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TRIPS Waiver Decision for Equitable Access to Medical Countermeasures in the Pandemic: COVID-19 Diagnostics and Therapeutics

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SOUTH CENTRE

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TRIPS WAIVER DECISION FOR EQUITABLE ACCESS TO MEDICAL COUNTERMEASURES IN THE PANDEMIC: COVID-19 DIAGNOSTICS AND THERAPEUTICS

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ABSTRACT

The Marrakesh Agreement Establishing the World Trade Organization (WTO) allows WTO Members to agree to temporarily waive obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). However, the TRIPS Decision adopted by the 12th WTO Ministerial Conference in June 2022, after lengthy and protracted negotiations lasting for 20 months in the middle of a pandemic, allowed only a fragment of the waiver proposal submitted by India and South Africa. Moreover, since the adoption of the Decision there has been an impasse in the WTO about extending the Decision to COVID-19 diagnostics and therapeutics even though the WTO Members were mandated by the Decision to decide on this matter within six months of the Decision. This research paper analyses the current state of play and concludes that there is a need to immediately and unconditionally extend the Decision to COVID-19 diagnostics and therapeutics. Moreover, the paper suggests options for how the TRIPS flexibilities can be optimally utilized in a pandemic situation without developing countries being resigned to the vagaries of negotiations on a waiver which is supposed to be an urgent emergency solution. In this regard, the paper also suggests options that could be considered for reforming the process of decision-making on a waiver proposal to ensure that decisions on waivers are taken in a timely and expedited manner without being negotiated for an extensive period of time in the midst of an emergency.

L'accord de Marrakech instituant l'Organisation mondiale du commerce (OMC) permet aux membres de l'OMC de convenir d'une dérogation temporaire aux obligations découlant de l'accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (accord sur les ADPIC). Reste que la décision adoptée par la 12e Conférence ministérielle tenue en juin 2022, après de longues négociations qui ont duré 20 mois en pleine pandémie, n'a approuvé qu'en partie la proposition de dérogation soumise par l'Inde et l'Afrique du Sud. Qui plus est, depuis son adoption, l'OMC est dans l'impasse en ce qui concerne l'extension de la décision aux produits diagnostiques et thérapeutiques contre la COVID-19 malgré l'obligation faite aux états membres de l'OMC de se prononcer sur cette question dans les six mois suivant l'adoption de la décision. Le présent document de recherche analyse la situation actuelle et conclut qu'il est nécessaire d'étendre immédiatement et sans condition la décision aux produits diagnostiques et thérapeutiques contre la COVID-19. Il présente également diverses options concernant la manière dont les flexibilités prévues par l'Accord sur les ADPIC peuvent être utilisées de manière optimale en cas de pandémie afin de permettre aux pays en développement de ne pas subir les aléas liés aux négociations sur une dérogation qui vise à résoudre une question urgente. À cet égard, le document suggère également différentes pistes qui pourraient être envisagées pour réformer le processus de décision concernant les propositions de dérogation afin de garantir que les décisions les concernant soient prises en temps utile et de manière rapide et non pas au terme de négociations longues et en plein milieu d'une situation critique.

El Acuerdo de Marrakech por el que se establece la Organización Mundial del Comercio (OMC) permite que los Miembros de la OMC acuerden eximir temporalmente a algún Miembro de las obligaciones impuestas por el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (Acuerdo sobre los ADPIC). Sin embargo, la Decisión relativa al Acuerdo sobre los ADPIC adoptada por la Duodécima Conferencia Ministerial de la OMC celebrada en junio de 2022, tras unas negociaciones prolongadas que duraron 20 meses en plena pandemia, refleja únicamente un fragmento de la propuesta de exención presentada por la India y Sudáfrica. Además, desde la adopción de la Decisión, la ampliación de la Decisión a la producción y el suministro de medios de diagnóstico y tratamientos contra la COVID-19 ha quedado en punto muerto en la OMC

aunque sus Miembros tuvieran la obligación de decidir sobre esta cuestión en un plazo máximo de seis meses después de la fecha de adopción de esta Decisión. En este documento de investigación se analiza la situación actual y se concluye que existe la necesidad de ampliar inmediata e incondicionalmente la Decisión a los medios de diagnóstico y tratamientos contra la COVID-19. Asimismo, el documento expone opciones en relación con el uso óptimo de las flexibilidades previstas en los ADPIC en una situación de pandemia sin que los países en desarrollo tengan que aceptar los caprichos de las negociaciones sobre una exención que presuntamente es una solución urgente. En este sentido, el artículo indica igualmente alternativas que podrían considerarse para reformar el proceso de adopción de decisiones sobre una propuesta de exención que garantice que las decisiones acerca de las exenciones se toman de manera oportuna y acelerada sin que tengan que negociarse durante largos periodos en mitad de una emergencia.

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I. INTRODUCTION

There has been a problematic relationship between patent law and global public health because the exclusive rights granted under patent law pose serious barriers to diversified manufacturing of and equitable access to innovative health technologies. By enabling patentee corporations to control manufacturing and set higher prices by limiting generic competition, patents on drugs and vaccines can adversely impact their availability, affordability, and accessibility for patients. Keeping in view the serious implications of patent protection for access to healthcare, especially in a health emergency, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO) provides certain built-in flexibilities to protect public health. In addition, a temporary waiver from TRIPS obligations is a flexibility set out in Article IX(3) of the Marrakesh Agreement Establishing the World Trade Organization (Marrakesh Agreement) to accommodate other urgent priorities in exceptional circumstances.[1]

The COVID-19 health emergency clearly qualifies as an 'exceptional circumstance'. By making use of the flexibility under Article IX(3), India and South Africa submitted a proposal to waive certain TRIPS obligations in response to COVID-19. However, after protracted negotiations for 20 months the WTO Ministerial Conference adopted a decision which provides a very limited waiver in comparison to what was proposed.[2] This limited waiver was also applicable only to COVID-19 vaccines. However, the Ministerial Decision (hereinafter the Decision) had also mandated WTO Members to decide on the extension of the Decision to COVID-19 therapeutics and diagnostics within six months. Nevertheless, developed country Members of the WTO have been resistant to such extension of the Decision. Consequently, the issue of extension of the Decision to therapeutics and diagnostics remains unresolved in the WTO more than one year since the adoption of the Decision. This paper revisits the debate around the TRIPS waiver proposal and strongly supports the extension of the Decision to COVID-19 diagnostics and therapeutics. It also discusses how the decision-making process on a waiver proposal can be strengthened in the WTO, and how the available TRIPS flexibilities can be optimally utilized to respond to public health crises like a global pandemic.
At the time of this writing in September 2023, the global COVID-19 death toll had passed 6.9 million.[3] The lack of universal access to COVID-19 vaccines, diagnostics, and therapeutics has been a major contributing factor to this massive death toll. During the first and second years of COVID-19 vaccinations, low-income countries received just 0.89% and 4.71% of available doses respectively.[4] Even though inequalities in vaccine distribution have reduced over time, still high-income and upper-middle-income countries have more than 80% of their populations vaccinated while the vaccination rate in lower-middle-income countries is 66% and only 33% of the population in lower-income countries has received the COVID-19 vaccine.[5]

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[1] Marrakesh Agreement Establishing the WTO, Article IX(3).
[2] See Carlos M. Correa and Nirmalya Syam, *The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement It?*, Research Paper, No.169 (Geneva, South Centre, 2022). Available from https://www.southcentre.int/wp-content/uploads/2022/11/RP169_The-WTO-TRIPS-Decision-on-COVID-19-Vaccines_EN.pdf.
[3] World Health Organization, "WHO COVID-19 dashboard". Available from https://covid19.who.int.
[4] Amnesty International, "Inequality of Pandemic Proportions State and Pharma Failures Not to Be Repeated", POL 30/6518/2023 (2023), p. 6.
[5] Our World in Data, "Coronavirus (COVID-19) Vaccinations". Available from https://ourworldindata.org/explorers/coronavirus-data-explorer?zoomToSelection=true&time=latest&facet=none&country=OWID_WRL~Low+income~Lower+middle+income~Upper+middle+income~High+income&pickerSort=desc&pickerMetric=population&hideControls=true&Metric=People+vaccinated+%28by+dose%29&Interval=Cumulative&Relative+to+Population=true&Color+by+test+positivity=false.

From the beginning of the pandemic, the 'people's vaccines' debate started even though there were no vaccines developed at that point. The United Nations (UN) Secretary-General stated that 'we must ensure that vaccines are seen as a global public good – people's vaccines – accessible and affordable to all'.[6] The President of the European Union and heads of state of Canada, Norway, Italy, Germany, and France declared that COVID-19 vaccines should be a global public good.[7] Two resolutions passed by the UN General Assembly in April 2020 emphasised the need to rapidly scale the manufacturing of pandemic-related health technologies.[8] In March 2020, the Group of Twenty (G20) Leaders' Summit made the following statement:

> We commit to take all necessary measures and seek to ensure adequate financing to contain the pandemic and protect people, especially the most vulnerable. We will share timely and transparent information; exchange epidemiological and clinical data; share materials necessary for research and development; and strengthen health systems globally.[9]

The goal of achieving diversified and expanded manufacturing capacity required 'the unhindered global sharing of technology and know-how'.[10] A true spirit of solidarity to share the technology and know-how was lacking. The virtue signalling by political leaders[11] was not followed up with concrete actions to ensure the broad sharing of intellectual property rights (IPRs) to facilitate diversified manufacturing and equitable dissemination of COVID-19 vaccines, therapeutics, and diagnostics.

In April 2020, the World Health Organization (WHO) launched the COVID-19 Vaccines Global Access (COVAX) as a public-private initiative to achieve the goal of fair and equitable access by pooling global demand for COVID-19 vaccines. The COVAX facility failed to deliver on its commitment because of shortages in the supply of vaccines caused by 'vaccine nationalism' in high-income countries.[12] When vaccines were still in the research phase, affluent countries used their financial might to secure advance purchase agreements.[13]

In May 2020, the WHO launched the COVID-19 Technology Access Pool (C-TAP) initiative which was aimed at creating a common knowledge pool by providing a platform to voluntarily share intellectual property (IP), know-how, and data related to COVID-19 vaccines and

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[6] United Nations, "Secretary-General Calls for Early Action to Avoid World of 'Vaccine Haves and Have-Nots, at African COVID-19 Strategy Meeting", SG/SM/20557 (2021). Available from https://press.un.org/en/2021/sgsm20557.doc.htm.

[7] Sara E. Fischer *et al.,* "Intellectual Property and the Politics of Public Good in COVID-19: Framing Law, Institutions, and Ideas during TRIPS Waiver Negotiations at the WTO", *Journal of Health Politics, Policy and Law,* Vol. 49, No. 1 (2024).

[8] United Nations, "Amid COVID-19 Pandemic, General Assembly, in Silence Procedure, Adopts 7 Resolutions, 13 Decisions between 27 March and 14 May", GA/12244 (2020). Available from https://press.un.org/en/2020/ga12244.doc.htm.

[9] G20 Research Group, "Extraordinary G20 Leaders' Summit: Statement on COVID-19", Saudi Arabia (March 26, 2020), G20 Information Centre. Available from http://www.g20.utoronto.ca/2020/2020-g20-statement-0326.html.

[10] Peter Drahos, "Public Lies and Public Goods: Ten Lessons from When Patents and Pandemics Meet", in *Reforming Intellectual Property,* Gustavo Ghidini and Valeria Falce, eds. (Cheltenham and Northampton (Ma.), Edward Elgar Publishing, 2022), pp. 30-44 at 38.

[11] See Nirmalya Syam, "The UN General Assembly Resolutions on COVID-19: Solemn Assurances for Access to Health Technologies without an Action Plan", Policy Brief, No.81 (Geneva, South Centre, 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/07/PB-81.pdf.

[12] Amnesty International, "Inequality of Pandemic Proportions State and Pharma Failures Not to Be Repeated", POL 30/6518/2023 (2023), p. 9.
. See more at Siva Thambisetty *et al.*, "The TRIPS Intellectual Property Waiver Proposal: creating the right incentives in patent law and politics to end the COVID-19 pandemic", LSE Legal Studies Working Paper, No. 6 (2021).

[13] Muhammad Zaheer Abbas, *Practical Implications of Vaccine Nationalism: A Short-Sighted and Risky Approach in Response to COVID-19*, Research Paper, No. 124 (Geneva, South Centre, 2020). Available from https://www.southcentre.int/research-paper-124-november-2020/.

pharmaceuticals.[14] C-TAP was 'intended to provide a means to accelerate the development of products needed to fight COVID-19 as well as to accelerate the products available globally'.[15] This initiative for a global and non-exclusive licensing platform was explicitly rejected by the biopharmaceutical industry because the holders of vaccine technologies were not willing to voluntarily license patents and share know-how. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) openly criticised the C-TAP initiative in its statement.[16] Rights holders such as Moderna persistently refused the voluntary technology transfer requests from the People's Vaccine Alliance, C-TAP, and others.[17]

Though COVID-19 vaccines were yet to be developed, less affluent countries could foresee that the business-as-usual approach of patentee corporations in the middle of a pandemic would pose a global health risk because a limited number of manufacturers would control the production and dissemination of vaccines and other essential products. The past experiences of developing countries with H1N1 vaccines and H5N1 vaccines suggest that these concerns were realistic.[18] These concerns about the inadequacy of measures taken in response to COVID-19 provided a context in which India and South Africa submitted the TRIPS waiver proposal. As noted by the South African delegation in their opening statement to the TRIPS Council:

> [G]lobal cooperation and collaboration is key to addressing the COVID-19 pandemic; initiatives such as the COVAX facility are helpful but insufficient. Our waiver proposal is designed to work synergistically with such initiatives by enabling the rapid scaling of production by multiple producers across many countries, enabling sharing of knowledge and transfer of technology with the aim of addressing the pandemic.[19]

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[14] World Health Organization, "COVID-19 Technology Access Pool". Available from https://www.who.int/initiatives/covid-19-technology-access-pool.
[15] World Health Organization, "C-TAP: A concept paper" (27 October 2020). Available from https://www.who.int/publications/m/item/c-tap-a-concept-paper.
[16] IFPMA Statement on the "Solidarity Call to Action to realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data" (28 May 2020). Available from https://www.ifpma.org/news/ifpma-statement-on-the-solidarity-call-to-action-to-realize-equitable-global-access-to-covid-19-health-technologies-through-pooling-of-knowledge-intellectual-property-and-data/. See more at Amnesty International, "Money Calls the Shots: Pharma's Response to the COVID-19 Vaccine Crisis" (14 February 2022). Available from https://www.amnesty.org/en/documents/pol40/5140/2022/en/.
[17] Brook K. Baker and Rachel D. Thrasher, "From Business as Usual to Health for the Future: Challenging the Intellectual Property Regime to Address COVID-19 and Future Pandemics", *Boston University International Law Journal,* Vol. 41, No. 1 (2023).. See more at WEMOS, "Make Pooling Work to End Pandemics: A Qualitative Analysis of the COVID-19 Technology Access Pool", *The People's Vaccine* (November 2022). Available from https://peoplesvaccine.org/wp-content/uploads/2022/11/Wemos_Make-pooling-work-to-end-pandemics_November-2022.pdf.
[18] Muhammad Zaheer Abbas, *Practical Implications of Vaccine Nationalism: A Short-Sighted and Risky Approach in Response to COVID-19*, Research Paper, No. 124 (Geneva, South Centre, 2020). Available from https://www.southcentre.int/research-paper-124-november-2020/.
[19] World Trade Organization, Council for TRIPS, Minutes of Meeting, IP/C/M/96/Add.1.

II. THE TRIPS WAIVER PROPOSAL

On October 2, 2020, India and South Africa submitted a proposal to the Council for TRIPS for a waiver of obligations under several specific provisions of the TRIPS Agreement. The proposal covered COVID-19 health technologies and encompassed obligations in respect of copyright and related rights, industrial designs, patents, and protection of undisclosed information as set out under Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement.[20] India and South Africa proposed that the waiver would 'continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity'.[21]

The approval processes for waiver requests are intended to be rapid. Under Article IX(3)(b) of the WTO Agreement, all waiver requests must be considered within 90 days. The relevant Council is required to submit a report to the Ministerial Conference at the end of this time-period.[22] However, the progress in relation to this waiver request was slow. Opponents of this waiver proposal raised concerns at the TRIPS Council that the scope of the original proposal was too broad. The prescribed process within the stipulated timeframe could not be implemented. In December 2020, the WTO General Council instructed the Council for TRIPS to work further with the proposal.[23]

On May 5, 2021, the WTO Director-General said during the General Council meeting that 'vaccine policy is an economic policy because the global economic recovery cannot be sustained unless we find a way to get equitable access to vaccines, pharmaceuticals and diagnostics'.[24] The same day, the United States Trade Representative (USTR) Katherine Tai announced that the United States would support a waiver (with the reservation that its scope would be confined to vaccine patents only).[25] The Biden-Harris administration cited 'extraordinary times call for extraordinary measures'.[26] More openness towards the waiver proposal was indicated by several other developed countries such as Canada.

In a bid to reconcile positions, on May 21, 2021, India and South Africa along with co-sponsors submitted a revised proposal with a specified duration of at least 3 years from the date of the decision, subject to annual review of the waiver.[27] The revised proposal narrowed down the scope of COVID-19 health technologies to 'health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19'.[28] The technologies and products covered by the proposed waiver and the duration of the waiver were specified to make the proposal more acceptable to wealthy countries and other stakeholders.

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[20] WTO document IP/C/W/669, 2 October 2020.
[21] Ibid., Paragraph 13.
[22] Marrakesh Agreement Establishing the WTO, Article IX(3)(b).
[23] World Trade Organization, General Council, Minutes of Meeting, WT/GC/M/188.
[24] WTO General Council, "Remarks by DG Okonjo-Iweala on the IP Waiver", 5 May 2021. Available from https://www.wto.org/english/news_e/spno_e/spno9_e.htm#:~:text=The%20issue%20of%20equitable%20access,to%20vaccines%2C%20therapeutics%20and%20diagnostics.
[25] United States Trade Representative, "COVID-19 Trips Waiver" (Press Statement, 5 May 2021).
[26] See, White House, "Fact Sheet: Biden-Harris Administration is Providing at least 80 million COVID-19 Vaccines for Global Use, Commits to Leading a Multilateral Effort toward Ending the Pandemic", 17 May 2021. Available from https://www.whitehouse.gov/briefing-room/statements-releases/2021/05/17/fact-sheet-biden-harris-administration-is-providing-at-least-80-million-covid-19-vaccines-for-global-use-commits-to-leading-a-multilateral-effort-toward-ending-the-pandemic/.
[27] WTO TRIPS Council, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa (IP/C/W669/Rev.1, 25 May 2021).
[28] WTO TRIPS Council, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa (IP/C/W/669, 2 October 2020).

On June 18, 2021, the European Union submitted an alternative proposal which called for making adjustments to the existing compulsory licensing mechanisms under Articles 31 and 31bis of the TRIPS Agreement, without granting a waiver.[29] The alternative proposal recommended that 'the exporting Member may provide in one single notification a list of all countries to which vaccines and medicines are to be supplied by the exporting Member'.[30] It was a tightly limited proposal which basically focused on streamlining the use of export-oriented compulsory licensing by covering multiple countries under a single notification. This patent-only counter-proposal provided the basis for 'compromise' negotiations involving India, South Africa, the EU, and the US (the Quad members).[31]

[29] WTO document IP/C/W/681, 18 June 2021.
[30] Ibid.
[31] Brook K. Baker and Rachel D. Thrasher, "From Business as Usual to Health for the Future: Challenging the Intellectual Property Regime to Address COVID-19 and Future Pandemics", *Boston University International Law Journal,* Vol. 41, No. 1 (2023).

III. An Analysis of Arguments Against the Waiver

The revised proposal was supported by 'more than 100 countries as well as over 300 civil society organizations, the World Health Organization, Unitaid, South Centre and other international organizations, lawmakers in various countries, many academics and political leaders'.[32] Though there were obvious barriers posed by the exclusive rights of patentee corporations, many developed countries - including the United Kingdom, the EU, Switzerland, Norway, Japan, Canada, and Australia - strongly opposed the waiver proposal and continued to argue in favour of status quo or minor adjustments to the existing compulsory licensing mechanism. This section considers the validity of arguments against the waiver proposal.

A. Intellectual Property is not a Barrier

Opponents of the waiver argued that IP is not the real challenge hindering access to COVID-19 health technologies as there is no credible evidence that IPRs acted as a constraint.[33] At the TRIPS Council, the EU argued that 'there is no indication that IPRs issues have been a genuine barrier in relation to COVID-19-related medicines and technologies'.[34] Likewise, the IFPMA stated:

> While we share a number of the objectives of access and cooperation of the "Solidarity Call to Action," we disagree with some of its premises, as they imply that intellectual property (IP) rights that are not waived or licensed globally are potential barriers to R&D, public-private collaborations or access to COVID-19 products. This does not correspond to our experience and may be counterproductive to achieving the objectives of the Solidarity Call to Action.[35]

In November 2020, Australia, Canada, Chile, and Mexico questioned the necessity of the waiver, as opponents of the waiver maintained that IP was not posing barriers.[36] In the same month, the G20 summit was held in Riyadh. The Leaders' Declaration from the G20 summit said: 'We recognize the role of extensive immunization against COVID-19 as a global public good'.[37] However, the G20 noted that IP 'has not been an impediment to the common goal of ending this pandemic'.[38]

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[32] Carlos M. Correa, Nirmalya Syam and Daniel Uribe, *Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims under Free Trade and Investment Agreements*, Research Paper, No. 135 (Geneva, South Centre, 2021), p. 1. Available from https://www.southcentre.int/research-paper-135-september-2021/.

[33] Michael Rosen, "Confronting Joe Biden's Proposed TRIPS Waiver for COVID-19 Vaccines and Treatments: Highlights from an Expert Panel Discussion", AEIdeas (2 July 2021). Available from https://www.aei.org/technology-and-innovation/confronting-joe-bidens-proposed-trips-waiver-for-covid-19-vaccines-and-treatments-highlights-from-an-expert-panel-discussion/.

[34] World Trade Organization, Council for TRIPS, Minutes of Meeting, IP/C/M/96/Add.1. See more at Emmanuel Kolawole Oke, "The Waiver of The Trips Agreement for COVID-19 at the WTO: A Rhetorical Analysis", *Indian Journal of Intellectual Property Law,* Vol.12 (2022).

[35] IFPMA Statement on the "Solidarity Call to Action to realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data" (28 May 2020). Available from https://www.ifpma.org/news/ifpma-statement-on-the-solidarity-call-to-action-to-realize-equitable-global-access-to-covid-19-health-technologies-through-pooling-of-knowledge-intellectual-property-and-data/.

[36] WTO TRIPS Council, Questions on Intellectual Property Challenges Experienced by Members in relation to COVID-19: Communication from Australia, Canada, Chile and Mexico (IP/C/W671, 27 November 2020).

[37] G20, "Leaders' Declaration, G20 Riyadh Summit", November 21-22, 2020, Paragraph 3. Available from https://www.consilium.europa.eu/media/46883/g20-riyadh-summit-leaders-declaration_en.pdf.

[38] G20, "Joint Statement – G20 Joint Finance and Health Ministers Meeting", 17 September 2020. Available from https://centerforvaccineethicsandpolicy.net/2020/09/20/covid-19-g20-health-ministers/.

On the other hand, proponents of the waiver argued that the waiver was necessary to facilitate rapid and equitable access to COVID-19-related health technologies by removing IP barriers to decentralization of their manufacturing.[39] A letter to the USTR, signed by many prominent scholars – including Graham Dutfield, Srividhya Ragavan, and Ana Santos Rutschman, stated that 'patents protecting pharmaceuticals remain an important barrier although a vast spectrum of medical products required to deal with the pandemic such as diagnostics, therapeutics, vaccines are protected as private property using other forms of intellectual property as well'.[40]

To downplay the impact of IP protections on access, opponents of the waiver argued that the factors limiting supply and access are a lack of adequate public healthcare infrastructure, trade restrictions, regulatory barriers, and limitations on logistics, transportation, and storage.[41] Historically, patentee corporations have exaggerated the challenge of logistics and infrastructure in poorer countries. In 2000, when access to HIV/AIDS treatment emerged as a global issue, patentee corporations claimed that inadequate public healthcare infrastructure was the main challenge. It was a failed attempt to divert the focus from the real issue of affordability of patented treatments with a price tag of more than USD 10,000 per patient per year. The prices dropped to USD 61 per patient per year when generic versions of HIV/AIDS treatments were introduced into the market.[42]

If IP is irrelevant, why do patentee corporations strongly object to a temporary waiver of TRIPS requirements? The pharmaceutical industry's vigorous opposition to the waiver suggests that they view it as a threat to their control over the manufacturing and dissemination of COVID-19 vaccines, therapeutics, and diagnostics. A patent landscape report of the World Intellectual Property Organization (WIPO) found that by the end of September 2021, there were '5,293 patent filings on technologies related to COVID-19 in general, including 1,465 patent filings about therapeutics and 417 about vaccine development'.[43] On one hand, pharmaceutical corporations were actively seeking IP protections to fortify their monopoly control while on the other hand, they argued that IP is not a barrier.

Another related argument against the waiver was that it would cause a strain on highly specialised raw materials and ingredients needed to manufacture COVID-19 vaccines. Pfizer CEO Albert Bourla raised a concern that the waiver 'would set off a worldwide race for raw materials that threatens the safe and efficient manufacturing of Covid shots'.[44] A report by the Center for Strategic and International Studies, released in November 2021, explained that 'waiving IP protections would not lead to the manufacture of a single additional dose of a vaccine. One key reason is that there is currently no capacity to make more; production

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[39] WTO TRIPS Council, Response to Questions on Intellectual Property Challenges Experienced by Members in relation to COVID-19 in Document IP/C/W/671: Communication from Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, Venezuela and Zimbabwe (IP/C/W673, 15 January 2021).
[40] Letter sent to the Honorable Ambassador Katherine C. Tai, United States Trade Representative, "Re: United States Facilitation of the TRIPS Waiver", 15 May 2021 (letter's copy with author), p. 2.
[41] Information Technology & Innovation Foundation, "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", Post-Hearing Comments of Stephen Ezell Before the U.S. International Trade Commission, Washington, D.C, FR Doc. 2023-02466 (2023). See more at Aldent F. Abbott and Christine McDanial, "A WTO Trips Agreement Waiver To Promote The Dissemination of COVID-19 Diagnostics And Therapeutics Is Unneeded And Would Impose Harm", U.S International Trade Commission fact finding investigation, Covid 19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities (Inv. No. 332-596).
[42] Third World Network, "RE: Post hearing Brief by Third World Network - Investigation No. 332-596" (12 April 2023), p. 7.
[43] World Intellectual Property Organization, "Patent Landscape Report: COVID-19-related vaccines and therapeutics" (2022), p. 5.
[44] Kevin Breuninger, "Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues", *CNBC* (May 7, 2021). Available from https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html.

facilities are running at full tilt, and the supply of key ingredients in the manufacturing process has already been fully tapped'.[45]

On one hand, patentee corporations warned that the waiver would slow down production because of competition for raw materials while on the other hand, they claimed that they could produce enough vaccines for the entire world's population if they had control over production. It clearly means that there were enough raw materials and ingredients. The real issue for patentee corporations was to find excuses to preserve their monopoly control over production in order to maximise their profits. It is unfortunate that maintaining this absolute control has become a goal unto itself.

B. Voluntary Licensing and Existing Flexibilities are Sufficient

One of the key arguments of opponents was that the waiver was wholly unnecessary because the goals of global collaboration and manufacturing at scale could be achieved with voluntary licensing agreements.[46] Opponents of the waiver asserted that 'life-sciences innovators extensively voluntarily licensed IPRs to produce COVID-19 vaccines and therapeutics'.[47] The Biotechnology Innovation Organization (BIO) argued that the voluntary collaborative approach of innovators to share their knowledge with manufacturing partners was the best way to expand access to COVID-19 vaccines and treatments.[48] There are a handful of examples to support these assertions. Oxford/AstraZeneca negotiated a voluntary licensing agreement with the Serum Institute of India. Likewise, Johnson & Johnson voluntarily negotiated a contract with Aspen Pharmacare in South Africa.[49]

The impact of voluntary licensing for equitable access is not global or universal. Countries or regions excluded from voluntary licensing agreements are not able to benefit. As noted by Maybarduk, 'voluntary licenses typically contain geographic restrictions, resulting in market fragmentation and gaps in access, particularly for upper middle-income countries'.[50] For instance, Pfizer's voluntary licensing agreement with the Medicines Patent Pool (MPP) in relation to Paxlovid does not include most of Latin America.[51] According to Médecins Sans Frontières (MSF), Latin American countries will face challenges in accessing Paxlovid until at least 2041 because Pfizer has filed patents in all of these countries.[52] Another example is MPP's license for molnupiravir which excludes supply to almost half of the global population.[53]

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[45] Andrei Iancu , Gary Locke , and David J. Kappos, "The Shot Heard around the World", *Center for Strategic and International Studies* (November 17, 2021). Available from https://www.csis.org/analysis/shot-heard-around-world.
[46] The TRIPS Agreement does not explicitly regulate voluntary licensing.
[47] [47] Information Technology & Innovation Foundation, "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", Post-Hearing Comments of Stephen Ezell Before the U.S. International Trade Commission, Washington, D.C, FR Doc. 2023-02466 (2023), p. 6.
[48] Biotechnology Innovation Organization, "Re: COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", ITC Investigation No. 332-596, Post-hearing Supplementary Written Submission", Letter to Katherine M. Hiner, Acting Secretary to the U.S. International Trade Commission (May 5, 2023), p. 6.
[49] Brook K. Baker and Rachel D. Thrasher, "From Business as Usual to Health for the Future: Challenging the Intellectual Property Regime to Address COVID-19 and Future Pandemics", *Boston University International Law Journal,* Vol. 41, No. 1 (2023)..
[50] Public Citizen, "RE: Written Comments for Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics and Flexibilities Under the TRIPS Agreement" (May 5, 2023), p. 1.
[51] Ibid., 15.
[52] MSF Access campaign, "Latin America: How patents and licensing hinder access to COVID-19 treatments", (March 8, 2022). Available from https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments.
[53] Third World Network, "RE: Prehearing Brief by Third World Network - Investigation No. 332-596" (March 20, 2023), p. 16.

The limitations of voluntary licensing have also been explicitly recognized in the United States International Trade Commission (USITC) on 'COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities'. The report states that:

> … the substantial control maintained by the licensor can give rise to disadvantages in terms of access to medicine in LICs, LMICs, and UMICs. First, the licensor determines what IP rights and products are made available to licensees. There is no assurance that the most successful or most needed treatments will be made available for licensing. Second, licensors control the countries to which licensees may export their products and the countries that may obtain access through imports from licensees. … Third, BLAs (voluntary licenses) generally are not published; this means complete information about the terms and conditions of the agreements is not available. This lack of transparency makes it difficult for the public to assess competing claims about the advantages and limitations of the agreements' terms and conditions.[54]

The USITC report also mentions that in addition to the geographical limitations of MPP licenses, some of these licenses also contain conditions that sub-licensees must have WHO prequalification. Meeting the standards for WHO prequalification as well as the high application cost for the same is challenging for some manufacturers, '… particularly small manufacturers in LMICs'.[55] Similar challenges are noted with respect to MPP sub-licenses that require sub-licensees to obtain regulatory approval from a regulatory agency, which can significantly delay the access to the product after the voluntary license is granted.[56]

The restrictive approach of voluntary licensing disincentivises generic manufacturers by limiting potential markets and not enabling them to achieve economies of scale. Moreover, even if a voluntary license exists for a country or region, there are delays in supply because it normally takes a substantial amount of time for a licensee to comply with all terms and conditions of the license.[57]

Technology-holding corporations are able to dictate terms as they are empowered to control their bilateral voluntary licensing deals with manufacturing partners. They tend to impose restrictive terms and conditions to keep their control over production and supply.[58] For instance, the Oxford/AstraZeneca deal does not allow the Serum Institute of India to independently manufacture and supply COVID-19 vaccines across the globe. The technology owner keeps control because 'such contracts do not constitute conventional licensing agreements under which a licensee can decide how and when to manufacture and distribute the licensed products'.[59]

Technology-holding corporations enjoy absolute discretion to pick and choose their manufacturing partners. Requests made by Teva from Israel, Getz Pharma from Pakistan, Biolyse from Canada, and Incepta from Bangladesh to obtain licenses for the production of COVID-19 vaccines were either ignored or dismissed.[60] The WHO's C-TAP initiative could address some of these issues by providing a platform for transparent and non-exclusive global voluntary licensing, but patentee corporations rejected that initiative. Overreliance on bilateral

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[54] United States International Trade Commission, *COVID-19 Diagnostics and Therapeutics: Supply, Demand and TRIPS Agreement Flexibilities,* (Washington, D.C., October 2023), p.178. Available from https://www.usitc.gov/publications/332/pub5469.pdf.
[55] Ibid., p. 255.
[56] Ibid., p. 187.
[57] Third World Network, "RE: Post hearing Brief by Third World Network - Investigation No. 332-596" (12 April 2023), p. 6.
[58] Civil Society Organizations' Letter to WTO and WHO Directors-General and WTO Members (April 13, 2021).
[59] Carlos M. Correa, "Expanding the production of COVID-19 vaccines to reach developing countries: Lift the barriers to fight the pandemic in the Global South", Policy Brief, No. 92 (Geneva, South Centre, 2021), p. 2. Available from https://www.southcentre.int/policy-brief-92-april-2021/.
[60] Ibid.

voluntary licensing is not a superior policy choice to facilitate expanded access to COVID-19 vaccines, treatments and diagnostics.

Another key argument against the waiver was that the TRIPS Agreement has sufficient flexibilities to deal with a health emergency. Though it is hard to argue that the flexibilities contained in the TRIPS Agreement are sufficient given the scale and urgency of the COVID-19 health emergency, opponents of the proposal asserted that the waiver was needless because the TRIPS Agreement already allows for compulsory licensing.

Without using the term 'compulsory licensing', Article 31 of the TRIPS Agreement stipulates a set of conditions for the grant of a non-voluntary license or 'other use without authorization of the right holder'.[61] The effectiveness of this mechanism is undermined by the product-by-product and country-by-country requirements. Coordinating compulsory licenses across countries for COVID-19 vaccines with complex global supply chains is not a feasible policy option when speedy action is most required. The implications of using the compulsory licensing flexibility are summarised as under:

> The negotiation is complex, costly, and often inefficient because a) it needs a previous negotiation with the patent holder as a pre-condition and for the establishment of adequate remuneration; b) they are case-by-case and product-by-product; c) a compulsory license applies only to technologies already patented and not those in the pipeline; d) the technical and institutional inability of many countries to deal with compulsory license, especially when it comes to forms of protection other than patents; e) they mainly serve to supply the domestic market and the case of issuing licenses to supply countries without productive capacity is even more complex and costly.[62]

A compulsory license under Article 31 can be issued over a patent, but does not cover other forms of IPRs. Compulsory licensing has limitations if a product or technology is protected under multiple forms of IPRs. There are problems in using compulsory licensing even if a technology is protected under patents only. There can be multiple patents owned by multiple patentees in multiple countries. As noted by MSF:

> [W]hen it comes to products like vaccines, patents may exist at many stages of the development, production and delivery process. The COVID-19 vaccine portfolio involves numerous novel platforms and technologies, such as mRNA. Patents may cover specific strains, adjuvants, antigen production and other such elements. These background patents are frequently owned by different entities in different countries, adding great complexity, as well as potential legal risks, even where compulsory licensing tools are available.[63]

Navigating through a complex patent landscape can be cumbersome and time-consuming. It involves undertaking prior art searches and other due diligence. The effective use of compulsory licensing for COVID-19 vaccines is undermined by several drawbacks that include:

> [T]he lack of detailed knowledge about the web of patents which may be applicable to any vaccine, inadequate information about manufacturing or regulatory processes, the terms of cross-licensing (because license agreements are not disclosed to the

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[61] TRIPS Agreement, Art. 31.
[62] Henrique Zeferino De Menezes, *The TRIPS waiver proposal: an urgent measure to expand access to the COVID-19 vaccines*, Research Paper, No. (Geneva, South Centre, 2021), p. 9. Available from https://www.southcentre.int/research-paper-129-march-2021/.
[63] Doctors Without Borders, "WTO COVID-19 TRIPS Waiver Doctors Without Borders Canada Briefing Note" (9 March 2021), p. 3.

public) and limited knowledge about the contents of the patent application which may be relevant for a CL application as many are still unpublished by the relevant patent offices.[64]

The compulsory licensing mechanism is loaded with restrictions and challenges and does not provide a streamlined route to promote access. This mechanism is too slow to be effective in an emergency and does not provide a global solution because patents are territorial in nature and compulsory licenses are granted under national laws within each country.

Less affluent countries are generally reluctant to grant compulsory licenses because of potential backlash from patentee corporations, the U.S., the EU, and other high-income countries.[65] There are fears of trade sanctions and loss of foreign direct investment (FDI) if the process for issuing a compulsory license is invoked by a poorer country.[66] Even during the pandemic, the 2020 Special 301 Report of the USTR criticised countries for using, threatening to use, or encouraging others to use compulsory licensing.[67] Pfizer aggressively opposed the compulsory licensing application for Paxlovid in the Dominican Republic by issuing a human rights defence.[68]

Export-oriented compulsory licensing under Article 31bis of the TRIPS Agreement is even more problematic.[69] Canada's Access to Medicines Regime (CAMR) implements Article 31bis. Understanding CAMR requires legal training as this complex legislation contains 19 sections and 100 clauses and sub-clauses. Tanzania's High Commissioner to Canada noted in relation to using export-oriented compulsory licensing under Article 31bis, 'It's not that we don't want to do it. It's just that we haven't because … all the bureaucratic, administrative, and legal requirements take a lot of time … The system is too complicated'.[70]

The Bolivia-Biolyse case highlights the impracticability of export-oriented compulsory licensing. In February 2021, Bolivia notified the WTO of its intent to purchase COVID-19 vaccines from a Canadian generic manufacturer Biolyse Pharma by using the WTO's export-oriented compulsory licensing mechanism as set out under Article 31bis of the TRIPS Agreement.[71] Since March 2021 Biolyse Pharma has been trying to initiate the process without gaining any traction so far. Relying on unworkable existing flexibilities to expand access to essential products in times of crisis has not proven to be a viable and effective approach.

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[64] Siva Thambisetty *et al.*, "The TRIPS Intellectual Property Waiver Proposal: creating the right incentives in patent law and politics to end the COVID-19 pandemic", LSE Legal Studies Working Paper, No. 6 (2021).
[65] Muhammad Zaheer Abbas and Shamreeza Riaz, "TRIPS Flexibilities: Implementation Gaps between Theory and Practice", *Nordic Journal of Commercial Laws* Vol. 1 (2013), pp. 1-25.
[66] Ibid.
[67] Office of the United States Trade Representative, *Special 301 Report* (April 2020). Available from https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf.
[68] Ed Silverman, "Pfizer faces criticism for arguing that intellectual property for its Covid-19 pill is a human right", *STAT News* (April 20, 2022). Available from https://www.statnews.com/pharmalot/2022/04/20/patent-pfizer-covid19-patent-paxlovid-dominican-republic/.
[69] Muhammad Zaheer Abbas and Shamreeza Riaz, "WTO 'Paragraph 6' System for Affordable Access to Medicines: Relief or Regulatory Ritualism?", *Journal of World Intellectual Property,* Vol. 21, Nos. 1–2 (2018), pp. 32–51.
[70] MSF Access Campaign, "Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable" (August 30, 2006). Available from https://msfaccess.org/neither-expeditious-nor-solution-wto-august-30th-decision-unworkable.
[71] Muhammad Zaheer Abbas, *Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case*, Research Paper, No. 136 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/research-paper-136-september-2021/.

C. Threat to Innovation

Opponents of the waiver asserted that circumvention of IP protections would undermine innovation by disincentivising future R&D activity.[72] Some stakeholders framed the waiver as 'international disrespect for IP' and 'IP theft' that would devastate the future of medical science by undercutting biopharmaceutical innovation.[73] On one hand, opponents of the waiver argued that the waiver would not make any difference as IP is not a barrier while on the other hand, they asserted that the waiver would devastate their future operation.

There is no credible evidence to support the assertion that strengthening patent protection increases innovation.[74] On the contrary, there is evidence to suggest that patents can sometimes discourage innovation.[75] Patents held by one party can impede innovation work because of costly and time-consuming patent disputes that hinder or delay important medical advances. This was illustrated by recent patent disputes over mRNA technology.[76]

The rhetoric of threat to innovation does not make much sense in the extraordinary context of COVID-19 vaccines because of two key factors. The first factor is public sector financing and subsidies to support the development of vaccines and treatments. In 2020, the US government not only assisted seven potential manufacturers of COVID-19 vaccines and treatments with funding of more than USD 19 billion through the Biomedical Advanced Research and Development Authority (BARDA) but also provided them with tax relief.[77] Several vaccines relied on technologies developed at universities (such as the University of Pennsylvania and Oxford University) and public institutions (such as the US National Institutes of Health).[78] The development of mRNA technology involved billions in government funding for R&D over decades.[79]

The second factor is advance market orders to mitigate financial risks. In addition to receiving direct public funding for R&D, patentee corporations minimised their investment risk by signing advance purchase agreements with national governments in many countries as well as with the Global Alliance for Vaccines and Immunizations (GAVI) and the Coalition for Epidemic Preparedness Innovations (CEPI).[80] Even before their vaccines and treatments met standards of safety and effectiveness, they had a guaranteed, rather desperately waiting, market for their products. This market is literally the entire world. Profitability is not an issue because of the long-term need for global supply of COVID-19 vaccines. Vaccine manufacturers have already

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[72] Peter J. Pitts, Robert Popovian, and Wayne Winegarden, "Waiving COVID-19 Vaccine Patents: A Bad Idea and a Dangerous Precedent", *Journal of Commercial Biotechnology,* Vol. 26, No. 2 (2021). See more at Biotechnology Innovation Organization, "Re: COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", ITC Investigation No. 332-596, Post-hearing Supplementary Written Submission", Letter to Katherine M. Hiner, Acting Secretary to the U.S. International Trade Commission (May 5, 2023), p. 1..

[73] Citizens Against Government Waste, "Re: COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities (Inv. No. 332-596)", May 4, 2023, p. 2.

[74] Michele Boldrin and David K. Levine, "Economic and Game Theory Against Intellectual Monopoly" (January 22, 2007). Available from http://www.dklevine.com/general/intellectual/againstnew.htm.

[75] Petra Moser, "Patents and innovation in economic history", *Annual Review of Economics,* Vol. 8 (2016), pp. 241-258.

[76] Guillermo Aquino-Jarquin, "The patent dispute over the breakthrough mRNA technology", *Frontiers in Bioengineering and Biotechnology,* Vol. 10 (2022).

[77] Mrityunjay Kumar, and Nalin Bharti, "Why patent waiver for Covid-19 vaccines and pharmaceuticals?", *The Journal of World Intellectual Property* (2023).

[78] Siva Thambisetty *et al.*, "The TRIPS Intellectual Property Waiver Proposal: creating the right incentives in patent law and politics to end the COVID-19 pandemic", LSE Legal Studies Working Paper, No. 6 (2021).

[79] Lori Wallach, "U.S. International Trade Commission Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", *Rethink Trade, American Economic Liberties Project* (2023), p. 5.

[80] Olga Gurgula, "Compulsory licensing vs. the IP waiver: what is the best way to end the COVID-19 pandemic?", Policy Brief, No. 104 (Geneva, South Centre, 2021), p. 6. Available from https://www.southcentre.int/policy-brief-104-october-2021/.

made record-breaking bumper profits. The argument that investments in R&D will not be recouped is baseless.

IV. THE MINISTERIAL DECISION WATERED DOWN THE ORIGINAL PROPOSAL

On June 17, 2022, the 12th WTO Ministerial Conference adopted a Ministerial Decision on the TRIPS Agreement.[81] Negotiations to reach this Decision for a limited 5-year waiver took almost 20 months. In the meantime, COVID-19 claimed millions of lives despite the existence of vaccines and treatments and caused massive financial harm. The inequitable rollout of vaccines and treatments allowed COVID-19 to disproportionately impact the lives and livelihoods of people while the waiver debate was stalled at the WTO. Proponents of the waiver tried to frame 'shared urgency' while opponents of the waiver worked diligently to frame 'technical complexity' and the need for continued debate on the proposal.[82] Opponents of the waiver kept on repeating stonewalling questions which were already formally answered in various written submissions.

The Decision has a very limited scope confined to COVID-19 vaccines specifically. The outcome of lengthy negotiations is more aligned with the positions of wealthy countries. Supporting the EU's position, the Decision states that compulsory licensing is the ultimate solution. Apart from reaffirming and clarifying what is already allowed by the TRIPS Agreement, the prominent feature of the Decision is that it waives export restrictions in Article 31(f) of the TRIPS Agreement to allow the export of COVID-19 vaccines to eligible countries.

What was achieved after a lengthy debate is only a fragment of what was originally proposed. The Decision hardly resembles the original waiver proposal in terms of its scope and effectiveness. As noted by James Love, the 'original proposal tabled by India and South Africa in 2020 as IP/C/W/669 would have waived 40 articles of the WTO Trade-Related Agreement on Intellectual Property Rights' while the 'compromise only waives a single 20-word paragraph in one article: the one dealing with exports under a non-voluntary authorization'.[83]

Footnote 1 further narrows down the scope of the Decision. It first states that 'all developing country Members' are 'eligible Members', but then goes on to provide that: 'Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision'.[84]

Because of its excessively narrow scope, the Decision has been condemned by more than 300 civil society organizations.[85] Health activists from South Africa view the Decision as 'a massive step back' and a 'slap in the face'.[86] It is clear from the below statement of the Indian commerce minister Piyush Goyal that India views the outcome as favouring the status quo position:

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[81] World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/W/15/Rev.2 (17 June 2022). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True.
[82] Sara E. Fischer *et al.,* "Intellectual Property and the Politics of Public Good in COVID-19: Framing Law, Institutions, and Ideas during TRIPS Waiver Negotiations at the WTO", *Journal of Health Politics, Policy and Law,* Vol. 49, No. 1 (2024).
[83] James Love, "The Proposed TRIPS Compromise Risks Setting Several Bad Precedents", Bill of Health, April 7, 2022. Available from https://blog.petrieflom.law.harvard.edu/2022/04/07/trips-compromise-bad-precedents/.
[84] World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/W/15/Rev.2 (17 June 2022). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True.https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True
[85] Brook K. Baker and Rachel D. Thrasher, "From Business as Usual to Health for the Future: Challenging the Intellectual Property Regime to Address COVID-19 and Future Pandemics", *Boston University International Law Journal,* Vol. 41, No. 1 (2023)..
[86] Yousuf Vawda, Fatima Hassan and Tian Johnson, "New WTO deal is a slap in the face for poorer countries", *News 24*, 18 June 2022. Available from https://www.news24.com/fin24/opinion/opinion-new-wto-deal-is-a-slap-in-the-face-for-poorer-countries-20220618.

> My own sense right now with the number of meetings that are being held and with the number of green room engagements, is that the effort they are putting in, is more to showcase to the world that 'Oh! We found a wonderful solution, we agreed with 80 countries or more to give a TRIPS waiver'. Now the common man does not understand that this is nothing near a TRIPS waiver, they do not understand that this is a little elevation from compulsory licensing.[87]

What started with calls for global solidarity and health equity ended with a negligible outcome controlled by developed countries and acceptable to patentee corporations. The Decision was not only limited but also partial because no agreement could be reached in relation to COVID-19 diagnostics and therapeutics after spending nearly two years on negotiations in the middle of the pandemic. The postponement of the decision to extend the waiver to COVID-19 diagnostics and therapeutics reflects poorly on WTO's ability to deal with public interest matters deserving urgent attention.

[87] PIB Delhi, "Statement by Shri Piyush Goyal during the WTO 12th Ministerial Conference at the meeting with co-sponsors of TRIPS Waiver", Ministry of Commerce and Industry, India. Available from https://pib.gov.in/PressReleasePage.aspx?PRID=1834066.

V. Deviation from WTO Rules Relating to Waiver from Obligations under TRIPS

The protracted negotiations on the TRIPS waiver proposal and the consequent delay in the adoption of the final Decision after almost 20 months also raise systemic concerns about the divergence between rules and practices in the WTO regarding the process of granting a waiver.

Article IX(3) of the Marrakesh Agreement states that the Ministerial Conference may decide to waive such obligations under the covered agreements, in exceptional circumstances. What constitutes exceptional circumstances are not explained in the legal text. Thus, it is at the discretion of the Ministerial Conference to determine if an exceptional circumstance exists, which would require the waiver of certain obligations under a covered agreement.

Moreover, while generally decision-making is to be according to consensus as specified in Article IX(1), decision on a waiver of an obligation under a covered agreement can be taken without a consensus if three-fourths of WTO Members agree to a waiver. This is clear from the fact that while Article IX(3)(a) states that a waiver of an obligation under the Marrakesh Agreement shall be taken by consensus, Article IX(3)(b) does not specifically require a decision by consensus for waiver of obligations under a covered agreement. This means that a decision on waiver of an obligation under a covered agreement can be taken by a three-fourth majority. Thus, Article IX(3) is designed to ensure that lack of consensus does not block the grant of a waiver if a sufficient majority of WTO Members agree to the waiver of an obligation under a covered agreement.

The Marrakesh Agreement also lays down the period within which a decision on a waiver must be taken. In respect of waivers of any obligation under a covered agreement, the respective WTO body relating to that agreement is required to consider a request for a waiver and report to the Ministerial Conference within a period not exceeding 90 days from the date of the request. There is no requirement of a consensus in the relevant body in respect of a requested waiver. The relevant body is only required to report to the Ministerial Conference on the views expressed by members upon consideration of the waiver request.

It should also be noted that the WTO body responsible for the covered agreement in relation to which a waiver request is made is not required or expected to decide on the waiver. It is only required to *consider* the request and *report* to the Ministerial Conference. When the Ministerial Conference is not in session, such report is to be given to the General Council performing the functions of the Ministerial Conference. The decision on whether to grant the waiver is to be taken by the Ministerial Conference (or the General Council exercising the functions of the Ministerial Conference). This decision need not be based on the recommendation of the relevant WTO body.

Thus, in a legal sense, the Ministerial Conference can adopt by a three-fourth majority a decision granting a waiver from certain obligations under a covered agreement, provided that the waiver request has been submitted for consideration for a period not exceeding 90 days, in the relevant WTO body. After a waiver request has been considered in the relevant WTO body within the stipulated 90-day period, the Ministerial Conference must take a decision immediately, either by consensus or if there is no consensus, by a majority vote. It is not for the members to request a decision by vote. The rules implicitly require the Ministerial Conference to decide by vote and not delay the decision to allow for the emergence of a consensus in the future by remitting the request back to the relevant WTO body.

However, the TRIPS waiver request was not decided upon as per the procedure established under WTO law. The waiver request was considered in the TRIPS Council, which submitted a report to the General Council requesting further consideration of the matter, which was agreed to by the General Council. This led to an extended discussion in the TRIPS Council that provided no concrete outcome but effectively delayed decision-making. The practice of WTO Members in terms of how the waiver request was considered was contrary to both the letter and spirit of the Marrakesh Agreement.

In its first report to the General Council on the outcome of the consideration of the waiver proposal, the TRIPS Council pointed to the existence of divergent views between developed and developed countries and requested the General Council to grant further time to consider the proposal. While the General Council agreed to this request, this was the first breach of the procedure under Article 9 of the Marrakesh Agreement concerning decision-making on a waiver under a covered agreement. After the proposal had been considered in the TRIPS Council and 90 days had expired since the proposal had been submitted, Article IX of the Marrakesh Agreement requires a decision to be taken by the Ministerial Conference, or the General Council when the Ministerial Conference is not in session. If there is a lack of consensus within this period, Article IX makes it mandatory that a decision be taken by a majority vote. Article IX(3)(a) clearly states that, 'If consensus is not reached during the time-period, *any decision to grant a waiver shall be taken by three fourths of the Members*' (emphasis added).

Instead of taking a decision to respond to an emergency for which the waiver was proposed, although the Marrakesh Agreement had sufficiently empowered the Ministerial Conference and the General Council to take such a decision without seeking consensus indefinitely, the practise of the WTO Members was to the contrary. This enabled WTO Members that were opposed to or questioned the necessity of the TRIPS waiver proposal to procrastinate the discussions in the TRIPS Council.

Hence, it will be imperative that the decision-making process relating to a waiver under a covered agreement is further streamlined to eliminate discretionary action on the part of WTO Members that could delay decision-making on a waiver proposal on the pretext of building consensus. This could be undertaken as part of the commitment made by the twelfth Ministerial Conference to reform the functioning of the WTO in all its aspects. As part of these reforms, the WTO Members should consider improving the decision-making rules relating to a waiver to prevent further extension of the time for consideration of the proposal in the relevant Council.

VI. Extending the Decision to COVID-19 Therapeutics and Diagnostics

It is stated in Paragraph 8 of the Decision that: 'No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics'.[88] Members had until December 17, 2022, to make this decision. However, a consensus could not be reached within the stipulated timeframe and the General Council extended the deadline.

On December 16, 2022, the USTR requested the USITC to undertake an investigation concerning the value of extending the Decision to COVID-19 diagnostics and therapeutics.[89] It is beyond understanding why the USTR did not request this investigation earlier as it had been considering the waiver proposal since October 2020 and the outstanding issue of diagnostics and therapeutics since June 2022. Though the USITC has undertaken an important task, the deliberations of a single institution of a single Member should not unduly influence a decision of global significance.

The USITC report published in October 2023 concluded that, 'Determining a definitive scope of what products are covered by the terms "diagnostics" and "therapeutics" as they pertain to COVID-19 and what constitutes relevant COVID-19 diagnostics and therapeutics covered by patents is complicated and subject to interpretation'.[90] On the future need for COVID-19 diagnostics and therapeutics, the report states that such determination would depend on the assumption of a number of factors.[91] Indeed, there is significant variance in the estimates of the need for COVID-19 therapeutics and vaccines summarized from the various sources referenced in the report.[92] The report also points to a vast scope of patenting for COVID-19 diagnostics and therapeutics.[93]

Diagnostics and therapeutics are an essential part of the WHO's COVID-19 response strategy.[94] On January 30, 2023, the 14th meeting of the WHO International Health Regulations (IHR) Emergency Committee recommended that Members must improve access to COVID-19 diagnostics and therapeutics for their populations.[95] In this meeting, the Director General of WHO expressed a concern that 'the COVID-19 response remains hobbled in too many countries unable to provide these tools [vaccines, diagnostics, and therapeutics] to the populations most in need'.[96] He previously said in December 2022 that 'access to diagnostics and life-saving treatments for COVID-19 remains unacceptably unaffordable and unequal'.[97]

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[88] World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/W/15/Rev.2 (17 June 2022). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True.

[89] Office of the United States Trade Representative, "Ambassador Tai Requests USITC Investigation of COVID-19 Diagnostics and Therapeutics" (December 16, 2022). Available from https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/december/ambassador-tai-requests-usitc-investigation-covid-19-diagnostics-and-therapeutics.

[90] USITC, *supra* note 54, p.15.

[91] Ibid., p. 228.

[92] Ibid.

[93] Ibid., pp. 60-5.

[94] World Health Organization, "Strategic preparedness, readiness and response plan to end the global COVID-19 emergency in 2022", March 30, 2022. Available from https://www.who.int/publications/i/item/WHO-WHE-SPP-2022.1.

[95] World Health Organization, "Statement on the fourteenth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic" (January 30, 2023). Available from https://www.who.int/news/item/30-01-2023-statement-on-the-fourteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic.

[96] Ibid.

[97] World Health Organization, "WHO Director-General's opening remarks at the WHO, WIPO, WTO Joint Technical Symposium on the COVID-19 Pandemic: Response, preparedness, resilience", (16 December 2022).

This demonstrates that there is a need to immediately and unconditionally extend the Decision to these tools.

There is no legal barrier in extending the Decision beyond vaccines to cover diagnostics and therapeutics. Rather it would be a proportionate legal measure to facilitate global equitable access by enabling the freedom to operate for other corporations to export diagnostics and therapeutics to developing countries without fearing patent litigation. It will also provide legal certainty to WTO Members that they would not face complaints by other Members under the WTO rules. This section considers the validity of arguments against extending the Decision to COVID-19 diagnostics and therapeutics.

A. Low Demand for Diagnostics and Therapeutics

The pharmaceutical industry asserts that access is not an issue. The demand for COVID-19 diagnostics and therapeutics is low as measured by the volume of orders. The counterargument is that the demand for COVID-19 diagnostics and therapeutics has been artificially suppressed. The prices of diagnostics and therapeutics are unaffordable for low- and middle-income countries. The cost of these tools and the lack of affordable supply options are the key reasons for low demand.[98] As illustrated by Wallach, 'the lack of formal demand measured in orders is a measure of lack of affordable supply, not lack of need'.[99] Similarly, Baker noted that 'the assessment of quantities needed should focus on actual need not expressed market demand which has been negatively impacted by high prices and early supply constraints'.[100]

The cost of treatments affects their real-world demand. A senior health official in South Africa said that the government did not intend to buy Paxlovid for public sector patients because of its 'extremely expensive' price.[101] Dr Marco Tovar, Medical Director at Socios en Salud (Partners in Health) said, 'so long as the [COVID-19] medicines are expensive, they are not going to include them (in the treatment regimen)'.[102] Despite the global need for WHO-endorsed COVID-19 therapies, the high cost disproportionately favoured high-income countries. For instance, the first six months of Paxlovid supply was committed to high-income countries, especially the US.[103]

Most of the existing treatments for COVID-19 are widely patented.[104] Generic competition for the existing COVID-19 therapeutics is constrained by several patents granted in developing

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Available from https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-who--wipo--wto-joint-technical-symposium-on-the-covid-19-pandemic--response--preparedness--resilience---16-december-2022.

[98] Allana Kembabazi, "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, Before the United States International Trade Commission Investigation No. 332-596", *Initiative for Social and Economic Rights* (March 29, 2023), p. 3.

[99] Lori Wallach, "U.S. International Trade Commission Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", *Rethink Trade, American Economic Liberties Project* (2023), p. 3..

[100] Brook K. Baker, "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", For U.S. International Trade Commission Investigation No. 332-596 (March 15, 2023), p. 1.

[101] Reuters, "S.Africa not planning to buy Pfizer's COVID pill for public sector", *Reuters* (April 29, 2022). Available from https://finance.yahoo.com/news/africa-not-planning-buy-pfizers-073311851.html?guccounter=1.

[102] Dr Fifa A Rahman *et al.*, *Mapping Access Gaps in COVID-19: Results from 14 Countries and Territories*, Matahari Global Solutions (August 2022). Available from https://app.box.com/s/ewdjytgt0tk0fdgmqnlm4l30hmdyevxw, p. 11.

[103] Brook K. Baker, "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", For U.S. International Trade Commission Investigation No. 332-596 (March 15, 2023), p. 3.

[104] See, Medicines Patent Pool, "MedsPaL". Available from https://www.medspal.org/?disease_area%5B%5D=COVID-19&disease_area%5B%5D=COVID-19+(drug+candidate)&page=1.

countries with the capacity to manufacture generic drugs.[105] There are global shortages of treatments, such as Paxlovid.[106] As noted by Baker in March 2023, 'Most people in most developing countries still do not have timely access to therapeutics and diagnostics primarily due to high prices, shortages when demand is high, and the commercial disinterest of major diagnostics and biopharmaceutical companies to make their tests and medicines available in many developing country markets'.[107]

The price of existing COVID-19 diagnostics is much higher than the cost of production. As noted by Baker, 'the estimated cost of production for Cepheid's GeneXpert COVID-19 diagnostic test is just US$3-5 per test, yet Cepheid is charging US$14.90 in developing countries, at least 3 times the estimated cost of production'.[108] It is important to note here that Cepheid received at least USD 252 million in public and philanthropic funding to develop GeneXpert.[109]

The unavailability of diagnostics also contributes to the low demand for therapeutics. Without access to diagnostics, infections go unreported. According to the WHO's estimate, six out of seven COVID-19 infections are not detected in Africa.[110] According to the United Nations, at the end of 2022, there were 468,767 COVID-19 tests per million population in developing countries compared to 3,340,753 COVID-19 tests per million population in developed countries.[111] If infections go unreported, the demand for therapeutics does not reflect the actual population-based need because there is no accurate estimation of infection level in a population.[112]

The low-demand argument is not valid in relation to many new diagnostics and treatments that are currently under development and yet to be launched in the market. As noted by the US Food and Drug Administration (FDA), 'many more therapies are being tested in clinical trials to evaluate whether they are safe and effective in combating COVID-19'.[113] According to the BIO COVID-19 Therapeutic Development Tracker, 35 treatments are in the late-stage clinical development phase while 55 treatments are in the preclinical phase as of September 2023.[114]

B. Adverse Effect on Sales and Profits

One of the arguments against extending the Decision to diagnostics and therapeutics is that it would cause huge revenue losses to patent owners. Patentee corporations are trying to

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[105] Ibid.
[106] Siva Thambisetty *et al.*, "The COVID-19 TRIPS Waiver Process in Critical Review: An Appraisal of the WTO DG Text (IP/C/W/688) and Recommendations for Minimum Modifications", SSRN (2022), p. 7. Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4124497. See more at Public Citizen, "RE: Written Comments for Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics and Flexibilities Under the TRIPS Agreement" (May 5, 2023), p. 1.
[107] Brook K. Baker, "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", For U.S. International Trade Commission Investigation No. 332-596 (March 15, 2023), p. 1.
[108] Ibid., p. 4.
[109] Dzintars Gotham *et al.*, "Public investments in the development of GeneXpert molecular diagnostic technology", *PLoS One,* Vol.16, No. 8 (2021). Available from https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0256883.
[110] World Health Organization, "Six in seven COVID-19 infections go undetected in Africa" (October 14, 2021). Available from https://www.afro.who.int/news/six-seven-covid-19-infections-go-undetected-africa.
[111] United Nations, "COVID-19 testing in LDCs – status report of 31 Dec 2022" (2022). Available from https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/LDC-testing-31-Dec-22.pdf.
[112] Public Citizen, "RE: Written Comments for Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics and Flexibilities Under the TRIPS Agreement" (May 5, 2023), p. 13..
[113] US Food and Drug Administration, "Know Your Treatment Options for COVID-19" (June 28, 2023). Available from https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19.
[114] Biotechnology Innovation Organization, "BIO COVID-19 Therapeutic Development Tracker".Available from https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker.

create an impression that the Decision has waived the entire TRIPS Agreement, and that their technologies will be given away in the absence of any protections. This is not the case given the extremely limited scope of the Decision which waives just one condition attached to compulsory licensing. Extending the Decision will improve access by making it easier to use compulsory licensing mechanism for exporting COVID-19 diagnostics and therapeutics to developing countries. Patent holders will be paid royalties under Article 31(h) of the TRIPS Agreement. Paragraph 3(d) of the Decision reaffirms payment of adequate remuneration. Wallach rightly noted that 'the reason for the pharmaceutical industry's unhinged response is that even something as modest as a right to export generics that the WTO already permits to be produced is viewed as a threat to industry's absolute monopoly control over access to medicines'.[115]

Extending the Decision to COVID-19 diagnostics and therapeutics will not adversely affect the profits of pharmaceutical companies in developed countries because of the narrow scope of the purpose-specific Decision which is confined to developing countries.[116] The sales and profits of patentee corporations in developed country markets will not be affected. To protect the market returns of patentee corporations in developed countries, the Decision provides an additional safeguard of anti-diversion measures. Paragraph 3(c) of the Decision restricts re-export of products manufactured and imported under the Decision: 'Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorization in accordance with this Decision, and diverted to their markets inconsistently with its provisions'.[117]

Moreover, extending the Decision will not affect innovation incentives because most COVID-19 treatments are not novel compounds developed as a result of significant R&D investments. They are based on existing compounds that treat a variety of conditions. WIPO's patent landscape report found that most COVID-19 therapeutics were repurposed for new uses.[118] Repurposed drugs for COVID-19 include Remdesivir, Tocilizumab, Itolizumab, Casirivimab/Imdevimab, Sarilumab, and Baricitinib.[119] These drugs, developed to treat other medical conditions, showed some positive effects on COVID-19 patients. Some other existing drugs may also be included in the prescription for COVID-19 patients. As noted by the US Food and Drug Administration (FDA), 'researchers are studying drugs that are already approved for other health conditions as possible treatments for COVID-19'. This repurposing of existing treatments arguably required minimal R&D costs.

Another related argument against extending the Decision is that the profits of patentee corporations will be affected because the therapeutics authorized for COVID-19 will be diverted to the treatment of other diseases.[120] The Decision can only be used for COVID-19.[121] As noted by Wallach, 'even if treatments have multiple uses, the TRIPS Decision text very

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[115] Lori Wallach, "U.S. International Trade Commission Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", *Rethink Trade, American Economic Liberties Project* (2023), p. 2.
[116] World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/W/15/Rev.2 (17 June 2022), para. 1. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True.
[117] World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/W/15/Rev.2 (17 June 2022), para. 3(c). Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True.
[118] World Intellectual Property Organization, "Patent Landscape Report: COVID-19-related vaccines and therapeutics" (2022), p. 7.""
[119] Mrityunjay Kumar, and Nalin Bharti, "Why patent waiver for Covid-19 vaccines and pharmaceuticals?", *The Journal of World Intellectual Property* (2023), p. 205.
[120] National Foreign Trade Council, "Investigation No. 332-596 – Covid 19 Diagnostics and Therapeutics: Supply, Demand, and Trips Agreement Flexibilities", Statement of The National Foreign Trade Council, p. 5.
[121] World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/W/15/Rev.2 (17 June 2022), para. 1. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True.

specifically applies only to COVID-19 uses. There is no possibility to use the Decision text or its prospective extension to treatments and tests to treat other diseases'.[122] Further, Article 31(c) of the TRIPS Agreement stipulates in relation to compulsory licensing that 'the scope and duration of such use shall be limited to the purpose for which it was authorized'.[123]

C. Safety Concerns

Patentee corporations argue that extending the Decision to COVID-19 diagnostics and therapeutics would endanger the safe and effective production of these tools. Safety concerns would erode public trust in treatments because of the possibility of counterfeit products or a lowering of quality and standards.

The claims about lowering quality and standards are all based on mere speculations. In different parts of the world, there are many facilities capable of manufacturing safe and effective diagnostics and therapeutics. Many developing countries such as India, South Africa, Brazil, Indonesia, and Thailand have production capacity for diagnostics and therapeutics.[124] Generic manufacturers in the Global South have been producing generics for decades which are as good as the original brands and people trust their quality across the globe.

The biopharmaceutical sector is highly regulated. The quality of COVID-19 products will not be compromised as rigorous pharmaceutical regulations would apply to all new producers.[125] Manufacturers will need to obtain marketing approval from the national drug regulatory authority in each country. So, this argument about endangered safety is merely a scaremongering tactic of patentee corporations.

D. End of the Pandemic

It can also be argued that there is no necessity for expanding the TRIPS Decision to therapeutics and diagnostics because the COVID-19 pandemic has ended. Though the WHO Director-General had declared in May 2023 that the COVID-19 pandemic is now an ongoing issue that does not constitute a public health emergency of international concern, in August 2023 the WHO issued Standing Recommendations for COVID-19 which, among others, encourages States Parties to the International Health Regulations (2005) to continue to work towards ensuring equitable access to safe, effective and quality assured medical countermeasures for COVID-19.[126] Recently in January 2024, Dr. Maria Van Kerkhove, the technical lead for COVID-19 response at the WHO, wrote that COVID-19 is '… still a pandemic causing far too many (re)infections, hospitalizations, deaths and long covid when tools exist to prevent them. …Cases and hospitalisations for #COVID19 have been on the rise for months; hospitals in many countries are burdened and overwhelmed from COVID and other

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[122] Lori Wallach, "U.S. International Trade Commission Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities", *Rethink Trade, American Economic Liberties Project* (2023), p. 8.
[123] World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), Art. 31(c).
[124] Third World Network, "RE: Post hearing Brief by Third World Network - Investigation No. 332-596" (12 April 2023), p. 8.
[125] Olga Gurgula, "Compulsory licensing vs. the IP waiver: what is the best way to end the COVID-19 pandemic?", Policy Brief, No. 104 (Geneva, South Centre, 2021), p. 5. Available from https://www.southcentre.int/policy-brief-104-october-2021/.
[126] World Health Organization, "Standing recommendations for COVID-19 issued by the Director-General of the World Health Organization (WHO) in accordance with the International Health Regulations (2005) (IHR)" (August 9, 2023). Available from https://cdn.who.int/media/docs/default-source/documents/ihr/covid-19_standing-recommendations_9-august-2023.pdf?sfvrsn=805ad4e4_8&download=true.

pathogens, and deaths are on the rise.'[127] Dr. Van Kerkhove said governments and individuals can't give in to complacency. Hence, the need for ensuring equitable access to COVID-19 diagnostics and therapeutics remains. Moreover, it should be noted the TRIPS Decision is not tied to a duration of the pandemic determined by WHO, but for a defined period during which eligible members can use the Decision for products within its scope.

[127] Nicole Karlis, "WHO leader says COVID-19 is 'still an pandemic'", *Salon*, 4 January 2024. Available from https://www.salon.com/2024/01/04/leader-says-19-is-still-a-pandemic/.

VII. TRIPS FLEXIBILITIES WERE NOT OPTIMALLY UTILISED

One of the critical challenges in obtaining a waiver in the WTO is that despite the legal rules that allow for expedited decision-making without having to ensure consensus, WTO Members tend to conform to the practice of taking decision by consensus. Hence, proposals for waivers become the subject of extended negotiations and compromises. The result of such compromises could lead to sub-optimal outcomes.

If a waiver cannot be insulated from the vagaries of political negotiations where commercial interests could prevail over public health needs, how could WTO Members ensure that the provisions of the TRIPS Agreement do not impede their ability to respond promptly, adequately and effectively to public health crises like a global pandemic and take all measures they deem appropriate for ensuring access to medicines, vaccines and diagnostics?

Significantly, the TRIPS Agreement provides substantial flexibility to WTO Members to carve out policy space to address public health needs. In this context, in addition to focusing on how to strengthen the decision-making process on a waiver proposal, WTO Members should also consider how to make optimal use of the TRIPS flexibilities to respond to a global pandemic.

The flexibilities in the TRIPS Agreement are to be derived from interpretation of the scope of TRIPS obligations and exceptions enshrined in the various provisions of the Agreement. This interpretation is primarily to be done by member States when implementing the provisions of the TRIPS Agreement.

While WTO Members are free to determine how to implement the provisions of the TRIPS Agreement in their domestic laws and practice,[128] the scope of this freedom is further clarified in the context of public health needs by the Doha Declaration on TRIPS and Public Health. Accordingly, '… the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health ….' In *Australia-Tobacco*, the WTO panel held that this affirmation in the Doha Declaration constituted a subsequent agreement among WTO Members in terms of international treaty law, and hence each provision of the TRIPS Agreement should be so interpreted as stated in the Doha Declaration.

Thus, WTO Members can interpret and apply the provisions of the TRIPS Agreement in a manner that maximizes public health objectives and responds adequately and effectively to public health needs, including a global pandemic. Below are some options that could be pursued in a public health sensitive interpretation of the scope of TRIPS flexibilities for public health.

A. Excluding Pharmaceutical Products Specific to the Relevant Disease during a Health Emergency from Patent Protection

Article 27.1 of the TRIPS Agreement states that '... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'. If this obligation is read in the light of the interpretative rule laid down in the Doha Declaration, could it be possible to treat patent applications relating to health technologies that are relevant to response to a pandemic differently than other health technologies? It is clear from article 27.1 that discrimination based on the field of technology is prohibited. However, differential treatment to a sub-category of health technologies that are relevant to a public health response could be interpreted as not

[128] TRIPS Agreement, art. 1.

constituting discrimination that excludes an entire field of technology as such, especially when this differentiation is based on a public health need. Such an interpretation would be consistent with the Doha Declaration.

Hence, during a pandemic or a public health emergency, an affected WTO Member could legitimately suspend procedures for grant of a patent for health technologies that are needed to respond to the health emergency.

The enforceability of granted patents could also be suspended as an exception under Article 30 of TRIPS. Article 30 of TRIPS allows WTO Members to provide exceptions to patent rights that are limited, which do not unreasonably conflict with the normal exploitation of a patent, and do not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties. The indeterminate language of Article 30 provides considerable room for interpretation of its scope. In the light of the Doha Declaration, such interpretation would also need to take into consideration the public health perspective.

In WTO jurisprudence, Article 30 of the TRIPS Agreement has been interpreted only once in *Canada-Patent Protection for Pharmaceutical Products*. In that instance, the WTO panel took a very narrow view of the scope of Article 30 and held that the conditions stipulated in Article 30 are cumulative and each condition constituted a separate and independent requirement that must be satisfied by a measure to constitute an exception.

However, it should be noted that the interpretation of the terms of a covered agreement by a WTO panel does not constitute an authoritative interpretation. It does not constitute a binding precedent but may only have persuasive effect. Indeed, distinguished publicists have subsequently held the view that the conditions under Article 30 of TRIPS are not cumulative.[129] Hence, failure to comply with one of the three conditions need not result in the exception being disallowed. Such an interpretation would also be in harmony with the rule of interpretation suggested by the panel in *Australia-Tobacco*.

As held by distinguished publicists that are signatories to the Max Planck Declaration on Patent Protection – Regulatory Sovereignty Under TRIPS[130,] an exception under Article 30 could be construed to be limited if the scope of the exception is reasonably proportionate to its objective and scope. It must fulfil a legitimate purpose, be adequate to achieve that purpose, and not exceed what is necessary and sufficient to achieve that purpose. In this light, we submit that a measure suspending the enforcement of pharmaceutical products relevant to a specific disease that is the cause of a health emergency or a pandemic could be construed to be a limited exception within the meaning of Article 30. Moreover, it would also constitute a limited exception in the sense that the exception would not apply to patent protection in respect of pharmaceutical products relating to other diseases or health conditions.

The second condition under Article 30 requires an assessment of whether the exception unreasonably conflicts with the normal exploitation of the patent. This phrase in Article 30 itself makes it clear that some reasonable conflict with the normal exploitation of the patent would be allowed under Article 30. This raises the question whether commercial exploitation of the patent concerned during a health emergency or pandemic could be construed as normal exploitation of the patent?

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[129] See Matthias Lamping *et.al*., "Declaration on Patent Protection: Regulatory Sovereignty under TRIPS, *IIC - International Review of Intellectual Property & Competition Law*, Vol. 45, Is. 6 (2014), pp. 679-698. Available from https://dx.doi.org/10.2139/ssrn.2500784.

[130] Matthias Lamping *et.al*., "Declaration on Patent Protection: Regulatory Sovereignty under TRIPS, *IIC - International Review of Intellectual Property & Competition Law*, Vol. 45, Is. 6 (2014), pp. 679-698. Available from https://dx.doi.org/10.2139/ssrn.2500784.

In *Canada-Patents*, the panel had held that '"exploitation" refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent. The term "normal" defines the kind of commercial activity Article 30 seeks to protect'. The panel further held that, 'The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity'. However, a different reading of what constitutes normal exploitation can emerge in the light of the objects and purpose of the TRIPS Agreement and the rule of interpretation laid down in the Doha Declaration, as held in *Australia-Tobacco*.

Article 7 of the TRIPS Agreement states that, 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. Article 8.1 of the TRIPS Agreement specifically states that, 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement'. As stipulated in the Doha Declaration '... the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, … the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'.

If the stipulation in Article 30 is read in the light of Articles 7 and 8 of TRIPS and the Doha Declaration, it is evident that restraining all forms of competition by virtue of patent rights over a pharmaceutical product that is relevant for a public health response to a health emergency or a pandemic cannot be construed as 'normal exploitation'. Therefore, any measure excluding such patents from being enforced during a health emergency or a pandemic would not constitute an unreasonable conflict with the normal exploitation of the patent.

With regard to the third condition under Article 30, there is a need to assess whether the exception unreasonably prejudices the legitimate interests of the patent holder, taking into account the legitimate interests of third parties. It is evident from the phrase used in Article 30 that this must be assessed based on a balance of legitimate interests of the patent holder vis a vis third parties. Here also, the interpretation must be based on Articles 7 and 8 of TRIPS and the Doha Declaration. In this light, during a health emergency or pandemic, the legitimate interests of third parties to ensure a rapid end to the health crisis by scaling up manufacturing of the products that may be under patent protection, would trump the legitimate interests of patent holders.

B. Manufacturing for Exports

Article 30 of TRIPS could also be interpreted as allowing WTO members to legitimately allow (with or without remuneration) for the local production by third parties of patent-protected products for exportation. This is because in terms of Article 28 of the TRIPS Agreement, the rights conferred by a patent do not include the right to prevent exports. However, Article 28 prohibits unauthorised production by third parties. Hence, an exception allowing third parties to manufacture and supply to export markets would not constitute a curtailment of the normal exploitation of the patent.[131]

[131] Carlos M. Correa and Juan I. Correa, "Manufacturing for Export: A TRIPS-Consistent Pro-Competitive Exception", Research Paper, No.155 (Geneva, South Centre, 2022). Available from

C. Security Exception

In the initial stages of the COVID-19 pandemic in April 2020, the Executive Director of the South Centre had appealed to the Director-Generals of the WTO, WIPO and WHO to support use of Article 73(b) of the TRIPS Agreement to 'suspend the enforcement of any intellectual property rights (including patents, designs and trade secrets) that may pose an obstacle to the procurement or local manufacturing of the products and devices necessary to protect their populations'.[132]

Article 73(b) of the TRIPS Agreement, which mirrors Article XXI of the General Agreement on Tariffs and Trade (GATT), allows WTO Member States to temporarily suspend their intellectual property commitments. It is essentially a safeguard clause which reads as:

> *Nothing in this Agreement shall be construed:*
> *…*
> *(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;*
> *(i) relating to fissionable materials or the materials from which they are derived;*
> *(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;*
> *(iii) taken in time of war or other emergency in international relations;*

This TRIPS flexibility allows WTO Member States to suspend their substantive obligations by providing the justification of protecting their essential security interests. The trade-related security exceptions were initially drafted in the Charter for an International Trade Organization (ITO) or Havana Charter 1948. Military and strategic interests formed the core of security exceptions as negotiations for these exceptions occurred in the broader context of the Cold War between the US and the Soviet Union. Security exceptions from the failed ITO Charter were transplanted into the General Agreement on Tariffs and Trade (GATT) under Article XXI. The same security exceptions were later transplanted into TRIPS Agreement under Article 73. The vague language of the provision drafted in the Cold War period suggests that the strategic rivals wanted to retain wide discretion and flexibility in security matters.[133]

The WTO Member States enjoy a wide margin of discretion because of the broad scope of the ambiguous phrases like 'which it considers', 'essential security interests', and international 'emergency' used in this clause. The use of security exceptions is, however, not totally self-judging as it is reviewable and subject to dispute-settlement proceedings by the WTO Dispute Settlement Body (DSB). The recent Panel Report in *Russia – Measures Concerning Traffic in Transit*[134] provided a comprehensive interpretation of security exceptions under Article XXI of GATT and set out a two-step framework: the existence of a war, emergency or other basis for invoking the provision, which is subject to objective determination; and the necessity of the trade-related security measure, which is subject to a good-faith test. Though the good-faith

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https://www.southcentre.int/wp-content/uploads/2022/05/RP155_Manufacturing-for-Export-A-TRIPS-Consistent-Pro-Competitive-Exception_EN.pdf.

[132] See South Centre, "COVID-19 Pandemic: Access to Prevention and Treatment is a Matter of National and International Security", Open letter from Carlos Correa, Executive Director of the South Centre to WHO, WIPO and WTO Directors-General, 4 April 2020. Available from https://www.southcentre.int/wp-content/uploads/2020/04/COVID-19-Open-Letter-REV.pdf.

[133] Muhammad Zaheer Abbas, "The COVID-19 Pandemic and Trade-Related Security Exceptions: An Analysis of the Flexibility Under International Law", *ANZSIL Perspective,* Vol. 22 (2021), pp. 7-11. Available from https://infojustice.org/archives/43177.

[134] WTO document WT/DS512/R, 5 April 2019. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/DS/512R.pdf&Open=True.

test has not been formulated clearly, diplomacy and invoking members' good faith are considered as the best constraint on trade-related security measures. The WTO Panel in *Saudi Arabia – IPRs* also analysed the security exception under Article 73 of TRIPS by relying on the *Russia-Transit* case. In both disputes, the US argued as third party that the security exception is non-justiciable. This argument could restrain the US from arguing to the contrary if the security exception is invoked for pharmaceutical patents.[135]

To justify a security exception, the existence of an emergency in international relations within the meaning of Article 73(b)(iii) of TRIPS has to be proven. As the WHO has declared COVID-19 to be a public health emergency of international concern under the International Health Regulations, and in August 2023 the WHO Director-General issued Standing Recommendations for long-term risks posed by COVID-19, it is clear that COVID-19 remains to be of pandemic potential that can constitute an emergency in international relations. Moreover, as health of the national population is clearly an essential security interest as articulated by WHO member States in the ongoing negotiations for a pandemic treaty in the WHO, the TRIPS consistency of a measure to address the health security situation as necessary to address an essential security interest can be demonstrated.[136] Therefore, WTO Members can take measures impacting patent rights relating to pharmaceutical products for a health emergency as a security exception under Article 73 of TRIPS.

[135] Frederick Abbott, "TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic", Research Paper, No.116 (Geneva, South Centre, 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/08/RP-116.pdf.
[136] Abbott, *supra* note 135.

VIII. CONCLUSION

The inequitable rollout of COVID-19 vaccines, diagnostics, and therapeutics resulted in a vast gap in response measures in low- and middle-income countries. Inequities in access to vaccines, diagnostics, and therapeutics allowed COVID-19 to disproportionately impact the lives and livelihoods of people while the waiver debate was stalled at the WTO for 20 months. What was achieved after a lengthy debate is only a fragment of what was originally proposed. The Decision was not only limited but also partial because no agreement could be reached in relation to COVID-19 diagnostics and therapeutics.

Diagnostics and therapeutics are an essential part of the WHO's COVID-19 response strategy. There is no legal barrier in extending the Decision beyond vaccines to cover diagnostics and therapeutics. There is a need to immediately and unconditionally extend the Decision to these tools. The obligations under the TRIPS Agreement should not hinder the necessary actions of WTO Members in response to the pandemic. Global supply of COVID-19 diagnostics and therapeutics should not depend on voluntary measures and optional goodwill of patentee corporations.

Extending the Decision to COVID-19 diagnostics and therapeutics will make it easier for countries to use the export-oriented compulsory licensing mechanism. Immediate and unconditional extension of the Decision is also good for the WTO in terms of its legitimacy, credibility, and capability to deal with matters of public interest. The objections to extending the Decision to diagnostics and therapeutics are superficial and speculative.

In view of the extensive delay experienced in the process of deciding on the TRIPS waiver, it is necessary that the process is streamlined to eliminate discretionary action on the part of WTO Members that could delay decision-making on a waiver. This could be undertaken as part of the commitment made by the Twelfth Ministerial Conference to reform the functioning of the WTO in all its aspects. As part of these reforms, the WTO Members should consider improving the decision-making rules relating to a waiver, to ensure that a decision is taken by the Ministerial Conference or the General Council without undue delay after a waiver proposal has been considered by the relevant WTO Council within the stipulated period of 90 days under article IX(3) of the WTO Agreement.

Moreover, to safeguard against the negotiating uncertainties on a waiver, WTO Members should also consider how to make optimal use of the TRIPS flexibilities to respond to a global pandemic. This could be done by interpreting and applying the provisions of the TRIPS Agreement in a manner that maximizes public health objectives and responds adequately and effectively to public health needs, including a global pandemic. Some of the measures that could be taken based on a public health-oriented reading of the provisions of TRIPS include suspending examination of patent applications relating to pharmaceutical products specific to the relevant disease during a health emergency, suspending the enforceability of such patents during a health emergency as a limited exception under article 30 of TRIPS, allowing third parties to manufacture a patented product for exports and applying the security exception under the TRIPS Agreement.

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