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**Too Many Cooks or too many Recipes?
An analysis of the institutional landscape and proliferation
of proposals for Global Vaccine Equity for COVID-19**

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Too Many Cooks or too many Recipes?
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Global Vaccine Equity for COVID-19¹

Abstract

This article outlines and compares current and proposed global institutional mechanisms to increase equitable access to COVID-19 vaccines, focusing on their institutional and operational complementarities and overlaps. It specifically considers the World Health Organisation's (WHO) COVAX model as part of the ACT-A initiative, the WHO's COVID-19 Technology Access Pool (C-TAP) initiative, the proposed TRIPS intellectual property waiver, and other proposed WHO and World Trade Organisation (WTO) technology transfer proposals. We argue that while various individual mechanisms each have their specific merits - and in some cases weaknesses - overall, many of these current and proposed mechanisms could be highly complementary if used together to deliver equitable global access to vaccines.

Nonetheless, we also argue that there are risks posed by the proliferation of proposals in this context, including the potential to disperse stakeholder attention or to delay decisive action. Therefore, we argue that the relevant institutions and in particular the WHO and the WTO must be clearer in how various proposed mechanisms could interlink and work together to achieve global vaccine equity.

Alongside this, there is now also a clear need for concerted global multilateral action to recognise the complementarities of specific individual models proposed and to provide a pathway for collaboration in attaining global equitable access to vaccines. The institutional infrastructure or proposals to achieve this amply exists at this point in time – but much greater co-operation from industry and clear, decisive and co-ordinated action from States and international organisations is urgently needed.

Keywords

Access to medicines, COVID-19, global health, COVAX, C-TAP, TRIPS Waiver, Vaccine Equity.

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Introduction

For over a year now, the world has found itself in an unprecedented situation, collectively gripped by COVID-19, a virus that on official estimates has killed over 3.47 million people worldwide with 167.32 million confirmed cases.² It has devastated the livelihoods and wellbeing of many millions more³ and ravaged entire economic sectors.⁴ In the early phase of the pandemic, many global political leaders responded to this situation with calls that emerging vaccines against the virus should be made a 'global public good'.⁵ The term 'global public good' used in this context was likely intended as a rallying cry,⁶ highlighting that vaccines against the pandemic should be available and accessible to all, no matter where in the world they live, no matter how much money they have, or what their personal or social circumstances are. It also mirrored a growing acceptance that equitable global access for vaccines is vital for public health: it is needed to bring COVID-19 under control as without it risks of the virus re-emerging and new strains developing remain. As Dr Mike Ryan, the WHO's Executive Director of Health Emergencies Programme, has aptly put it: "No one is safe until everyone is safe".⁷

Yet, a year on, and we have still not achieved global equitable access for COVID-19 vaccines; rather, the inequity around vaccine access continues to increase. In April 2021, only 0.3% of vaccines were distributed to low-income countries,⁸ while

² See: <https://ourworldindata.org/coronavirus-data> correct at time of writing, 24th May 2021 (accessed 26 May 2021). There are also claims that the official figures of reported deaths are likely an underestimate, see: S Kung, M Doppen, M Black, I Braithwaite, C Kearns, M Weatherall, R Beasley, N Kearns. Underestimation of COVID-19 mortality during the pandemic. ERJ Open Research Jan 2021, 7 (1) 00766-2020.

³ D Burnett. The mental health problems waiting at the end of Covid-19. Irish Times 7 March 2021. <https://www.irishtimes.com/life-and-style/health-family/the-mental-health-problems-waiting-at-the-end-of-covid-19-1.4501223> (accessed 26 May 2021).

⁴ L Jones, D Palumbo & D Brown. Coronavirus: How the pandemic has changed the world economy. BBC News. 24 January 2021. <https://www.bbc.com/news/business-51706225> (accessed 26 May 2021).

⁵ For example, see: Statement by Secretary-General of the United Nations, António Guterres in May 2020 'Quick, Equal, Affordable Access to COVID-19 Vaccine Must Be Considered Global Public Good, Secretary-General Says in Remarks to Africa Dialogue Series. 20 May 2020. <https://www.un.org/press/en/2020/sgsm20089.doc.htm> (accessed 26 May 2021); 'Von der Leyen on Coronavirus Global Response: World stands united against coronavirus and will win' (5 May 2020) https://ec.europa.eu/commission/presscorner/detail/en/ac_20_811 (accessed 26 May 2021).

⁶ Some have argued there were semantic issues with how the term was used, see: J Love. The Use and Abuse of the Phrase "Global Public Good. 9 July 2020. <https://www.indiachinainstitute.org/2020/07/09/the-use-and-abuse-of-global-public-good/> (accessed 26 May 2021).

⁷ 'Not enough evidence to suggest that person infected with Covid-19 becomes immune – WHO' (14 May 2020) <https://www.irishexaminer.com/news/arid-30999442.html> (accessed 26 May 2021).

⁸ 'Covax: How will Covid vaccines be shared around the world?' BBC News. 3 May 2021 <https://www.bbc.com/news/world-55795297> (accessed 26 May 2021).

it was predicted in December 2020 that up to 90% of people in 67 low- and middle-income countries would not obtain access to vaccines in 2021.⁹ Meanwhile, many governments in high-income countries (HICs) have prioritised the vaccination of people within their state boundaries over global equitable access. This has led to accusations of vaccine nationalism,¹⁰ and of HICs only paying lip-service to a commitment to global equitable access to vaccines.

Accordingly, at the global level, the past twelve months have seen the establishment and promotion of several different mechanisms to either pool, share or donate COVID-19 vaccines and associated technologies and know-how. In fact, a complex global institutional landscape has emerged where various schemes have come into existence. Moreover, proposals around how to achieve global vaccine equity in some cases have become a matter of institutional tugs-of-war at an international and national level. The success of these global mechanisms and their respective modalities of operation is hugely significant for public health and policy. Thus, it is critical that these mechanisms, and particularly how they interact with each other, are subject to greater scrutiny. This scrutiny is vital for two reasons, namely: 1) to assess current pathways and blockages to achieving equitable access to COVID-19 vaccines, and 2) to ensure that current developments serve as viable blueprints for future pandemics.

This article contributes to existing debates around global equitable access to vaccines by providing an outline of each of the main (current or proposed) global mechanisms, and by examining the advantages and potential drawbacks, specifically, of the *multiplicity of institutional mechanisms* for global vaccine distribution that has emerged. We argue that the creation and co-existence of several global mechanisms/proposals to achieve global vaccine access is in some cases necessary due to their complementarities and different purposes. We also acknowledge that this multiplicity of instruments is a consequence of the rapidly evolving situation where different mechanisms were seen as needed at different

⁹ O Dyer. 'Covid-19: Many poor countries will see almost no vaccine next year, aid groups warn' BMJ 2020; 371. 11 December 2020 <https://www.bmj.com/content/371/bmj.m4809> (accessed 26 May 2021); See also: A Karan & T Pogge. Solving global vaccine inequity requires new incentives for pharmaceutical companies. 2 April 2021. <https://blogs.bmj.com/bmj/2021/04/02/solving-global-vaccine-inequity-requires-new-incentives-for-pharmaceutical-companies/> (accessed 26 May 2021).

¹⁰ International Chamber of Commerce. Study shows vaccine nationalism could cost rich countries US\$4.5 trillion. 25 January 2021. <https://iccwbo.org/media-wall/news-speeches/study-shows-vaccine-nationalism-could-cost-rich-countries-us4-5-trillion/> (accessed 26 May 2021); S Amaro. IMF's top economist says Covid vaccines are the 'main weapon' to achieve a faster economic recovery. CNBC. 7 April 2021. <https://www.cnbc.com/2021/04/07/covid-experts-on-the-importance-of-vaccinating-low-income-nations.html> (accessed 26 May 2021); R Forman, M Anderson, E Mossialos, 'Me-first vaccine nationalism makes the spread of dangerous new COVID variants more likely' LSE Blogs. 11 March 2021. <https://blogs.lse.ac.uk/covid19/2021/03/11/me-first-vaccine-nationalism-makes-the-spread-of-dangerous-new-covid-variants-more-likely/> (accessed 26 May 2021).

points of this crisis. At the same time, we contend that the proliferation of entities and instruments, particularly in the case of instruments with similar aims, which potentially compete for financial resources, public attention and buy-in from governments and the pharmaceutical industry, could serve (or be used) to stall or jeopardise the attainment of global equitable access to vaccines.

In sum, this article argues that it is critical that there is greater scrutiny not just of the benefits or potential shortcomings of each proposed global mechanism in isolation, but also of their complementarities, and of the potential effects that the emerging *multiplicity* of initiatives and institutional dynamics between such proposals give rise to. In our view, such institutional issues warrant much greater attention within the global health and public policy communities, and this forms the primary focus of this article.

In making such arguments, Section I provides an overview and brief critique of the key global models proposed or in existence, which seek to achieve equitable access to vaccines, focusing specifically on international proposals at the World Health Organization (WHO) and World Trade Organization (WTO) level.¹¹ Section II then develops to examine the extent to which this proliferation of instruments in itself may be a necessity to address, or may in some cases hinder the attainment of global equitable access to vaccines. A brief conclusion in Section III highlights the significance of scrutiny around the institutional dynamics between and across these various proposed instruments to achieving the public health aim of global vaccine equity for this and future pandemics.

For the purposes of brevity, we consider only *global* WHO/WTO level mechanisms to achieve equitable vaccine access in this comparison. We acknowledge the existence of regional proposals to achieve broader vaccine access for COVID-19 (including the EU's European Health Emergency Preparedness and Response Authority (HERA) proposal), but do not examine these in detail here.¹² Having said that, the existence of such regional proposals for new instruments reinforces the current proliferation and multiplicity of endeavours in this context.¹³

¹¹ We focus here specifically on vaccine access – in doing so, we acknowledge that access to therapeutics and diagnostics is also important for global health needs for COVID-19.

¹² European Health Emergency Preparedness and Response Authority (HERA) Initiative, see <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-en> (accessed 26 May 2021).

¹³ There are also proposals for a pandemic treaty to address pandemic preparedness – as this has not yet been adopted, and for the purposes of brevity, we do not consider this in this paper: see, S Nebehay, 'Time has come' for pandemic treaty as part of bold reforms - WHO's Tedros' 31 May 2021 Reuters <https://www.reuters.com/world/china/who-agrees-study-major-reforms-meet-again-pandemic-treaty-2021-05-31/> (accessed 31 May 2021).

I. **Global Equitable Access to COVID-19 Vaccines: Proposed Mechanisms**

In this section, we outline and critique the main mechanisms put forward at the WHO and WTO level for global equitable access to vaccines, namely: the WHO's COVAX model, whose functions include acting as a vaccine procurement model within the traditional *status quo* approach, and as a system for the sharing of vaccines with low and middle income countries (LMICs); the WHO's proposed COVID-19 Technology Access Pool (C-TAP), a voluntary system for industry to share intellectual property, data, know-how, technology transfer etc. around COVID-19 vaccines, medicines and diagnostics with the aim of upscaling production of health-technologies globally; the WTO's proposed 'third way' approach which as will be discussed appears to be akin to existing voluntary technology transfer and licensing models and is subject to industry co-operation; and the TRIPS intellectual property waiver proposal to (temporarily) mandatorily waive intellectual property rights over COVID-19 health-technologies.¹⁴ We outline the key elements of each system and highlight key potential benefits and/or shortcomings of these schemes in terms of their likely ability to contribute to effective pathways towards global equitable access to vaccines. Such understandings are then drawn on in Section II, where we will focus specifically on the likely effects of the current multiplicity of instruments for achieving global equitable access, including the complementarities of models and/or the potential of some proposals to delay or detract from the finalisation or success of other proposals.

a. Equitable Access within Traditional Paradigms: COVAX

From the early stages of the pandemic, concerns arose that when vaccines against COVID-19 were developed, those who could pay the most (i.e. HICs) would likely gain priority and early access, leaving LMICs behind. Arguably, in large part in response to address such concerns, the vaccine allocation aspect of the COVAX model was formulated. COVAX is the vaccine pillar and a key component of the WHO's ACT Accelerator system. It is a public-private partnership and was launched in April 2020 by the WHO with support from donors including the Bill & Melinda

¹⁴ For a detailed legal analysis of the individual proposals, see: A McMahon. Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance. *Journal of Medical Ethics* 2021;47:142-148; M Eccleston-Turner and H Upton, 'International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility' (2021) *The Milbank Quarterly*. <https://doi.org/10.1111/1468-0009.12503>. For a detailed legal analysis of the WTO waiver proposal and the case in support of this, see: S Thambisetty, A McMahon, HY Kang, L McDonagh and G Dutfield, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic' *LSE Legal Studies Working Paper* (Forthcoming 2021) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737

Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI), and Gavi.¹⁵

Three main objectives to the COVAX pillar have been identified, namely: 1) to provide funding to rapidly accelerate the research and development of vaccines against COVID-19; 2) to use financing measures to stimulate investment in manufacturing capacity for vaccines; and 3) to seek equitable access and distribution of vaccines for COVID-19.¹⁶ In this section, we focus primarily on the latter aspect and the role of COVAX in achieving equitable vaccine access.

COVAX distinguishes between “self-funded” and “funded” countries. To achieve global “equitable access” to vaccines, the ideal behind COVAX was that “self-funded” countries (mostly HICs) would provide an upfront payment and a commitment to purchase their allocated vaccine doses through the COVAX facility.¹⁷ For HICs, three main advantages of participation were proposed by COVAX. First, COVAX stated that participation would allow HICs to hedge their vaccine procurement strategy and to diversify their vaccine candidate portfolios.¹⁸ From the perspective of HICs, this was a significant benefit as COVAX was established in April 2020 while vaccine candidates were still in early development. At that time, it was not clear which vaccines would be successful, and so giving such States access to a portfolio of multiple vaccine candidates was attractive.¹⁹ Second, for HICs participation in COVAX was said to ‘act as an insurance policy’ as it would significantly increase their chances of securing vaccines for their citizens, even if their own bilateral arrangements or negotiations failed. Third, COVAX indicated participation was in the self-interest of HICs as global equitable access to vaccines is needed to bring the pandemic under control everywhere. Procuring through COVAX meant LMICs gained access to vaccines, which would reduce the chances of “resurgence by ensuring that the rest of the world gets access to doses too”.²⁰ It was envisaged that participating HICs would be able to request vaccine doses for up to 10-50% of their population, the number of doses that would go to each HIC under COVAX being determined based on the amount of money paid into COVAX.²¹

¹⁵<https://www.gavi.org/vaccineswork/covax-explained> (31 May 2021). See also: “COVID-19 ACT Accelerator launch - 24 April, 2020” https://www.who.int/docs/default-source/coronaviruse/transcripts/transcript-who-actlaunch-24apr2020.pdf?sfvrsn=45977318_2 (accessed 31 May 2021).

¹⁶ Eccleston-Turner and Upton, note 14, 5; see also: Usher AD. COVID-19 vaccines for all? *Lancet*. 2020;395(10240):1822-1823.

¹⁷ Eccleston-Turner and Upton, note 14, 11.

¹⁸ <https://www.gavi.org/vaccineswork/covax-explained> (accessed 31 May 2021).

¹⁹ <https://www.gavi.org/vaccineswork/covax-explained>

²⁰ <https://www.gavi.org/vaccineswork/covax-explained>

²¹ <https://www.gavi.org/vaccineswork/covax-explained>

Alongside this, 92 LMIC countries participate in COVAX as ‘funded’ countries. These countries are financially supported to obtain vaccines through the COVAX Advance Market Commitment financing instrument.²² COVAX, according to its own documentation, would become “literally a lifeline and the only viable way in which their citizens will get access to COVID-19 vaccines”.²³ Crucially, under the original plans for COVAX no country could receive doses through COVAX for more than 20% of their populations until funded countries had obtained enough for 20% of their populations.²⁴

COVAX’s initial target was to secure two billion doses of COVID-19 vaccines in 2021,²⁵ with a particular emphasis on securing doses to protect healthcare workers and vulnerable people. However, one year in, COVAX has been beset with supply and funding shortfalls.

Supply for COVAX has been severely limited due to the general scarcity of vaccine supplies to meet demand, hampering COVAX’s ability to deliver vaccines to LMICs.²⁶ By the end of April 2021, 40 million doses had been shipped through COVAX into 118 countries.²⁷ It was recently predicted that COVAX would deliver approx. 1.8 billion doses of vaccines to 92 LMICs by the end of 2021, amounting to approx. 27% population coverage in such countries.²⁸ These targets are considerably below the amount needed for population coverage and also well below the current vaccine coverage that most HICs have already achieved.²⁹ Furthermore, these predictions are arguably very optimistic, particularly in light of the fact the Serum Institute of India, one of the largest suppliers to COVAX, is

²² 92 low- and middle-income economies eligible to get access to COVID-19 vaccines through Gavi COVAX AMC available at <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc> ; Gavi launches innovative financing mechanism for access to COVID-19 vaccines available at <https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines> (accessed 31 May 2021).

²³ <https://www.gavi.org/vaccineswork/covax-explained>

²⁴ <https://www.gavi.org/vaccineswork/covax-explained>

²⁵ <https://www.gavi.org/vaccineswork/covax-explained>

²⁶ Michael Safi & Ashley Kirk, ‘Revealed: big shortfall in Covax Covid vaccine-sharing scheme’ *The Guardian* (22nd April) <https://www.theguardian.com/world/2021/apr/22/revealed-big-shortfall-in-covax-covid-vaccine-sharing-scheme> (accessed 26 May 2021); C del Rio, G Gonsalves, F Hassan, M Kavanagh, “Covid-19: A call for global vaccine equity. *The BMJ*. 17 March 2021. <https://blogs.bmj.com/bmj/2021/03/17/covid-19-a-call-for-global-vaccine-equity/#:~:text=One%20year%20into%20the%20covid,to%20help%20control%20the%20pandemic> (accessed 26 May 2021).

²⁷ COVAX reaches over 100 economies, 42 days after first international delivery. 8 April 2021. <https://www.who.int/news/item/08-04-2021-covax-reaches-over-100-economies-42-days-after-first-international-delivery> (accessed 26 May 2021).

²⁸ The Independent Panel for Pandemic Preparedness and Response, Access to Vaccines, Therapeutics, and Diagnostics: Background paper 5 (May 2021) <https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-5-Access-to-vaccines-Therapeutics-and-Diagnostics.pdf> p. 7 (accessed 26 May 2021).

²⁹ See generally: <https://ourworldindata.org/covid-vaccinations>

currently not expected to be able to export COVAX vaccines until the end of 2021, due to the current COVID-19 health crisis in India.³⁰

Alongside supply issues, COVAX has a considerable funding gap for 2021 - a gap of over \$2.6billion USD for COVAX and \$19billion USD for the entire ACT-A, according to the WHO.³¹

Furthermore, it is questionable whether HICs are merely showing lip service to the ideal of global equity in vaccine access through COVAX. The way the COVAX model is set up means that self-financing HICs can join the COVAX Facility through a Committed Purchase Arrangement or an Optional Purchase Arrangement. In the former case, they commit to purchasing a set number of vaccines through the Facility; in the latter case, they can opt-out of receiving their allocated number of vaccines and instead procure these through bilateral agreements with pharmaceutical manufacturers.³² In reality, HICs have often opted to procure their vaccines outside of the COVAX system, favouring bilateral agreements with pharmaceutical companies. HICs have openly competed with each other, and with COVAX, for access to COVID-19 vaccines.

As Eccleston-Turner and Upton argued previously: many self-financing countries made donations to COVAX but did not give commitments to procure their own vaccines through the COVAX facility. Writing in April 2020, they cautioned that:

“This half-in, half-out approach to multilateral cooperation can only be detrimental to the COVAX Facility in the long term, and it reinforces fears ... that the facility will begin to receive doses only after developed countries have started to receive their supplies”.³³

Sadly, such fears have now materialised – and while some doses have been received by LMICs through COVAX, a vast inequity is evident when one compares HICs and LMICs vaccine access. This competition for limited vaccine supplies between HICs and COVAX is also highly problematic, as the scarcity of supplies and buyer competition could enable companies to demand more favourable terms for vaccine access.³⁴

³⁰ See statement of Serum Institute: Serum Institute of India public statement posted to social media on 18 May 2021:

<https://twitter.com/SerumInstIndia/status/1394652001573629958/photo/1> ; See also: S Thambisetty et al (2021) n. 14, at p. 9 (accessed 26 May 2021).

³¹ <https://www.who.int/initiatives/act-accelerator/how-to-contribute> (accessed 31 May 2021).

³² <https://www.gavi.org/vaccineswork/covax-explained> (accessed 31 May 2021).

³³ Eccleston-Turner and Upton, note 14, p 14.

³⁴ Arguably, such competition could make it difficult for States/regions to resist clauses providing for e.g. indemnity for companies in such contexts: see generally: F Guarascio, ‘COVID-19 Vaccine Makers Expect EU Liability Shield for Unexpected Side-Effects’ Insurance Journal (22nd September 2020) <https://www.insurancejournal.com/news/international/2020/09/22/583555.htm> (accessed 26 May 2021).

Finally, critics of COVAX voice concerns about COVAX's progression from a focus on equity to a charity or a donation-based model.³⁵ For instance, South Africa's statement to the WTO on 23rd February 2021 stated that:

"The model of donation and philanthropic expediency cannot solve the fundamental disconnect between the monopolistic model it underwrites and the very real desire of developing and least developed countries to produce for themselves."³⁶

COVAX has no remit or mechanisms to increase manufacturing or enable technology transfer or intellectual property sharing with LMICs so that some LMICs could produce their own vaccines. Instead, under the COVAX model alone LMICs remain reliant on HICs for vaccine supplies, or at least, COVAX on its own as an institutional measure does not serve to change this reliance.

Thus, to date, in terms of how vaccines are allocated, COVAX has not levelled the playing field for vaccine procurement. Moreover, very mixed views exist around COVAX, with some criticising it for being part of the problem by maintaining or enabling the *status quo*.³⁷ Such issues are compounded when one considers that COVAX is institutionally heavily interlinked with GAVI and the Gates Foundation, which may lead to potential conflicts of interests arising.³⁸

That being said, when viewed through a pragmatic lens, COVAX is currently the only mechanism delivering vaccine access to LMICs,³⁹ and this current public health need for COVAX cannot be discounted. However, in our view, COVAX is at best a short-term solution that will simply not achieve the global equitable access aspired to, and needed, to bring this pandemic under control, nor will it lead to broader systemic change to prepare systems for future pandemics. The aforementioned shortcomings underpin the need for alternative, sustainable solutions to expand production capacity if global equitable access to vaccines for COVID-19 or future pandemics are to be achieved.

³⁵ A Giridharadas. Of patents and power: "Doses are charity. Knowledge is justice. The Ink. 11 May 2021. <https://the.ink/p/doses-are-charity-knowledge-is-justice> (accessed 26 May 2021); Gonzalves, G. (2021) The covid-19 vaccine patent waiver: a crucial step towards a "people's vaccine". <https://www.bmj.com/content/373/bmj.n1249> (accessed 28 May 2021).

³⁶ Statement of South Africa to the WTO Council on 23rd February 2021 in deliberations on a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19 (IP/C/W/669), as reported here: <https://www.keionline.org/35453>

³⁷ J Lei Ravelo, Is COVAX part of the problem or the solution? (11 March 2021) available at <https://www.devex.com/news/is-covax-part-of-the-problem-or-the-solution-99334> (accessed 26 May 2021).

³⁸ Kang, Hyo Yoon (2021): Patent Capital in the Covid-19 Pandemic: Critical Intellectual Property Law. Critical Legal Thinking. 9 February 2021. <https://criticallegalthinking.com/2021/02/09/patent-capital-in-the-covid-19-pandemic-critical-intellectual-property-law/> (accessed 26 May 2021).

³⁹ This is correct at the time of writing 26 May 2021.

b. Voluntary Licensing/Sharing Mechanisms

Two alternative types of mechanisms have been put forward as a pathway to attaining global vaccine equity, namely: *voluntary systems* for licensing or sharing of intellectual property rights, data and know-how around COVID-19 health-technologies such as: i) WHO's COVID-19 Technology Access Pool (C-TAP) or ii) the WTO's proposal of a 'third way', which appears to act as another voluntary licensing of rights and technology transfer model; and initiatives which are *mandatory in nature* that suspend intellectual property rights for COVID-19 health-technologies, under the iii) TRIPS Waiver proposal. Several differences exist across such systems, which we will now discuss.

At the outset, it is notable that intellectual property rights are a feature of all these models – this is because, as discussed elsewhere,⁴⁰ intellectual property rights are central to discussions on vaccine/medicine access for many reasons.⁴¹ For instance, if a third party uses a technology (e.g., an element of a medicine/vaccine) that is patented without the rightsholder's permission, they could be liable for patent infringement. Thus, patents, and particularly how they are used by the rightsholder(s), affects who can produce that medicine/vaccine and has a knock-on effect on how a technology is provided, by whom and on what terms. In practice, multiple rightsholders will likely have intellectual property rights related to any one technology such as a vaccine. Thus, manufacturing the vaccine will require multiple licenses from different rightsholders.⁴² In many such cases, facilities for technology transfer could expediate the scale-up/production of vaccines, hence, many proposals also discuss systems to enable technology transfer alongside the sharing or suspension of intellectual property rights.

(i) WHO's C-TAP Initiative

The idea behind C-TAP was first proposed by the President of Costa Rica on 24th March 2020.⁴³ C-TAP was then officially launched in May 2020 by the WHO in

⁴⁰ In particular, see: A McMahon. Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance. *Journal of Medical Ethics* 2021;47:142-148; S Thambisetty, A McMahon, HY Kang, L McDonagh and G Dutfield, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic' LSE Legal Studies Working Paper (Forthcoming 2021) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737

⁴¹ For a comprehensive discussion of the role of intellectual property rights in the COVID-19 vaccine context, which presents a case in favour of the TRIPS waiver for COVID-19 see: S Thambisetty, et al (2021), *ibid*.

⁴² *Ibid*.

⁴³ 'Letter from Carlos Andres Alvarado Quesada & Daniel Salas Peraza to Dr Tedros Adhanom Ghebreyesus (WHO). '23 March 2021. <https://www.keionline.org/wp->

partnership with the Government of Costa Rica as part of the Global ‘Solidarity Call to Action’. C-TAP is a multilateral global pooling mechanism for intellectual property, data, know-how, cell lines related to COVID-19 vaccines, medicines, and diagnostics. C-TAP is based on an open-science ideal and backed by the values of social solidarity, international co-operation and shared responsibility.⁴⁴ Importantly, under the C-TAP model it is intended that pharmaceutical companies would voluntarily pool and share relevant intellectual property rights, knowledge, know-how etc. in the spirit of solidarity to address COVID-19. C-TAP works with implementing partners including the UN-backed Medicines Patent Pool (MPP). The MPP will assist C-TAP, for example, by facilitating C-TAP to make intellectual property rights available via non-exclusive licensing through the MPP for public health. C-TAP is also intended to have enhanced arrangements for technology transfer to boost local production of vaccines and other health technologies in LMICs via the Technology Access Partnership and the MPP.⁴⁵ The MPP has a track record in the licensing of intellectual property rights within the public health context. It was established in 2010 to address access to HIV medicines. Between 2012 and 2020, the MPP agreed licensing deals with ten patent holders and provided almost 18.55 billion doses of treatment.⁴⁶ This link provides C-TAP with a solid operational foundation to deliver a voluntary licensing and technology transfer platform for COVID-19 health-technologies.

Backed by the WHO, institutionally, the C-TAP could be seen as complementary to COVAX.⁴⁷ Unlike COVAX, the focus of C-TAP is on the scale-up of manufacturing capacity, which has the potential to provide for longer-term capacity building locally in LMICs for vaccines and other crisis-relevant technologies such as personal protective equipment or diagnostics.

Nonetheless, whilst the aims of C-TAP are laudable, its practical implementation has encountered challenges. At the time of writing (May 2021), no pharmaceutical company has shared their intellectual property rights through C-TAP; the pool

[content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf](#) (accessed 26 May 2021).

⁴⁴ WHO (2020) “Operationalising the COVID-19 Technology Access Pool (C-TAP) A Concept Paper”, https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9_36&download=true (accessed 26 May 2021).

⁴⁵ Ibid.

⁴⁶ <https://medicinespatentpool.org/> (accessed 26 May 2021).; see also discussion in: Geiger, S., & Gross, N. (2018). Market Failures and Market Framings: Can a market be transformed from the inside?. *Organization Studies*, 39(10), 1357-1376.

⁴⁷ WHO (2020), note, 46. P. 4.

remains 'empty', so to speak. Even in the face of the pandemic, most pharmaceutical companies continue to refuse to share technology and know-how with C-TAP for vaccine upscaling.⁴⁸ Moreover, globally, only 41 country governments have publicly supported C-TAP,⁴⁹ with limited support for C-TAP by HICs. Critics of C-TAP have in fact spoken of C-TAP's "failure to launch."⁵⁰ Calls have also been made for the WHO to clarify the relationship between C-TAP and ACT-A, which has remained blurry, especially considering the institutional overlaps between these. There were also criticisms of the lack of WHO support in promoting the C-TAP, the lack of political leadership of C-TAP, and a lack of clarity over what if any funding has been committed to the mechanism.⁵¹ On 27th May 2021, the WHO and the President of Costa Rica issued another call for all WHO States to support the C-TAP initiative stating it was an 'underutilized tool' and that: "As a global community we must leverage C-TAP's potential to accommodate different stakeholders and provide timely, sustainable, and effective solutions to promote access and accelerate local production."⁵² It remains to be seen if this will increase support for C-TAP at this time.

In sum, while C-TAP has many useful features, its voluntary nature and the continued lack of industry co-operation with it, despite the continued threat posed by COVID-19, remain its Achilles heel.⁵³

(ii) A Third Way - Technology Transfer Hubs

⁴⁸ E 't Hoen, The elephant in the room at the WHO Executive Board. *Medicines Law and Policy*. 22 January 2021 <https://medicineslawandpolicy.org/2021/01/the-elephant-in-the-room-at-the-who-executive-board/> (accessed 26 May 2021).

⁴⁹ 'Endorsements of the Solidarity Call to Action' <https://www.who.int/initiatives/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action> (accessed 26 May 2021).

⁵⁰ A Zaitchik, 'How Bill Gates Impeded Global Access to Covid Vaccines' *The New Republic*. 12 April 2021. <https://newrepublic.com/article/162000/bill-gates-impeded-global-access-covid-vaccines> (accessed 26 May 2021).

⁵¹ Letter Oxfam International & Health Action International to Dr Tedros Adhanom Ghebreyesus. 21 January 2021. <https://medicineslawandpolicy.org/wp-content/uploads/2021/01/HE-Dr-Tedros-Letter-from-Peoples-Vaccine-Alliance-and-Health-Action-International.pdf> (accessed 26 May 2021).

⁵² 'The President of the Republic of Costa Rica and the Director-General of the World Health Organization call once again on all WHO Member States to actively support the COVID-19 Technology Access Pool (C-TAP)' (27 May 2021) [https://www.who.int/news/item/27-05-2021-the-president-of-the-republic-of-costa-rica-and-the-director-general-of-the-world-health-organization-call-once-again-on-all-who-member-states-to-actively-support-the-covid-19-technology-access-pool-\(c-tap\)](https://www.who.int/news/item/27-05-2021-the-president-of-the-republic-of-costa-rica-and-the-director-general-of-the-world-health-organization-call-once-again-on-all-who-member-states-to-actively-support-the-covid-19-technology-access-pool-(c-tap)) (accessed 31 May 2021).

⁵³ McMahon, 'Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance' *Journal of Medical Ethics* 2021;47:142-148.

Alongside C-TAP's vision of global multilateral co-operation and sharing of intellectual property rights, data, know-how etc. for COVID-19 health technologies, several other specific technology transfer and licensing mechanisms have been proposed, ranging from simply facilitating bilateral commercial licensing (namely deals between manufacturing and pharmaceutical companies to produce greater numbers of vaccines - based on the status quo industry model), to tools that focus on multilateral exchanges driven by public goods concerns.

In February 2021, for example, WTO Director-General Ngozi Okonjo-Iweala called for a 'third way' between private licensing arrangements and the proposed TRIPS IP waiver (discussed below). This proposed 'third way' approach was presented as a mechanism for "facilitating technology transfer within the framework of multilateral rules, so as to encourage research and innovation while at the same time allowing licensing agreements that help scale up manufacturing of medical products".⁵⁴ Limited details have been provided on the 'third way' approach since, however, it would appear to be at the discretion of industry, and it is not entirely clear how it differs from existing models.

Just under a month later, as a separate initiative, the WHO published an Expression of Interest call to potential manufacturers and intellectual property rights' holders for an mRNA vaccine technology transfer hub as part of the ACT-A mechanism, which would be extended to other technologies in the medium term.⁵⁵ The hub aims to expand capacity in LMICs aiming to "transfer a comprehensive technology package and provide appropriate training to interested manufacturers in LMICs".⁵⁶ The proposal envisages either the sharing of IP or non-exclusive licensing of intellectual property rights for this purpose in LMICs – with the text of WHO proposal stating that:

"It is essential that the technology used is either free of intellectual property constraints in LMICs, or that such rights are made available to the technology hub and the future recipients of the technology through

⁵⁴ Statement of Director-General Elect Dr. Ngozi Okonjo-Iweala to the Special Session of the WTO General Council (13th February 2021)

https://www.wto.org/english/news_e/news21_e/dgno_15feb21_e.pdf (accessed 26 May 2021).

⁵⁵ WHO, Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub. 16 April 2021. <https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub> (accessed 26 May 2021).

⁵⁶ WHO, 'Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing' (16 April 2021) <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing> (accessed 26 May 2021).

non-exclusive licenses to produce, export and distribute the COVID-19 vaccine in LMICs, including through the COVAX facility”⁵⁷

The initiative would initially prioritise mRNA but the WHO has stated that it ‘could expand to other technologies in future’.⁵⁸ At a meeting approximately four weeks after this announcement, a WHO representative indicated that the hub had already received 50 expressions of interest from interested mRNA vaccine manufacturers, though the major mRNA intellectual property rights’ holders had yet to react.⁵⁹ The aforementioned Medicines Patent Pool (MPP) also publicly endorsed this WHO proposal, highlighting that this type of facility may “help meet the pressing demand for COVID-19 vaccines in the near term while in the longer term creating the infrastructure and technical know-how to produce routine vaccines locally once this pandemic subsides, thereby establishing sufficient local capacity to meet the needs of any future pandemic.”⁶⁰ Thus, similar to the C-TAP proposal, by focusing on capacity building, a technology transfer hub has the potential to play a decisive global public health role beyond the current pandemic. Yet, also similarly to C-TAP, there seems to be considerable reluctance by the major vaccine rightsholders to engage with it.

In general terms, creating a technology transfer hub of the type envisaged by the WHO here would be undoubtedly useful to enable more expedient upscaling of vaccine manufacturing for COVID-19 and as part of a broader approach to the COVID-19 vaccine equity issues. However, the fact that multiple organisations are suggesting the creation of mechanisms for technology transfer, depending on the context, could also divide resources and capacity for their creation. Moreover, the relationship between the WTO and WHO proposed scheme(s) is unclear. It is also not entirely clear how the proposed WHO hub links with the existing WHO’s C-TAP model. The WHO hub for instance could complement the existing C-TAP proposal, but the pathways between the hub and C-TAP would benefit from greater clarity.

Furthermore, voluntary models like those discussed set up systems where industry generally remains in a position of power over whether, or to what extent, they wish to engage with such models. With industry co-operation such models could prove fruitful. However, to date despite the pandemic context, industry has shown

⁵⁷ Ibid.

⁵⁸ Ibid.

⁵⁹ S Lerner & L Fang, ‘Factory Owners Around the World Stand Ready to Manufacture COVID-19 Vaccines’ *The Intercept*. 29 April 2021. <https://theintercept.com/2021/04/29/covid-vaccine-factory-production-ip/> (accessed 31 May 2021).

⁶⁰ ‘The Medicines Patent Pool offers its support to the WHO COVID-19 technology transfer hub’ 30 April 2021. <https://medicinespatentpool.org/news-publications-post/who-covid-19-tech-transfer-hub/> (accessed 26 May 2021).

limited willingness to engage with such proposals. This in turn raises broader ethical issues around the power of rights-holders as gate-keepers for access to vaccines and other essential health technologies in health emergencies and more generally.⁶¹

c. Suspending Intellectual Property Rights: The TRIPS Waiver

In the absence of greater engagement by industry with voluntary global mechanisms to achieve global vaccine equity, a proposal was brought by India and South Africa to the WTO in October 2020 and revised in May 2021,⁶² which calls for a temporary global waiver of certain TRIPS (Trade-related Aspects of Intellectual Property Agreement) provisions. The waiver proposes to suspend certain intellectual property obligations for ‘health products and technologies’ as to the prevention, treatment or containment of COVID-19.⁶³ If the waiver were implemented, it would suspend intellectual property rights at the TRIPS level for COVID-19 health-technologies – thereby clearing intellectual property obstacles with a view to contributing towards a pathway for greater global manufacturing capacity and production for COVID-19 vaccines, and other health technologies.⁶⁴ The waiver is proposed for a minimum period of three years, following which there would be a review, and if the circumstances justifying the waiver were deemed to cease to exist the WTO General Council would then determine the termination date for the waiver.⁶⁵

Many HICs including the EU have strenuously opposed this waiver proposal, despite mounting public pressure and civil society calls for its adoption. As of May 2021, the waiver is co-sponsored by over 60 countries, as well as the entire Africa Group and Least-Developed Country Group at the WTO. In addition, on May 5th 2021, the U.S. announced its support of a narrower version of the waiver for vaccines only,⁶⁶ whereas the original and revised proposal by India and South Africa covers ‘health products and technologies’ (including vaccines, therapeutics and diagnostics). Nonetheless, this move by the US was generally seen as a clear

⁶¹ See: A McMahon. Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance. *Journal of Medical Ethics* 2021;47:142-148

⁶² Revised Waiver Text (May 2021) is available here: <https://www.keionline.org/wp-content/uploads/W669Rev1.pdf>

⁶³ Ibid

⁶⁴ S Thambisetty, A McMahon, HY Kang, L McDonagh and G Dutfield, ‘The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic’ LSE Legal Studies Working Paper (Forthcoming 2021) – which provides a comprehensive legal analysis and discussion of the TRIPS waiver proposal and the significance of intellectual property issues for global access to vaccines in this context.

⁶⁵ Ibid

⁶⁶ Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver’ (5th May 2021) <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> (accessed 31 May 2021).

signal to other countries that had resisted its passing at the WTO, a move that prompted immediate echos of support from other world leaders, signalling their openness to follow suit.⁶⁷

It remains to be seen how proposals around the waiver will evolve at the WTO level: there are concerns that agreeing a waiver text may be difficult, that it may take time for a text to be adopted, or that negotiations may result in a text that is not workable in practice.⁶⁸ Nonetheless, the waiver proposal is an important step in achieving global equitable access to vaccines, to address intellectual property obstacles,⁶⁹ to facilitate the upscale of manufacturing capacity for COVID-19 vaccines. It also has strong legal, political, and strategic value and could also act as a lever to encourage greater co-operation by pharmaceutical companies in voluntary systems for sharing/licensing of intellectual property rights in the COVID-19 vaccine context.⁷⁰

Nonetheless, institutional jostling is also evident in this context, and some activists have voiced fears that debates around a WTO proposal for a 'third way' were mainly aimed to detract from the momentum the TRIPS waiver proposal has built over the Spring months 2021.⁷¹ Yet over these months the consensus has clearly broadened that decisive action needs to be taken to enable more manufacturers particularly in LMICs build capacity for COVID-19 vaccine production, with more and more prominent politicians and scientists publicly supporting the move towards a waiver⁷² and with the US endorsement seen as a historical moment in the fight against COVID-19.

II. Institutional multiplicity: dissipating resources or consolidating public discourse?

⁶⁷ EU will über Patent-Aussetzung für Coronaimpfstoffe sprechen' Der Spiegel (6th May 2021) 2021<https://www.spiegel.de/wirtschaft/unternehmen/patente-auf-corona-impfstoffe-eu-offen-fuer-gespraech-ueber-aussetzung-a-58de1f52-26b9-404a-a492-fe85d4c74dee> (accessed 31 May 2021).

⁶⁸ Thambisetty et al 2021, note 63.

⁶⁹ Ibid

⁷⁰ Ibid

⁷¹ A Green, TRIPS waiver tripped up in WTO by 'third way' Devex (5 March 2021).

<https://www.devex.com/news/trips-waiver-tripped-up-in-wto-by-third-way-99329> (accessed 26 May 2021).

⁷² 'Ex-leaders, Nobel winners urge U.S. to back COVID vaccine waiver' (14th April 2021)

<https://www.reuters.com/world/us/ex-leaders-nobel-winners-urge-us-back-covid-vaccine-waiver-2021-04-14/> (accessed 26 May 2021).

Focusing on the main *global* COVID-19 technology sharing and licensing mechanisms, the previous section has sought to demonstrate the multiplicity of mechanisms/proposals that are emerging, which are overlapping in some respects, including in their institutional sponsorship or the prospective sources of funding. A key question that arises is whether the range of efforts required to build and maintain all of these tools in parallel is warranted in all cases, and whether, as some argue, each of these mechanisms does indeed serve “different, complementary policy objectives”,⁷³ which can act in harmony to achieve the collective aim of global equitable access to vaccines for COVID-19. In this section, we analyse the potential synergies and complementarities between these instruments highlighting the complementary nature of many instruments, but also providing a set of arguments around why multiplicity, in some cases, and particularly among tools with similar mechanisms and institutional backing, could be detrimental to achieving global equitable access to vaccines.

a. Timeline for the development of such initiatives

Prior to delving into the relative merits of each of these initiatives, at the outset, we acknowledge that the proliferation of instruments to address global equitable access to vaccines could be seen as an organic development. Having emerged at different points during the pandemic, these differing proposals could be seen as evolving in response to the developing crisis, to the global pharmaceutical industry’s reactions, and to numerous countries engaging in ‘vaccine nationalism’.

The idea behind C-TAP was first discussed by the President of Costa Rica on 24th March 2020, but it was not officially launched by the WHO until May 2020, while the COVAX system was officially launched in April 2020 in response to a call by G20 leaders in March 2020 for global collaboration for COVID-19.⁷⁴

When COVAX was launched in April 2020, it was soon after the WHO declaration of a global pandemic. The system, including its model for vaccine distribution, was set up amidst the backdrop of (as now shown well-founded) fears that LMICs may be left behind in securing access to vaccines once these were approved. Thus, COVAX could be viewed as an immediate response to an emerging crisis. However, as the crisis worsened, and as vaccine nationalism emerged/intensified with many HICs purchasing several times the doses of vaccines required for their countries,

⁷³ Médecins Sans Frontières (MSF), ‘WTO COVID-19 TRIPS Waiver Proposal: Myths, realities and an opportunity for governments to protect access to lifesaving medical tools in a pandemic’ (8 December 2020) <https://msfaccess.org/wto-covid-19-trips-waiver-proposal-myths-realities-and-opportunity-governments-protect-access> (accessed 26 May 2021).

⁷⁴ M Winsor, ‘What is COVAX? How a global initiative is helping get COVID-19 vaccines to poorer countries’ (26th February 2021) <https://abcnews.go.com/Health/covax-global-initiative-helping-covid-19-vaccines-poorer/story?id=76106981> (accessed 26 May 2021).

COVAX's limitations became evident.⁷⁵ A key issue is that COVAX has been unable to access enough supplies of vaccines to deliver targets for LMICs. Moreover, even if COVAX met its initial target, as noted, this target is significantly less than a goal of population wide access for LMICs. Furthermore, more recently, as new strains of the virus emerged and concerns arose around whether some vaccines would be less effective for particular variants, the lack of autonomy within COVAX for LMICs in being able to choose from a range of vaccines that may best suit their needs was also exposed.⁷⁶

Accordingly, proposals towards sustainable solutions for global access to vaccines emerged and have garnered greater global support. This support is due at least in part to a recognition that COVAX alone is not sufficient to achieve global equitable access to vaccines. This may explain the WHO's continued (if arguably to date relatively low-key) support of C-TAP to encourage industry to act in the spirit of solidarity to bring COVID-19 under control.⁷⁷ However, as noted, as of the time of writing and one year after C-TAP was originally launched, this hope that industry will voluntarily join such mechanisms has not materialised.

In the absence of a voluntary coming together of HICs and pharmaceutical companies to upscale manufacturing in and for LMICs, it is unsurprising that proposals emerged for a mandatory solution leading to the TRIPS waiver proposal being put forward by India and South Africa in October 2020. This proposal has been debated at the WTO ever since in the face of mounting public support for the waiver. More recently, as discussed above, in recognition that a key issue for vaccines is how to enable greater manufacture of vaccines, there have been proposals for technology transfer hubs to help *expediate* technology transfer for vaccines. However, as part of such technology transfer hubs for the scale up of manufacturing one would still need to address the IP sharing issues. Thus, any technology transfer mechanism would need to be accompanied by a pathway to license/share relevant IP - either one which involves voluntary licensing/sharing of IP (like a C-TAP) model subject to co-operation from industry, or one which

⁷⁵ As noted above, it has also been claimed that COVAX could be enabling the status quo and hence it is questioned by some if COVAX is part of the problem rather than a solution: J Lei Ravelo, Is COVAX part of the problem or the solution? (Devex 11 March 2021) <https://www.devex.com/news/is-covax-part-of-the-problem-or-the-solution-99334> (accessed 26 May 2021).

⁷⁶ Godlee F. Covid 19: Widening divisions will take time to heal *BMJ* 2021; 372 :n96.

⁷⁷ WHO Press Release, "The President of the Republic of Costa Rica and the Director-General of the World Health Organization call once again on all WHO Member States to actively support the COVID-19 Technology Access Pool (C-TAP): Open letter to all WHO Member States" (27 May 2021) available at [https://www.who.int/news/item/27-05-2021-the-president-of-the-republic-of-costa-rica-and-the-director-general-of-the-world-health-organization-call-once-again-on-all-who-member-states-to-actively-support-the-covid-19-technology-access-pool-\(c-tap\)](https://www.who.int/news/item/27-05-2021-the-president-of-the-republic-of-costa-rica-and-the-director-general-of-the-world-health-organization-call-once-again-on-all-who-member-states-to-actively-support-the-covid-19-technology-access-pool-(c-tap)) (accessed 31 May 2021).

involves a mandatory suspension of IP (via the waiver).⁷⁸ Such mechanisms could therefore have complementary features (returned to below in b) and if operationalised together could deliver a pathway towards *expediting* equitable access to vaccines.

Yet, there is also a risk that the multiplicity of (particularly similar) mechanisms proposed (for instance multiple technology transfer proposals) by different entities could be a factor that delays the attainment of global equitable access, as we will also examine below (in c).

b. Institutional multiplicity - A Necessity to achieve Global Equitable Access to Vaccines?

Beyond mirroring an organic development of the vaccine equity debate over the past 15 months, the proliferation of arrangements has several advantages that may help to deliver a solution for equitable global access to vaccines. First, it offers a range of solutions, which importantly are both voluntary and mandatory in nature. Moreover, this could be used to drive change, for example, proposals like the waiver act as an important legal tool as noted, which would suspend IP rights for COVID-19 health-technologies to enable scale-up of manufacturing capacity.⁷⁹ However, the waiver proposal also acts a legal and political lever to encourage increased industry support for voluntary mechanisms around the sharing of intellectual property, data, know-how etc related to health technologies.⁸⁰ It is widely acknowledged in other public health contexts that the threat of compulsory licensing can be used to encourage companies to agree to voluntarily license a technology on preferential terms.⁸¹ Since the news of US support for the waiver, greater spotlight has been placed on the role of industry in this context, and reports of greater numbers of voluntary licenses are emerging.⁸² Thus, the waiver proposal may spur on greater industry action and co-operation.

Second, and relatedly, the different proposals and mechanisms create greater public pressure on pharmaceutical companies, and the debate around these

⁷⁸ Compulsory licensing is often suggested as an alternative against the waiver, but the shortcomings of using compulsory licensing in a pandemic situation are discussed elsewhere, including: Thambisetty et al note 14; McMahon, note 14; MSF, Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies' May 2021.

https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf (accessed 26 May 2021).

⁷⁹ Thambisetty et al, note 14.

⁸⁰ Thambisetty et al, note 14, 37.

⁸¹ Ooms G, Hanefeld J. Threat of compulsory licences could increase access to essential medicines *BMJ* 2019; 365 :l2098 doi:10.1136/bmj.l2098]

⁸² F Guarascio, 'G20 leaders to back COVID-19 vaccine voluntary licensing, no patent waiver' *Financial Post* (20 May 2021) <https://financialpost.com/pm/business-pmn/g20-leaders-to-back-covid-19-vaccine-voluntary-licensing-no-patent-waiver> (accessed 26 May 2021).

increases public attention around how to deliver global equitable access to vaccines for COVID-19 at a general level. The fact that each of these instruments discusses intellectual property rights (albeit in proposing different solutions/mechanisms for intellectual property rights in this context) may culminate to bringing much greater attention in the public domain to the role of IP in the access to vaccines context, including illuminating longstanding problems within the current innovation model. This could in turn act as a catalyst for industry action by increasing public pressure on industry.

Third, to achieve expedient global equitable access we must address several barriers to increase global manufacturing capacity particularly for vaccines. These include barriers related to intellectual property rights, knowledge, technology transfer and data sharing issues. Having a range of instruments can be useful, because some mechanisms are complementary and could be employed together to address different parts of the broader access puzzle.

c. Institutional Multiplicity: An Impediment to Global Equitable Access to Vaccines?

As discussed, there are numerous potential benefits to the multi-mechanism landscape that has grown in the global institutional context for the purpose of achieving vaccine equity. This section, by contrast, highlights some of the potential issues arising from this multiplicity.

The weightiest and most obvious concern associated with this multiplicity of mechanisms around achieving global access to vaccines is that it may lead to a dispersal of stakeholder attention. This is particularly problematic if seeking national government support for such instruments as the current multiplicity may potentially create confusion at a policy/governmental level. For instance, the WHO sponsors both C-TAP and COVAX, ACT-A; its Director General Dr Tedros Adhanom Ghebreyesus has also publicly advocated for the adoption of the proposed TRIPS waiver.⁸³ As outlined above, from the WHO's perspective these tools may be complementary and advocating for all of them represents an encouragement to industry and governments to "pull out all the stops", to quote Dr Ghebreyesus.⁸⁴ Yet this message is a difficult one to convey beyond a highly specialised expert public. It is likely that the highly technical nature of the instruments leaves many - perhaps even some government officials - with unanswered questions as to how

⁸³Tedros Adhanom Ghebreyesus, 'A 'me first' approach to vaccination won't defeat Covid' The Guardian 5 March 2021 <https://www.theguardian.com/commentisfree/2021/mar/05/vaccination-covid-vaccines-rich-nations> (accessed 26 May 2021).

⁸⁴ Ibid.

these interact or overlap to achieve the oft-cited goal of a ‘global public good’ in attaining global vaccine equity.

Moreover, at times, governments have relied on support for one instrument to refute the need for governmental support for other mechanisms or deviate from the status quo approach. For instance, in response to the US’s announcement of their support for the TRIPS waiver on May 5th 2021, the Irish Minister for Enterprise, Trade and Employment Leo Varadkar said that “our strong view is that COVAX is the best way to do this”.⁸⁵ Important as it is, the fact that COVAX is working as a short-term instrument to provide some vaccines to LMICs may take the urgency off governments to support more systemic or radical changes to traditional intellectual property arrangements, especially in countries that have strong domestic pharmaceutical industries. It is notable that some of the countries that have pledged the greatest amounts of funding to COVAX/ACT-A, according to the mechanism’s official funding tracker,⁸⁶ are the same countries that have shown most resistance to the TRIPS waiver.

In addition, it is possible that the dispersal of public and institutional attention also entails a dispersal of societal and advocacy pressure. Civil society organisations advocating for access to COVID-19 vaccines seem to variously engage in campaigns around COVAX,⁸⁷ C-TAP, the more general idea of a ‘People’s Vaccine’, and the TRIPS waiver, dependent on their own institutional and ideological affiliations. While there is broad consensus that there is an urgent need for relatively drastic steps towards the sharing or suspension of IP to avoid prolonging the ‘catastrophic moral failure’ as diagnosed by the WHO Director-General,⁸⁸ posed by the current levels of vaccine inequity, it seems that there is a level of uncertainty among concerned publics as to the best path to take to achieve this aim. At the time of writing, and in the absence of voluntary industry co-operation with existing mechanisms, a concerted focus is emerging around the TRIPS waiver proposal, which has garnered significant support from current and former politicians, scientists, and many representatives of civil society.⁸⁹

Nonetheless, by dispersing stakeholder attention, rather than increasing the overall pressure on the private pharmaceutical sector to engage, keeping all

⁸⁵ S Carswell & M O’Halloran, Government and big pharma face clash on Covid-19 vaccine patent waiver. The Irish Times. 6 May 2021 <https://www.irishtimes.com/news/health/government-and-big-pharma-face-clash-on-covid-19-vaccine-patent-waiver-1.4557184> (accessed 26 May 2021).

⁸⁶ <https://www.who.int/initiatives/act-accelerator/funding-tracker> (accessed 26 May 2021).

⁸⁷ S el Gharib, ‘5 Things to Know About COVAX , the Life-Saving Vaccine Initiative’ *Global Citizen* . 9 March 2021. <https://www.globalcitizen.org/en/content/what-is-covax/> (accessed 26 May 2021).

⁸⁸ WHO. Call to Action: Vaccine Equity. <https://www.who.int/campaigns/annual-theme/year-of-health-and-care-workers-2021/vaccine-equity-declaration> (accessed 26 May 2021).

⁸⁹ Over 100 civil society organisations call on the European Parliament to support COVID-19 WTO waiver proposal (19 November 2020) <https://msfaccess.org/over-100-civil-society-organisations-call-european-parliament-support-covid-19-wto-waiver-proposal> (accessed 26 May 2021).

instruments in play may at times muddle the playing field to such an extent that pressure for decisive action lessens. With this, not only do pharmaceutical firms have a choice menu of levels of engagement, but inertia can also continue, allowing industry (and arguably also some national governments) to effectively ‘sit out’ the current pandemic with the traditional intellectual property structures intact if they so choose.⁹⁰

Beyond lessening focused stakeholder pressure, overlapping mechanisms may also signal a dispersal of institutional efforts and financial resources. Voluntary sharing mechanisms such as C-TAP are relatively light on resource needs as they merely co-ordinate rather than fund license agreements between other parties, with one estimate comparing the potential operating costs of such a facility to the US\$7 million that the MPP costs to run per year.⁹¹ Yet, these organisations still must be staffed and governed, and stakeholders need to be engaged. In a context where public health resources run thin, this may represent an operational but nonetheless significant problem. Moreover, the donor and country funding provided to COVAX may stand in direct competition with countries’ subsidising licensing deals or funding public technology transfer facilities.

A final issue posed by the multi-mechanism landscape is the potential for institutional territorial jostles. This may be seen for instance between the WHO and the WTO, both of whom are currently proposing different technology transfer hubs in addition to the WHO’s C-TAP model. This could be seen as arguably blurring the discursive landscape even further. While there are clear overlaps of competencies and responsibilities with regard to pharmaceutical innovation and distribution, at the multinational level there needs to be a tighter co-ordination between the different bodies to achieve the aim of global equitable access for vaccines. This is particularly important given the many instances of ‘going it alone’ by nations or regional entities such as the EU that we have witnessed throughout the pandemic, with vaccine nationalism being the visible tip of an iceberg of political manoeuvring for soft power.

⁹⁰ See also: ‘The Pharmaceutical Accountability Foundation scores pharmaceutical companies’ behaviour regarding Covid-19 in a GCCP Scorecard. Conclusion: Big differences in adherence to human rights principles’ (22nd January 2021)

<https://www.farmaterverantwoording.nl/en/2021/01/22/the-pharmaceutical-accountability-foundation-scores-pharmaceutical-companies-behaviour-regarding-covid-19-conclusion-big-differences-in-adherence-to-human-rights-principles/> (accessed 26 May 2021).

⁹¹ WEMOS, Q&A on Pooling Patents and Knowledge for COVID-19 Vaccines

<https://www.wemos.nl/en/pooling/> (accessed 26 May 2021).

III. Conclusion

The foregoing analysis has highlighted some of the likely reasons and consequences of the multi-mechanism global landscape, with the shared end goal of attaining global equitable vaccine access, that has emerged since the beginning of the COVID-19 pandemic.

To achieve, and importantly to expedite, an increase in vaccine manufacturing capacity globally, several components are necessary, including addressing intellectual property obstacles and expediting technology transfer. Thus, in our view, from a practical operational perspective, the current proposed instruments in many cases have the potential to be highly complementary to each other, rather than overlapping in nature, if such instruments were sufficiently supported and used together in a targeted manner. For example, current proposals to mandate a waiver of IP via the TRIPS waiver, or to encourage voluntary sharing of IP via C-TAP, could be used alongside mechanisms to facilitate technology transfer via technology transfer hubs or via proposals under C-TAP around technology transfer, to form key elements of a broader strategy to upscale vaccine manufacturing capacity. The COVAX system used alongside such mechanisms could continue to provide a short-term vaccine distribution system for LMICs while broader systems that build sustainable solution for increasing vaccine manufacturing globally were developed.

Yet, despite this potential for complementarities, much debate, and numerous assertions of state and pharmaceutical leaders toward global vaccine equity, current estimates still point toward a two-to-three-year delay in achieving broad vaccine coverage in LMICs in comparison to HICs,⁹² with one estimate stating that it may take over four years to achieve global herd immunity.⁹³ This delay is simply untenable from a moral and public health perspective.

It is in this context that we must consider that the multiplicity of mechanisms, in some cases, may in fact be slowing down decisive action. For one, as discussed, this multiplicity may be used strategically either by States, pharmaceutical firms or other actors to stall action or at least circumvent public pressure until they are forced, or to engage by adopting a ‘wait and see’ attitude and letting institutional jostling play out. Moreover, the proposals for further new voluntary instruments such as additional licensing or technology transfer mechanisms when there is mounting support for the TRIPS waiver, in some cases, may also be interpreted or

⁹² Economist Intelligence Unit: More than 85 poor countries will not have widespread access to coronavirus vaccines before 2023. 27 Jan 2021. <https://www.eiu.com/n/85-poor-countries-will-not-have-access-to-coronavirus-vaccines/> (last accessed 28 May 2021);

⁹³ IT Katz, R Weintraub, LG Bekker, and AM Brandt, (2021). From Vaccine Nationalism to Vaccine Equity — Finding a Path Forward. *New England Journal of Medicine*, April 8 2021. <https://www.nejm.org/doi/full/10.1056/NEJMp2103614> (last accessed 28 May 2021).

used by some stakeholders as a delaying tactic. Indeed, certain parties/stakeholders interested in preserving the *status quo* could be banking on the distraction caused by new proposals to dilute support for existing mechanisms.

The corollary of this, however, as discussed earlier, is that the greater support grows for mandatory solutions like the waiver, the more likely industry may be to engage with voluntary mechanisms such as C-TAP. Thus, institutional jostling could in fact generate change. Nonetheless, to date we have not seen sufficient industry co-operation to achieve global vaccine equity – and only time will tell whether this will change.

To address the potential issues posed by institutional multiplicity in this context, in our view, there is a need for greater clarity by supporting institutions, in particular the WHO and the WTO, for instance, about how proposed voluntary mechanisms interlink. These institutions should also closely co-ordinate similar proposals, such as for technology transfer mechanisms, to address any possible duplication or any potential for public confusion where overlaps may appear evident. At the same time, given the overall attention created in the past months around intellectual property issues in the healthcare and pharmaceutical context, firms in this sector cannot in our opinion continue with a ‘business as usual’ approach. The COVID-19 pandemic has opened-up questions about what had been considered fundamental truths about the pharmaceutical innovation system.⁹⁴ These questions will need to be addressed in the longer term, for instance in relation to governments asserting voluntary licensing conditionalities when publicly funding pharmaceutical research and development.

To summarise, we recognize that the multiplicity of mechanisms described in this article has many potential benefits, including the complementary nature of many such mechanisms, their ability to raise overall public attention of the need for (and roadblocks to) vaccine access, and their potential to act as a catalyst for change. However, there is now a clear need for concerted global multilateral action to recognise the complementariness, and the benefits and inefficiencies of specific individual models proposed, and to provide a pathway for collaboration in attaining global equitable access to vaccines. The institutional infrastructure or proposals to achieve this amply exist at this point in time – but much greater co-operation from industry, or in the absence of this, decisive and co-ordinated action from States and international organisations in supporting mandatory solutions like the TRIPS waiver, is urgently needed. Access to vaccines must be our priority if we are to bring COVID-19 under control, and the steps needed to achieve this must be taken as soon as possible.

⁹⁴ See also, Thambisetty et al, note 14. For a discussion of the industry see: G Duffield, *That High Design of Purest Gold: A Critical History of the Pharmaceutical Industry, 1880-2020* (World Scientific Publishing, 2020).

Declaration of Interests

Aisling McMahon and Susi Geiger are members of Access to Medicines Ireland (AMI), a voluntary membership group of Comhlámh. The views expressed here are the authors' own and are not representative of AMI.

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