in the DSM in the

Agrawal A and others, ‘A Comparative Analysis of the Spanish Flu 1918 and

Al Jazeera and News Agencies, ‘COVID: New Cases Decline by 19% Worldwide,
com/news/2022/2/16/covid-new-cases-decline-by-19-worldwide-deaths-
stabilise>.

Aleem A, Samad ABA and Slenker AK, ‘Emerging Variants of SARS-CoV-2 and
Novel Therapeutics against Coronavirus (COVID-19)’, \textit{StatPearls} (StatPearls
Publishing 2022).

Alicia Bárcena and Carissa Etienne, ‘The Prolongation of the Health Crisis and
Its Impact on Health, the Economy and Social Development’ (\textit{Cepal}, 2021)
accessed 3 March 2022.

Solution to Improving Access to Affordable Medicines’ (2007).

Antonelli GA, Leone MI and Ricci R, ‘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.

\textsuperscript{176} Shabalala (n 157).
\textsuperscript{177} Jecker, Wightman and Diekema (n 92).[310].\textsuperscript{178} Ncube (n 128).[39].


Joseph E. Stiglitz and Lori Wallach, ‘Preserving Intellectual Property Barriers


M McConville and WH Chui (eds), Research Methods for Law (Edinburgh...


Okediji RL, ‘The International Relations of Intellectual Property: Narratives of


World Health Organisation, ‘Coronavirus Disease: Variants of the Severe Acute
Respiratory Syndrome (COVID19) (The World Health Organisation, 2019)


--This page is intentionally left blank--