The "Intellectual Property" Puzzle in the WHO Pandemic Preparedness Treaty: An Appraisal

Abstract

This article provides an overview of the ongoing World Health Organization (WHO) Pandemic Treaty. The analysis focuses on examining WHO's past responses to pathogen containment and provides context and rationale for the Treaty's negotiation. It also critically examines relevant intellectual property and technology transfer provisions that are essential in preparedness for future pandemics.

1. Introduction

The onset of the COVID-19 pandemic has served as a test for the efficacy of existing global public health laws in the face of an unprecedented health emergency. This crisis has not only stressed the limits of our collective readiness but also brought to light significant deficiencies within the current international legal framework. The obstacles mostly lie in its ability to respond to outbreaks of diseases swiftly and effectively on a global scale. Amidst these challenges, the World Health Organization (WHO) and its key stakeholders have emerged as pivotal players, actively endeavouring to bridge the widening gap between nations and cultivate a more comprehensive system equipped to navigate and mitigate the impacts of future pandemics.

Rooted in the aftermath of World War II, the establishment of the WHO in 1945 represented a monumental step forward in international cooperation aimed at consolidating efforts to combat emerging health threats on a global scale.[1] The WHO is legally responsible for developing international treaties, regulations, and resolutions addressing global health challenges. To this end, WHO has been directing and coordinating authority on international health work and establishing effective collaboration with various stakeholders, including the United Nations, specialised agencies, governmental health administrations, and professional groups.[2] Within this framework, the WHO possesses the power to adopt different types of legal instruments to advance its objectives. Its constitution empowers it to create treaties and agreements that establish legally binding standards to promote public health, mandating specific actions by member states.[3] Additionally, the WHO

[1] Sonam K. Shah, 'Developing the WHO's Pandemic Treaty to Facilitate Global Solidarity and International Accountability' (2022) 101 (1) North Carolina Law Review 227; Marco Cueto, Theodore M. Brown and Elizabeth Fee, *The World Health Organization* (Cambridge University Press, 2019).
[2] WHO's Constitution, available at https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1 (accessed 13 May 2024).
[3] Ibid., Articles 19 and 21.

has a mandate to issue nonbinding guidelines to member states outlining standards to promote public health.

Central to its mandate was the International Health Regulations (IHR) adopted in 2005 by the WHO Health Assembly,[4] which was a reborn of the pre-existing International Sanitary Regulations.[5] Despite some adaptations, the IHR's efficacy hinges greatly on the commitment and compliance of member states. This highlights the critical role of national governments in translating international legal obligations into tangible actions and outcomes. Yet, the realities of political and economic constraints have rendered many countries ill-prepared to fulfil these obligations adequately. [6]

The COVID-19 pandemic further challenged international health mechanisms, and WHO, being the centre of the crisis, received severe criticism for its lack of responsiveness. The absence of robust accountability mechanisms has further exacerbated the situation.[7] From border closures restricting freedom of movement to the inequitable distribution of essential vaccines driven by restrictive Intellectual Property (IP) laws, the pandemic response has laid bare the inadequacies of existing legal frameworks in safeguarding individual liberties and ensuring equitable access to healthcare services. As pointed out by the independent Panel established by the WHO, the 'combination of poor strategic choices… and an uncoordinated system created a 'toxic cocktail which allowed the pandemic to turn into a catastrophic human crisis'.[8]

Due to the failures in handling recent health crises, global health leaders increasingly call for major international legal reforms to 'decolonize international law for infectious diseases'.[9] In March 2021, in response to the urgent need for better pandemic preparedness, the WHO proposed a new international treaty. This

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[4] See International Health Regulations (2005), available at https://www.who.int/publications/i/item/9789241580496 (accessed 18 May 2024).

[5] For more discussion on International Sanitary Regulations, see WHO Regulations No.2: International Sanitary Regulations, WHO Health Assembly (1951), available at https://iris.who.int/handle/10665/101391 (accessed 1 May 2024). For the historical development of International Sanitary Regulations from 1851, see David P. Fidler, 'From International Sanitary Conventions to Global Health Security: The New International Health Regulations' (2005) 4(2) Chinese Journal of International Law; Carvalho and M. Zacher, 'The International Health Regulations in Historical Perspective' in Andrew T. Price-Smith (ed) *Plagues and Politics: Infectious Disease and International Policy* (Palgrave 2001).

[6] Shah (n 1) 232.

[7] Ibid, 237.

[8] See 'COVID-19: Make it the Last Pandemic' (The Independent Panel for Preparedness & Response, 2021) 42-43, available at https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf (accessed 24 March 2024).

[9] Alexandra L Phelan, 'The World Health Organization's Pandemic Treaty' (2023) 380 BMJ, 463. For an intellectual property perspective, see generally Khorsed Zaman, 'Decolonizing Human Rights Law in Global Health – the Impacts of Intellectual Property Law on Access to Essential Medicines: A Perspective from the COVID-19 Pandemic' (2024) Asian Journal of International Law 1-18.

proposal gained momentum, prompting member states to begin drafting and negotiating the treaty in November 2021. The WHO commenced formal negotiations in July 2022 and, in October 2023, released its *Proposal for negotiating text of the WHO Pandemic Agreement* (the Proposal).[10] This Proposal faced criticism for its robust language, aimed at weakening IP protection.[11] The most recent draft was released on 13th March 2024 under the title: *Revised draft of the negotiating text of the WHO Pandemic Agreement* (the Revised Draft)[12] with a softer approach towards IP provisions than its predecessor.

The proposed Treaty has the potential to be transformative. It is rooted in equity principles and supported by robust financing and accountability mechanisms.[13] These reforms are crucial not only for addressing immediate challenges but also for strengthening the resilience of global health systems and enhancing pandemic preparedness for future threats. The initial *Proposal for negotiating text of the WHO Pandemic Agreement* of 2023 recognises the importance of IP rights in driving innovation and developing new medical products. It also acknowledges concerns about the potential impact of IP rights on access to essential healthcare.[14] The Treaty encourages collaboration among countries and international organisations to address these concerns and ensure fair and timely access to pandemic-related products. This includes facilitating sharing of IP and technology, particularly with manufacturers in developing countries, to increase the availability of diagnostic tools, vaccines, and therapeutics during pandemics.

One of the most significant commitments is the time-bound wavers of IP rights to accelerate or scale up the manufacturing of pandemic-related products. Amidst the Pandemic, India and South Africa proposed a waiver for certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS), which received support from most developing countries.[15] Unfortunately, after two years of

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[10] WHO, Proposal for negotiating text of the WHO Pandemic Agreement (A/INB/7/3, 30 October 2023), available at https://apps.who.int/gb/inb/pdf_files/inb7/A_INB7_3-en.pdf (accessed 26 May 2024).

[11] Brett Schaefer and Steven Groves, "WHO Pandemic Treaty Remains Fatally Flawed" (The Heritage Foundation, 5th Feb 2024), available at https://www.heritage.org/global-politics/report/who-pandemic-treaty-remains-fatally-flawed (accessed 22 April).

[12] WHO, Revised draft of the negotiating text of the WHO Pandemic Agreement (A/INB/9/3, 13 March 2024), available at https://apps.who.int/gb/inb/pdf_files/inb9/A_inb9_3-en.pdf (accessed 24 May 2024).

[13] Harald Schmidt, 'Equity needs to be (even) more central under the WHO Pandemic Agreement' (2023) 49(12) BMJ 797.

[14] See WHO, Proposal for negotiating text of the WHO Pandemic Agreement (n 10) Preamble, para10.

[15] WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19', Communication from India and South Africa, WTO Doc. IP/C/W/669 (2 October 2020) ['**Waiver Proposal**']. See also the revised version of the proposal: WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19', Communication from the African Group, Bolivia, Egypt, Eswatini, Fiji, India, Indonesia,

negotiation, in June 2022, the WTO members shifted from 'necessity to flexibility' by clarifying the scope of relevant TRIPS provisions to facilitate an increased supply of vaccines.[16] While the debate on the TRIPS waiver at the WTO is settled, discussions on mitigating the barriers posed by IP in promoting access to medicine continue.

Given the strong relationship between research and development (R&D), IP and technology transfer, it is crucial to develop a preparedness framework that swiftly coordinates health response. The ongoing negotiations for the WHO Pandemic Preparedness Treaty aims to become a framework convention of parties. It embeds the principles of solidarity, capability-based approach, benefit sharing to name few to manage public health challenges and increased global health co-ordination.

This article provides a holistic assessment of ongoing discourse on WHO Pandemic Preparedness. However, it does not aim to review the Treaty *per se* or even propose an alternative model for effective global health governance, as there is already substantial literature on those topics.[17] Instead, this article intends to review and evaluate the relevant IP provisions of the WHO Pandemic Preparedness Treaty.

To so do, this article is divided into three parts. The first part concisely overviews the WHO's emergency preparedness initiatives, examines their past responses to pathogen containment, and provides context and rationale for negotiating the WHO Pandemic Treaty. The second part delves into the debate over IP and the TRIPS waiver, followed by an analysis of IP-related provisions in the Pandemic Treaty. The last part critically assesses critical IP issues that deserve attention to make the Pandemic Treaty effective.

2. The WHO's Role in the Global Health Governance

2.1 Initiatives for Emergency Preparedness

Certain factors are beyond our control during outbreaks or emergencies and vary with each specific event.[18] However, by taking comprehensive preparedness measures and responding promptly, we can mitigate the loss of life, societal chaos,

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Kenya, LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, Venezuela and Zimbabwe, WTO Doc. IP/C/W/669/Rev.1 (21 May 2021).

[16] For generally, see Bryan Mercurio and Pratyush Nath Upreti, 'From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for COVID-19 Vaccines and Treatments' (2022) 21 World Trade Review 633-649; Emmanuel Kolawole Oke, 'The Waiver of the TRIPS Agreement for COVID-19 at the WTO: A rhetorical analysis' (2022) 12 Indian Journal of Intellectual Property Law 128-169; Monica Thomas, 'To Waive or Not to Waive: International Patent Protection and the Covid-19 Pandemic' (2022) 49(1) Legal Issues of Economic Integration 7-42.

[17] See Abbie Rose Hampton *et al*., ''Equity' in the Pandemic Treaty: The False Hope of 'Access and Benefit Sharing'' (2023) 72(4) International & Comparative Law Quarterly 909-943.

[18] WHO, The Power of Preparedness (2018), available at https://www.who.int/japan/news/feature-stories/detail/the-power-of-preparedness (accessed 26 May 2024).

and economic downturns. This is why emergency preparedness has always been a priority for the WHO. Investing in preparedness not only saves lives but also protects communities and economies, strengthens healthcare systems, and contributes to the WHO's goal of safeguarding an additional billion people worldwide from health emergencies. In other words, every dollar spent on health emergency preparedness yields over eight dollars in returns.[19]

The SARS epidemic in 2003, which lasted six months and rapidly spread to 29 countries, highlighted the potential for social disruption caused by a fast-moving pathogen. This crisis prompted a revision and expansion of the IHR, imposing legally binding duties on States and the WHO for disease notification and information sharing to contain the spread. These regulations serve as a global defence against severe public health threats[20] by focusing on preventing, protecting, controlling, and responding to the international spread of diseases.[21]

The WHO has further developed the concept of emergency preparedness through its strategic framework. It defines preparedness as

> the knowledge, capacities, and organizational systems developed by governments, response and recovery organizations, communities, and individuals to anticipate, respond to, and recover from the impacts of likely, imminent, emerging, or current emergencies. [22]

Accordingly, emergency preparedness refers to the ability of various institutions, including public health bodies, healthcare systems, and emergency responders, to detect, report, and address outbreaks effectively. This includes identifying and assessing outbreaks, promptly reporting them to relevant national and international entities, and implementing measures to mitigate their health, social, and economic impacts.[23] While surveillance, response mechanisms, and healthcare capacity are crucial aspects of preparedness, they rely on broader institutional, financial, and infrastructural factors. At the country level, preparedness involves readiness across all sectors and systems to manage risks at both national and subnational levels. This includes urban and rural areas, as well as diverse institutions such as healthcare facilities, laboratories, and emergency services. It involves developing and maintaining capacities in strategic risk assessment, emergency operations

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[19] Ibid.
[20] Ben Oppenheim *et al.*, 'Assessing global preparedness for the next pandemic: development and application of an Epidemic Preparedness Index' (2019) BMJ, 1-9.
[21] Article 2, International Health Regulations 2005 (Third Edition), available at https://iris.who.int/bitstream/handle/10665/246107/9789241580496-eng.pdf?sequence=1 (accessed 26 May 2024)
[22] WHO (2017), A Strategic Framework for Emergency Preparedness, Appendix 2, 14, available at https://iris.who.int/bitstream/handle/10665/254883/9789241511827-eng.pdf?sequence=1 (accessed 28 May 2024).
[23] Brennen Puryear and David M Gnugnoli, 'Emergency Preparedness' (StatPearls Publishing 2024) available at https://www.ncbi.nlm.nih.gov/books/NBK537042/ (accessed 26 May 2024).

planning, tailored contingency planning, preparedness for influenza and pandemics, arrangements for large-scale public events, and effective communication of emergency risks.[24]

To accelerate progress toward the achievement of the IHR, the Global Health Security Agenda (GHSA) was launched in 2014. It is a global effort to strengthen the world's ability to prevent, detect, and respond to infectious disease threats, whether naturally occurring, accidentally or intentionally released. The Centers for Disease Control and Prevention (CDC) plays a leading role in implementing the GHSA. CDC is committed to strengthening its capabilities to identify, track, and stop outbreaks or other public health emergencies. Through GHSA, the CDC works with countries to strengthen public health systems and contain outbreaks at the source before they spread into regional epidemics or global pandemics.[25] The role of the global CDC system has been proved undeniably through the COVID-19 pandemic.

In addition, the WHO also coordinates the Global Outbreak Alert and Response Network (GOARN). GOARN is a collaboration of technical institutions and networks worldwide dedicated to detecting, assessing, and responding to outbreaks of infectious diseases. Member institutions of GOARN include public health agencies, research institutions, and international organisations with expertise in epidemiology, laboratory diagnostics, infection control, and emergency response. GOARN facilitates the rapid deployment of multidisciplinary teams, known as outbreak response teams (ORTs), to affected countries to support surveillance, case management, infection control, and other response activities during outbreaks.[26]

However, levels of preparedness vary across and within countries, leaving communities and states at risk of significant short- and long-term health and societal impacts.[27] The emergence of COVID-19 presented unprecedented challenges to the WHO's emergency preparedness efforts. A collapse of cooperation and the nature of transnational disease threatened social harmony and resulted in a nationalist approach to containing the virus and vaccine production.[28] Given the

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[24] WHO, Preparedness for emergencies, available at https://www.who.int/europe/emergencies/our-work-in-emergencies/preparedness (accessed 26 May 2024)

[25] CDC, Advancing the Global Health Security Agenda CDC Achievements and Impact 2017, available at https://www.cdc.gov/globalhealth/security/ghsareport/images/ghsa-report-2017.pdf (accessed 26 May 2024).

[26] Global Outbreak Alert and Response Network, available at https://goarn.who.int/about (accessed 26 May 2024).

[27] WHO (2017), A Strategic Framework for Emergency Preparedness, p.2, available at https://iris.who.int/bitstream/handle/10665/254883/9789241511827-eng.pdf?sequence=1 (accessed 26 May 2024).

[28] See David P. Fidler, 'The Case Against a Pandemic Treaty' (Think Global Health, 26 November 2021) https://www.thinkglobalhealth.org/article/case-against-pandemic-treaty (accessed 2 May 2024); Zhongyuan Wang, 'From Crisis to Nationalism? The Conditional Effects of the COVID-19 Crisis on Neo-nationalism in Europe' (2021) 6(1) Chinese Political Science Review 20-39; Thomas, J. Bollyky and Chad P. Brown, 'The Tragedy of Vaccine Nationalism: Only Cooperation Can End the

scale of the crisis, there was a need for better resource allocation, information management, and international cooperation through the WHO system. Therefore, the WHO was seriously criticised for handling the pandemic and failed to act decisively to stop the outbreak. That said, the politicisation of COVID-19 and the failure of collective efforts of the international community further questioned the legitimacy and effectiveness of WHO as a global institution.[29] Perhaps, people's confidence in the WHO is shaken, and the study supports the WHO and other international institutions in shouldering responsibility and maintaining public credibility.[30] Moreover, COVID-19 also highlighted the importance of equity and access to healthcare services, underscoring the necessity of robust emergency response mechanisms and global solidarity to effectively address future health crises. The ongoing negotiations for the WHO Pandemic Treaty are a step towards that, but they also aim to overcome the 'catastrophic failure' of the WHO during the COVID-19 pandemic.[31]

2.2. Pandemic Preparedness Treaty: An Overview

On 29 November – 1 December 2021, the WHO's WHA met in a special session to discuss a new treaty on pandemic preparedness and response.[32] This was only the second-ever special session in the Assembly's history, underscoring the initiative's ultimate importance.[33] Many member states and global health actors advocate for this so-called "pandemic treaty" to work alongside other international legal standards under the existing International Health Regulations. Throughout the work on the Treaty, the WHO endeavours to foster the involvement of the United Nations ("UN"), non-state actors, and other stakeholders in global health governance. The proposed agreement aims to learn lessons from the COVID-19 experience to pave the way for a more resilient future, with equity emerging as a central theme. While the International Health Regulations serve as a cornerstone of international health

Pandemic' (2020) 99(5) Foreign Affairs 96-108; Joan Barcelo *et al.*, 'Vaccine Nationalism among the public: A cross-country experimental evidence of own-country bias towards COVID-19 vaccination' (2022) 310 Social Science & Medicine 115278.

[29] See Michael A. Peters *et al.*, 'The WHO, the Global Governance of Health and Pandemic Politics' (2020) 54(6) Educational Philosophy and Theory 707-716.

[30] Chao Guo *et al.*, 'The Effect of COVID-19 on Public Confidence in the World Health Organization: A Natural Experiment among 40 Countries' (2022) 18 (77) Globalization and Health 2-10.

[31] Luke Taylor, 'COVID-19: WHO treaty hopes to overcome "catastrophic failures" of pandemic response' (2023) 380 BMJ 357.

[32] World Health Organization, 'Special Session of the World Health Assembly to Consider Developing a WHO Convention, Agreement or Other International Instruments on Pandemic Preparedness and Response' (WHO, WHA74(16), 31 May 2021), available at https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74(16)-en.pdf (accessed 26 May 2024).

[33] The first special session, held 18 years ago, in 2006, was to address the consequences of the death of the previous Director-General, Dr Lee Jong-wook, and to accelerate the procedure to elect the next Director-General. See WHO, Special Sessions of the World Health Assembly, available at https://www.who.int/news-room/events/detail/2006/11/09/default-calendar/first-special-session-of-the-world-health-asembly (accessed 19 April 2024).

law, rooted in the WHO Constitution, efforts to craft the new pandemic agreement intend to complement and align with these regulations.[34]

The proposed agreement ensures equitable access to essential pandemic prevention tools, such as vaccines, personal protective equipment, information, and healthcare services for all individuals. It is envisioned as a global commitment to collaborative action within the international community to mitigate the impact of disease outbreaks, aiming to prevent scenarios akin to the COVID-19 pandemic. The proposed agreement is expected to establish guiding principles, priorities, and targets for pandemic preparedness and response, focusing on building resilience, supporting prevention, detection, and responses to potential outbreaks, ensuring fair access to pandemic countermeasures, and enhancing global coordination through a more robust and more accountable WHO. The agreement also seeks to foster high-level political commitment by promoting comprehensive approaches within countries and sustained domestic and international investment.[35]

In short, the Revised Draft of the WHO pandemic agreement consists of three chapters.[36] The first chapter outlines general objectives and key terms, with equity emerging as a central theme. Article 2 sets the objective to prevent, prepare for and respond to the pandemics underpinned with the idea of equity. While the concept of equity is implicit and would benefit from further elaboration, there is recognition that inequity stems from unfair disparities in health outcomes and opportunities within and among countries. Similarly, the second chapter delves into achieving equity in pandemic prevention, preparedness, and response, comprising seventeen articles. While many articles provide general principles, some offer concrete guidance, such as establishing periodic regional exercises and strengthening clinical trial capacity. The last chapter addresses procedural matters, including the establishment and rules of various advisory committees.

The Treaty's key provisions include aspirational goals for enhancing pandemic preparedness and response capabilities. Contentious topics under discussion include financing for pandemic preparedness and response, pathogen access and benefit sharing, IP rights, technology transfer, and R&D for pandemic-related products.[37] Notably, the One Health approach, which examines the interactions between humans, animals, and the environment contributing to pandemic risk, is

[34] WHO, Preparedness for emergencies (n 24) (*"Both the IHR and the new instrument are expected to play central roles in pandemic prevention, preparedness and response in the future.")*
[35] Lawrence O. Gostin, Kevin A Klock and Alexandra Finch, 'Making the World Safer and Fairer in Pandemics' (2023) 53(6) Hastings Center Report, 3-10, 6.
[36] The Revised Draft (n 12).
[37] Taruna Juneja Gandhi, Neha Dumka and Atul Kotwal, 'Is the proposed global treaty an answer for public health emergencies? (2023) 8(9) BMJ, 2.

also a focal point.[38] In addition, the concept of common but differentiated responsibilities, which address equity concerns by assigning greater obligations to richer countries in pandemic preparedness and response, has sparked debate.[39]

The Treaty includes establishing a main governing body, the 'Conference of the Parties'. This governing body would consist of delegates representing state parties who convene regularly to oversee the implementation of the Treaty.[40] While the concept of a legally binding global agreement in response to public health emergencies is not new, the experience of the COVID-19 pandemic highlighted the inadequacies of existing regulations.[41] The lack of an independent accountability mechanism to ensure state compliance, reliance on self-reporting and voluntary evaluations, and limited investigative powers for the WHO were evident shortcomings. State self-reports often suffer from delays, incompleteness, or inaccuracies, and political factors can influence peer reporting. However, the language regarding compliance in the drafts has been vague and noncommittal, raising questions about whether these provisions will remain in the final text or be subject to further negotiation. Currently, the WHO lacks explicit investigative authority during both the preparation stage and the pandemic response.[42] The following section will analyse the proposed Treaty while considering IP and vaccine debates.

3. IP, COVID-19 Pandemic and WHO Pandemic Treaty

3.1. The TRIPS Waiver Debate

In early October 2020, India and South Africa proposed a temporary suspension of intellectual property rights (such as patents, copyrights, industrial designs, and trade secrets) related to COVID-19 prevention, containment, or treatment. This proposal aimed to remain in effect until widespread vaccination was achieved worldwide and a significant portion of the global population gained immunity.[43] The waiver covered various medical products essential for combating COVID-19, including vaccines and medicines, and expanded research, development,

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[38] Ibid.
[39] Josh Michaud, Jennifer Kates and Anna Rouw, 'The 'Pandemic Agreement': What it is, What it isn't, and What it Could Mean for the U.S.' (Global Health Policy, 2024), available at https://www.kff.org/global-health-policy/issue-brief/the-pandemic-agreement-what-it-is-what-it-isnt-and-what-it-could-mean-for-the-u-s/ (accessed 2 May 2024).
[40] The Proposal (n 10), Article 21.
[41] Haik Nikogosian, 'Pandemic Treaty – Will it fragment or consolidate the global health emergency infrastructure?' (2023) 1 Oxford Open Infrastructure and Health 1-3.
[42] Elliot Hannon, Nina Schwalbe, and Susanna Lehtimaki, 'WHO member states are negotiating a pandemic treaty. But will countries follow the new rules?' (Bulletin of the Atomic Scientists, 15 February 2024), available at https://thebulletin.org/2024/02/who-member-states-are-negotiating-a-pandemic-treaty-but-will-countries-follow-the-new-rules/ (accessed 2 May 2024).
[43] WTO, Waiver Proposal (n 15).

manufacturing, and distribution.[44] Unsurprisingly, this initiative, like past endeavours addressing patents and public health, has divided the international community. While most of the developing world and Least Developed Countries (LDCs) backed this proposal,[45] high-income regions such as the UK, the US, Australia, Japan, Canada, Norway, and the EU vehemently opposed it, arguing that IPRs did not hinder vaccine distribution.[46]

Supporters presented two main reasons for introducing the waiver. First, they argued that the TRIPS Agreement offers a limited avenue to address the obstacles posed by IP in combatting COVID-19.[47] Second, they contended that IP rights and exclusive licensing agreements threatened manufacturing expansion, potentially excluding diverse suppliers and undermining competition, leading to higher prices.[48]

However, the US, under the Biden administration, had a change of heart to support the proposal.[49] This shift in position by the US, a key player known for its patent aficionado, not only surprised the global community but also bolstered the debate over trade and public health.[50] The US's reversal paved the way for four members, including the US, European Union (EU), South Africa, and India, to broker a compromise 'Outcome Document'.[51] Presented at the TRIPS Council in May 2022,

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[44] Ibid, para. 3.

[45] 'TRIPS Council to Continue to discuss temporary IP waiver, revised proposal expected in May', *WTO News* (30 April 2021), available at www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm (accessed 28 May 2024).

[46] AD Usher, 'South Africa and India push for COVID-19 patents ban' (2020) The Lancet 396, 1790, 1790-1791; J Bacchus, 'An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines' (Free Trade Bulletin No. 78 of Cato Institute, 16 December 2020) available at www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines (accessed 24 May 2024). See issues raised by the UK, the US, the EU, and Switzerland in Communication from The Plurinational State of Bolivia, Eswatini, India, Kenia, Mozambique, Mongolia, Pakistan, South Africa, The Bolivarian Republic of Venezuela, and Zimbabwe, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, containment and Treatment of Covid-19 – Responses to Questions.' (WTO, Council for TRIPS, 15 January 2021), IP/C/W/672.

[47] WTO, 'Waiver Proposal', (n 15), at 10.

[48] WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Response to Questions', Communication from Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, Venezuela, and Zimbabwe, WTO Doc. IP/C/W/672 (15 January 2021).

[49] Office of the United States Trade Representative, Press Office (05 May 2021) available at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver (accessed 10 May 2024).

[50] The US's proactive role in defending the patent system was discussed in Van Anh Le, *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health* (Springer 2022) 18 – 44.

[51] WTO Council for Trade-Related Aspects of Intellectual Property Rights, 'Communication from the Chairperson on TRIPS COVID-19', WTO/IP/C/W/688 (3 May 2018) ['Outcome Document'], available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W688.pdf&Open=True (accessed 26 May 2024).

this document is markedly different and more restrictive than the original waiver proposal. It aligned more with the EU's preference for easing compulsory licensing restrictions[52] instead of advocating for an IP waiver.[53]

However, the "Outcome Document" still served as the foundation for the Ministerial Decision on the TRIPS Agreement in June 2022.[54] Similar to the "Outcome Document", the Decision cannot be described as a waiver but rather a deviation from compulsory licensing, a limitation to patent rights. Specifically, the Decision focuses on TRIPS Article 31(f), which restricts such licensed use predominantly to the domestic market.[55] It also builds upon Article 31*bis*, which permits the export of pharmaceuticals under compulsory license to Members lacking manufacturing capabilities, subject to procedural requirements. Some commentators criticise these requirements for reducing effectiveness,[56] while others see them as a "better path for the WTO to achieve a sustainable increase in access to vaccines".[57]

As the discussion over the waiver proposal shifted, so did the COVID-19 landscape. Developing countries no longer faced vaccine shortages but grappled with expired doses and delivery delays. Meanwhile, in some cases, new manufacturing facilities struggle to attract clients and receive production orders.[58]

3.2 IP in the WHO Pandemic Treaty

The Revised Draft of the Pandemic Treaty, released in March of this year, addresses several IP-related provisions; it takes a more lenient approach to IP than its previous version. The Treaty's preamble, which acknowledges the significance of IP rights in

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[52] More on the restriction of compulsory licensing can be found in Le, VA. and Hyland, M., "Compulsory Licensing for Patented Medicines: A Comparative Legal Analysis of India, Brazil and Thailand" (2020) 17(3) Manchester Journal of International Economic Law, 315-337.

[53] More discussion on the "Outcome Document" can be found in Bryan Mercurio and Pratyush Nath Upreti, "From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments" (2022) 21 Word Trade Review 633, 637.

[54] WTO, 'Draft Ministerial Decision on the TRIPS Agreement', Ministerial Conference, 12th Session, WT/MIN (22)/W/15/Rev.2 (17 June 2022).

[55] Extensive discussion on compulsory licensing under TRIPS Article 31 can be found in Van Anh Le, *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health* (Springer 2022).

[56] Siva Thambisetty *et al*., The COVID-19 TRIPS Waiver Proposal in Critical Review: An Appraisal of the WTO DG Text (IP/C/W/688) and Recommendations for Minimum Modifications, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4124497 (accessed 19 April 2024).

[57] Bryan Mercurio & Pratyush Nath Upreti, "Tripping up Intellectual Property: From waiver to a more flexible interpretation of compulsory licensing" 2023 (41)2 Berkeley Journal of International Law 345, 352.

[58] L. Diseko, 'Covid in Africa: Why the Continent's Only Vaccine Plant is Struggling', BBC News (6 May 2022), www.bbc.co.uk/news/world-africa-61347091; "Why are African countries destroying covid-19 vaccines?" (*The Economist,* 12th August 2021) available at https://www.economist.com/the-economist-explains/2021/08/12/why-are-african-countries-destroying-covid-19-vaccines (accessed 26 May 2024).

fulfilling public health objectives, appears to draw inspiration from the Doha Declaration.

The preamble states:

> Recognizing that the protection of intellectual property rights is important for the development of new medical products, and recalling that intellectual property rights do not, and should not, prevent Member States from taking measures to protect public health, and further recognizing concerns about the effects of intellectual property rights on prices.[59]

Similarly, the Doha Declaration emphasises:

> 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
>
> 4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that 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.[60]

The Treaty's preamble and the Doha Declaration share a common recognition of the importance of IP rights in public health, yet they exhibit differences in emphasis and wording.

First, the Treaty highlights the role of IP rights in developing "new medical products," whereas the Doha Declaration narrowly focuses on "new medicines." Second, the former asserts that "*IP rights* [emphasis added] do not, and should not, prevent Member States from taking measures to protect public health," while the latter singles out the TRIPS Agreement. This stresses the Treaty's broader focus on IP rights compared to the Doha Declaration's specific reference to the TRIPS Agreement. Third, the Treaty acknowledges concerns "about the effects of IP rights on prices," whereas the Doha Declaration mentions similar concerns without reiterating IP rights explicitly. Finally, the Doha Declaration restates a dedication to the TRIPS Agreement and underscores its accommodating interpretation concerning public health—an endorsement not openly articulated in the Treaty preamble, which instead directly centres on IP. To sum up, the WHO Treaty boldly addresses IP rights as a hindrance to public health, a stance elegantly sidestepped by the Doha Declaration.

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[59] The Revised Draft (n 12).

[60] Declaration on the TRIPS agreement and public health (WT/MIN(01)/DEC/2, 20 November 2001).

However, the Revised Draft has adopted a more moderate stance on IP protection than its predecessor, the Proposal.[61] For instance, the latter, which advocated for entities to "offer non-exclusive, royalty-free licenses" in cases of public-funded research,[62] has been replaced by a call for relevant patent holders to "forgo or otherwise charge reasonable royalties" in the Revised Draft.[63] This adjustment acknowledges the right to remunerate the right owners, which was not available in the Proposal.

Furthermore, the Revised Draft encouraged Member States to "develop and strengthen" technology and know-how for pandemic-related products by pooling IP accessible to all developing countries.[64] It also reaffirmed Member States' right to use TRIPS flexibilities, including those recognised in the Doha Declaration, and fully respect others' use.[65]

While the IP waiver issue remains the most significant, the Revised Draft adopts a flexible approach. Whereas the Proposal asked each Party to "commit to agree upon, […] time-bound waivers of intellectual property rights […]",[66] the Revised Draft simply requires them to "consider supporting"[67] such an idea. Such change reflects a shift towards flexibility regarding the IP waiver issue, signalling a nuanced approach that encourages consideration and support rather than mandatory commitment.

Having compared the Treaty to the Doha Declaration and its previous draft, we now scrutinise its IP-related provisions in greater detail.

Firstly, the WHO Treaty is a soft law approach, lacking the legally binding force of traditional law or possessing a weaker binding force. This is evident in the dispute settlement mechanism outlined in the Revised Draft, which emphasises using diplomatic channels, negotiation, or other peaceful means to resolve disputes.[68] Consequently, its enforceability is uncertain. The diplomatic language further underscores this non-binding approach, as all IP-related measures depend on the goodwill of member states.

Secondly, while the preamble acknowledges the dual nature of IP, recognising its importance in developing new medicinal products while also recognising its impact on prices, the IP-related provisions in the Revised Draft only focus on the latter aspect.

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[61] The Proposal (n 10).
[62] Ibid., Article 10.1.c.
[63] The Revised Draft (n 12), Article 11.3.a.
[64] The Revised Draft (n 12), Article 11.2.
[65] The Revised Draft (n 12), Article 11.4.
[66] The Proposal (n 10), Article 11.3.a.
[67] The Revised Draft (n 12), Article 11.3.b.
[68] The Revised Draft (n 12), Article 25.1.

Thirdly, trade secrets have emerged as a critical point of contention in the discourse surrounding the proposed IP waiver.[69] However, both the initial Proposal and the subsequent Revised Draft have notably refrained from using the term "trade secrets", opting instead for "know-how". This substitution may serve to sidestep concerns regarding the infringement of companies' proprietary information, as "know-how" is not inherently synonymous with trade secrets. Unlike trade secrets, which entail confidential information, know-how encompasses broader knowledge and skills acquired through experience. Although its confidentiality may vary, the extent to which it is known to others and the competitive edge it provides directly influence its value. Clearly, using the term "know-how" instead of "trade secrets" in both versions reflects a strategic approach to navigating concerns surrounding proprietary information.

Finally, the Revised Draft makes it clear that the WHO Treaty shall not affect the rights and obligations of any Party under other legally binding international instruments to which it is party.[70] In cases where conflicts arise between the WHO Treaty and the TRIPS Agreement, which features a more robust dispute settlement mechanism and carries legally binding force, the TRIPS Agreement would likely take precedence.

Drawing from the preceding analysis, it is evident that while the WHO Pandemic Agreement represents a collective endeavour to prepare for and address future pandemics, its stance on IP protection is consistent with the Doha Declaration. This resemblance can be attributed to the underlying complexities of vaccine accessibility, encompassing issues such as trade secret protection,[71] incentives for innovation,[72] vaccine cost and accessibility,[73] and logistical hurdles in vaccine production.[74] While the WHO's initiative is commendable, its effectiveness in implementation may ultimately prove to be symbolic.

4. The 'sharing dilemma' in the IP text of the WHO Pandemic Treaty

From the onset of the COVID–19 pandemic in 2020 until March 2022, the US federal government has invested over $2.3 billion in researching and developing mRNA

[69] Ellen 't Hoen, "Sharing trade secrets is key to the pandemic agreements" (*FT*, 25 September 2024); Olga Gurgula and John Hull, "Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer" (2021) 16(11) Journal of IP Law and Practice 1242.
[70] The Revised Draft (n 12), Article 26.3.
[71] Mercurio & Upreti (n 57) 352 – 356.
[72] *Ibid, 356 – 360;* Reto M. Hilty et al., Covid-19 and the Role of Intellectual Property (Position Statement of the Max Planck Institute for Innovation and Competition of May 7, 2021), available at https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_statement_Covid_IP_waiver.pdf (accessed 26 May 2024).
[73] Mercurio & Upreti (n 57) 345, 360 – 362.
[74] V.A. Le and L. Samson, 'Are IPRs and patents the real barriers to COVID-19 vaccine supplies?' (2021)18(2) Manchester Journal of International Economic Law, 192–204.

COVID-19 vaccines.[75] This substantial investment underscores the pivotal role of government funding in driving pharmaceutical breakthroughs. Indeed, the COVID-19 crisis has reshaped discussions on the collaboration between public and private sectors in drug development, shifting focus from policy debates to urgent matters of "life and death".[76] The government influences research and development decisions in several ways. One is funding basic biomedical research, which strengthens the supply of new drugs and lays the groundwork for private industry's drug development efforts.[77] State agencies are primary contributors to essential biomedical research funding. This research not only expands the pool of potential drug targets but also reduces private companies' R&D expenses, encouraging further investment in drug development.[78]

The Treaty recognises the importance of government-funded research in pandemics and mandates the transparent sharing of research inputs and outputs for pandemic-related products.[79] Parties must establish national policies for equitable global access during health crises, including licensing, affordable pricing, technology transfer, publication of research data, and adherence to WHO product allocation frameworks.[80] Furthermore, to ensure sustainable and geographically-diversified production of pandemic-related products, the Treaty obliges parties to disclose the terms of agreements promoting fair access and to provide transparent, non-exclusive licenses for government-owned products, with a focus on developing countries.[81]

The Treaty's approach has exposed a problem. As discussed earlier, the synergy between public and private R&D spending stems from the divergent focuses of government and industry. While government funding typically supports basic research, private investment leans towards applied research and development. Private stakeholders often build upon insights gained from basic research, driving clinical testing, innovation, and product refinement.[82] Despite significant public funding, a relatively small portion directly supports clinical trials, highlighting a gap in funding for this crucial stage of drug development. For example, $187 billion in

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[75] Hussain S Lalani *et al*., 'US public investment in development of mRNA covid-19 vaccines: retrospective cohort study' (2023) 380 BMJ.
[76] Fred Ledley *et al*., 'US Tax Dollars Funded Every New Pharmaceutical in the Last Decade' (Institute for New Economic Thinking, 28 February 2022), available at https://www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade (accessed 10 May 2024).
[77] 'Research and Development in the Pharmaceutical Industry' (Congressional Budget Office, April 2021) available at https://www.cbo.gov/publication/57126) (accessed 10 May 2024).
[78] Michael R. Ward and David Dranove, "The Vertical Chain of Research and Development in the Pharmaceutical Industry," (1995) 33(1) Economic Inquiry, 70–87.
[79] The Revised Draft (n 12), Article 9.
[80] Ibid.
[81] The Revised Draft (n 12), Article 11.1(c).
[82] 'Research and Development in the Pharmaceutical Industry', (n 77).

the US National Institutes of Health (NIH) funding for research related to the 356 drugs approved between 2010 and 2019, only 3.3% of all NIH funding related to new drug approvals pertains to clinical trials. [83]

Challenges arise when basic research fails to produce tangible inventions eligible for patents.[84] One study found that about one new private-sector patent was awarded for every two NIH research grants.[85] In other words, despite public investments, exclusivity rights often belong to a small group of pharmaceutical corporations. This situation may affect the Treaty's regulations related to government-funded products. If nations do not hold rights to share, the Treaty cannot require such sharing of licensing or technology transfer.

To address the issue, the Treaty explicitly advocates for the transfer of technology and expertise in pandemic and routine health products, particularly those that receive public funding and for the benefit of developing countries. It also calls on publicly funded patent holders to waive or reasonably reduce royalties for manufacturing pandemic-related products in developing countries during the pandemic. Furthermore, it proposes considering temporary waivers of IP rights to speed up the production of pandemic-related goods, ensuring broader access to affordable options.[86]

This sentiment echoes within the TRIPS Agreement, which mandates developed countries to promote technology transfer to LDCs. Article 66.2 of the TRIPS Agreement states that:

> 'Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base'.

This paragraph entails that while governments are not required to conduct technology transfer, they must incentivise their enterprises and institutions to facilitate technology flow to LDC members. This obligation is not merely a suggestion; it represents the positive obligations of developed countries to provide 'incentives' to enterprises and institutes to promote technology transfer in LDCs. This is legally binding commitment is further reaffirmed by the 2001 WTO Doha

[83] Fred Ledley, 'Who Really Pays for Drug Development? Both Government and Industry' (Biospace, [17 June 2023) available at https://www.biospace.com/article/opinion-who-really-pays-for-drug-development-both-government-and-industry/ (accessed 10 May 2024).
[84] Fred Ledley et al. (n 76).
[85] Pierre Azoulay *et al*., "Public R&D Investments and Private-Sector Patenting: Evidence from NIH Funding Rules," (2019) Review of Economic Studies 86(1), 117–152.
[86] The Revised Draft (n 12), Article 11.

Decision.[87] Unfortunately, there has been a poor outcome in enforcing this provision. First, the scope and meaning of the provision have been discussed with no outcomes. Many LDCs such as Zambia, Haiti, and Lesotho, have sought clarification on what constitutes incentives and how developed countries has been fulfilling their obligations.[88] To this end, LDCs requested to seek clarification on meaning of technology transfer and what constitutes incentives at WTO Ministerial conference but without success. At the 2017 WTO Ministerial Conference, a group of LDCs requested an effective mechanism of the 'incentives mandated by Article 66.2…in a manner that enables Least Developed Countries to absorb, adapt and improve on the received technologies'.[89]

It also requested the WTO Working Group on Trade and Transfer of Technology to 'examine restrictive practices adopted by multinational enterprises' in the area of technology transfer'[90] and to identify constraints on the lack of implementation of Article 66.2, as well as 'possible ways to provid[e] incentives by developed country Members to their enterprises and institutions order to meaningfully implement the letter and spirit of that provision'.[91] Despite the urgency from LDCs to clarify the scope of Article 66.2, many developed countries held different positions on the meaning of technology transfer and incentives. Some countries, like New Zealand, had a broader interpretation of technology transfer, including 'training, education and 'know-how'.[92] In contrast, many other developed countries interpreted incentives for technology transfer primarily in the form of financial support or official development assistance.[93]

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[87] Suerie Moon, 'Does TRIPS Art.66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999 – 2007) (UNCTAD, 2020) 2, available at https://unctad.org/system/files/official-document/iprs_pb20092_en.pdf (accessed 10 May 2024).

[88] See generally, Council for Trade-Related Aspects of Intellectual Property Rights, *Submission under Article 66.2 of the TRIPS Agreement* (WTO Document, IP/C/W/522, 22 October 2008); Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of the meeting held on 28 October 2008, WTO Document IP/C/M/58, 6 February 2009.

[89] See Draft G90 Ministerial Decision, Ministerial Conference Eleventh Session Buenos Aires, 10-13 December 2017 (WT/MIN(17)/23, 6 December 2017).

[90] Ibid, para 9.6.

[91] See World Trade Organization, Ministerial Declaration (WTO Document, WIN (17)/40, (10 December 2017)

[92] Council for Trade-Related Aspects of Intellectual Property Rights, 'Report on the Implementation of Article 66.2 of the TRIPS Agreement' (WTO Document, IP/C/W/580/Add.1, 19 October 2012), para 3 (Technology transfer is interpreted in this report broadly to include training, education and "know-how", along with any capital component. New Zealand sees four key modes of technology transfer: (i) physical objects or equipment; (ii) skills and human aspects of technology management and learning; (iii) designs and blueprints which constitute the document-embodied knowledge on information and technology; and (iv) production arrangement linkages within which technology is operated.

[93] Council for Trade-Related Aspects of Intellectual Property Rights, 'Report on the Implementation of Article 66.2 of the TRIPS Agreement (WTO Document, IP/C/R/TTI/Aus/3, 3 October 2022) para 5('In Australia, many incentives for technology transfer take the form of official development

Despite this experience, the Pandemic Treaty prioritise technology transfer to uphold equity principles. However, the revised document does not offer a clear definition of what constitutes technology transfer. This shared ambiguity raises concerns about a potential "Déjà vu" scenario.

After 30 years, the impact of Article 66.2 in empowering third-world countries to establish a robust technological foundation remains unaddressed.[94] The need for clarity in defining technology transfer allows developed countries to interpret any activity as meeting their obligations, even without substantive policy changes.[95] Amid the fluctuations, the TRIPS implementation has proved the importance of active engagement from LDCs and positive responses from developed country Members. Commencing with Haiti's initial request in 1998, a gradual series of reports and the subsequent establishment of a monitoring mechanism ensued.[96] As discussed earlier, the lesson that negotiators must learn from the Article 66.2 Technology Transfer Saga is that the Revised Draft of the Pandemic Treaty must include a clear definition and incentive mechanism that countries can rely on to promote health-related technology transfer. In other words, the scope of the technology transfer provision must be clearly defined. Based on the experience with Article 66.2 of TRIPS, we recommend an explicit, exhaustive list of examples that clearly delineate what is excluded from the scope of technology transfer, such as donations or development aid. This is just an example. All in all, there should be a clear obligation for the parties to promote technology transfer, with examples guiding possible incentives that countries could offer to achieve meaningful outcomes.

One of the positive outcomes of the Revised Draft of the Pandemic Treaty is the recognition of the state's rights to use TRIPS flexibilities, as reiterated in the Doha Declaration of the TRIPS and Public Health and the endorsement of 'time-bound waiver of IP rights' to ensure a rapid response and avoid inequitable delays. This is a positive development. However, the history of international IP treaties negotiations reveals that many developed countries have used coercion strategies

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assistance. These incentives align with Australia's strategic focus on using aid as a catalyst to promote sustainable economic growth and poverty reduction. Since 2012, Australia has provided AUD5.8 million of aid for trade funding to the Australia-World Intellectual Property Organization (WIPO) Funds in Trust (FiT) program, to assist technology and knowledge transfer to least developing (LDC) and developing countries in the Indo-Pacific region')

[94] David M. Fox, 'Technology Transfer and the TRIPS Agreement Are Developed Countries Meeting Their End of the Bargain?' (2019) 10(1) Hastings Science and Technology Law Journal, 1.

[95] Jayashree Watal and Leticia Caminero, 'Least-developed countries, transfer of technology and the TRIPS Agreement', WTO Staff Working Paper, No. ERSD-2018-01 (WTO 2017) 23, available at https://doi.org/10.30875/412bee53-en (accessed 10 May 2024).

[96] Jessica van Weelde *et al*., 'Reflection on the Implementation of Decision on Implementation of Article 66.2 of the TRIPS agreement: Incentive for Technology Transfer to Least-developed Countries', Staff Working Paper: Policy ERSD-2023-12 (WTO 2023), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4623380 (accessed 10 May 2024).

to push their own interests.[97] This trend continues today, with countries employing diplomatic tactics to advance their IP agendas or to pressure governments into adopting norms that may not benefit their domestic markets. To this end, many developing countries have proposed a peace clause which states:

> The Parties shall not challenge, or otherwise exercise any direct or indirect pressure on the Parties that undermine the right of WTO Members to use TRIPS flexibilities at any multilateral, regional, bilateral, judicial or diplomatic forum.[98]

This proposal has yet to be included in the text, but this innovative provision would minimise the pressure many developing countries face in utilising TRIPs flexibilities or implementing public-health-related IP measures.

Another concern is that exercising or implementing TRIPS flexibilities might conflict with a state's international treaty obligations. To address this, the Revised Draft includes two provisions. First, Article 25 states that in the event of a dispute between parties regarding the interpretation and application of the Treaty, the parties should aim to resolve it through diplomatic channels or other means, such as good offices, mediation, or conciliation, with the option of compulsory ad hoc arbitration.[99] Second, Article 26 emphasises that the Treaty must be guided by the Charter of the United Nations and the Constitution of the WHO. However, it further states that the Treaty's provisions 'should not affect the rights and obligation of any party under other legally binding international instruments which it is party'.[100]

Although these provisions are quite straightforward, the question remains whether a more specific clause should allow countries to make changes in their domestic systems to ensure the objectives and purpose of the WHO Pandemic Treaty are met without facing challenges. In our view, including a specific provision that prevents countries from challenging measures taken to pursue the Treaty should be encouraged.

5. Conclusion

The ongoing negotiation of the WHO Pandemic Treaty is a response to the impact of the COVID-19 pandemic, aiming to develop a new international agreement focused on pandemic preparedness and response. The driving force behind this effort is to ensure that communities, governments, and all sectors of society—nationally and globally—are better equipped to prevent and address future

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[97] See Susan K. Sell, Private *Powers, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press, 2003).
[98] See, 'The WHO Pandemic Treaty: The Peace Clause and Its Discontents' (KEI, 2024), available at https://www.keionline.org/39585 (accessed 20 May 2024).
[99] The Revised Draft (n 12), Article 25.
[100] The Revised Draft (n 12), Article 26.

pandemics. Governments underscored the significant loss of life, societal disruption, and developmental setbacks caused by the pandemic, emphasising the need for sustained action to prevent similar crises from recurring. One of the major issues discussed during the COVID-19 pandemic was the inequitable distribution of vaccines. This led to significant debate on waiving health-related IP provisions, resulting in clarification of the TRIPS provision. Therefore, there was a strong urge to include relevant technology transfer and the possibility of recognising the necessity of waiving IP rights to ensure equitable distribution of vaccines in future pandemics. The Revised Draft of the Treaty emphasises technology transfer; however, as discussed in this article, it will be beneficial if the Treaty language is more focused and more precise on IP-related provisions to minimise ambiguity when the Treaty is eventually implemented.