Fighting for IP Equity: A Zoom on the Forthcoming WHO Pandemic Agreement

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ABSTRACT

Faced with the impact of the COVID-19 pandemic, Member States of the World Health Organization (‘WHO’) agreed to negotiate an agreement on pandemic prevention, preparedness and response. A proposal for the negotiating text of this WHO Pandemic Agreement was prepared by the Intergovernmental Negotiating Body’s Bureau and shared with its Drafting Group in October 2023 for consideration. This process should lead to the adoption of a legally binding accord. This article considers the usefulness of this international instrument in relation to intellectual property, ultimately recognising its usefulness but arguing that the negotiating text could have been more ambitious. Specifically, it focuses on the WHO Pandemic Agreement’s potential to mitigate the impact of intellectual property regulations that favour developed countries and their pharmaceutical industries. First, the article highlights how the international intellectual property system disempowered developing countries in their battle against COVID-19. It then focuses on provisions relating to intellectual property law found in the negotiating text of the WHO Pandemic Agreement to explore and question its potential to contribute to intellectual property equity for developing countries for future pandemics. Finally, the article proposes recommendations to strengthen the impact of a WHO Pandemic Agreement in the fight for intellectual property equity.

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INTRODUCTION

Faced with the impact of the COVID-19 pandemic (‘COVID-19’), Member States of the World Health Organization (‘WHO’) agreed to negotiate a ‘convention, agreement or other international instrument’ on pandemic prevention, preparedness, and response.¹ A proposal for the negotiating text of this WHO Pandemic Agreement was prepared by the Intergovernmental Negotiating Body’s (‘INB’) Bureau and shared with its Drafting Group in October 2023 for consideration. This process should lead to the adoption of a legally binding accord — a legal agreement between countries dedicated to pandemics, and their prevention and management at a national and international level.² The WHO Pandemic Agreement seeks to stimulate global cooperation and ensure better preparation and protection in the face of future pandemics. This is to be achieved through the improvement of equitable access to healthcare, information, and technologies relating to vaccines and material resources like personal protective equipment.³ It, thus, reflects an international intent to avoid the recurrence of a crisis on the scale of COVID-19.

This article considers the usefulness and limitations of this international instrument for pandemic prevention, preparedness, and response in relation to intellectual property (‘IP’). It is suggested that although the utility of the agreement is undeniable, the negotiating text could be more ambitious. Specifically, this suggestion focuses on the WHO Pandemic Agreement’s potential to mitigate the impact of IP regulations that favour developed countries and their pharmaceutical industries. COVID-19 was marked by disparities in vaccine production and access between developed and developing countries.⁴

² ibid.
³ World Health Organisation, ‘Pandemic prevention’ (n 1).
Among other factors, intellectual property rights (‘IPRs’) played a role in the shortcomings of global management. The IPRs regime allowed western-based firms such as Oxford-AstraZeneca, Pfizer-BioNTech, Moderna, and Johnson & Johnson to considerably profit from monopolising vaccine production while complicating global south initiatives’ efforts to develop their own response. Consequently, Part II provides context to this reality and demonstrates how the international IP system, through the World Trade Organization’s 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (‘TRIPS’), disempowered developing countries in their battle against COVID-19. One negotiated solution is the TRIPS waiver, though it was ultimately insufficient to counteract TRIPS’s negative impact on global health during COVID-19, as will be shown. This reinforces the need for an international pandemic instrument.

The WHO Pandemic Agreement is evaluated in Part III. The process that led to the work surrounding the negotiating text and the next steps envisaged by the INB’s timeline are outlined. Part IV focuses on provisions of the proposed international law instrument relating to IP law to explore and question its potential to contribute to IP equity for developing countries in future pandemics. It analyses measures and approaches that would enhance IP ‘equity’ as defined in Part IV(i) of this article. Furthermore, criticisms are offered in terms of its effectiveness: a poorly managed relationship between the WHO Pandemic Agreement and TRIPS, and the discretion offered by ‘time-bound’ waivers. The issue of enforceability of the accord and accountability of Parties to it is also briefly addressed. It is then argued that the negotiating text’s approach is in line with previous instruments that tried to mitigate TRIPS’s effects on developing countries’ development and does not represent a radical shift. Nonetheless, it is perceived as a step beyond the 2001 Doha Declaration on the TRIPS Agreement and Public Health (‘Doha Declaration’). Since the WHO Pandemic Agreement

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5 Thambisetty and others (n 4) 389-392, 403-404.
addresses the interconnectedness of public and private sectors’ efforts, this offers a transnational perspective.

Finally, Part V offers two recommendations to strengthen the impact of the WHO Pandemic Agreement in the fight for IP equity. The first relates to a systematic waiver of IPRs attached to pandemic-related products during a pandemic, with pre-negotiated terms. The second concerns mandatory ‘targeted’ licensing for organisations that benefit from public funding for their research and development activities (‘R&D’). Part VI then concludes with both the potential and limits of the WHO Pandemic Agreement in contributing to IP equity for developing countries.

COUNTERACTING TRIPS’S NEGATIVE IMPACT ON GLOBAL HEALTH — THE NEED FOR AN INTERNATIONAL PANDEMIC INSTRUMENT

IPRs are negative and exclusive rights over creations of the mind. They allow their owners to prevent activities that would constitute an infringement on their rights, such as unauthorised use of an artistic work protected by copyrights or of a distinctive sign protected by a trademark.\(^7\) Specifically for the purposes of this article, patents protect inventions. The owner may decide who can ‘produce, distribute, import, or license a protected good or technological process’ that constitutes the invention,\(^8\) for a minimum of 20 years.\(^9\) The IP system thus aims to reward creators and provide them with an incentive to innovate. The protection offered by patent rights encourages inventors to disclose their new technology for

\(^8\) Maskus (n 7) 395.
\(^9\) TRIPS, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (adopted April 15, 1994, entered into force January 1, 1995, as amended on January 23, 2017) 1869 UNTS 299, art 33. TRIPS’s effects go beyond patents since the agreement concerns all forms of IPRs. This article however discusses TRIPS’s impact on patents and trade secrets. This relates more closely to pandemics and access to medications.
the benefit of society and invest resources in further innovation, because they are thereby recognised and recompensated.¹⁰

These exclusive rights granted to inventors also imply alternative consequences for consumers meant to benefit from patented inventions. Indeed, patent rights allow a patent owner to control, and most importantly, restrict access to an invention. Access to what may be essential medical products can, thus, be impacted by IPRs like patents. This issue came into the spotlight with COVID-19 vaccines. A few manufacturers dominated this specific vaccine market by securing patent rights under the conditions particular to the COVID-19 pandemic: ‘extraordinary demand for an unprecedented technology product, expedited regulatory approvals, long timelines for potential substitutes, and a lack of follow-on competition due to insufficient technology-transfer agreements’.¹¹ This allowed them to prioritise vaccine sales to developed countries that could afford higher prices, thereby taking advantage of the oligopoly enabled by patent law to the detriment of developing countries’ health needs.¹² As will be discussed throughout this article, this could constitute legitimate use of vaccine patents by firms who invested in their development. However, in the highly precarious context of a global pandemic, it is suggested that private interests may need to be circumvented, as public investments in such cases outstrip private funding, and global threats require a collaborative response.

Importantly, the Agreement on Trade-Related Aspects of Intellectual Property Rights (‘TRIPS’) reshaped the scope of IP protection by mandating that product and process patents be available for inventions ‘in all fields of technology’,¹³ placing pharmaceutical products under the realm of IPRs. Comparatively, pre-TRIPS, several nations (such as India and Brazil) had not enforced patents on products from this industry or only allowed process patents.¹⁴

Adopted through the establishment of the World Trade Organization (‘WTO’) in

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¹¹ Thambisetty and others (n 4) 385, footnote 5.
¹² Thambisetty and others (n 4) 390.
¹³ TRIPS (n 9) art 27.1.
1994, TRIPS is arguably the most important international instrument concerning IPRs. It creates the only current, comprehensive, enforceable, and *de facto* global set of minimum protection rules that must be implemented through national regimes.\(^{15}\) TRIPS successfully changed the international IP landscape because adherence to the agreement was made a requirement for countries to join the WTO,\(^{16}\) which is effectively the most important and influential international trade organisation (at the time of writing, it has 164 Member States representing 98% of world trade).\(^{17}\) The prospect of economic gains from joining the WTO, therefore, not only motivated developing countries to accept TRIPS,\(^{18}\) but also pressured them to do so.

Adherence to TRIPS was also promoted to developing countries under the promise of greater technological transfer.\(^{19}\) Accordingly, one of TRIPS’s stated objectives is to ‘contribute to the promotion of technological innovation and to the transfer and dissemination of technology’.\(^{20}\) Technology transfer is crucial to a viable IP system as it is the mechanism by which IPRs and knowledge flow from IPRs’ owners as creators to third party users who, in turn, produce further innovation.\(^{21}\) Development prospects were thereby linked to, and made contingent upon, the prospect of technology transfer from developed countries. This promise of development has, however, gone unfulfilled. Some parts of the world have attained notably greater economic growth than others: East Asia has transformed itself from a developing economy to one that houses successful

\(^{15}\) Maskus (n 7) 394-396.


\(^{18}\) Maskus (n 7) 396-397.

\(^{19}\) Maskus (n 7) 412.

\(^{20}\) TRIPS (n 9) art 7.

industrialised countries. Yet, as Okediji underlines, others remained in a state of ‘technological dependence’ and underdevelopment despite TRIPS, relying on foreign sources to meet domestic needs instead of developing their own technical knowledge and manufacturing capacity. These are the countries within the purview of this article. For instance, according to a recent report by the United Nations Conference on Trade and Development, about 67% of developing countries (95 countries) relied on the export of commodities between 2019 and 2021, which means that 60% of their merchandise export revenues came from primary goods. This commodity-dependence leaves their economy vulnerable and is effectively linked to low levels of technological capacities, whereas improved technological capacities could allow them to restructure their economies.

Furthermore, developed countries have pressured developing countries not to use TRIPS flexibilities for threat of trade-related reprisals. The term ‘flexibilities’ refers to TRIPS measures that seek to relax otherwise strict IP rules. Compulsory licences are an example: governments may issue licences on a patented product to a third party without the right holder’s consent. For instance, the United States has often opposed trade sanctions on developing

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23 ibid.
25 United Nations Conference on Trade and Development (n 24) 2.
30 TRIPS (n 9) art 31.
countries seeking to make use of compulsory licences, notably on South Africa in relation to HIV/AIDS drugs in the 1990s\(^{31}\) and Thailand in 2007 over medication for heart disease and cancer.\(^{32}\) The mechanism of compulsory licenses did not prove useful during COVID-19 because TRIPS only pertains to patent licensing, but not trade secrets.\(^{33}\) Trade secrets refer to information with commercial value that is not publicly known and subject to reasonable measures by its legitimate holder to keep it secret.\(^{34}\) Their inclusion is necessary because they protect information essential for manufacturing vaccines,\(^{35}\) an argument further developed in section IV. Additionally, TRIPS-plus norms reduce flexibilities available to Member States under TRIPS. These are IP norms negotiated in regional and bilateral free trade agreements that offer stronger and more restrictive protections than TRIPS.\(^{36}\) For instance, some result in restricting the possibility of challenging an invalid patent until after it has been granted, thereby prohibiting pre-grant opposition which would otherwise be available under TRIPS.\(^{37}\) These more onerous norms, emanating from developed countries,\(^{38}\) contribute to an even less flexible IP system.

Developing countries were also confronted with vaccine nationalism during COVID-19. This refers to the economic and health strategy of wealthy manufacturing countries of COVID-19 vaccines restricting access to vaccines for


\(^{34}\) Robin Feldman, ‘Trade Secrets in Biologic Medicine: The Boundary with Patents’ (2022) 24 Columbia Science & Technology Law Review 1, 12. Although it is noted that Feldman refers to United States’ law in particular, this corresponds to the standard definition of trade secrets.

\(^{35}\) Gurgula and Hull (n 33) 1244.


\(^{37}\) El Said (n 36) s 6.4.

\(^{38}\) Helfer (n 16) 121-122.
other countries.\textsuperscript{39} Indeed, doses were more heavily distributed in developed countries. Notably, in June 2021, 85\% of total doses had been administered in high and upper-middle income countries, compared to only 0.3\% in low income countries.\textsuperscript{40} Months later, in February 2022, developed countries (like the United Kingdom and many EU Member States) had double-vaccinated 70 to 75\% of their adult populations, while 85\% of Africans had not yet received the first dose.\textsuperscript{41} Still, in March 2023, 72.3\% of the world population had received at least one dose of a COVID-19 vaccine, but only 37.2\% had in Africa.\textsuperscript{42} Admittedly, restriction to access and inequitable distribution of vaccines were, in part, due to financial interests of manufacturers, as some developed countries presented higher purchasing power.\textsuperscript{43} Developed countries nonetheless secured more doses than they needed. For example, the United Kingdom bought doses that would allow the country to vaccinate its population eight times over.\textsuperscript{44} Developing countries were further engaged in vaccine dose and knowledge hoarding when initiatives like the COVID-19 Vaccine Global Access Facility (‘COVAX’) and the COVID-19 Technology Access Pool (‘C-TAP’) both failed due to a lack of cooperation from both private and public sectors.\textsuperscript{45} These initiatives respectively sought to increase vaccination in low and middle income countries and allow vaccine developers to share their IP.

This global management of COVID-19 was contrary to the spirit of TRIPS’s Article 66.2 that mandates developed countries to incentivise their private sector and public institutions to contribute to ‘technology transfer to least-developed country Members in order to enable them to create a sound and viable

\textsuperscript{39} Chimpango (n 29) 168.
\textsuperscript{40} Nancy Jecker and Caesar Atuire, ‘What’s Yours is Ours: Waiving Intellectual Property Protections for COVID-19 Vaccines’ (2021) 47 Journal of Medical Ethics 595, 595.
\textsuperscript{41} Thambisetty and others, ‘Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond’ (n 4) 388.
\textsuperscript{43} Thambisetty and others, ‘Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond’ (n 4) 390.
technological base’. The international IP system, therefore, favours large and influential pharmaceutical companies and the developed countries hosting them. These powerful players are hence able to keep developing countries in a state of dependency.

The WHO mRNA vaccine technology transfer hub further highlights the reality of technological dependence that developing countries face. This South African-based initiative, announced in June 2021, aimed to provide technology transfer to local producers in developing countries and establish multilateral technology sharing to bypass the lack of interest in bilateral agreements displayed by pharmaceutical companies during COVID-19. Instead of relying on foreign vaccine manufacturers, developing countries would work together to develop their own vaccine. By January 2022, it had successfully reproduced Moderna’s vaccine. The hub’s scientists benefitted from the research exception. They were permitted to experiment on patented vaccines for the purpose of innovation rather than commercialisation. They used publicly available information because none of the industry’s giants shared their technology, which slowed the hub’s work. Tedros Adhanom Ghebreyesus, WHO Director-General, argued that with those companies’ cooperation a vaccine could have been ready a year earlier than planned. Moderna also admitted that increasing the scale of manufacturing would be much more difficult for those seeking to manufacture mRNA vaccines without the necessary technology and knowledge transfer. As such, resisting technology transfer, far from spurring developing countries on to pursue their own initiatives, rather further entrenches a state of dependency. Moderna also filed for several vaccine-related patents in South Africa when the hub announced

49 Maskus (n 7) 403.
50 Davies (n 48) 1, 3.
51 Maxmen (n 47) 231.
52 Thambisetty and others, ‘Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond’ (n 4) 403.
its intention to recreate Moderna’s vaccine.\textsuperscript{53} Public statements by Moderna early in the pandemic declaring it would not enforce its COVID-19 related patents\textsuperscript{54} only serve to reinforce the claim that local initiatives in developing countries remain at the mercy of the pharmaceutical industry. Moreover, the hub’s achievement in replicating Moderna’s vaccine refutes the claim that developing countries have no choice but to remain dependent on developed countries because they lack manufacturing capacity and expertise.\textsuperscript{55} Rather, building independent production capacity in developing countries safely and rapidly is an attainable goal to which projects such as the hub contribute. In April 2023, the hub’s COVID-19 vaccine, AfriVac 2121, was being manufactured at a laboratory scale and in a scale-up phase for use in clinical trials.\textsuperscript{56} The hub is also providing training and technology transfer to fifteen biomanufacturing partners from its mRNA Technology Transfer Programme.\textsuperscript{57} Even Bangladesh and Senegal, listed as least developed countries by the United Nations and thus demonstrating the lowest level of socio-economic development,\textsuperscript{58} are part of the network of selected technology recipients that received technology transfer on mRNA vaccines from the hub to develop local production capacity.\textsuperscript{59}

To overcome the hurdles described in this section, a TRIPS waiver was negotiated. It was put forward as an exceptional measure to respond to vaccine accessibility issues in recognition that IPRs had affected the ‘timely provisioning of affordable medical products’ during COVID-19.\textsuperscript{60} Without a pre-existing

\textsuperscript{53} Maxmen (n 47) 231.
\textsuperscript{54} Thambisetty and others (n 4) 403.
\textsuperscript{55} ‘Thambisetty and others (n 4) 402-404.
\textsuperscript{57} ibid.
\textsuperscript{60} TRIPS Council, ‘Waiver from certain provisions of the trips agreement for the prevention, containment and treatment of Covid-19’ (Original proposal) (IP/C/W/669, 2 October 2020) 2
international pandemic accord addressing the management of IPRs during a pandemic, the international community had to negotiate a solution when faced with the crisis. A TRIPS waiver entails the suspension of certain TRIPS provisions that Member States are not obliged to implement, apply, or enforce at a national level for the scope and duration negotiated.61 It results in the targeted IPRs not being enforceable against third parties.62

However, the negotiated TRIPS waiver offered too little, too late. WTO’s Ministerial Decision on the TRIPS Agreement was belatedly adopted in June 2022,63 despite the original proposal having been made by India and South Africa in October 2020. In terms of substance, it merely focuses on patents and vaccines, allowing ‘the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic’,64 limiting its effect. Indeed, other IPRs like trade secrets also matter in pandemics, and relevant health technologies are not limited to vaccines.65 The Ministerial Decision had mandated a reconsideration of its scope to assess expansion to diagnostics and therapeutics within six months of its adoption.66 However, the deadline was extended as no consensus was reached and deliberations are still ongoing as of December 2023.67 The deficiencies of the waiver adopted illustrate the inefficacy of negotiations in times of crisis, a point considered later in the article.

Due to the global IP inequity, changes are required if the world is to prepare effectively for future pandemics. An international pandemic instrument such as the WHO Pandemic Agreement represents this opportunity for change.

61 Gurgula and Hull (n 33) 1244.
62 ibid.
63 Ministerial Decision on the TRIPS Agreement (adopted on 17 June 2022) WT/MIN(22)/30 (Ministerial Decision).
64 ibid art 1.
65 Thambisetty and others (n 6) 3-4, 7.
66 Ministerial Decision on the TRIPS Agreement (n 63) art 8.
THE MAKING OF THE WHO PANDEMIC AGREEMENT

In December 2021, the World Health Assembly, WHO’s decision-making body, met in a Special Session for only the second time since its establishment in 1948. The outcome was the creation of the Intergovernmental Negotiating Body (‘INB’), responsible for the global process of drafting and negotiating the WHO Pandemic Agreement. The INB is composed of all Member States and Associate Members of the WHO, in addition to regional economic integration organisations such as the EU. Since then, focused consultations with experts, public hearings, and the INB’s meetings have been conducted.

The INB’s Bureau, comprising delegates from the WHO’s six world regions, first developed a zero draft of the WHO Pandemic Agreement. It provided the basis for commencing negotiations. The INB’s Bureau then released a first draft, referred to as the Bureau’s Text. A proposal for the negotiating text of the WHO Pandemic Agreement has now been prepared and was shared with the INB’s Drafting Group in October 2023 for consideration. It is based on all inputs discussed during the INB’s meetings on the zero draft and on the Bureau’s Text. The current negotiating text is being discussed by the Drafting Group with the objective of reaching a consensus text. Ultimately, as permitted by Article 19 of the WHO’s Constitution, the INB aims to produce a

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71 World Health Organisation, ‘INB process’ (n 69).
72 Constitution of the World Health Organisation (adopted 22 July 1946, entered into force 7 April 1948) 14 United Nations Treaty Series 185, art 19: the Health Assembly has ‘authority to adopt conventions or agreements with respect to any matter within the competence of [the WHO]’. The door is open for Article 21 to be used instead, which
The WHO Pandemic Agreement is meant to be an international instrument addressing the national and international management of pandemics, in terms of causes and consequences, in vast areas of actions such as healthcare, production and distribution of pandemic-related products, and scientific research. It seeks to ‘prevent, prepare for and respond to pandemics, with the aim of comprehensively and effectively addressing the systemic gaps and challenges that exist in these areas, at national, regional and international levels’. Thus, it targets not only the ‘crisis’ phase, but all stages of a pandemic. This approach acknowledges, firstly, that countries must be equipped to prepare for and to face pandemics. Secondly, and more significantly, it implies that developing countries must be supported in this capacity-building. This is reinforced by the fact that negotiations surrounding the WHO Pandemic Agreement started in recognition of the catastrophic failure of the international community in showing solidarity and equity in response to the coronavirus disease (COVID-19) pandemic. In future pandemics, the international community seeks to ensure equitable access to tools essential for pandemic prevention, such as vaccines, and it is hoped that a pandemic accord will help achieve this goal.

The accord is to be a legally binding international document insofar as the Parties choose to be bound by it. The INB seeks to reach a consensus text permits WHO to adopt binding regulations: see World Health Organisation, ‘Bureau’s text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+)’ (2023) Bureau’s Text A/INB/5/6 <https://apps.who.int/gb/inb/pdf_files/inb5/A_INB5_6-en.pdf> accessed 2 December 2023.

73 World Health Organisation, ‘INB process’ (n 69).
75 World Health Organisation, ‘Negotiating Text’ (n 74) art 2.1.
76 World Health Organisation ‘Bureau’s Text’ (n 72) 1.
77 World Health Organisation, ‘Pandemic prevention, preparedness and response accord, Q&A’ (n 1).
78 World Health Organisation, ‘Pandemic instrument should be legally binding, INB meeting concludes’ (World Health Organisation, 21 July 2022)
that will foster bindingness and be global in scale. Effectively, the negotiating text suggests the creation of an Implementation and Compliance Committee as a subsidiary body of the Conference of the Parties.\(^79\) It also discusses dispute settlement avenues in case of disagreement on the interpretation or application of the Accord.\(^80\) The negotiating text further promotes solidarity and global commitment through open participation. Apart from WHO Member States, member and non-member observer states of the United Nations and regional economic integration organisations will be able to sign and become a Party to the accord.\(^81\)

**POTENTIAL AND LIMITATIONS: WILL THE WHO PANDEMIC AGREEMENT HELP ACHIEVE IP EQUITY FOR DEVELOPING COUNTRIES?**

This article now turns to the substance of the negotiating text, specifically elements related to IP, and analyses its potential to enhance IP equity in future pandemics.

**i. A Call for IP Equity: A Call for What Exactly?**

Before exploring the WHO Pandemic Agreement’s potential to achieve IP equity, it is essential to define what is meant by this term in the context of pandemics.

Central to the concept of equity is the ‘absence of unfair, avoidable or remediable differences, including in their capacities, among and within countries’.\(^82\) Most importantly, the negotiating text links equity to effectiveness when it calls for Parties to ensure ‘unhindered, fair, equitable and timely’ access to pandemic-related products and pandemic-related technologies.\(^83\) This implies

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\(^{79}\) World Health Organisation, ‘Negotiating Text’ (n 74) art 21.9.

\(^{80}\) World Health Organisation, ‘Negotiating Text’ (n 74) art 34.

\(^{81}\) World Health Organisation, ‘Negotiating Text’ (n 74) arts 31–32.

\(^{82}\) World Health Organisation, ‘Zero Draft’ (n 70) art 4.4.

\(^{83}\) World Health Organisation, ‘Negotiating text’ (n 74) art 3.3.
that barriers exist that prevent such access and that equity mandates their removal. As has been argued, IPRs and their protection through TRIPS played a role in erecting these barriers. IPRs are designed to allow developed countries and pharmaceutical firms to control access to essential drugs without mandating the technology and knowledge sharing that would help developing countries develop their own pandemic-related products. Pandemic prevention, however, thrives on self-reliance.\textsuperscript{84} Indeed, strong response capabilities for individual countries will lead to better global preparedness. This is particularly so since pandemics are global in scale insofar as they involve ‘the global spread of a pathogen or variant’.\textsuperscript{85} Therefore, for the world to effectively face a pandemic, countries must be individually prepared for when it inevitably reaches their territory. To that end, Thambisetty and colleagues’ explanation of ‘vaccine equity’ seems appropriate: equity requires ‘not only fairness, but wealth and knowledge sharing’ which would be achieved through ‘technology transfer to enable regional production in the global south’.\textsuperscript{86} Self-reliance thus becomes key to equity. This argument has also been framed as advocating for the ‘decolonization of global health’.\textsuperscript{87} Instead of relying on a charity model, equity means enabling development and capacity-building in developing countries. To achieve this, IP equity in the sense of a flexible IP system that posits collaboration and innovation-sharing at the centre, rather than exclusion, must be sought. The idea of dominance that underlies the IP system needs to be challenged.\textsuperscript{88}

Furthermore, IP equity should include a conception of the right to health, a guiding principle of the WHO Pandemic Agreement.\textsuperscript{89} The right to health is a recognised human right. The Constitution of the WHO states that the ‘enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being’.\textsuperscript{90} Notably, the International Covenant on

\textsuperscript{84} Maxmen (n 47) 227.

\textsuperscript{85} World Health Organisation, ‘Negotiating text’ (n 74) art 1(e).

\textsuperscript{86} ‘Thambisetty and others, ‘Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond’ (n 4) 415.


\textsuperscript{88} Maxmen (n 47) 233.

\textsuperscript{89} World Health Organisation, ‘Negotiating text’ (n 74) arts 2.1 and 3.1.

\textsuperscript{90} Constitution of the World Health Organisation (n 72) preamble.
Economic, Social and Cultural Rights speaks of the right to the ‘highest attainable standard of physical and mental health’.\textsuperscript{91} TRIPS is often seen as a system protective of corporations in which IPRs are allowed to overshadow conflicting human rights.\textsuperscript{92} For example, in relation to the right to health which incorporates availability and accessibility of medication,\textsuperscript{93} mandating patents on pharmaceutical products increases their price, affecting their accessibility.\textsuperscript{94} As such, it is argued that patenting essential drugs violates that right because it restricts access to them.\textsuperscript{95} The negotiating text’s preamble similarly recognises ‘concerns about the effects of intellectual property rights on prices’.\textsuperscript{96} In any case, the right to health in terms of access to medicines is affected by the enforcement of IPRs. However, IP equity calls for a reconsideration of what the right to health entails in a pandemic. It should include not only global access to pandemic-related products, but also achieving global capacity in producing and manufacturing them, as argued in this subsection. This vision is aligned with one of the WHO Pandemic Agreement’s guiding principles: the recognition of different levels of capacity.\textsuperscript{97} It entails that countries with capacity needs should be supported\textsuperscript{98} and, further, they should be enabled to support themselves. There are opportunities to do so through a pandemic accord. Self-reliance and international collaboration can be fostered with a pre-negotiated waiver of IPRs on pandemic-related products during a pandemic and mandatory licensing during and between pandemics when R&D for pandemic-related products was publicly funded. Those will be the recommendations analysed in the last section of this article.

\textsuperscript{92} Joseph (n 27) 216-217.
\textsuperscript{93} Helfer (n 16) 126.
\textsuperscript{95} Helfer (n 16) 126.
\textsuperscript{96} World Health Organisation, ‘Negotiating text’ (n 74) preamble, para 10.
\textsuperscript{97} World Health Organisation, ‘Negotiating text’ (n 74) art 3.5.
\textsuperscript{98} ibid.
ii. ‘The World Together Equitably’

During the INB’s fourth meeting, Member States insisted that equity should be a cross-cutting theme and not the focus of a single chapter, as it was first presented in the zero draft. Effectively, in the Bureau’s Text as well as in the negotiating text, all substantive measures of the instrument are to be found under one chapter now titled, ‘The world together equitably: Achieving equity in, for and through pandemic prevention, preparedness and response’. Equity remains a guiding principle of the negotiating text, that is at ‘the centre’ of pandemic prevention, preparedness and response. The idea of equity was, thus, influencing the spirit of the accord from its early beginnings, and can now be interpreted as its core purpose. The negotiating text’s preamble also notes the Political Declaration of the United Nations General Assembly High-level Meeting on Pandemic Prevention, Preparedness and Response, adopted during the United Nations General Assembly’s 78th session, which ‘affirms the need to prioritise equity’. Accordingly, the negotiating text adopts an equity-driven approach and militates for IP equity through various provisions. What follows is an analysis of the six concrete ways identified in which the WHO Pandemic Agreement espouses IP equity.

(a) Tackling the whole life of pandemics

The negotiating text specifies that the WHO Pandemic Agreement would apply ‘at all times’. This highlights a continuing responsibility. Effectively, the accord does not limit its scope to states’ responses to pandemics, but also focuses on their ability to prepare and build response capabilities, for

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100 World Health Organisation ‘Negotiating text’ (n 74) art 3.3. See also World Health Organisation ‘Zero draft’ (n 70) art 4.4; Bureau’s Text (n 72) art 3.3.
102 World Health Organisation, ‘Negotiating text’ (n 74) art 2.2.
example through measures on research and development. This highlights the importance of global preparation to be able to effectively respond in times of crisis.

(b) Discussing licences and waivers

Articles 10.1(d) and 11.3(a) respectively support non-exclusive and royalty-free licensing of IP, particularly to manufacturers located in developing countries, and a waiver of IPRs during a pandemic, both in relation to pandemic-related products. The scope of the relevant subparagraphs is not constrained to patents and vaccines like in the Ministerial Decision. IPRs are generally targeted and ‘pandemic-related products’ are not defined exhaustively, but include vaccines, diagnostics, therapeutics, medicines, and more.\(^\text{103}\) Although a restricted approach entailing greater certainty might attract more support from private actors like pharmaceutical companies, this recognises that a broad and flexible description of what should be deemed essentially accessible is required. India, which initiated the discussion on waivers during COVID-19 together with South Africa, insisted that ‘health products and technologies like test kits, masks, medicines, vaccines, components of ventilators like valves, control mechanisms and the algorithms and CAD\(^\text{104}\) files used in their manufacturing’ are protected by a range of IPRs, and as such a proportionate approach should target all of them.\(^\text{105}\) Moreover, as pointed out by Yu in his discussion on the COVID-19 TRIPS waiver, the WTO Ministerial Conference’s narrow focus on vaccines’ accessibility ignores the need for development in diagnostics and therapeutics for ‘meaningful impact’ in pandemics response.\(^\text{106}\) Strategically, licenses and waivers should not solely target vaccines as other products, like diagnostics or therapeutics, are usually easier to reverse-engineer and require less knowledge transfer.\(^\text{107}\)

\(\text{103}\) World Health Organisation, ‘Negotiating text’ art 1(f).
\(\text{104}\) ‘Computer-aided design’.
\(\text{106}\) Yu (n 6) 15.
Broadening the scope of licences and waivers thus enables all health technologies useful to pandemic prevention and response to be made available, and for all IPRs-related barriers to be removed, for the purpose of capacity-building in developing countries.

(c) Addressing technology and ‘know-how’ transfer

The negotiating text puts technology and ‘know-how’ transfer at the centre of the accord. This contributes to one of TRIPS’s most equitable facets: the promotion of technology transfer. Experts emphasised how effective measures to facilitate the production of COVID-19 vaccines needed to include technology transfer. Indeed, the often-mentioned idea that ‘the process becomes the product’ in relation to pharmaceutical products took its meaning during COVID-19, especially in relation to vaccines. As ‘complex biological products’, their development involves elaborate processes which necessarily require ‘specialist knowledge and experience’ to achieve the manufacturable product. Technology and knowledge transfer thus represent the way towards capacity-building for developing countries.

In relation to the two previous points, the negotiating text mandates states to ‘encourage’ manufacturers within their jurisdiction to ‘share undisclosed information, in accordance with paragraph 2 of article 39 of the TRIPS Agreement, with qualified third-party manufacturers’ specifically when non-disclosure would otherwise negatively affect the urgent manufacture of a pharmaceutical product essential for pandemic response. This echoes TRIPS’s obligation on developed countries to ‘provide incentives’ for technology transfer.

108 World Health Organisation, ‘Negotiating text’ (n 74) arts 10.1(e), 10.3(c), 11, 12.4(c)(i).
110 Feldman (n 34) 33.
111 Gurgula and Hull (n 33) 1246.
113 World Health Organisation, ‘Negotiating text’ (n 74) art 11.3(c).
from local enterprises and institutions,\textsuperscript{114} which, as already discussed, did not prove fruitful during COVID-19. In comparison, such language on trade secrets was entirely absent from both the zero draft and the Bureau’s text. Therefore, this provision is a step in the right direction and should be considered a positive addition. However, it may still not offer a comprehensive solution because the negotiating text refers to IPRs without other specification when it promotes licences and waivers. It should therefore make mention of trade secrets in relation to those measures. This would incorporate the promotion of undisclosed knowledge sharing in concrete mechanisms instead of in a vacuum.

Undisclosed information is addressed by TRIPS’s article 39, which notably protects clinical test data.\textsuperscript{115} However, TRIPS does not explicitly mention trade secrets, and IP law as such does not provide mechanisms to mandate their sharing.\textsuperscript{116} Effective waivers and licences should nonetheless involve granting access to manufacturing information, which is protected not only by patents, but also increasingly by trade secrets.\textsuperscript{117} Indeed, the vaccine formula protected by patents is only one element of a successful vaccine production. Other essential components, such as the ‘combination of steps required, the method of production, the equipment […] and the experience of the engineers controlling the process’, instead involve trade secrets.\textsuperscript{118} Therefore, there might be a struggle to successfully manufacture the generic version of a product, despite patent rights being waived. One may recall the example of the WHO mRNA vaccine technology transfer hub cited earlier: it is precisely because the hub’s scientists did not have access to that type of undisclosed information, such as data on clinical trials, that they were slowed down in their enterprise to produce a COVID-19 vaccine.\textsuperscript{119}

\begin{thebibliography}{119}
\bibitem{114} TRIPS (n 9) art 66.2.
\bibitem{115} On clinical test data specifically, the negotiating text’s article 9.3(e) encourages transparency and disclosure.
\bibitem{116} Gurgula and Hull (n 33) 1248. A thorough discussion on the legal feasibility of mandating trade secrets’ sharing is beyond the scope of this article, but the authors argue for it in their paper; see Gurgula and Hull (n 33) 1249-125.
\bibitem{117} Gurgula and Hull 1243-1248, 1252.
\bibitem{118} Gurgula and Hull 1246.
\bibitem{119} Maxmen (n 47) 231.
\end{thebibliography}
Barnes-Weise and colleagues note that mandating trade secrets transfer might not be feasible in fields like the pharmaceutical industry because they are characterised by trade secrecy as opposed to knowledge transfer.120 Such a waiver might thus be difficult to enforce in practice.121 There is also space for reluctance with a waiver involving trade secrets as it would involve a loss of control. Non-disclosure clauses to protect secrecy cannot be added to a global waiver mechanism, whereas risks are mitigated with licences including such requirements. The issue is that confidentiality breaches with respect to trade secrets entail the loss of their value as an asset.122 However, the protection of trade secrets must remain in line with the ‘implicit bargain’ justifying the patent system. It seeks to incentivise inventors to innovate by granting them exclusivity through IPRs protection. However, in counterpart, patent holders are expected to fully disclose the invention and render it accessible to the public’s benefit.123 More than a fairness argument, this balance lies at the heart of the justification for upholding a patent system in the first place: ensuring that innovation leads to further innovation. In that sense, Feldman argues that trade secrets ought to be included in patent disclosure from the outset: she argues for a reform of patent law that would require patent applicants for a drug product to disclose all trade secrets necessary for its making.124 Feldman justifies her suggestion with the claim that pharmaceutical companies manage to evade the rule that ‘a person skilled in the art’ must be able to make and use the invention.125 They rather protect such manufacturing process information under the umbrella of trade secrets.126 Insofar as trade secrets are used to hinder access to an invention and prevent technology transfer, as experienced by developing countries during the COVID-19 pandemic,
pharmaceutical companies are not respecting their side of the bargain. Consequently, trade secrets should not be blindly protected.

(d) Recognising the significance of publicly funded research

The zero draft of the WHO Pandemic Agreement stressed that conditions should be attached to publicly funded research because of its importance for the development of pandemic-related products.\textsuperscript{127} Article 9.4 of the negotiating text promotes contract terms that would involve knowledge sharing and transparency, licensing in developing countries, and ensuring ‘affordable, equitable and timely access’ to products during pandemics, in consideration of the extent of public funding provided.

It seems reasonable to request that public investment in a risky R&D phase not only profit private firms, but also meet global needs. Indeed, groundwork for innovations relating to technologies used in COVID-19 vaccines was publicly funded.\textsuperscript{128} For instance, the technology behind the Oxford-AstraZeneca vaccine, ChAdOx, was developed at 97\% to 99\% with public funding,\textsuperscript{129} and the United States government invested 10 billion USD in research leading to the NIH-Moderna vaccine.\textsuperscript{130} Therefore, while the private sector invested in their development, funding towards several COVID-19 vaccines came almost entirely from public funds.\textsuperscript{131} Although governments have invested significant amounts in the development of COVID-19-related products, they nevertheless failed to require equitable production and distribution mechanisms in exchange, or any IPRs-related interest.\textsuperscript{132} Rather, private firms conditioned the terms for global access to vaccines. Notably, pharmaceutical companies generated

\begin{footnotes}
\textsuperscript{127} World Health Organisation, ‘Zero draft’ (n 70) preamble, para 47; see also arts 9.2–9.3.
\textsuperscript{128} Erfani and others (n 45) 3.
\textsuperscript{131} Thambisetty and others, ‘Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond’ (n 4) 391-392.
\textsuperscript{132} ibid 391-392, 405.
\end{footnotes}
sizeable profits from COVID-19 vaccine distribution.\(^{133}\) For example, Pfizer’s vaccine revenue totalled 37 billion USD in 2021,\(^{134}\) which makes its COVID-19 vaccine ‘one of the most lucrative products in history’ and resulted in the company being accused of ‘pandemic profiteering’.\(^{135}\) Similarly, Moderna reported a revenue of 17.7 billion USD in sales from its COVID-19 vaccine in 2021, allowing its total revenue to increase from 803 million USD in 2020 to 18.5 billion USD in 2021.\(^{136}\) Meanwhile, the net unit cost of manufacturing a COVID-19 vaccine ranges from 0.54 to 0.98 USD a dose for 100 million doses ready for shipping.\(^{137}\) Publicly funded R&D offers an opportunity to depart from this corporate profits-driven mentality when pandemic prevention, preparedness, and response are involved.

Moreover, since the patent system is a way for governments to encourage innovators without significantly spending public funds,\(^{138}\) the promotion of strong IPRs protection while procuring significant public funding for R&D makes little sense. As Thambisetty and others have argued, ‘why privatis[e] the fruits of public funding with the additional incentive of private monopoly rights?’\(^{139}\) In fact, in 2016 the United Nations Secretary General’s High-Level Panel on Access to Medicines recommended that publicly funded research should oblige results sharing and IPRs licensing.\(^{140}\) It could be argued that creating a system in which certain products are subject to less protection

\(^{133}\) ibid 390-391.
\(^{135}\) ibid.
\(^{138}\) Eisenberg (n 14) 932-933.
\(^{139}\) Thambisetty and others, ‘Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond’ (n 4) 412.
could lead to less research investment in that field by private firms.\textsuperscript{141} This concern is precisely mitigated by publicly funding that R&D: it hopes to constitute a sufficient incentive to encourage innovation for pandemic-related products.

However, public involvement in vaccine development does not necessarily lead to global altruism. As discussed in section II, developed countries had access to more COVID-19 vaccine doses than developing countries and sometimes bought more doses than necessary to vaccinate their population. Additionally, not all countries invested in the same manner into vaccine R&D and production. For instance, from the start of COVID-19 in 2020 to March 2022, the United States government invested at least 2.3 billion USD in R&D for the mRNA COVID-19 vaccines.\textsuperscript{142} As such, investing governments could argue during a pandemic that their country’s significant investments ought not necessarily to benefit the international community but primarily their own. However, the global nature of pandemics highlights the need for each country to be equipped in terms of pandemic response. Therefore, preparing for the next pandemic requires that this tendency to prioritise one’s own population without ensuring that protection is also available in other parts of the world be resisted through upstream conditioning of publicly funded research. Technology and knowledge sharing, licensing, and equitable access can become the norm through conditioned public investment. As the negotiating text affirms, states under the WHO Pandemic Agreement would be accountable for fighting ‘for fair, equitable, effective and timely pandemic prevention, preparedness, response’.\textsuperscript{143} The negotiation process surrounding the WHO Pandemic Agreement itself testifies to developed states’ commitment to act differently in future pandemics, notably with regard to conditioned financing of R&D for pandemic-related products,\textsuperscript{144} gearing towards what the negotiating text describes as ‘the widest possible international cooperation’ in terms of pandemic response.\textsuperscript{145} It might signal the beginning of a change in attitude from developed countries. In any case, it will not be sufficient in and of itself. For this change to translate into concrete

\textsuperscript{142} Hussain Lalani and others, ‘US Public Investment in Development of mRNA Covid-19 Vaccines: Retrospective Cohort Study’ (2023) 380 British Medical Journal 3-4.
\textsuperscript{143} World Health Organisation, ‘Negotiating text’ (n 74) art 3.8.
\textsuperscript{144} World Health Organisation, ‘Negotiating text’ (n 74) art 9.4.
\textsuperscript{145} World Health Organisation, ‘Negotiating text’ (n 74) preamble, para 3.
measures benefitting developing countries, as suggested by the WHO Pandemic Agreement, the issue of accountability must be better addressed in the accord. This limitation of the WHO Pandemic Agreement will be discussed in subsection IV(iii).

(e) Encouraging transparency

Transparency is a guiding principle of the WHO Pandemic Agreement.\textsuperscript{146} Publicly funded research commands accountability which can be achieved through transparency and disclosure of contract terms relating to, for example, distribution, and pricing.\textsuperscript{147} The negotiating text provides that states should encourage private right holders to publish the terms of licensing agreements and technology transfer agreements for pandemic-related products.\textsuperscript{148} Similarly, article 9.4 concerns transparency in government contracts for publicly funded R&D. Such a transparent and open science approach aims to enhance R&D capacities in developing countries,\textsuperscript{149} a key element of IP equity.

(f) Providing for global solidarity

The negotiating text encourages a ‘globalist’ approach to health governance, as opposed to a ‘statist’ one. Solidarity in the sense of ‘collaboration, coordination and cooperation to achieve the common interest of a safer, fairer, more equitable and better prepared world’ is described as one of the WHO Pandemic Agreement’s guiding principles.\textsuperscript{150} More specifically, measures of the negotiating text, such as increasing research partnerships and capacity-building around the world through technology and ‘know-how’ transfer, support this collaborative approach.\textsuperscript{151} Instead of each country adopting a statist attitude and focusing on its own population’s needs, individuals become part of a ‘single global

\textsuperscript{146} World Health Organisation, ‘Negotiating text’ (n 74) art 3.7.
\textsuperscript{147} Hilty and others (n 121) 6.
\textsuperscript{148} World Health Organisation, ‘Negotiating text’ (n 74) art 10.3(b).
\textsuperscript{149} World Health Organisation, ‘Negotiating text’ (n 74) art 9.1.
\textsuperscript{150} World Health Organisation, ‘Negotiating text’ (n 74) art 3.6.
\textsuperscript{151} World Health Organisation, ‘Negotiating text’ (n 74) arts 9.1, 9.2(b), 10.1(c), 10.3(c) and 11.
community’ meant to collaborate in the pursuit of health.\textsuperscript{152} The negotiating text insists that a government’s individual responsibility towards its people will be met through ‘global collective action’.\textsuperscript{153} This aspiration can, however, be doubted in light of the state-centrist attitude displayed by developed countries during COVID-19.\textsuperscript{154} In spite of the consensus that ‘[n]one of us will be safe until everyone is safe’,\textsuperscript{155} a statist mentality characterised by vaccine nationalism led to populations in developing countries awaiting their first COVID-19 vaccine dose, while those of some developed countries such as the United States and the United Kingdom had already received a third or fourth booster dose.\textsuperscript{156} This scepticism is justified. Developed countries to be Parties to the accord should not simply set high standards that they are not willing to implement: they cannot ‘treaty their way out’ of the pandemic\textsuperscript{157} in the sense that practical change in pandemics’ management must follow the adoption of the WHO Pandemic Agreement. Member States are effectively aiming for interconnectedness and global solidarity through the instrument. This denotes an acknowledgment from the international community that a ‘solidarity discourse based on the recognition of interconnectedness and interdependence’ represents the right approach to see improvements in the management of the next pandemic.\textsuperscript{158} Global initiatives might indeed foster the likelihood of the emergence of globally accessible solutions. Nonetheless, as stated above, while this ambition is a desideratum for a future pandemic accord, it must be complemented by effective implementation through accountability and monitoring mechanisms.

\textsuperscript{152} Clare Wenham, Mark Eccleston-Turner, and Maike Voss, ‘The Futility of the Pandemic Treaty: Caught Between Globalism and Statism’ (2022) 98 International Affairs (UK) 837, 838.
\textsuperscript{153} World Health Organisation, ‘Negotiating text’ (n 74) art 3.4.
\textsuperscript{154} Wenham, Eccleston-Turner, and Voss (n 152) 844, 852.
\textsuperscript{155} World Health Organisation, ‘A global pandemic requires a world effort to end it – none of us will be safe until everyone is safe’ <https://www.who.int/news-room/commentaries/detail/a-global-pandemic-requires-a-world-effort-to-end-it-none-of-us-will-be-safe-until-everyone-is-safe> accessed 2 December 2023.
\textsuperscript{156} Thambisetty and others, ‘Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond’ (n 4) 388.
\textsuperscript{157} Karunakara (n 87).
The following can, therefore, be listed as useful measures and approaches of the negotiating text that promote a world together towards the achievement of IP equity:

1. It tackles the ‘whole life’ of a pandemic, thus supporting the proposition that IP equity needs to encompass prevention and capacity-building;
2. It discusses licences and waivers as measures to be encouraged by states, and as such recognises the importance of flexibility and contextualisation in enforcing IPRs;
3. It addresses technology and ‘know-how’ transfer as elements essential for effective manufacturing and access to pandemic-related products;
4. It recognises the significance of publicly funded research and the obligations imposed on private firms as a result;
5. It encourages transparency in the contracting process for pandemic-related products research and manufacturing, which helps to render both governments and private firms accountable;
6. It provides for global solidarity as opposed to state-centrism.

### iii. The Negotiating Text’s Limitations

The INB’s Bureau drafted the negotiating text with the aim of responding to criticisms raised during the INB’s meetings that considered the zero draft and the Bureau’s Text. For example, as previously mentioned, equity can now be seen as an overarching objective of the instrument following those meetings. Several Member States, including Mexico, Namibia, Morocco, and Malaysia, also bemoaned a lack of accountability and binding language in the zero draft.\(^{159}\) Indeed, the zero draft was addressing compliance, but allowed for the specificities to be negotiated in the future.\(^{160}\) By contrast, the negotiating text specifies that Parties would need to submit periodic reports to the Conference of the Parties on their implementation of the accord,\(^{161}\) and suggests establishing an Implementation and Compliance Committee.\(^{162}\) However, the Bureau’s Text was

\(^{159}\) World Health Organisation Intergovernmental Negotiating Body, ‘INB’s fourth meeting, Session 2’ (n 99).
\(^{160}\) World Health Organisation, ‘Zero draft’ (n 70) art 22.
\(^{161}\) World Health Organisation, ‘Negotiating text’ (n 74) art 23.
\(^{162}\) World Health Organisation, ‘Negotiating text’ (n 74) art 21.9.
more detailed and, going further on this specific measure, established the Committee to consider reports submitted by Parties, make recommendations, and generally oversee the implementation of, and compliance with, the WHO Pandemic Agreement.163 This regression, on the issue of accountability, confirms earlier concerns that the accord risks not having sufficient ‘teeth’ and ‘spine’ to overcome mere voluntary compliance.164

Nonetheless, insofar as states might be reluctant to enter a treaty with a robust sanction system,165 accountability could be achieved through strong incentives. Faviero and others suggest non-financial incentives such as ‘reputation, priority access to limited resources and treaty voting rights’ as well as periodic financial support for developing countries linked to past achievements in terms of pandemic prevention and response.166 In addition, a transparent monitoring mechanism must be put in place for Parties to share information on their implementation of the WHO Pandemic Agreement to be verified by an impartial and independent oversight body.167 Imposing reporting requirements on Parties facilitates public scrutiny and awareness which can, in turn, put pressure on them to comply with the accord.168 The Implementation and Compliance Committee could act as this oversight mechanism and must thus be reintroduced in the negotiating text to be established rather than merely suggested. It could also be made independent of the WHO for increased political influence.169 Indeed, the WHO appeared to lack enforcement power and legitimacy during COVID-19 since states did not always follow its public health recommendations, whereas an effective oversight body must be able to influence governments to ensure compliance with the accord.170 For example, the WHO advised early on in the

163 World Health Organisation, ‘Bureau’s Text’ (n 72) art 22.
166 ibid.
167 Faviero and others (n 165).
169 Faviero and others (n 165) 730.
170 Wenham, Eccleston-Turner and Voss (n 152) 849.
COVID-19 pandemic that healthcare professionals and high-risk individuals in all countries should be vaccinated first, but developed countries have tended to prioritise their own populations, including those at a relatively low risk. With that concern in mind, the Implementation and Compliance Committee could even take the form of a ‘Global Health Threats Council’ that would model the United Nations Security Council to move the issue closer to national security than to cosmopolitanism. The WHO Pandemic Agreement currently lacks meaningful accountability mechanisms to ensure its enforceability. Limited accountability rightly concerns the operationalisation of the accord. Any reform must instead define states’ obligations in relation to disease outbreaks because global health law precisely lacks significant accountability. Serious commitment to this instrument will follow from Member States’ willingness to include accountability mechanisms since mere ‘good will’ proved insufficient during COVID-19 when national health and safety were key priorities for governments.

Besides that, other aspects of the current negotiating text risk undermining its effectiveness during the next pandemic. This subsection will now focus on two potential limitations of the negotiating text that directly relate to IP.

(a) The relationship between the WHO Pandemic Agreement and TRIPS

Article 25 addresses the relationship of the WHO Pandemic Agreement with other international agreements and instruments. It must be clarified how this accord will work specifically alongside TRIPS. For example, the WTO insists on the importance of clarifying how the suggested time-bound waivers would relate to existing TRIPS flexibilities. The potential for conflicts is high as the WHO Pandemic Agreement directly addresses IPRs, setting rules in areas that were

171 Thambisetty and others, ‘Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond’ (n 4) 388.
172 Wenham, Eccleston-Turner and Voss (n 152) 15.
173 Shah (n 168) 238, 246.
174 Faviero and others (n 165) 730-731.
discussed under the TRIPS framework during COVID-19. This could impact the WHO Pandemic Agreement’s relevance and influence in future pandemics; hence, it should be established whether the WHO Pandemic Agreement would have priority when a pandemic is declared. This was included as part of a series of recommendations on a future pandemic accord prepared by Perehudoff and colleagues.\footnote{Katrina Perehudoff and others, ‘A Pandemic Treaty for Equitable Global Access to Medical Countermeasures: Seven Recommendations for Sharing Intellectual Property, Know-How and Technology’ (2022) 7 British Medical Journal of Global Health, 3.} A principle of primacy entails that Parties’ obligations under the WHO Pandemic Agreement would take precedence over the ones they have under TRIPS in case of conflict.\footnote{Helfer (n 16) 129.}

In any case, the negotiating text provides that time-bound waivers should be agreed upon during a pandemic ‘within the framework of relevant institutions’.\footnote{World Health Organisation, ‘Negotiating text’ (n 74) art 11.3(a).} Moreover, the pandemic accord and ‘other relevant international instruments’ should be ‘complementary and compatible’.\footnote{World Health Organisation, ‘Negotiating text’ (n 74) art 25.2.} At the same time, it should not affect Parties’ rights or obligations under other instruments.\footnote{ibid.} As such, the WHO’s International Health Regulations (‘IHR’) are currently being amended. Suggestions on amendments are to be considered at the 77th World Health Assembly, at which a final draft of the WHO Pandemic Agreement will also be presented.\footnote{World Health Organisation, ‘Governments make progress towards agreeing amendments to the International Health Regulations (2005)’ (7 October 2023) <https://www.who.int/news/item/07-10-2023-governments-make-progress-towards-agreeing-amendments-to-the-international-health-regulations-(2005)#:~:text=The%20IHR%2C%20in%20their%20version,by%20the%20COVID%2019%20pandemic.> accessed 2 December 2023.} These two subject-matters are intrinsically linked because both concern the ‘international spread of disease’\footnote{International Health Regulations (2005) (adopted 23 May 2005, entered into force 15 June 2007) 2509 United Nations Treaty Series 79, art 2.} and, as the WHO acknowledges, ‘are expected to play central roles in pandemic prevention, preparedness and response in the future’.\footnote{World Health Organisation, ‘Seventy-fifth World Health Assembly Decision Agenda Item 16.2: Strengthening WHO preparedness for and response to health emergencies’ (WHA75(9), 27 May 2022)} The process of amendment is, thus,
closely related to the INB’s work and is recognised as such. The work of both Bureaus should be complementary, insofar as they are interlinked.\footnote{World Health Organisation Intergovernmental Negotiating Body, ‘INB’s fifth meeting, Session 1’ (3 April 2023) <https://apps.who.int/gb/inb/e/e_inb-5.html> accessed 2 December 2023.} A joint plenary session was held in July 2023. The INB and the Working Group on Amendments to the IHR met to further discuss the complementarity between the two instruments.\footnote{WHO, ‘Fourth meeting of the Working Group on Amendments to the International Health Regulations (2005)’ <https://www.who.int/news-room/events/detail/2023/07/24/default-calendar/fourth-meeting-of-the-working-group-on-amendments-to-the-international-health-regulations-(2005)> accessed 2 December 2023.}

Similarly, there should be discussions at the WTO about amending TRIPS to ensure its compatibility with the WHO Pandemic Agreement. Reviews may be undertaken by the TRIPS Council ‘in the light of any relevant new developments which might warrant modification or amendment of [TRIPS]’.\footnote{TRIPS (n 9) art 71.2.} Indeed, policy actors such as the WTO and the World Intellectual Property Organisation (‘WIPO’) also have a responsibility to promote global health.\footnote{Wijesinghe, Adikari and Ariyaratna (n 109) 188.} An issue exists insofar as different organisations oversee the two instruments. By contrast, collaboration between working groups on the WHO Pandemic Agreement and the IHR’s amendment is facilitated as both instruments stem from the WHO. However, WHO, WTO, and WIPO already work in a framework of trilateral cooperation,\footnote{Marion Motari and others, ‘The Role of Intellectual Property Rights on Access to Medicines in the WHO African Region: 25 Years After the TRIPS Agreement’ (2021) 21 BMC Public Health, 3.} which should facilitate coordination between the WHO Pandemic Agreement and TRIPS. Notably, the WTO participates in the plenary sessions at INB’s meetings, which indicates interest from the Organisation. An appropriate step would be to hold joint sessions between the INB and the TRIPS Council to address the instruments’ complementarity, similarly to what is being done between the INB and the Working Group on Amendments to the IHR.
(b) The wording ‘time-bound’ waivers

The wording of ‘time-bound’ waivers used in article 11.3(a) of the negotiating text may offer too much discretion to states. A clearer definition in terms of duration would be preferable, as will be suggested in section V. Vagueness opens the door to uncertainty, potentially leading to an inefficient and time-consuming reproduction of the negotiation process that occurred with the COVID-19 TRIPS waiver. Here, negotiations lasted almost two years — during which time the virus continued mutating and deaths accumulated.\(^{189}\) Yu points out how, even after text-based negotiations began, eight months after the original proposal had been made, they were of general nature.\(^{190}\) Member States tried to find accommodating ‘landing zones’ instead of discussing the waiver’s precise terms.\(^{191}\) The Ministerial Decision also ended with very different terms than what was originally proposed,\(^{192}\) which shows how lengthy negotiations weaken initial positions. Importantly, the original proposal put forward by India and South Africa targeted a vast range of healthcare products and technologies and four types of IPRs, namely ‘patents, industrial designs, copyright and protection of undisclosed information’.\(^{193}\) By contrast, only COVID-19 vaccines and patents are covered by the Ministerial Decision.\(^{194}\) As already pointed out, there is much more to be considered in pandemics; trade secrets are important in terms of relevant IPRs and essential medical products include diagnostics, therapeutics, and medicines. Therefore, this throws doubt on the WTO’s ability to effectively respond to a crisis.\(^{195}\) Moreover, the agreement ultimately reached was the result of consultations conducted exclusively between the United States, the European Union, India and South Africa.\(^{196}\) Open-ended negotiations may lead to secrecy and closed-door meetings involving fewer stakeholders, resulting in a lack of transparency.


\(^{190}\) Yu (n 6) 6.

\(^{191}\) ibid.

\(^{192}\) Yu (n 6) 13. In his paper, Yu offers a complete discussion outlining the changes between the original waiver proposal and the ultimately adopted Ministerial Decision.

\(^{193}\) TRIPS Council, Original proposal (n 60).

\(^{194}\) Ministerial Decision (n 63).

\(^{195}\) Yu (n 6) 15.

\(^{196}\) ibid 6-7.
Lastly, a time-efficient mechanism is needed. This echoes a comment made at the opening of the INB’s fourth meeting by WHO Director-General, Tedros Adhanom Ghebreyesus. Referring to COVID-19, he warned Member States ‘not to repeat the same mistakes again’ and to ‘include the rights lessons’ in the accord.¹⁹⁷ It is through an agreement on the waiver’s terms during the WHO Pandemic Agreement’s negotiations that the deadlock reached during COVID-19 can be avoided.¹⁹⁸ A proposal regarding the terms that would promote efficiency in pandemic response will be offered in section V.

iv. Is the WHO Pandemic Agreement Challenging the Status Quo?

In view of the foregoing, the negotiating text aligns with previous international attempts at mitigating TRIPS’s negative effects on developing countries’ development and on the right to health. TRIPS, itself, foresees the inevitability of its Member States adopting 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’.¹⁹⁹ Aligned with this principle are TRIPS flexibilities and article 66.2 on incentives to technology transfer, previously discussed.

However, an insurmountable barrier to compulsory licences for developing countries with no production capacities resides in article 31(f).²⁰⁰ It states that such licensing can be issued ‘predominantly’ for use in the domestic market, preventing importation from licensees abroad to meet local needs. The Doha Declaration sought to address this issue by mandating the TRIPS Council to find a prompt solution.²⁰¹ It culminated in a formal amendment to TRIPS in 2005, which entered into force in 2017. New article 31bis waived the territorial restriction to allow exports of pharmaceutical products produced under a compulsory licence to countries without manufacturing capacities. Nonetheless,

¹⁹⁸ Mallapaty (n 164) 3.
¹⁹⁹ TRIPS (n 9) art 8.1.
²⁰⁰ Chimpango (n 29) 173.
²⁰¹ Doha Declaration on the TRIPS agreement and public health (adopted 14 November 2001) WT/MIN(01)/DEC/2 (Doha Declaration), art 6.
the waiver may be used subject to onerous procedural conditions. This complicates the waiver’s procedure and results in remaining barriers to access. To date, article 31bis has only been used once, by Rwanda, in 2007, to import a generic version of a patented HIV/AIDS drug from Apotex, a Canadian generic firm. As such, there is still relevance for a new international instrument that would further promote access, which the WHO Pandemic Agreement aims to do for pandemic-related products.

More generally, the Doha Declaration, while maintaining an IPRs protection discourse, acknowledged that Member States can make full use of TRIPS flexibilities to protect public health and ensure global access to medicine and that those objectives should not be frustrated by TRIPS. It also restated that developed countries should promote technology transfer to developing countries among their own enterprises and institutions. This reaffirmed TRIPS’s existing language on those matters. The negotiating text of the WHO Pandemic Agreement adopts a similar approach. It emphasises the importance of the right to health, technology transfer, the flexible enforcement of IPRs, and the particular needs of developing countries. Its language does not depart drastically from the Doha Declaration, maintaining the protection of IPRs as central to the ‘development of new medical products’. Nonetheless, the future pandemic accord is a step in the right direction. The negotiating text attempts to include ‘communities and relevant stakeholders across all levels’ to pursue its objectives. This can be interpreted as referring notably to the private sector, and pharmaceutical companies in particular as important actors that provide pandemic-related products like vaccines. One way the negotiating text fosters engagement with them is by addressing pandemic-

202 See: TRIPS (n 9) art 31bis, annex to the TRIPS Agreement.
204 ibid 1823.
205 Doha Declaration (n 201) arts 3-5.
206 Doha Declaration (n 201) art 7.
207 See TRIPS (n 9) arts 7, 8.1, 66.2.
208 Doha Declaration (n 201) 3; Negotiating text (n 74) preamble, para 10.
209 World Health Organisation, ‘Negotiating text’ (n 74) art 3.9.
related publicly funded research and how states can hold manufacturers accountable for global objectives in this collaborative process. This inclusion comes from a much needed ‘all-of-society’ effort which goes beyond mere state involvement. As discussed above in subsection IV(ii), even if pharmaceutical companies may profit from their innovation, then the amount of public funding received should entail obligations on their part. Thus, while TRIPS and the Doha Declaration generally speak of incentivising technology transfer with TRIPS’ article 66.2, the negotiating text goes further. It pinpoints an area where countries have bargaining power and urges them to use it. Therefore, the pandemic accord hopes to challenge the status quo and do more than current TRIPS provisions on collaboration. This is because it openly adopts a transnational perspective in recognising that the effective management of pandemics requires coordinated efforts from both the public and private sectors.

RECOMMENDATIONS

The following section will propose two amendments to the negotiating text that will enhance its ambitiousness and thus its potential to contribute to IP equity in the context of pandemics.

i. Do not Leave it for the Negotiation Table: A Systematic Waiver

Article 11.3(a) of the negotiating text should be strengthened by imposing a systematic waiver of IPRs attached to pandemic-related products during a pandemic, instead of allowing for the waiver’s detailed terms to be agreed on only during the next pandemic. This would achieve the impact sought by the original TRIPS waiver proposal, whilst avoiding endless negotiations. Indeed, COVID-19 was proof that even in situations of urgency, negotiations are not time-efficient. Pre-negotiated terms are therefore needed. However, articulating a time period for the waiver and otherwise determining its scope before the next pandemic would entail less or no flexibility in its execution, which could slow the negotiation process even more. Nonetheless, this time, Member States will be able to rely on the outcomes of the COVID-19’s TRIPS waiver’s negotiations. The COVID-19 pandemic can also be useful in establishing a threshold to be met in

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210 Jecker (n 112) 274.
terms of what conditions are to be included in an IPRs waiver for it to effectively ‘increase the availability and adequacy of affordable pandemic-related products’.\(^{211}\) For instance, an initial duration corresponding to a minimum standard in light of COVID-19 could be pre-negotiated, with explicit possibilities for renewal. A practical difficulty with the method of pre-negotiated terms is that it will only be effective if the pandemic accord is in operation in time for the next pandemic. It will be of little help if no consensus can be reached on a waiver negotiated under the WHO Pandemic Agreement before the next pandemic strikes. In this regard, another approach that is easier to implement in practice, although less ambitious in terms of pandemic prevention, would be to settle on certain key aspects of the waiver while agreeing to reopen negotiations at a set time on the most contentious issues.

Yu suggests relying on triggering events, such as when a pandemic reaches a certain objective level of severity, instead of negotiating *ad hoc* waivers for each pandemic.\(^{212}\) This strategy avoids a debate on timing. Nonetheless, following the discussion in subsection IV (iii) on TRIPS and the WHO Pandemic Agreement’s co-existence, it will have to be decided which organisation between the WTO and the WHO will be in charge of declaring the waiver and extending its pre-determined duration if needed. This duration could consider the time necessary to develop production facilities or to complete regulatory approval procedures around vaccines.\(^{213}\) Additionally, a waiver should apply to all Parties and not mimic the narrow definition of an ‘eligible Member’ in the Ministerial Decision which encompasses only developing countries.\(^{214}\) Rather, the accord should maximise its geographical impact and seek the support of countries with existing manufacturing capacities.\(^{215}\) In terms of scope, the negotiating text adopts both effective and broad language; but, an explicit added mention of trade secrets could be considered, as discussed earlier, since trade secrets protect essential information for manufacturing pandemic-related products like vaccines.

\(^{211}\) World Health Organisation, ‘Negotiating text’ (n 74) art 11.3(a).

\(^{212}\) Yu (n 6) 17.

\(^{213}\) Yu (n 6) 13.

\(^{214}\) Ministerial Decision (n 63) footnote 1.

It is suggested that TRIPS was imposed on developing countries for the benefit of the already developed world.\textsuperscript{216} Incorporating a systematic waiver into the WHO Pandemic Agreement represents an opportunity to restore the power balance, at least in times of health crisis. Developing countries must take this chance to re-negotiate their terms of participation in the international IP system to ensure ‘full, active, and rewarding involvement’ on their part.\textsuperscript{217} In that sense, Okediji suggests that when IPRs adversely affect national development strategies, a right to development linked to collective self-determination should prevail.\textsuperscript{218} Equally, when such rights undermine developing countries’ health strategy in a crisis, they should be waived to advance self-development possibilities for those nations that the current TRIPS system allows to arrive last in the run for protection.

\textit{ii. Fostering Prevention and Recovery: Mandatory ‘Targeted’ Licensing}

Article 9 of the negotiating text on R&D should require states to mandate licensing during and between pandemics for organisations that benefit from public funding for R&D related to pandemic-related products. Contract-imposed licensing complements waivers and response actions occurring during a pandemic. It focuses on prevention and health systems’ recovery, which are key components of the WHO Pandemic Agreement’s objectives and entire text. It would respond to Member States’ concerns that prevention was not given enough attention in the zero draft.\textsuperscript{219} It would also reinforce article 10.1(d) of the negotiating text that merely mandates that states encourage licensing from those receiving ‘significant public financing’ to manufacturers in developing countries. Corporate social responsibility, involving giving back to society, is important in a pandemic,\textsuperscript{220} and countries must demand it.

Such ‘targeted’ licensing is necessary because voluntary licences are insufficient to meet public needs.\textsuperscript{221} The world should not rely on corporate

\textsuperscript{216} Maskus (n 7) 396.
\textsuperscript{217} Gana (now Okediji) (n 22) 335.
\textsuperscript{218} Gana (now Okediji) 326, 336.
\textsuperscript{219} World Health Intergovernmental Negotiating Body, ‘INB’S fourth meeting, Session 2’ (n 99).
\textsuperscript{220} Jecker and Atuire (n 40) 597.
\textsuperscript{221} Erfani and others (n 45) 2.
altruism, which proved utopic during COVID-19. Compulsory licences under TRIPS are also inefficient since their scope is limited to patents. As already mentioned, all IPRs are rightly targeted in the negotiating text, as well as technology and ‘know-how’, with a suggestion that trade secrets be explicitly discussed. Moreover, imposing licensing in contract terms would render this mechanism global. This is needed for developing countries to benefit from those that already have performing manufacturing capacities in the pharmaceutical sector.\textsuperscript{222} To contribute to this goal, the solution of ‘licensing facilities’ could be adopted. It would involve licensed elements to be made available worldwide through a ‘pool’ from which licences would be granted under conditions such as compensation.\textsuperscript{223}

As previously stated, countries must make sure patent owners respect their part of the ‘implicit bargain’ underlying IPRs protection; exclusivity is granted in exchange for effective accessibility to innovations.\textsuperscript{224} For that, better contracting practices that facilitate partnerships between IPRs holders and manufacturers are needed.\textsuperscript{225} Non-voluntary licences can legitimately be used for public reasons to secure access to technologies related to public goods,\textsuperscript{226} of which vaccine-induced immunity and health are examples. Joseph would even see them as ‘global public goods’ as those issues require multilateral management to be effectively addressed.\textsuperscript{227} In that sense, alternative views on IP ownership should be encouraged.\textsuperscript{228} Publicly funded research should call for an element of public ownership.\textsuperscript{229} Indeed, a ‘public and open access basis’ should be prioritised

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\textsuperscript{222} Subhan (n 141) 158.
\textsuperscript{224} Maskus (n 7) 395.
\textsuperscript{225} Barnes-Weise, Santos Rutschman and Adler (n 120) 318.
\textsuperscript{226} Maskus (n 7) 403. For example, in the United States, the federal government may exercise ‘march-in rights’ when public funding was provided and mandate licensing for health purposes, among others. They have however never been used: Feldman (n 34) 47. This reluctance to invoke march-in rights further demonstrates the need to provide for mandatory licensing in contract arrangements rather than to let it become a political decision in times of crisis.
\textsuperscript{227} Joseph (n 27) 240.
\textsuperscript{228} Gana (now Okediji) (n 22) 342.
\textsuperscript{229} Jecker and Atuire (n 40) 596.
for some goods and services over a ‘profit basis’ when access restriction is made too great by private ownership.\textsuperscript{230} Targeted licensing strikes that balance. IPRs ownership is retained, but governments can make sure that their investment also benefits stakeholders in the global community.

**CONCLUSION**

As exemplified by COVID-19, developing countries remain dependent on developed countries for access to essential medicines, such as pandemic-related vaccines. This is closely related to the protection of IPRs and the international TRIPS framework under which the promises of technology transfer and associated development were not respected. IP equity is needed for developing countries to build their own manufacturing capacity in a spirit of self-reliance. This will ensure better global preparedness for future pandemics and strengthen respect for the right to health.

A WHO pandemic accord leads the way to answer Okediji’s call for the phrase ‘developing countries’ to move ‘from rhetoric to reality, from cheap imitation to genuine progress’.\textsuperscript{231} It has the potential to achieve IP equity for developing countries. The latest negotiating text of the WHO Pandemic Agreement demonstrates commitment to IP equity, although Parties to the accord will need to be meaningfully held to account. This commitment is evident from its promotion of values like global solidarity, transparency, prevention, and technology and knowledge sharing. The same can be said of waivers and licensing mechanisms that recognize the need for flexible enforcement of IPRs.

The INB will, however, need to clarify the WHO Pandemic Agreement’s relationship with TRIPS, and refine the language related to waivers. The wording ‘time-bound’ offers too much discretion. A strong WHO Pandemic Agreement in terms of IP equity will likely face opposition from a powerful pharmaceutical lobby\textsuperscript{232} and nations that originally opposed the COVID-19 TRIPS waiver. Nonetheless, two further recommendations to strengthen a commitment to IP

\textsuperscript{230} Joseph (n 27) 240.
\textsuperscript{231} Gana (now Okediji) (n 22) 343.
\textsuperscript{232} Gonsalves and Yamey (n 44) 2.
equity were put forward in this article: to impose a systematic and pre-negotiated waiver of IPRs during a pandemic and to condition public funding of R&D on licensing arrangements during and between pandemics.

A well-known balancing exercise underlies the international IP system. As described by the WIPO in its general comments on the zero draft of the WHO Pandemic Agreement: ‘enabling access to the fruits of innovation while preserving incentives to innovate catch the core of the international intellectual property framework’.233 Especially relevant during pandemics, this captures the tension central to IP in this context; ensuring access to public goods like global health versus allowing ‘sufficient’ profit-making by pharmaceutical companies. The global health crisis has, so far, taught the world that the latter is prioritised. However, as pointed out by Brazil at the INB’s fourth meeting, ‘IP on health products cannot be restricted on a trade issue’.234 Peter Drahos writes that patents involve ‘commodification’ and ‘global circuits of capital accumulation’.235 IP equity, rather, demands respect for TRIPS’s framing of the IP system as ‘a social policy tool rather than a means to gather and hold on to assets’.236 The WHO Pandemic Agreement opens the door for this reconceptualisation.

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233 World Health Intergovernmental Negotiating Body, ‘INB’s fourth meeting, Session 3’ (n 175).
234 World Health Intergovernmental Negotiating Body, ‘INB’s fourth meeting, Session 2’ (n 99).
235 Drahos (n 189) 30.
236 Ellen ‘t Hoen, ‘Protecting Public Health through Technology Transfer: The Unfulfilled Promise of the TRIPS Agreement’ (2022) 24 Health and Human Rights Journal 211, 212; See TRIPS (n 9) art 7.