

Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang & Graham Dutfield, 'Addressing Vaccine Inequity During the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal & Beyond' 81 *Cambridge Law Journal* (forthcoming, July 2022).

Abstract

This article examines global vaccine inequality during the COVID-19 pandemic. We critique intellectual property (IP) law under the 1995 WTO TRIPS Agreement, and specifically, the role that IP plays in enabling the inequities of production, distribution and pricing in the COVID-19 vaccine context. Given the failure of international response mechanisms, including COVAX and C-TAP, to address vaccine inequity, we argue the TRIPS waiver proposal offers a necessary and proportionate legal measure for clearing IP barriers that cannot be achieved by TRIPS flexibilities. Finally, we reflect on the waiver in the wider context of TRIPS.

Keywords: TRIPS; Vaccine inequity; Waiver; Intellectual Property;

I. Introduction

Equitable access to vaccines during the COVID-19 pandemic is a moral imperative - it is in the public health, political and economic interests of everyone everywhere. Achieving equity requires concerted global solidarity and coordination. But to date there has been little evidence of this. Gaps in access to vaccines have created, in the words of World Health Organization (WHO) Director Tedros Adhanom Ghebreyesus, a “two tier” pandemic defined by “vaccine apartheid” between high income countries (HICs) and lower- and middle-income countries (LMICs).¹ The transnational intellectual property (IP) framework is implicated in vaccine inequity, as demonstrated by the profound disparities in the production and distribution of COVID-19 health technologies needed to combat the pandemic. The phenomena of COVID-19 corporate monopoly and secrecy (IP hoarding by companies) and “vaccine nationalism” (vaccine dose hoarding by states) have brought into sharp relief the misalignment of current legal and financial incentives to produce and distribute vaccines equitably.

The IP legal framework forms an integral part of the multilateral trade regulatory system overseen by the World Trade Organization (WTO), as set out in the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).² In this article we analyse the drivers embedded within the TRIPS framework that have played a key role in leading to, and maintaining, global vaccine inequity.³ We situate the TRIPS waiver proposal within IP law’s legal and structural shortcomings.⁴ We argue that given the ongoing failure of measures seeking vaccine equity by voluntary means, the waiver offers a necessary and proportionate legal measure for clearing IP barriers

¹ “WHO’s Tedros says COVID-19 vaccine inequity creates ‘two-track pandemic’” *Reuters* (June 2021) available at <https://www.reuters.com/business/healthcare-pharmaceuticals/whos-tedros-says-covid-19-vaccine-inequity-creates-two-track-pandemic-2021-06-07/> (last accessed 14 February 2022).

² Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO) (1994).

³ S.F. Halabi, *Intellectual Property and the New International Economic Order: Oligopoly, Regulation, and Wealth Redistribution in the Global Knowledge Economy* (Cambridge University Press 2018).

⁴ Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19. Communication from India and South Africa (2 Oct 2020) IP/C/W/669(hereafter “TRIPS Waiver Proposal IP/C/W/669”); See also revised text: Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 Revised Decision Text IP/C/W/669/Rev.1 (25 May 2021). (hereafter “Waiver Revised Text IP/C/W/669/Rev.1”)

in a direct, consistent and efficient fashion. If adopted it would provide companies the freedom to operate and to produce COVID-19 vaccines (and other COVID-19 health-technologies) without the fear of infringing another party's IP rights and the attendant threat of litigation.

We develop the argument by first analysing the major COVID-19 vaccines in relation to their development, production, distribution and pricing. Our analysis shows that the IP framework, typified by TRIPS, has enabled IP holders to wield exclusive rights, resulting in artificial scarcity and inequitable supply of vaccines (alongside and beyond delays caused by the initial shortage of raw materials and the scaling of production capacity).⁵ We argue that IP has been central to facilitating an oligopolistic market in vaccines, particularly in mRNA vaccines, with rightsholders exercising significant control over access to such vaccines. By relying on voluntary licensing and philanthropic donations, the multilateral and multi-institutional efforts to tackle the supply of COVID-19 vaccines, typified by COVAX, have taken IP exclusivity as a given. This has perpetuated asymmetric bargaining power between vaccine makers and LMICs. The COVAX model has, thus far, failed to achieve vaccine equity.

In light of this, we examine the TRIPS waiver proposal initially put forward by India and South Africa in October 2020. As of February 2022, the TRIPS waiver proposal is co-sponsored by more than 60 states⁶ and has received statements of support from the WHO.⁷ In considering whether the TRIPS waiver can provide a solution to vaccine

⁵ Patents create exclusive rights to make, use or sell an invention but do not lead inevitably to market monopoly. Limited market demand, existence of substitutes, and follow-on competition can, ordinarily, limit the possibility of monopolies. In this 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 have allowed a small number of vaccine manufacturers to accrue monopolistic market advantages based on exclusive rights. If we consider each vaccine to be substitutable with another, the current market for vaccines can be viewed as an oligopoly.

⁶ "UK statements during the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council from 13-14 October 2021" available at <https://www.gov.uk/government/news/wto-trips-council-october-2021-uk-statements> (last accessed 14 February 2022). See also E. 't Hoen and P. Boulet, "The EU proposed Covid waivers of certain TRIPS rules are mostly meaningless" *Medicines Law and Policy* (14th October 2021) available at <https://medicineslawandpolicy.org/2021/10/the-eu-proposed-covid-waivers-of-certain-trips-rules-are-mostly-meaningless/> (last accessed 14 February 2022).

⁷ WHO, "WHO Director-General Commends United States Decision to Support Temporary Waiver on Intellectual Property Rights for Covid-19 Vaccines" (5 May 2021) available at

inequity we analyse the two different IP rights – patents and trade secrets – which are most relevant to the present COVID-19 vaccine context.⁸

We address the key arguments used by opponents of the waiver, which are often presented as a defence of the legal status quo, namely: (i) that the waiver will not be effective because it is not feasible to boost production capacity in the global south; (ii) that the waiver is not needed because compulsory licensing presents an appropriate alternative to the waiver; and (iii) that the waiver should be opposed because it would have a harmful effect on “innovation incentives”. In critiquing these three arguments we reflect on the role of the public interest as a key feature underpinning the development and rationale for IP frameworks.

Finally, we assess the implication of IP rights in the COVID-19 vaccine shortages as a significant inflection point, more than a quarter of a century after TRIPS.⁹ The COVID-19 pandemic has shed light on an existing problem of inequality within the TRIPS system which has kept LMICs in an IP importer dependency position. The call for a waiver as an emergency measure is thus symptomatic of deep inequalities that are entrenched in international and national legislation protecting IP.¹⁰ Notably, it demonstrates the failure of HICs to realise the promise they made at the time of the conclusion of the TRIPS negotiations in 1994, that by agreeing to the terms of TRIPS, LMICs would benefit from technology transfer and the building of productive capacity.¹¹ As such, the pandemic is revealing not only of inadequacies of how to deal with global emergencies, but also of deficiencies within the international “patent bargain” itself. The article concludes with a discussion of the potential legacy of the waiver debate in addressing these deficiencies.

<https://www.who.int/news/item/05-05-2021-who-director-general-commends-united-states-decision-to-support-temporary-waiver-on-intellectual-property-rights-for-covid-19-vaccines> (last accessed 14 February 2022).

⁸ O. Gurgula and J. Hull, “Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer” (2021) *Queen Mary Law Research Paper No. 363/2021*.

⁹ S. Ragavan and A. Vanni (eds.), *Intellectual Property Law and Access to Medicine: TRIPS Agreement, Health, and Pharmaceuticals* (Routledge 2021).

¹⁰ P. Drahos, “Public lies and Public goods: Ten lessons from when Patents and Pandemics meet” (2021) *EUI Working Paper 2021/5*.

¹¹ O. Aginam, J. Harrington and P.K. Yu (eds.), *The Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines* (Edward Elgar 2013).

II. TRIPS and the Role of Intellectual Property in Global Health

The chequered history of the TRIPS Agreement since its inception shows that criticism of IP's role in the production and marketing of health technologies is not new.¹² Deep inequalities were evident in the late 1990s and early 2000s, amidst the HIV/AIDS epidemic and the confrontation that pitted health activists and the South African government against pharmaceutical companies.¹³ This battle over access to life-saving medicines led to the 2001 Doha Declaration,¹⁴ which focused on balancing IP rights with global health, albeit mostly by clarifying the meaning of the existing language of TRIPS.¹⁵ Although access to generic HIV/AIDS medicines has improved, the Doha Declaration did not rectify the core inequalities present within the TRIPS framework affecting global access to healthcare. Even prior to the pandemic, the role of IP in contributing to the poor state of access to healthcare globally was documented in the 2016 United Nations Secretary-General's report on access to medicines.¹⁶ The COVID-19 pandemic has added urgency to this long-running debate over global access to health technologies by once again illustrating the conflicts between IP rules and global health objectives.¹⁷

Fundamental to this relationship is the patent system, which creates legal exclusivity rights in the use of a patented invention, making access and use of that patented invention subject to rightholder permission. If the rightholder denies this, they can preclude or disable competition for a period of 20 years. This gives the holder the ability to secure a dominant market share and the freedom to dictate the price, and other terms, for access to the invention. Although patents are frequently licensed for

¹² D. Gervais, "Intellectual Property, Trade & Development: The State of Play" (2005) 74 *Fordham Law Review* 505.

¹³ E. 't Hoen, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha" (2002) 3 *Chicago Journal of International Law* 27.

¹⁴ Declaration on the TRIPS agreement and public health, Doha WTO Ministerial, 2001: TRIPS, WT/MIN(01)/DEC/2, Adopted 14 November 2001

¹⁵ S. Ghosh, "Comment: Competitive Baselines for Intellectual Property Systems" in K.E. Maskus and J.H. Reichman, *International Public Goods and Transfer of Technology Under A Globalised Intellectual Property Regime* (Cambridge University Press 2005) at 793.

¹⁶ Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting innovation and access to health technologies (September 2016) <http://www.unsgaccessmeds.org/final-report/>

¹⁷ Universal Declaration of Human Rights (UDHR), Article 25; International Covenant on Economic, Social and Cultural Rights, Article 12.

the benefit of both parties, a position of dominance can hinder technology sharing.¹⁸ Patents can be used to maintain artificial scarcity - restricting the production of the patented good for strategic reasons - for as long as legally possible.¹⁹ The use of trade secrets and restrictive technology transfer agreements can bolster and further extend this potential exercise of a monopoly power. Crucially, vast market power in the pharmaceutical industry has significant consequences for the public, unlike market domination in, say, mousetraps.²⁰ Given that IP is fundamental to the way the pharmaceutical market operates, IP must be understood as a key factor when the market produces dysfunctional or inequitable results, as it is doing now during the COVID-19 crisis.

TRIPS and the Covid-19 Vaccine Market: Inequity as a function of production, distribution and pricing

The pandemic has exacerbated existing global health inequalities, none more apparent than in vaccine production, distribution and pricing.²¹ Although early in the pandemic the WHO guidelines recommended that health workers and high-risk people in all nations should get vaccinated first, HICs, including the US, the UK and EU states, failed to follow through, instead prioritising their own populations, including those at relatively low risk.²² As of February 2022, rich countries such as the UK and many EU member states have double-vaccinated 70-75% of their adult populations; but 85% of Africans have not received even one dose.²³ Furthermore, while Israel, the US, the UK and Germany are administering third or fourth “booster” doses to their citizens,

¹⁸ E. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (AMB Publishing 2009).

¹⁹ S. Thambisetty, “Why Patent Law Doesn't Do Innovation Policy” (2013) *LSE Legal Studies Working Paper No. 20/2013*.

²⁰ G. Dutfield, *That High Design of Purest Gold: A Critical History of the Pharmaceutical Industry, 1880-2020* (World Scientific Publishing 2020).

²¹ WHO, “WHO Director-General's opening remarks at 148th session of the Executive Board” (18 January 2021) available at <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board> (last accessed 18 October 2021).

²² WHO, “Roadmap for Prioritizing Population Groups for Vaccines Against Covid-19” (27 September 2020).

²³ See the map at <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> (last accessed 14 February 2022).

billions of people, including vulnerable healthcare workers, in LMICs are still waiting for their first dose.²⁴

Although pharmaceutical companies promised to produce enough doses to vaccinate all adults globally by the end of 2021, their supply consistently fell short of targets.²⁵ Moreover, distribution of available vaccines has been highly uneven. The key manufacturing states of the US, UK and EU have stockpiled most of the doses that have been produced - even allowing millions of doses to expire - which has left a vast vaccine access gap in LMICs.²⁶

Production of the most effective global vaccines is concentrated in a handful of Western companies, notably Oxford-AstraZeneca, Pfizer-BioNTech, Moderna and Johnson and Johnson (J&J). During 2021 only a limited number of voluntary licensing arrangements aimed at increasing vaccine production capacity were established, exacerbating the problem of insufficient global production. For example, J&J and Merck signed an agreement to boost US production of the J&J vaccine, and J&J agreed a limited “fill and finish” deal with Aspen in South Africa.²⁷ Other voluntary arrangements included AstraZeneca’s deals with Serum Institute of India (Serum)²⁸ and Fiocruz in Brazil;²⁹ BioNTech’s joint venture with Fosun Pharmaceuticals in China

²⁴ “‘F In Ethics’: UN Chief Grades World On Vaccine Rollout’ *NDTV* (September 21 2021) available at <https://www.ndtv.com/world-news/f-in-ethics-un-chief-antonio-guterres-grades-world-on-vaccine-rollout-2548827> (last accessed 14 February 2022).

²⁵ Amnesty, “A double dose of inequality: Pharma companies and the Covid-19 vaccines crisis” (22 September, 2021) available at <https://www.amnesty.org/en/documents/pol40/4621/2021/en/> (last accessed 14 February 2022).

²⁶ M. Schreiber, “US throws out millions of doses of covid vaccine as the world goes wanting” *The Guardian* (16 October 2021) available at <https://www.theguardian.com/world/2021/oct/16/us-throws-out-millions-doses-covid-vaccine-world-shortages> (last accessed 14 February 2022)

²⁷ “Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines” (2 March 2021) available at <https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html> (last accessed 14 February 2022).

²⁸ “Serum Institute of India obtains emergency use authorisation in India for AstraZeneca’s COVID-19 vaccine” (January 2021) available at <https://www.astrazeneca.com/media-centre/press-releases/2021/serum-institute-of-india-obtains-emergency-use-authorisation-in-india-for-astrazenecas-covid-19-vaccine.html> (last accessed 14 February 2022).

²⁹ “MSF welcomes Fiocruz’s step towards transparency of AstraZeneca deal” (November 2020) available at <https://msfaccess.org/msf-welcomes-fiocruzs-step-towards-transparency-astrazeneca-deal> (last accessed 14 February 2022).

(separate from BioNTech's deal with Pfizer);³⁰ and Pfizer-BioNTech's narrow "fill and finish" agreement with Biovac in South Africa;³¹. These arrangements, while positive, have thus far been inadequate to meet the world's needs for COVID-19.

On vaccine distribution and access, the pandemic has brought a stark realisation into view: regions without vaccine production hubs lack security of supply. In the global south during 2021 only India had sufficient local production to ensure supply security.³² Most other LMICs were, and are, far less fortunate. During 2021 vaccine production in Latin America lagged behind that of the US and Europe.³³ Very limited production of COVID-19 vaccines occurred in Africa, and even where vaccine doses were produced, for instance in South Africa under the J&J-Aspen contract, many millions of these doses were exported to the EU rather than used locally.³⁴ Overall, a lack of distributed production led to an insecurity of supply in these regions, as vaccine nationalism in the HICs like the US, Canada, the UK, and EU states saw mass hoarding of the produced doses.

Aside from the moral inequity, inequalities of production and distribution may prove short-sighted: without sufficient vaccine production and equitable global distribution, new COVID-19 variants, such as Omicron, will likely continue to emerge. Such variants may render existing vaccines less effective. As Dr Tedros Ghebreyesus

³⁰ A. Liu, "BioNTech, Fosun Pharma eye 1B doses of COVID-19 vaccine capacity with new China JV" *Fierce Pharma* (10 May 2021) available at <https://www.fiercepharma.com/manufacturing/biontech-fosun-pharma-eye-1b-doses-covid-19-vaccine-capacity-new-china-jv> (last accessed 14 February 2022).

³¹ Pfizer Press Release (21 July 2021) available at <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac> (last accessed 14 February 2022).

³² S. Findlay, M. Peel and D.P. Mancini, "India's block on vaccine exports deals blow to dozens of nations" *The Irish Times* (26 March 2021) available at <https://www.irishtimes.com/news/world/asia-pacific/india-s-block-on-vaccine-exports-deals-blow-to-dozens-of-nations-1.4520812> (last accessed 14 February 2022).

³³ "Editorial: The World Needs Many More Coronavirus Vaccines" *New York Times* (24 April 2021) available at <https://www.nytimes.com/2021/04/24/opinion/covid-vaccines-poor-countries.html> (last accessed 14 February 2022).

³⁴ G. Brown, "The world is making billions of Covid vaccine doses, so why is Africa not getting them?" *The Guardian* (16 August 2021) available at <https://www.theguardian.com/commentisfree/2021/aug/16/world-billions-covid-vaccine-doses-africa-unprotected> (last accessed 14 February 2022).

remarks, “[v]accine nationalism is not just morally indefensible. It is epidemiologically self-defeating and clinically counterproductive”.³⁵

Exclusive rights and the profit incentive – enabled by IP law – cannot be separated from inequities in vaccine production and distribution. From a purely financial perspective, the ongoing global pandemic offers pecuniary incentives for IP-holding vaccine producers and their shareholders. There is even a perverse incentive for COVID-19 vaccine manufacturers to prioritise selling vaccines, including booster doses, to countries that can afford to pay the highest price, regardless of other countries’ health needs.³⁶ Financial interests may clash with what is required to achieve the goal of bringing the pandemic to an end.³⁷

The production of mRNA vaccines by Pfizer-BioNTech and Moderna has been particularly profitable. The unit cost of producing a mRNA vaccine dose is less than US\$3, but BioNTech-Pfizer priced initially it at US\$19.50.³⁸ Claiming this as a form of “pandemic pricing” yielding around 20% gross profit margin, Pfizer stated that in a non-pandemic environment it would normally be priced between US\$150 and US\$175.³⁹ The vast majority of the Pfizer-BioNTech and Moderna doses have been sold to HICs. Indeed, in its most recent sale of “boosters” to the UK and EU, Pfizer actually raised the price, increasing its profits.⁴⁰ Consequently, Pfizer generated \$36-37 billion in vaccine revenue in 2021.⁴¹ BioNTech’s share of sales was \$16-17bn

³⁵ T.A. Ghebreyesus, “Vaccine Nationalism Harms Everyone and Protects No One” *Foreign Policy* (2 February 2021) available at <https://foreignpolicy.com/2021/02/02/vaccine-nationalism-harms-everyone-and-protects-no-one/> (last accessed 14 February 2022).

³⁶ R. Robbins, “Moderna, Racing for Profits, Keeps Covid Vaccine Out of Reach of Poor” *New York Times* (9 October 2021) available at <https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html> (last accessed 14 February 2022)

³⁷ P. Patnaik & H.Y. Kang, “India: The Quagmire for COVAX; Q&A: Hyo Yoon Kang on the financialization of intellectual property & COVID-19” (20 April 2021) available at <https://genevahealthfiles.substack.com/p/india-the-quagmire-for-covax-q-and> (last accessed 14 February 2022).

³⁸ Z. Kis, C. Kontoravdi, R. Shattock and N. Shah, “Resources, Production Scales and Time Required for Producing RNA Vaccines for the Global Pandemic Demand” (2021) 9 *Vaccines* 3.

³⁹ Pfizer, “Edited Transcript, Q4 2020 Earnings Call” (2 February 2021) available at https://s21.q4cdn.com/317678438/files/doc_financials/2020/q4/PFE-USQ_Transcript_2021-02-02.pdf (last accessed 14 February 2022).

⁴⁰ D.P. Mancini, H. Kuchler and M. Khan, “Pfizer and Moderna raise EU Covid vaccine prices” *Financial Times* (August 2021) - <https://www.ft.com/content/d415a01e-d065-44a9-bad4-f9235aa04c1a> (last accessed 14 February 2022).

⁴¹ J. Kollewe, “Pfizer accused of pandemic profiteering as profits double” *The Guardian* (8 February 2022) available at <https://www.theguardian.com/business/2022/feb/08/pfizer-covid-vaccine-pill-profits-sales> (last accessed 14 February 2022).

(approximately 0.5% of Germany's GDP for 2021).⁴² Moderna earned \$15-17bn in revenue for mRNA vaccine sales during 2021.⁴³ Undoubtedly, Pfizer-BioNTech and Moderna are the key "beneficiaries" of the status quo.⁴⁴

Only AZ is supplying vaccines at cost.⁴⁵ Despite this pledge, there is evidence of LMICs being charged a higher price than HICs.⁴⁶ Prof. Louise Richardson, Vice-Chancellor of the University of Oxford, defends the Oxford/AZ approach, noting that, unlike AZ, several other pharmaceutical companies "have derived enormous profits from the pandemic".⁴⁷ Yet, in late 2021 AZ replaced their at cost pricing system with a tiered pricing model.⁴⁸ Financial markets are aware of the potential for profitability. In April 2021, the Oxford University spin-out company that helped develop the vaccine – Vaccitech – filed its Initial Public Offering (IPO) on the US Nasdaq exchange, raising more than \$100 million.⁴⁹

Inequities with regard to global public vaccine access and pricing are all the more glaring given that several vaccines relied on major breakthroughs achieved at universities and public institutions, including at the University of Oxford, Johannes Gutenberg-University Mainz, the University of British Columbia, the University of Pennsylvania (Penn), and the US National Institutes of Health (NIH); as well as the fact that unprecedented amounts of public funding have gone into vaccine research

⁴² "BioNTech alone could lift German economy by 0.5% this year – economist" *Reuters* (10 August 2021) available at

<https://www.reuters.com/article/germany-economy-biontech-idUSL8N2PH32O>
(last accessed 14 February 2022)

⁴³ "Moderna expects \$18.4 billion in COVID-19 vaccine sales in 2021" *Reuters* (25 February 2021) available at <https://www.reuters.com/article/us-health-coronavirus-moderna-idUSKBN2AP1JG> (last accessed 14 February 2022)

⁴⁴ S. Marks, "Human Rights and Root Causes" (2011) 74 *MLR* 57.

⁴⁵ D.P. Mancini, "AstraZeneca vaccine document shows limit of no-profit pledge" *Financial Times* (7 October 2020) available at <https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686> (last accessed 14 February 2022).

⁴⁶ C. Paun and A. Furlong, "Poorer countries hit with higher price tag for Oxford/AstraZeneca vaccine" *Politico* (22 February 2021).

⁴⁷ L. Richardson, 'Time for other vaccine makers to follow Oxford/AstraZeneca's lead' *Financial Times* (18 May 2021) available at <https://www.ft.com/content/65856fab-e394-4407-adf9-63edd8acdad3> (last accessed 14 February 2022).

⁴⁸ H. Kuchler, "AstraZeneca reveals strong Covid vaccine sales but warns of US approval delays" *Financial Times* (29 July 2021) available at <https://www.ft.com/content/8e14257f-8bf8-4dc7-9680-9d489654d2b6> (last accessed 14 February 2022)

⁴⁹ A. Keown, "AstraZeneca Vaccine Collaborator Vaccitech Snares \$110.5 Million IPO" (30 April 2021) available at <https://www.biospace.com/article/vaccitech-raises-110-5-million-in-ipo/> (last accessed 14 February 2022).

and production by private companies. The global public sector has spent at least €93 billion on the development of COVID-19 vaccines and therapeutics – including over €88 billion on vaccines.⁵⁰ Detailed analysis shows that “public funding accounted for 97.1–99.0% of the funding towards the R&D of ChAdOx and the Oxford-AstraZeneca vaccine”.⁵¹ The Moderna vaccine, which is sometimes referred to as the “NIH-Moderna vaccine” due to co-inventorship by NIH scientists, was almost entirely funded by the US government, which provided \$10bn.⁵² BioNTech is a spin-off company of the public Johannes Gutenberg-University Mainz and it received more than \$445m from the German government.⁵³

Despite significant public funding, and public research initiatives, underpinning many COVID-19 vaccines, legal conditions were generally not attached to this funding to secure equitable global access to vaccines. Instead, IP holders exercise largely unfettered power to dictate which country gains access to vaccines and on what terms.⁵⁴ As COVID-19 moves gradually from a pandemic to endemic scenario in HICs, a private market that views vaccines as commodities, and seeks profit maximisation, appears to be incentivising and prioritising production of expensive vaccine booster doses for HICs over first doses for LMICs. Meanwhile, the profit incentive, with the emphasis on maintaining IP restrictions rather than sharing IP or related technology transfer, is clashing with efforts to increase productive capacity for manufacturing vaccines.⁵⁵ In short, the current IP framework is failing to create the right incentives to resolve vaccine inequity.⁵⁶

⁵⁰ “Governments Spent at Least €93bn on COVID-19 Vaccines and Therapeutics During the Last 11 Months” *Business Wire* (11 Jan 2021) available at <https://www.businesswire.com/news/home/20210110005098/en> (last accessed 14 February 2022).

⁵¹ S. Cross et al., “Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology” (2021) *medRxiv* preprint doi: <https://doi.org/10.1101/2021.04.08.21255103> – (version 10 April 2021).

⁵² B. Herman, “Biden admin warns Moderna to ‘step up’ global vaccine supply” *Axios* (13 October 2021) available at <https://www.axios.com/covid-vaccine-moderna-biden-global-supply-covax-ff74663f-8123-40e1-bc91-f91fdbb92f4c.html> (last accessed 14 February 2022)

⁵³ Amnesty, “A double dose of inequality”.

⁵⁴ A. McMahon, “Biotechnology, Health and Patents as Private Governance Tools: The Good, the Bad and the Potential for Ugly?” (2020) *Intellectual Property Quarterly* 161.

⁵⁵ N. Aizenman, “Moderna won’t share its vaccine recipe. WHO has hired an African startup to crack it” *NPR* (14 February 2022) available at <https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun?t=1635774977497> (last accessed 14 February 2022)

⁵⁶ P. Erfani et al., “Intellectual property waiver for covid-19 vaccines will advance global health equity” (2021) 374 *BMJ* n1837.

III. Intellectual Property and the International COVID-19 Pandemic Response: C-TAP, COVAX and the TRIPS Waiver Proposal

Aside from the TRIPS waiver proposal, which we discuss below, there are two existing WHO global initiatives for pandemic response – COVID-19 Technology Access Pool (C-TAP) and COVID-19 Vaccines Global Access (COVAX) – with each incorporating different approaches to IP sharing in the fight against COVID-19.⁵⁷ As we outline here, these initiatives have not (as of February 2022) succeeded in delivering global vaccine equity. It is these failings and, in particular, the lack of sufficient industry engagement and co-operation with voluntary systems like C-TAP, that have necessitated the TRIPS waiver proposal.

C-TAP and COVAX

The C-TAP scheme originated from Costa Rica’s call for a voluntary pool of IP, data and know-how etc. in March 2020.⁵⁸ Modelled on the UN-backed Medicines Patent Pool, C-TAP was launched by the WHO in May 2020 as an internationally co-ordinated mechanism of voluntary sharing of IP, data and know-how.⁵⁹ However, the pharmaceutical industry has ignored C-TAP.⁶⁰ There are also concerns about a lack of support for a similar vehicle, the mRNA Vaccine Transfer Hub, although, as discussed further below, the WHO and South Africa are proceeding even in the absence of cooperation from Moderna and other mRNA vaccine firms.⁶¹

⁵⁷ At time of writing, the World Health Organisation is seeking to establish a global legal instrument or pandemic treaty for future pandemic preparedness. This is still at proposal stage, and it is not clear what form the discussion of IP will take, if any. At present there is no reason to think that this process cannot work alongside a WTO TRIPS waiver.

⁵⁸ E. Silverman, “WHO is asked to create a voluntary intellectual property pool to develop Covid-19 products” *Stat News* (24 March 2020) available at <https://www.statnews.com/pharmalot/2020/03/24/covid19-coronavirus-costa-rica-intellectual-property/> (last accessed 14 February 2022).

⁵⁹ See: <https://www.who.int/initiatives/covid-19-technology-access-pool> (last accessed 14 February 2022).

⁶⁰ E. ‘t Hoen, “The elephant in the room at the WHO Executive Board” *Medicines Law and Policy* (22 January 2021) available at <https://medicineslawandpolicy.org/2021/01/the-elephant-in-the-room-at-the-who-executive-board/> (last accessed 14 February 2022).

⁶¹ Aizenman, “Moderna won’t share its vaccine recipe”.

In contrast to C-TAP, COVAX operates as a public–private initiative, supported by HICs, the UN, GAVI, CEPI and the Gates Foundation.⁶² COVAX is designed to meet immediate, rather than systemic needs, with states coming together to purchase and distribute vaccines. Despite several governance-related problems, COVAX has achieved some success in delivering vaccines to LMICs, with over 800m doses allocated by end December 2021; however, this fell far short of COVAX’s goal to distribute approximately 2 billion doses to LMICs by end 2021.⁶³ Furthermore, more than 100m of the donated doses were too close to expiry to be usable by LMICs.⁶⁴ The failure of COVAX to deliver on its aims can be attributed to vaccine nationalism in HICs and the insufficiency of vaccine production worldwide, with insecurity of supply to COVAX at its height after May 2021 when the Indian government halted exports from Serum to focus on the crisis in India.⁶⁵

COVAX has a role to play, but a model based on philanthropy and charity will not build sustainable medium- or long-term public health preparedness. The inherently insecure COVAX model “supports the monopolistic model that it is based on”, ignoring the “very real desire of developing and least developed countries to produce for themselves”.⁶⁶ Logically, LMICs will only be able to attain the kind of security of vaccine supply that countries and regions such as the UK, the US, the EU (and India) rely on by taking production into their own hands via regional hubs. The failure of the donation model to solve the problem of inequity, coupled with the desire for LMICs to boost local production, highlights an alternative proposal: the TRIPS waiver.

⁶² See: <https://www.gavi.org/gavi-covax-amc-launch-event-april-2021>

⁶³ O. Goldhill, “Naively ambitious’: How COVAX failed on its promise to vaccinate the world” *Stat News* (8 October 2021) – available at <https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/> (last accessed 14 February 2022)

⁶⁴ “Poorer nations forced to dump close-to-expiry COVID vaccines” *Al Jazeera* (13 January 2022) – available at <https://www.aljazeera.com/news/2022/1/13/poorer-nations-dump-close-to-expiry-covid-vaccines-unicef>

⁶⁵ S. Findlay and D Pilling, “Indian vaccine maker extends freeze on export of Covid jabs” *Financial Times* (18 May 2021) available at <https://www.ft.com/content/63fbbb79-f657-4e6c-b190-cffd0d630593> (last accessed 14 February 2022).

⁶⁶ “23 February 2021: South Africa’s interventions at the WTO TRIPS Council” *KEI* (1 March 2021) available at <https://www.keionline.org/35453> (last accessed 14 February 2022).

The TRIPS Waiver

Concerns over the effects that IP rights have on global equitable access to COVID-19 health technologies, and the (then foreseeable) problem of vaccine inequity, prompted India and South Africa to put forward the TRIPS waiver. In October 2020, India and South Africa proposed that World Trade Organization (WTO) members should:

work together to ensure that intellectual property [IP] rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat Covid-19.⁶⁷

Justifying the proposal by reference to “exceptional circumstances”, India and South Africa called for a waiver that would “continue until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity”. Although sometimes referred to in shorthand as a “patent waiver”, in both its original and revised forms, the India/South Africa proposal is a broad package extending to all relevant IP, and applicable to diagnostics, treatments and vaccines. After going unheeded at successive WTO meetings, the call received a boost in May 2021 when the US expressed support, albeit for a narrower IP waiver that would apply only to COVID-19 vaccines.⁶⁸

The proposal is co-sponsored by over 60 WTO countries.⁶⁹ The waiver would apply “in relation to prevention, containment or treatment of COVID-19”, covering not only the temporary waiver of patents (and, where relevant, copyrights) internationally, but also, crucially, the sharing of IP under the umbrella of undisclosed information, such as trade secrets and know-how.⁷⁰

⁶⁷ TRIPS Waiver Proposal IP/C/W/669.

⁶⁸ “Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver” (5 May 2021) available at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> (last accessed 14 February 2022).

⁶⁹ Current WTO sponsors are available to view at https://www.twn.my/title2/intellectual_property/trips_waiver_proposal/W684.pdf (last accessed 14 February 2022)

⁷⁰ Waiver Revised Text IP/C/W/669/Rev.1.

In principle, this kind of ‘sharing’ is not new.⁷¹ The 2011 WHO Pandemic Influenza Preparedness (PIP) Framework makes explicit reference to technology transfer, albeit in the somewhat limited context of benefit sharing (in return for receiving biological materials), and offers language that is short of a legally binding obligation. However, section 6.13.4 bears repeating - it states:

Influenza vaccine manufacturers who receive PIP biological materials may grant, subject to any existing licensing restrictions, on mutually agreed terms, a non-exclusive, royalty-free licence to any influenza vaccine manufacturer from a developing country, to use its intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of influenza vaccine development and production, in particular for pre-pandemic and pandemic vaccines for use in agreed developing countries.

In line with this, the TRIPS waiver carries significant moral weight as a way to help stimulate building capacity in LMICs.⁷² Since the coming into force of TRIPS in 1995, efforts to enhance LMICs’ industrial and pharmaceutical capacity have been hindered by the lack of technology transfer from HICs.⁷³ Even when technology has been transferred, undisclosed licensing terms covering patents and other IP rights typically restrict how transferred technologies can be used and to what extent the resultant products – in this case vaccines – may be diffused within and across national boundaries. These issues are complex, and as we explain in the following section, it is vital to consider both patents and trade secrets – the IP rights that have particular impact in this context. Other IP issues, such as copyright, and overlapping commitments under free trade agreements, are arguably not as critical; but they may still increase the layers of protection which rightsholders can exercise. For the

⁷¹ A. Kapczynski, “Order without Intellectual Property Law: Open Science in Influenza” (2017) 102 *Cornell Law Review* 1539.

⁷² P. Erfani, L.O. Gostin and V. Kerry, “Beyond a symbolic gesture: What’s needed to turn the IP waiver into Covid-19 vaccines” *Stat News* (19 May 2021) available at <https://www.statnews.com/2021/05/19/beyond-a-symbolic-gesture-whats-needed-to-turn-the-ip-waiver-into-covid-19-vaccines/> (last accessed 14 February 2022).

⁷³ S. Humphreys, “Perspective: Technology Transfer and Human Rights: Joining Up the Dots” (2009) 2 *Sustainable Development Law & Policy*.

purposes of brevity these ancillary issues are not analysed here, but we note they have been scrutinised elsewhere.⁷⁴

IV. Operationalising a TRIPS Waiver – Patents and Trade Secrets

The TRIPS waiver puts into sharp relief the different layers of property rights that often ringfence innovation and operate as assets in the world economy.⁷⁵ Like a matryoshka doll, the inner core of an invention is often wrapped with layers of IP rights, each possessing a differing rationale, scope and subject matter. We focus here on the two key IP rights for present purposes: patents and trade secrets (interpreted widely to include know-how, data and other undisclosed information).

In line with TRIPS, a patent on an invention is granted to an inventor/owner by one or more patent offices, with its specification documentation made public, and a grant of exclusive protection lasting for 20 years.⁷⁶ A trade secret under TRIPS covers undisclosed information, including know-how.⁷⁷ Such secrets are usually protected under contract law or non-disclosure agreements (NDAs).⁷⁸

It is a twist of the patent-trade secret duopoly that IP legal incentives are structured in such a way that inventions that are easily replicable, or reverse-engineered, tend to be patented. For if such an invention lacks patent protection, then it will be easily read, reverse-engineered and reproduced by competitors.⁷⁹ On the other hand, if an invention is genuinely difficult to replicate, it may make more strategic commercial sense to hold that inventive information as a trade secret, and obtain longer protection than the 20 years a patent allows.

⁷⁴ S. Flynn, E. Nkrumah and L Schirru, “Non-Patent Intellectual Property Barriers to COVID-19 Vaccines, Treatment and Containment” (2021) *PIJIP/TLS Research Paper Series* No. 71; C.M. Correa, N. Syam and D. Uribe, “Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements” *South Centre Research Paper* 135 (August 2020); H. Grosse Ruse-Khan and F. Paddeu “A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investment Agreements” *South Centre Research Paper* 133 (January 2022).

⁷⁵ H.Y. Kang, “Patents as Assets: Intellectual Property Rights as Market Subjects and Objects” in K. Birch and F. Muniesa (eds.), *Assetization: Turning Things into Assets in Technoscientific Capitalism* (MIT Press 2020).

⁷⁶ Art 33 TRIPS.

⁷⁷ M. Polanyi, *The Tacit Dimension* (Chicago University Press 1966) at 4.

⁷⁸ Art 39 TRIPS.

⁷⁹ S. Scotchmar, *Innovation and Incentives* (MIT Press 2004).

As we outline below, inadequate patent disclosures, combined with trade secrets and tacit know-how, can obscure the theoretically assumed balance between IP restrictions and the public interest. For a TRIPS waiver to be effective for COVID-19 vaccines, it would need to comprise not only a patent waiver, but also enable trade secrets to be shared.

Patents

Patent law requires the disclosure of information about the invention in the patent application, with the aim of making this info publicly available. The pandemic has exposed three key deficiencies regarding the precise level of disclosure. The first is that in practice, and doctrinally, what is accepted as disclosure is often insufficient, such that it does not match the requirement of disclosure as a justificatory *quid pro quo* for the grant of a patent. The second is the fact that there is a lag in publication of patent applications, either individually, or within patent families. The third is demonstrated by the strategic possibilities created by overlapping patent rights.

On the first, patents require inventors to disclose information about their inventions, though arguably not in significant scientific or technical detail.⁸⁰ The patent system sets up a race – for the first to file an application – meaning that disclosure often occurs early in the process.⁸¹ In practice, the disclosure requirement underperforms, and speculative filing of merely plausible information is common.⁸² Details regarding manufacturing processes are usually not revealed in a patent application, or can be fragmented via multiple applications. Indeed, vaccines can involve many different patented inventions operating together; but patent disclosure does not require a description of how technologies operate together to “work” as a vaccine. Neither does patent law mandate further disclosures post-grant, when underlying technologies may

⁸⁰ H.S. Frost, “The Unique Problem of Inventions Which Are Fully Enabled and Fully Described, But Not Fully Understood (Merrell Dow’s Terfenadine Revisited)” (2007) 20 *Intellectual Property Journal* 369.

⁸¹ S.B. Seymore, “The Teaching Function of Patents” (2010) 85 *Notre Dame Law Review* 621.

⁸² J.C. Fromer, “Patent Disclosure” (2009) 94 *Iowa Law Review* 539.

become better understood.⁸³ Additionally, information generated to fulfil regulatory requirements (discussed below) is not currently linked to patent disclosure.⁸⁴

Second, IP offices are only obliged to publish patent applications within 18 months of filing - during this period the information is not public. In practice, inaccessibility of useful information can persist for longer than 18 months, as follow-on patents can be filed at a later date.⁸⁵ Consequently, more than two years since the beginning of the pandemic it remains unclear how many patents actually exist in the COVID-19 vaccine field.⁸⁶

This leads to the third deficiency: overlapping rights, which make it hard to decipher the IP landscape.⁸⁷ Multiple patent applications with minor modifications from an original application are collated into patent families, with dozens, even hundreds, of patents existing over the same product. This can result in a *de facto* extension of patent protection beyond 20 years.⁸⁸ Companies can amass vast numbers of patents to increase the duration and scope of their monopolies.⁸⁹ As a result, there are already patent thickets in the mRNA vaccine field.⁹⁰ This hinders the swift sharing of scientific and technical information.⁹¹

These three (related) deficiencies make it difficult to disentangle the patent thickets and to reproduce technologies by relying on information contained solely in the patent disclosure. This implies that a limited waiver of patent rights would not be sufficient to make available all the knowledge needed to increase manufacturing capacity for COVID-19 vaccines. A broad IP waiver is required.

⁸³ J.C. Fromer, *Dynamic Patent Disclosure* (2015) 69 *Vanderbilt Law Review* 1715.

⁸⁴ W.N. Price and A. Rai, "Are Trade Secrets Delaying Biosimilars?" (2015) 348 *Science* 188.

⁸⁵ USP Application 2021003085.

⁸⁶ For the most detailed database of known COVID-19 vaccine patents see <https://medicinespatentpool.org/what-we-do/vaxpal/>

⁸⁷ S. Thambisetty, "Patents as Credence Goods" (2007) 27 *O.J.L.S.* 707.

⁸⁸ O. Gurgula, "Strategic accumulation of patents in the pharmaceutical industry and patent thickets in complex technologies – two different concepts sharing similar features" (2017) 48 *I.I.C.* 385.

⁸⁹ EU Commission, *Antitrust: shortcomings in pharmaceutical sector require further action* (8 July 2009) IP/09/1098.

⁹⁰ C. Martin and D. Lowery, "mRNA vaccines: Intellectual Property Landscape" (2020) 19 *Nature Reviews Drug Discovery* 578.

⁹¹ M. Gaviria and B. Kilic, "BioNTech and Pfizer's BNT162 Vaccine Patent Landscape" *Public Citizen* (16 Nov 2020) available at https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/#_ftnref3 (last accessed 14 February 2022).

Undisclosed Information: Trade Secrets, Non-disclosure Agreements, Data Exclusivity and Regulatory Exclusivity

We define undisclosed information broadly here to include not only trade secrets, but also information about the invention, such as data gathered during the regulatory approval process.⁹² Trade secrets are, by their nature, not divulged publicly. In normal business practice, holders of IP related to vaccines are not obliged to reveal trade secrets and know-how.⁹³ Moreover, there are NDAs in place, for instance, between Pfizer, BioNTech and their suppliers.⁹⁴

Undisclosed information may also include information that can be protected separately from the IP framework within TRIPS via “data exclusivity” rights that protect clinical trial data from certain uses. In the US, complex biologics can have 12 years of data exclusivity, and in the EU protection can apply for up to 10 years.⁹⁵ In the vaccine context, such exclusivities mean there is no easy regulatory pathway for generic versions of, for example, a viral vector vaccine such as the Oxford-AZ one (a complex biologic). Even if technical know-how were shared and patents waived, a new generic manufacturer could struggle to bring a product swiftly to the market unless regulatory data were also shared, because clinical trials would need to be conducted from scratch. Nevertheless, expedited or truncated regulatory pathways are possible.⁹⁶

How the TRIPS Waiver Can Address Both Patents and Undisclosed Information

The specific challenges regarding patents (disclosure, transparency, overlapping rights) and undisclosed information (trade secrets and know-how, NDAs, data

⁹² M. Risch, “Why Do We Have Trade Secrets?” (2007) 11 *Intellectual Property Law Review* 1.

⁹³ P.K. Yu, “A Critical Appraisal of the COVID-19 TRIPS Waiver” (2021) 21-32 *Texas A&M University School of Law Legal Studies Research Paper* 1.

⁹⁴ See “Supply Agreement Pfizer and BioNTech with TriLink Biotechnologies” (9 October 2020) available at <https://contracts.justia.com/companies/maravai-lifesciences-holdings-inc-11469/contract/137780/> (last accessed 14 February 2022).

⁹⁵ Medicines Law and Policy, *Data Exclusivity in the EU: A Briefing Document* (June 2019) available at <https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf> (last accessed 14 February 2022).

⁹⁶ Indian Ministry of Health and Family Welfare Press Release, 13 April 2021 GOI - <https://pib.gov.in/PressReleasePage.aspx?PRID=1711381> (last accessed 14 February 2022)

exclusivity, marketing exclusivity) demonstrate the complexity of the current pharmaceutical model for vaccines. However, this should not be read as supporting the case against the proposed TRIPS waiver. Conversely, these issues strengthen the case for a comprehensive IP waiver, because in the absence of sufficient voluntary sharing and licensing by industry to meet pandemic needs, a simple patent waiver on its own would not be enough to increase global south vaccine production in an expedient manner.

The TRIPS waiver as proposed by India/South Africa would be a temporary waiver of *all* relevant IP, including, but not limited to, patents. On patents, given the problems of disclosure, transparency and overlapping rights, the benefit of a universal waiver of patents on COVID-19 health technologies is that it would allow manufacturers freedom to operate without the risk of litigation or the fear that exported vaccines or other technologies could be seized in transit and impounded for alleged infringement.⁹⁷

On trade secrets we disagree with some arguments brought forward by waiver sceptics in this context. Hilty et al. argue that it is “highly unlikely that the waiver of trade secret protection could be effectively implemented and enforced to propel companies to disclose all relevant know-how”.⁹⁸ Given the absence of adequate industry co-operation on voluntary sharing of trade secrets, this overly pessimistic and unconstructive view equates to justifying a status quo that is failing LMICs. The circumstances under which entities may be forced to disclose commercially sensitive or tacit technical knowledge may be limited; but they are certainly not without precedent. In fact, governments can utilise the waiver - and, if necessary, bring into domestic law accompanying measures - to incentivise and/or mandate the sharing of undisclosed information. Therefore, we argue for use of the TRIPS waiver as part of a “carrot and stick” approach.

⁹⁷ “Brazil, India denounce Dutch generic drug seizure” *Reuters* (30 Jan 2009) available at <https://www.reuters.com/article/us-davos-generic/brazil-india-denounce-dutch-generic-drug-seizure-idUSTRE50T27Q20090130> (last accessed 14 February 2022).

⁹⁸ R.M. Hilty, P.H.D. Batista, S. Carls, D. Kim, M. Lamping and P.R. Slowinski, “Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021” (7 May 2021) available at https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_07_Position_statement_Covid_IP_waiver.pdf (last accessed 14 February 2022).

Here, the question of whether and when to use incentives (carrots) for voluntary disclosures, or mandates (sticks) for the release of previously undisclosed information, is pertinent. A combination of incentives and mandates to achieve technology transfer is precisely what happened in the 1940s when, in a wartime situation and with no time to lose, the US Office of Scientific Research and Development oversaw the pooling of technology which resulted in a massive and rapid scale-up of penicillin production.⁹⁹ In 2020 the US used the Defense Production Act (DPA), invoking national security concerns, to scale up domestic vaccine production (Operation WarpSpeed).¹⁰⁰

In relation to incentives (carrots), Love offers a way to “unlock” know-how relevant to manufacturing: it could be bought out by governments.¹⁰¹ An example of a potential mandate (stick) is shown with the passing by the Brazilian Senate of a compulsory COVID-19 patent and know-how licensing bill in September 2021 aimed at obliging companies to share their trade secrets and data.¹⁰² Bernd Lange, a German MEP, proposes a way of mandating this via the contract-tender process, arguing that the EU Commission should “include a clause on technology transfer in future contracts ... so that companies actively transfer knowledge, also to developing countries”.¹⁰³

In terms of the specific know-how to be shared, it is relevant that regulatory requirements sometimes force originators and manufacturers to codify and submit some relevant tacit knowledge to government agencies. Morten argues that during a pandemic the public interest justifies the governmental release of such vaccine-related trade secrets.¹⁰⁴ We also observe that codification of know-how is common via

⁹⁹ R. Bud, *Penicillin: Triumph and Tragedy* (Oxford University Press 2007) 45.

¹⁰⁰ See <https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/> (last accessed 14 February 2022).

¹⁰¹ J. Love, “Buying out know-how to scale vaccine manufacturing” *Medium* (20 March 2021) available at <https://jamie-love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36> (last accessed 14 February 2022).

¹⁰² R. Castro de Figueiredo, ‘Brazilian President’s Assent to the bill on the Compulsory Licensing of Covid-19 Vaccines’ Patents’ *Kluwer Patent Blog* (14 September 2021) - <http://patentblog.kluweriplaw.com/2021/09/14/brazilian-presidents-assent-to-the-bill-on-the-compulsory-licensing-of-covid-19-vaccines-patents/> (last accessed 14 February 2022)

¹⁰³ See Official Letter sent to the EU Commission by Lange, available at <https://twitter.com/berndlange/status/1394902774832373760> (last accessed 14 February 2022).

¹⁰⁴ See C.J. Morten, “Publicizing Corporate Secrets for Public Good” (working paper on file with authors, forthcoming 2022). Art 39.3 of TRIPS allows for disclosure “where necessary to protect the public” but in some jurisdictions domestic legislation can pose significant challenges and may need amending.

technology transfer contracts between parties. The fragility of trade secrets means that they can, and do, leak, as occurred in 2021 when a US NGO released part of the Pfizer-BioNTech mRNA vaccine “recipe” found in a publicly available contract.¹⁰⁵ The TRIPS waiver would allow countries to make use of any shared, released or leaked trade secrets related to, for instance, the mRNA production process.¹⁰⁶ In terms of clinical data (where data and marketing exclusivities apply) there have already been calls for a waiver of these exclusivities in order to meet public health needs.¹⁰⁷ The introduction of a waiver on such data exclusivities (to support the TRIPS waiver) in regions/countries where this is relevant could be efficacious.

On implementation, it is worth emphasising that the legal effect of a TRIPS waiver would be to limit IP rights internationally, while national rights would remain within each country’s sovereignty. HICs could change their laws to allow know-how and data sharing globally, but the waiver would primarily be utilised and implemented by LMICs. It is therefore unlikely that the waiver would require wholesale changes to US, UK or European patent law. Instead, amendments to domestic legislation could be directed towards facilitating the sharing of governmental knowledge and regulatory data between the relevant authorities in one country (for example, the US) and those of another (for example, South Africa) to facilitate distributed production.¹⁰⁸ Such measures would not be entirely novel and would certainly not be inappropriate in a pandemic situation. Arguably, the US already has domestic authority under the Defense Protection Act to share knowledge regarding, for example, the NIH-Moderna vaccine, with bodies like the WHO-backed mRNA hub in South Africa.¹⁰⁹ Therefore, while clearing international legal barriers, the TRIPS waiver would also provide international legal and diplomatic cover for HICs, such as the US, to share as much knowledge as possible with global south regulators and producers. Greater sharing

¹⁰⁵ See <https://www.citizen.org/article/a-piece-of-the-covid-vaccine-recipe/> (last accessed 14 February 2022).

¹⁰⁶ A. Durking, P.A. Sta Maria, B. Willmore and A. Kapczynski, “Addressing the Risks that Trade Secrets Protections Pose for Health and Rights” (2021) 23 *Health and Human Rights Journal* 129.

¹⁰⁷ E. ’t Hoen, P. Boulet, B. Baker, “Data exclusivity exceptions and compulsory licensing to promote generic medicines in the EU” (2017) 10 *Journal of Pharmaceutical Policy and Practice* 19.

¹⁰⁸ R. Li et al., “Timely access to trial data in the context of a pandemic: the time is now” (2020) 10 *BMJ Open* e039326.

¹⁰⁹ A. Kapczynski and J. Ravinthiran, “How to Vaccinate the World, Part 2” *LPE Project Blog* (5 April 2022) – available at <https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/> (last accessed 14 February 2022).

would enable potential manufacturers to connect public IP knowledge (patents) with regulatory knowledge (codified know-how and data).¹¹⁰

V. Is Boosting Vaccine Production in the Global South Feasible?

Despite production shortfalls and inequitable distribution, COVID-19 vaccine producers have refused offers to collaborate to increase production in the global south, claiming that LMICs lack capacity.¹¹¹ We argue here that boosting LMIC capacity is feasible, and rather than competence failings it is transnational IP rights that tend to impede new manufacturers from entering and competing in the market.¹¹² The TRIPS waiver can thus be utilised to facilitate LMIC production of vaccines.¹¹³

Building Production Capacity

A common claim against the TRIPS waiver is that it will not alleviate the vaccine shortage because it will take a long time to build local manufacturing capacity in LMICs; and in the meantime existing HIC/LMIC facilities may be at, or near, capacity.¹¹⁴ The claim that there is no spare HIC/LMIC production capacity has largely been debunked. During 2021 companies in both HICs and LMICs – Canada (Biolyse), Israel (Teva), Denmark (Bavarian Nordic) and Bangladesh (Incepta) – offered manufacturing capacity and were rebuffed and/or were unable to obtain a licence.¹¹⁵ In October 2021 the New York Times identified ten production sites in LMICs - in Argentina, Brazil, India, Indonesia, and South Africa – that could begin manufacturing

¹¹⁰ P. Krishtel and F. Hassan, “Editorial: Share Vaccine Know-How” (2022) 374 *Science* 379.

¹¹¹ A. Furlong, “Big vaccine makers reject offers to help produce more jabs” *Politico* (14 May 2021) available at <https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/> (last accessed 14 February 2022).

¹¹² S. Chandrasekharan et al, “Intellectual property rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: Patent landscaping and perspectives of developing country vaccine manufacturers” (2015) 33 *Vaccine* 6366.

¹¹³ T. Amin, “The Folly of Hoarding Knowledge in the COVID-19 Age: Let Vaccine Producers in Poor Countries Help End the Pandemic” *Foreign Affairs* (29 Jan 2021) available at <https://www.foreignaffairs.com/articles/world/2021-01-29/folly-hoarding-knowledge-covid-19-age> (last accessed 14 February 2022).

¹¹⁴ International Federation of Pharmaceutical Manufacturers and Associations, “Towards Vaccinating the World – Landscape of Current Covid-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible “Solution Space” – A Discussion Document” (9 March 2021) available at https://www.ifpma.org/wp-content/uploads/2021/03/Summit_Landscape_Discussion_Document.pdf (last accessed 14 February 2022);

¹¹⁵ Furlong, “Big vaccine makers”.

mRNA vaccines within a matter of months;¹¹⁶ and a subsequent expert study identified more than one hundred potential mRNA vaccine manufacturers across Africa, Asia and Latin America.¹¹⁷ These findings go against what many industry sources, and even some IP commentators, have argued: that all suitable manufacturing facilities are already being utilised; or that there is little or no manufacturing capacity and expertise outside HICs. Assertions that it would take “four years” to build capacity in a country like Bangladesh lack credibility (see the Incepta example above).¹¹⁸

Building new capacity quickly is achievable. Moderna did not own a vaccine manufacturing facility at the beginning of 2020, but within less than a year it became a leading manufacturer of COVID-19 vaccines. Suhaib Siddiqi, former director of chemistry at Moderna, states that with the blueprint and technical advice a modern factory should be able to produce mRNA vaccines in three to four months.¹¹⁹ There is little doubt that more companies in the global south could be producing COVID-19 vaccines today if technology had been shared.¹²⁰

On this, it is clear that voluntary pledges to not enforce IP rights, though welcome, do not go far enough. For example, although Moderna announced in 2020 that it would not enforce its COVID-19 vaccine patents during the pandemic, this promise came with significant constraints: it could be withdrawn at any time; and it did not encompass trade secrets, know-how or technology transfer. Additionally, Moderna admitted that without relevant know-how and technology transfer, others seeking to manufacture a mRNA vaccine face significant hurdles, for example, in scaling up manufacturing.¹²¹

¹¹⁶ S. Nolen, “Here’s Why Developing Countries Can Make the Top Covid Vaccines” *New York Times* (22 October 2021).

¹¹⁷ A. Prabhala and A. Alsahlani, “Pharmaceutical manufacturers across Asia, Africa and Latin America with the technical requirements and quality standards to manufacture mRNA vaccines” (10 December 2021) available at <https://accessibsa.org/mrna/> (last accessed 5 February 2022).

¹¹⁸ See comment of Professor Sir Robin Jacob in H. Kuchler, “Will a Suspension of Covid Vaccine Patents Lead to More Jobs?” *Financial Times* (6 May 2021) available at <https://www.ft.com/content/b0f42409-6fdf-43eb-96c7-d166e090ab99> (last accessed 14 February 2022).

¹¹⁹ M. Cheng and L. Hinnant, “Countries urge drug companies to share vaccine know-how” *AP News* (1 March 2021) <https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92afbc3ea9ed519be007f8887bcf6> (last accessed 20 October 2021).

¹²⁰ A. Furlong, “Copying Moderna’s jab: The project to democratize vaccine production” *Politico* (2 February 2022) available at <https://www.politico.eu/article/who-copy-moderna-jab-project-democratize-vaccine-production/> (accessed 4 February 2022).

¹²¹ “Moderna sees no impact on COVID-19 vaccine from potential patent waiver” *Reuters* (6 May 2021) available at

This calls into question the rationale behind Moderna's promise or indeed their good faith in making it.

Nonetheless, despite Moderna's refusal to co-operate with global south manufacturers, in February 2022 Afrigen Biologic and Vaccines, a company based in South Africa that forms part of the WHO mRNA hub, announced it was at the end stages of developing a mRNA vaccine comparable to the NIH-Moderna vaccine.¹²² Moderna's public statement that it would not enforce its patents, coupled with the wider availability of public information on the NIH-Moderna vaccine compared with other candidates, led Afrigen to choose to replicate this specific vaccine. Scientists from around the world offered assistance to Afrigen in this effort, though it is unclear as yet whether anyone disclosed information to Afrigen that would be considered a trade secret.¹²³

That Afrigen had to reverse-engineer the vaccine without Moderna's know-how, data or technology transfer unquestionably delayed the development process by many months. Furthermore, without shared regulatory data from Moderna (or as argued above, from US government agencies), it may take up to 12-18 months longer for Afrigen to "roll out" the vaccine than if such data were shared.¹²⁴ It also remains to be seen whether Moderna will keep its commitment not to enforce the patents it has filed in South Africa, as well as whether other relevant rightsholders will issue legal challenges.¹²⁵

Nonetheless, Afrigen's achievement proves that companies in the global south can replicate mRNA vaccines. Therefore, despite the claims of IP rightholders, it is untrue that the relative lack of comprehensive licensing deals and technology transfer agreements between mRNA companies and LMIC producers is because LMICs lack capacity. Rather than agreeing licensing deals with LMICs that would be mutually beneficial in the immediate term and would help resolve vaccine inequity, Moderna

<https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-raises-2021-sales-forecast-covid-19-vaccine-192-bl-2021-05-06/> (last accessed 14 February 2022).

¹²² A. Maxmen, "South African scientists copy Moderna's COVID vaccine" (2022) 602 *Nature* 372.

¹²³ *Ibid.*

¹²⁴ "Approval of COVID vaccine made in South Africa could take 3 years, WHO says" *Reuters* (5 February 2022) available at <https://www.reuters.com/world/africa/approval-covid-vaccine-made-south-africa-could-take-3-years-who-says-2022-02-04/> (last accessed 14 February 2022)

¹²⁵ M. Davies, "Covid-19: WHO efforts to bring vaccine manufacturing to Africa are undermined by the drug industry, documents show" (2022) 376 *BMJ* o304.

and Pfizer-BioNTech appear to be prioritising maintaining protectionist control over mRNA, viewing it as a lucrative technological platform that may offer future revenue streams.¹²⁶ In the face of this protectionism, the TRIPS waiver would provide a counterweight, encouraging global south production efforts such as Afrigen's by providing legal certainty, both on the use of patents and trade secrets in development processes, and on the eventual transfer of doses and know-how to other global south countries.

Vaccine Quality and Safety

It has also been claimed that it is risky for vaccines to be produced in countries where IP rights are "weak" on the basis that the resulting vaccines may not be genuine or safe.¹²⁷ Yet, decades of examples prove vaccines and complex medicines can be produced safely in the global south.¹²⁸ Tamiflu was produced safely in 2005, despite claims that it involved such a complex process that could not be easily replicated.¹²⁹ Similarly, Indian company Shantha Biotechnics produced a reliable and safe recombinant hepatitis B vaccine in 2009.¹³⁰ In 2020, Hetero and Cipla produced Remdesivir in India after similar claims about safety fears.¹³¹ Crucially, the WHO is of the view that the production of COVID-19 vaccines in the global south can be done in a safe and efficient fashion.¹³²

Raw Materials

There has been a related claim that the global shortage of raw materials worldwide is more to blame than IP rights for the lack of COVID-19 vaccine supply.¹³³ In fact, IP

¹²⁶ U. Sahin, K. Karikó and Ö. Türeci, "mRNA Based Therapeutics – developing a new class of drugs" (2014) 13 *Nature Reviews Drug Discovery* 759.

¹²⁷ S. Gottlieb, "Covid Lessons from Bush's Effort Against AIDS" *Wall Street Journal* (28 March 2021).

¹²⁸ R.G. Douglas and V.B. Samant, "The Vaccine Industry" (2018) 41 *Plotkin's Vaccines* 41, e1.

¹²⁹ Amin, "The Folly of Hoarding Knowledge".

¹³⁰ J. Chakma, H. Masum, K. Perampaladas, J. Heys and P.A. Singer, "Indian vaccine innovation: the case of Shantha Biotechnics" (2011) 7 *Globalization and Health* 9.

¹³¹ "Remdesivir: Five Indian and Pakistani firms to make drug to "fight coronavirus" *BBC News* (14 May 2020) available at

<https://www.bbc.co.uk/news/world-asia-india-52659052> (last accessed 14 February 2022).

¹³² Aizenman, "Moderna won't share its vaccine recipe".

¹³³ A. Bourla, "Today I Sent this Letter to Have a Candid Conversation with our Colleagues about the Drivers of COVID-19 Access and Availability" Open Letter, published on LinkedIn (7 May 2021) available at

barriers are a factor in shortages of raw materials and consumables, preventing workarounds. For example, plastic single-use bioreactor bags have been scarce due to the global dependency on a few suppliers for these materials; indeed, there are currently more than 2,000 patents covering them, making entering the market as a new supplier onerous.¹³⁴ The TRIPS waiver would apply not just to vaccine end products but also, potentially, to mechanical equipment and components. Moreover, international negotiations over the waiver can help with co-ordinating the global supply of ingredients.

Profit and Price

On price, the status quo IP legal order upholds a system whereby LMICs, such as South Africa, Bangladesh and Uganda have reportedly been charged a higher price than HICs for vaccines;¹³⁵ and whereby Pfizer-BioNTech can, at will, increase the vaccine price to enhance profitability. Despite significant public subsidies, and effective de-risking of COVID-19 vaccines through advance market orders, governments have not taken an ownership interest in the IP, or demanded, for example, a royalty in the profits that these subsidies yield.¹³⁶

Yet, where there are price inequities it is not enough to focus solely on contracts, as if IP is not a core issue. Hilty et al. state: “In the abstract, there was certainly a risk of excessive prices when the vaccines were still under development. Such risk should have been addressed by governments in the framework of the contracts subsidising research on vaccines ...”¹³⁷ Their argument is offered from the basis of hindsight, with a lack of critical analysis. Inequalities of pricing and distribution are matters of grave

<https://t.co/kkk2NbtKAO?amp=1> (last accessed 14 February 2022)

¹³⁴ M. Stoller and D. Barclay, “Why are there Shortages of Plastic Bags needed for Vaccine Production? Monopolies and Patents” *Substack* (11 May 2021) available at <https://mattstoller.substack.com/p/why-are-there-shortages-of-plastic> (last accessed 14 February 2022).

¹³⁵ C. Paun and A. Furlong, “Poorer countries hit with higher price tag for Oxford/AstraZeneca vaccine” *Politico* (22 February 2021) available at <https://www.politico.eu/article/astrazeneca-vaccine-cost-higher-in-poorer-countries-coronavirus/> (last accessed 14 February 2022).

¹³⁶ P. Patnaik and H.Y. Kang, “The ‘Patent Bargain’, Public Good & COVID19” *Healthpolicy Watch News* (26 April 2021) available at <https://healthpolicy-watch.news/the-patent-bargain-public-good-covid-19/> (last accessed 14 February 2022).

¹³⁷ Hilty et al., “Covid-19” at 3.

concern that must not be explained away as if they do not relate to IP law. To portray the question of LMIC vaccine affordability as a matter of private contractual choices is to selectively ignore how IP facilitates asymmetry.¹³⁸ Hilty et al. fail to put forward an adequate solution for present (and future) pandemic situations in LMICs.

From both pragmatic and ethical perspectives, legal scholarship must suggest a way forward rather than defending *lex lata* that which has shown its fatal limitations. As access to medicines campaigners and patent scholars have pointed out in many different ways, IP is the fundamental structure that underlies and enables such inequities, because it gives IP holders exclusive control. We cannot divorce the layering of IP rights and exclusivity protections around regulatory data from pricing and profiteering; we cannot distinguish a culture of trade secrecy from absent transparency; we cannot rely on the free market to provide equitable distribution of vaccines globally any more than we relied on the free market to fund the necessary R&D, or bear the whole risk of developing such vaccines in the first place.

The TRIPS Waiver in the Political-Economic Sphere

Rather than merely critiquing the TRIPS waiver proposal in legal formalistic terms, we must locate it within its broader economic and political context: the costs of the status quo are borne disproportionately by the world's poor.¹³⁹ Until the waiver proposal there was no legal incentive or mandate for key players to see this crisis as an opportunity to articulate a more equitable and ethical mode of practice of global solidarity.

The WHO's Independent Panel for Pandemic Preparedness and Response made a recommendation in May 2021 envisaging precisely this: utilising the waiver as policy leverage by legal threat.¹⁴⁰ Although waiver negotiations continue, the proposal has already had several positive impacts in this respect, leading to increased transparency

¹³⁸ O. Dyer, "Covid-19: Countries are learning what others paid for vaccines" (2021) 372 *BMJ* n281.

¹³⁹ Economist Intelligence Unit, "How much will vaccine inequity cost?" (2021) available at <https://www.eiu.com/n/campaigns/how-much-will-vaccine-inequity-cost/> (last accessed 14 February 2022).

¹⁴⁰ The Independent Panel, *COVID-19: Make it the Last Pandemic* (May 2021) at 14 https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

about vaccine manufacturing and pricing.¹⁴¹ The waiver proposal has also been utilised as a lever to encourage industry co-operation in voluntary deals;¹⁴² and/or as a demand to mandate knowledge sharing and participation in global measures, such as the WHO-led mRNA hub in South Africa, within which Afrigen is a key player.¹⁴³ In light of growing and widespread pressure arising from the waiver, it is not surprising that some companies, such as Merck, prefer a controlled, voluntary transfer of information, via the Medicines Patent Pool, to enable COVID-19 treatments to be produced widely.¹⁴⁴ Pfizer has also agreed a Medicines Pool licence for its COVID-19 treatment Paxloid, allowing generic manufacturing in some global south countries (though, as noted above, Pfizer refuses to allow the same for mRNA vaccines).¹⁴⁵

VI. Do existing “flexibilities” under Article 31 and Article 73 of TRIPS Provide a Viable Alternative to the TRIPS Waiver?

Apart from its political weight, we argue the TRIPS waiver offers substantial practical and legal benefits over the (current) burdensome set of “TRIPS flexibilities”, in particular those found in Article 31 and Article 73 of TRIPS. With regard to compulsory licensing under Article 31, in situations of “a national emergency or other circumstances of extreme urgency or for public non-commercial use”, TRIPS allows for the forgoing of the requirement that there should first be an attempt to negotiate a voluntary licence with the IP rights holder before a compulsory licence (CL) is issued. The COVID-19 context would likely be viewed as one such emergency. Yet, the fragmented and complex existing COVID-19 IP landscape means the existing system of compulsory licensing under TRIPS is not well suited to addressing vaccine inequity.

¹⁴¹ Erfani, Gostin and Kerry, “Beyond a symbolic gesture”.

¹⁴² See BioNTech-Biovac agreement of July 2021 - “South African firm to help make Pfizer/BioNTech COVID vaccine” Reuters (21 July 2021) available at <https://www.reuters.com/business/healthcare-pharmaceuticals/pfizerbiontech-strike-south-africa-covid-19-manufacturing-deal-with-biovac-2021-07-21/> (last accessed 20 October 2021).

¹⁴³ Krishtel and Hassan, “Editorial: Share Vaccine Know-how”.

¹⁴⁴ See <https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countri/> (last accessed 14 February 2022).

¹⁴⁵ See <https://medicinespatentpool.org/news-publications-post/pfizer-and-the-medicines-patent-pool-mpp-sign-licensing-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-expand-access-in-low-and-middle-income-countries> (last accessed 14 February 2022).

Compulsory licensing features six significant drawbacks.¹⁴⁶ The first is that a CL can only be applied for on a product-by-product, and country-by-country basis. A blanket CL in all states for e.g. COVID-19 vaccines is not possible under TRIPS. Second, the WTO system sets down minimum criteria for a CL under Art. 31 (TRIPS), but nation states can impose additional requirements for a CL, meaning the procedures at the national level can often be time consuming. Third, some states have traditionally been reluctant to invoke the process for issuing a CL due to fears of diplomatic controversy, a WTO challenge from a more powerful country, or of trade threats, including the possibility of sanctions being imposed on them.¹⁴⁷

Fourth, there are additional obstacles to the use of a CL for vaccines, including regulatory obstacles.¹⁴⁸ As noted earlier, in regions where there are data and marketing exclusivities, generic producers cannot use such data to obtain regulatory approval for a generic product during a certain period; accordingly, obtaining generic approval may not be possible in a timely manner. A CL offers no further level to encourage data-sharing. Fifth, when a CL is issued, the rights holder must be provided with “adequate” remuneration, and asymmetrical conflicts can arise over this.¹⁴⁹

Sixth, Art. 31(f) of TRIPS states that products made under a CL must be used “predominantly for supply of the domestic market”. Under Art. 31 *bis*, in theory a CL for export and import is now possible.¹⁵⁰ Yet, there are obstacles to using Art. 31 *bis*, including the fact that some countries/regions (e.g. the EU) have opted out of Art. 31. *bis* as importing members.¹⁵¹ Conditions for using Art. 31 *bis* are onerous. To date this provision has only ever been used effectively once, when Rwanda obtained access to generic HIV TriAvir by importing this from the Canadian company Apotex.¹⁵² Even in

¹⁴⁶ A. McMahon, “Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance” (2021) 47 *Journal of Medical Ethics* 142.

¹⁴⁷ E. 't Hoen et al., “Medicine procurement and the use of flexibilities in the agreement on Trade-Related aspects of intellectual property rights, 2001–2016” (2018) 96 *Bull World Health Organ* 85.

¹⁴⁸ 't Hoen, Boulet, and Baker, “Data exclusivity exceptions”.

¹⁴⁹ H. Wong, “The case for compulsory licensing during COVID-19” (2020) 10 *Journal of Global Health*.

¹⁵⁰ Amendment of the TRIPS Agreement. WTO Doc. WT/L/641 (Dec. 8, 2005) (hereafter Article 31 *bis*).

¹⁵¹ WTO, “Annex and Appendix to the TRIPS Agreement (note 3)” available at https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm (last accessed 14 February 2022)

¹⁵² H. Hestermeyer, “Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines” *ASIL Insights* (10 December 2007).

that context, Rwanda did not obtain its first shipment of medicines until 15 months after notification.¹⁵³ More recently, in May 2021, Bolivia made a declaration to the WTO that it was seeking supply of the J&J vaccine from the Canadian company Biolyse via a CL under Art. 31 *bis*.¹⁵⁴ Bolivia's filing demonstrates that it is difficult to determine which patents and patent applications are relevant for a CL process; and the ongoing delays in the processing of the Bolivia/Biolyse application indicate, once again, the limits of Art. 31 *bis* when applied in a rapidly evolving and heavily patented technological field.¹⁵⁵

Crucially, we must also avoid the error of viewing the TRIPS waiver and compulsory licensing as an either/or situation. There can be reciprocity between the two approaches. COVID-19 has already resulted in some countries modifying compulsory licensing laws to make it easier for CLs to be used at the national level.¹⁵⁶ Recent US support for a TRIPS waiver was accompanied by the use of permissive language on CLs (in the relevant US Trade Representative report).¹⁵⁷ Unlike in the past, today there may be greater state willingness for CLs to be used to address at least some issues of the COVID-19 pandemic, in part because the TRIPS waiver has shifted the political balance in favour of their use. On this, CLs may be particularly useful in the context of therapeutics, diagnostics and medical equipment – as these are typically easier to reverse-engineer than vaccines. Hence, there is no reason not to pursue, in tandem, CLs (where specific state needs can be addressed) and the TRIPS waiver (to achieve universal benefits).¹⁵⁸ Nonetheless, a TRIPS waiver offers clear advantages that the mere use of CLs under TRIPS simply cannot achieve.

¹⁵³ B. Anderson, "Better Access to Medicines: Why Countries are getting "Tripped" up and Not Ratifying Article 31 Bis" (2010) *Case Western Reserve Journal of Law, Technology and the Internet* 165.

¹⁵⁴ WTO, "Bolivia outlines vaccine import needs in use of WTO flexibilities to tackle pandemic" (12 May 2021) available at https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm (last accessed 14 February 2022).

¹⁵⁵ B. Blanco. "With one simple decision, the Canadian government can save lives" *Aljazeera* (28 September 2021) available at <https://www.aljazeera.com/opinions/2021/9/28/the-canadian-government-can-save-bolivian-lives> (last accessed 20 October 2021).

¹⁵⁶ A. McMahon, "Patents, access to health and COVID-19 – The role of compulsory and government-use licensing in Ireland" (2020) 71 *N.I.L.Q.* 331.

¹⁵⁷ Office of the US Trade Representative (USTR), *2021 Special 301 Report* (2021) at 34 available at [https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20\(final\).pdf](https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf) (last accessed 14 February 2022).

¹⁵⁸ J.L. Contreras, "US Support for a WTO Waiver of COVID-19 Intellectual Property – What Does it Mean?" *Petrie Blog* (7 May 2021) available at <https://blog.petrieflom.law.harvard.edu/2021/05/07/wto-waiver-intellectual-property-covid/> (last accessed 20 October 2021).

Finally, Article 73 of TRIPS provides WTO member states with legal cover to suspend application of normal TRIPS obligations in times of national emergency. While useful, Art. 73 is of more limited scope than the TRIPS waiver: Art. 73 provides for unilateral action by a WTO member that is nonetheless justiciable (i.e. open to legal challenge under the WTO Dispute Settlement Understanding); whereas the waiver is different in that its adoption would clarify its legitimate availability to the WTO membership as a whole. If adopted in its current form, the waiver would automatically give immunity to countries opting for national implementation.¹⁵⁹

VII. The TRIPS Waiver and Innovation Incentives – will the Waiver “kill innovation”?

Critics of the TRIPS waiver claim it would damage incentives for pharmaceutical innovation;¹⁶⁰ or even that a TRIPS waiver would sound the death knell of the industry.¹⁶¹ Such claims are contestable and must be analysed rigorously in the context of the global innovation ecosystem.¹⁶²

Analysing the terms “Innovation” and “Incentive”

A plurality of meanings are associated with “innovation” - an incoherence that can be traced to the contested justificatory narratives of IP, and of patents in particular.¹⁶³ Even so, innovation is often stated as the aim of IP.¹⁶⁴ In the 1960s J.A. Allen identified six parts that form an innovation: practical idea; development; investment;

¹⁵⁹ F. Abbott, “The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic” *South Centre Research Paper* 116 (August 2020).

¹⁶⁰ Hilty et al., “Covid-19”. See also B. Mercurio, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review” (2021) 62 *Virginia Journal of International Law Online* 9.

¹⁶¹ R. Gupta and R. Ramachandran, “A Covid-19 Vaccine IP Waiver won’t kill Pharma innovation” *Bloomberg* (24 September 2021) - <https://news.bloomberglaw.com/ip-law/a-covid-19-vaccine-ip-waiver-wont-kill-pharma-innovation>

¹⁶² P. Drahos and J. Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Routledge 2002) at 196-97.

¹⁶³ F. Machlup & E. Penrose, “The Patent Controversy in the Nineteenth Century” (1950) 10 *The Journal of Economic History* 1.

¹⁶⁴ J.A. Schumpeter, *Business Cycles: A Theoretical, Historical and Statistical Analysis of the Capitalist Process* (McGraw – Hill Book Company Inc 1939); J Jewkes, *The Sources of Invention* (MacMillan & Co. Ltd 1958); J.A. Allen, *Scientific Innovation and Industrial Policy* (Elsevier 1967).

construction; production; and distribution. In this view, invention can be construed as merely the first stage of the complex process of innovation.¹⁶⁵

In the IP context, the term “incentive” is loaded with assumptions.¹⁶⁶ The idea that patents create positive incentives for innovation is oft stated; but it is highly contested, with neutral to negative academic support for such a claim.¹⁶⁷ Landes and Posner remark: “[W]hether the benefits exceed the costs is impossible to answer with confidence on the basis of present knowledge.”¹⁶⁸

Regarding healthcare, Feldman states that there is no direct correlation between the desire for exclusive control over the invention and such control translating to innovation gains.¹⁶⁹ Indeed, Love argues that “there is no connection between the incentives needed to induce investments in biomedical innovation and the ultimate cost of the incentives” – effectively delinking IP incentives from innovative outcomes.¹⁷⁰ Despite this, opposition to the TRIPS waiver often involves the fortification and amplification of IP through heroic innovation narratives.¹⁷¹ Such mythologies bolster the international IP system and serve the global capital underpinning it.

In light of the oligopolistic vaccine market, we must be wary of the inexact way in which the term “innovation incentives” is used in rhetoric about IP and COVID-19 vaccines.¹⁷² Even if we proceed on the basis that that IP law does create some incentives, we must

¹⁶⁵ Allen, *Scientific Innovation*.

¹⁶⁶ M. Biagioli, “Weighing intellectual property: Can we balance the social costs and benefits of patenting?” (2019) 57 *History of Science* 140.

¹⁶⁷ A. Jaffe and J. Lerner, *Innovation and its Discontents* (Princeton University Press 2007); J. Bessen and M. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton University Press 2009); F. Lévêque and Y. Ménière, “Patents and Innovation: Friends or Foes?” (2006) *CERNA* 1.

¹⁶⁸ W. Landes and R. Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press 2003) 310 (at n 5).

¹⁶⁹ R.C. Feldman, et al. “Negative innovation: when patents are bad for patients” (2021) 39 *Nature Biotechnology* 914.

¹⁷⁰ J. Love, ‘KEI statement in House hearing on Unsustainable Drug Prices (Part III)’ *KEI* (19 May 2021) available at <https://www.keionline.org/36222> (last accessed 14 February 2022).

¹⁷¹ D. Crow, “Pfizer chief Albert Bourla: ‘We are the most efficient vaccine machine’” *Financial Times* (13 August 2021) – available at <https://www.ft.com/content/97c597dc-03b1-4ece-a302-f9793698ded6> (last accessed 14 February 2022)

¹⁷² Jewkes, *Sources of Invention*.

ask the fundamental question: what specific practices is the IP system incentivising?¹⁷³

Analysing the Argument That the TRIPS Waiver Will Weaken Incentives

Hilty et al. state that a “comprehensive waiver of IP rights will likely have a detrimental effect on incentives for drug innovation” leading IP holders to abandon vaccine innovation.¹⁷⁴ This point implies that if we were to take any measures to weaken IP rules in order to boost vaccine production during this pandemic, when the next pandemic emerges the pharmaceutical industry may not produce vaccines and treatments. This is a speculative claim, one that appears to view the market status quo as the optimum scenario. Yet, analysed critically, it could also be interpreted an admission that the current system’s incentives are misaligned to the extent that pharmaceutical companies can demand IP rights be kept perpetually strong as a kind of ransom against states.¹⁷⁵

Notably, in the recent past the status quo market has not been very effective at responding to calls for pandemic preparedness, in part because of the way IP incentives operate.¹⁷⁶ There have been prominent examples of market failures with respect to producing vaccines for LMICs.¹⁷⁷ Failures also occurred in the responses to Zika and Ebola.¹⁷⁸ Precisely because the conventional incentives provided by IP tend to fail to meet the needs of the poor, we must resist calls to defend uncritically such incentives now, amid a global pandemic.¹⁷⁹

¹⁷³ H.Y. Kang, ‘Patents as Credit – When Intellectual Property Becomes Speculative’ (2015) 194 *Radical Philosophy* 29 at 30–31.

¹⁷⁴ Hilty et al., “Covid-19”.

¹⁷⁵ Z. Rizvi, “Pfizer’s Power” *Public Citizen* (14 February 2022) – available at <https://www.citizen.org/article/pfizers-power/> (last accessed 14 February 2022). See also D.J. Hemel and L Larrimore Ouellette, “Innovation Policy Pluralism” (2019) *Yale Law Journal* 128.

¹⁷⁶ A.S. Rutschman, “The Mosaic of Coronavirus Vaccine Development: Systemic Failures in Vaccine Innovation” *Journal of International Affairs* (21 March 2020).

¹⁷⁷ D.C. Kaslow, S. Black, D.E. Bloom, M. Datla, D. Salisbury & R. Rappuoli, “Vaccine candidates to poorer nations are going to waste” (2018) 564 *Nature* 334.

¹⁷⁸ M. Herder, J.E. Graham and R. Gold, “From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine” (2020) 7 *Journal of Law and the Biosciences* 1.

¹⁷⁹ J. Lezaun and C.M. Montgomery, “The Pharmaceutical Commons: Sharing and Exclusion in Global Health Drug Development” (2015) 40 *Science, Technology, & Human Values* 3.

Obfuscation often results from the “IP as innovation incentive” argument. For instance, the EU’s statement on the TRIPS waiver to the WTO General Council characterises IP as a platform that “incentivises collaboration and transfer of know-how”.¹⁸⁰ This statement confuses the incentive mechanism of IP with the transactability provided by such rights. The claim seems to be that the TRIPS waiver would remove an incentive of the developers of the original product to provide know-how or trade secrets to manufacturers of biosimilars under NDAs (a non-IP measure) on the back of voluntary licences. However, this presumes sufficient incentives already exist to encourage know-how transfer, a presumption which does not match the reality. As detailed above, the IP framework actually encourages a protectionist approach to, for example, mRNA vaccine trade secrets.

Even if one accepts the rhetoric of “IP as innovation incentive” in normal circumstances, the narrative makes very little sense in the extraordinary context of COVID-19-related vaccine IP. This is because the COVID-19 vaccine market has been created (and incentivised) to a large degree by public subsidies. Advance market orders by governments and COVAX have de-risked vaccine development and production to such a degree that the narrative makes very little sense - why privatise the fruits of public funding with the additional “incentive” of private monopoly rights?

The argument that the TRIPS waiver – and the distributed production of generic vaccines that it would encourage – will de-incentivise R&D in science and technology does not stand up to scrutiny. Generic production of HIV/AIDS medicines in LMICs has occurred since the early 2000s, undertaken by, for example, the generic company Cipla, and there is no evidence that it has adversely affected R&D incentives in new HIV medicines by companies in HICs.¹⁸¹ In the COVID-19 context, Pfizer has agreed to license low cost generic production of the Paxlovid treatment to several global south countries via the Medicines Patent Pool, yet Pfizer still expects to make \$15-25 billion

¹⁸⁰ Communication from the EU to the WTO General Council Urgent Trade Policy Responses to the COVID-19 Crisis Brussels (4th June 2021) available at https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159605.pdf (last accessed 14 February 2022).

¹⁸¹ M. Hawksbee, M. McKee and L. King, “Don’t worry about the drug industry’s profits when considering a waiver on covid-19 intellectual property rights” (2022) 376 *BMJ* e067367.

from sales to rich countries.¹⁸² Therefore, the idea that generic production of vaccines in, and for, the global south will destroy the incentives and economic model of pharmaceutical companies is untenable.

Defenders of the status quo tend to understate the risks of the pandemic for global public health, and overstate the risk to the overall IP system from the temporary, COVID-focused waiver proposal. In fact, there is a tangible risk that a status quo that valorises privately held IP rights and privileges profit maximisation strategies may create the *wrong* incentives in the pandemic context, prioritising the production and distribution of HICs' third (and subsequent) booster doses rather than first doses for LMICs.¹⁸³

VIII. The TRIPS Waiver & Beyond: Considering the Legacy of the COVID-19 debate

Over the past 27 years, TRIPS has been a central part of a capitalist discourse that commodifies knowledge as property. Pistor shows how modular and complex legal mechanisms can bestow privileges on IP holders, amplifying their capacity to generate wealth globally, enabling fluidity of capital.¹⁸⁴ Post-TRIPS, it has become common for net exporter nations and transnational corporations to engage in a kind of "IP maximalist" rhetoric that often takes on moralistic and natural property rights hues (accusations of "stealing" "our" inventions).¹⁸⁵ A clear example occurred during a May 2021 interview with a Curevac investor, who remarked that US support for a TRIPS waiver was an attempt to disrupt the German firms Curevac and BioNTech:

¹⁸² A. Tong, 'Covid-19 pill could add another \$15-25B to Pfizer's already torrid pandemic cash flow — analyst' *Endpts* (17 Nov 2021) - <https://endpts.com/covid-19-pill-could-add-another-15-25b-to-pfizers-already-torrid-pandemic-cash-flow-analyst/> (last accessed 14 February 2022)

¹⁸³ N. Triggle, "UK orders another 60m from Pfizer" *BBC* (28 April 2021) available at <https://www.bbc.co.uk/news/uk-56921018> (last accessed 14 February 2022).

¹⁸⁴ K. Pistor, *The Code of Capital* (Princeton University Press 2019).

¹⁸⁵ S. Oddi, 'TRIPS – Natural Rights and a Polite Form of Economic Imperialism' (1996) 29 *Vanderbilt Journal of Transnational Law* 415 at 423.

Germany's post-war constitution says that human life is inviolable, I'd say the same about intellectual property ... If the firms were all American I don't think we'd have had this proposal.¹⁸⁶

Aside from the problematic equation of the right to human life with IP,¹⁸⁷ it is necessary to unpack this claim regarding "inviolability". The origin of IP rights is as historical monopolies that over time became socially constructed rights: they are not "discovered" or natural property rights.¹⁸⁸ Oddi states that the "natural right in IP" theory only gained resonance during the negotiations that led to TRIPS.¹⁸⁹ Despite IP's ubiquity, there is still no consensus on its justification.¹⁹⁰ Even within neoliberal economics – an ideology associated closely with TRIPS – there are economists who view IP rights in a negative light because of their anti-competitive nature, as did the great defender of classical liberalism in economics, Friedrich Hayek.¹⁹¹

An undifferentiated and uncritical understanding of IP – whether as inviolable property and/or as innovation incentive – tends to ignore that effects of IP rights play out differently (and unequally) across various nation states and jurisdictions. The innovation incentive narrative may make some sense in a HIC domestic system (e.g. in Germany or the UK) or for different inventive fields. Nevertheless, TRIPS fails to account for differential national socio-economic conditions in different states; IP cannot serve differential international public interests equally because there is insufficient space for countries to tailor their design domestically to fit local needs and

¹⁸⁶ D. Scally, "Curevac investor sees bright future for German vaccine maker" *The Irish Times* (20 May 2021) available at <https://www.irishtimes.com/business/health-pharma/curevac-investor-sees-bright-future-for-german-vaccine-maker-1.4568758> (last accessed 14 February 2022).

¹⁸⁷ Committee on Economic, Social and Cultural Rights, *Statement on universal affordable vaccination for COVID-19, international cooperation and intellectual property* E/C.12/2021/1 stated that: '[B]usiness entities should also refrain from invoking intellectual property rights in a manner that is inconsistent with the right of every person to access a safe and effective vaccine for COVID-19 or to the right of States to exercise TRIPS flexibilities.'

¹⁸⁸ M. Biagioli, "Patent Republic" (2006) 73 *Social Research* 1129.

¹⁸⁹ Oddi, 'TRIPS'.

¹⁹⁰ R. Merges, *Justifying Intellectual Property* (Harvard University Press 2011).

¹⁹¹ Q. Slobodian, "Are Intellectual Property Rights Neoliberal? Yes and No" (2021) *ProMarket* (18 April 2021) available at <https://promarket.org/2021/04/18/intellectual-property-rights-neoliberal-hayek-history/> (last accessed 14 February 2022).

conditions.¹⁹² TRIPS was not designed to meaningfully accommodate such variation despite some favourable language in Articles 7¹⁹³ and 66.¹⁹⁴ Due to TRIPS, many developing countries' long-standing position as importers of technology may become permanent, damaging their ability to participate in the global knowledge economy.¹⁹⁵ However, when IP rights are couched in “property” terms, often naturalised without a regard for their overall social justification, this important history is lost.¹⁹⁶

Insights from the pharmaceutical industry in the pre- and post-TRIPS eras are useful here. During the 19th and 20th centuries several major states, including, for example, the Netherlands, abolished patent rights for a period in order to build up domestic industry; while others deliberately weakened IP rights to enhance domestic technological capacities.¹⁹⁷ Several countries, including those which now feature leading pharmaceutical corporations, such as Germany and Switzerland, were for a long time hesitant to allow medicines to be patentable.¹⁹⁸ The strong underlying features of the current Indian and Brazilian pharmaceutical industries can to some extent be traced to the pre-TRIPS period, when patent rights were weak or severely limited. By contrast, post-TRIPS, LMICs have been hindered from developing pharmaceutical capacity due to strong IP rights and a lack of technology transfer.

The claim that the TRIPS waiver may result in certain companies – and certain nation states – losing a technological and competitive lead also needs to be understood in this context: it is an admission of the present benefits that some countries and companies enjoy as a result of TRIPS.¹⁹⁹ These are hard to cede. Nonetheless, amidst

¹⁹² S. Lall with collaboration of M. Albaladejo, “Indicators of the Relative Importance of IPRs in Developing Countries’ *Issues Paper no. 3, UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development* (Geneva, 2003).

¹⁹³ Art 7 TRIPS.

¹⁹⁴ Art 66 TRIPS.

¹⁹⁵ Commission on Intellectual Property Rights *Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights* (2002).

¹⁹⁶ G.S. Alexander, E.M. Penalver, J. Singer and L. Underkuffler, ‘A statement of progressive property’ (2009) 94 *Cornell Law Review* 743.

¹⁹⁷ Dutfield, *That High Design of Purest Gold*.

¹⁹⁸ G. Dutfield and U. Suthersanen, *Dutfield and Suthersanen on Global Intellectual Property Law*. (Edward Elgar 2020) 172.

¹⁹⁹ PhRMA, “PhRMA Statement on the WTO TRIPS IP Waiver” (May 2021) available at <https://www.phrma.org/Press-Release/PhRMA-Statement-on-WTO-TRIPS-Intellectual-Property-Waiver> (last accessed 14 February 2022).

a pandemic, extraordinary measures such as the TRIPS waiver cannot be viewed as disproportionate to global needs.

Conclusion: Vaccine Equity and Beyond – What Will the Legacy of the TRIPS Waiver be?

The history of the negotiations over TRIPS and the 2001 Doha Declaration demonstrates that IP law cannot be separated from global political economy or broader concerns of public interest.²⁰⁰ The intense participation by civil society, notable figures and political leaders of all hues and nationalities in the campaign for the TRIPS waiver has brought many issues into the public eye concerning how IP rights are granted, used, and sometimes, even abused. The debate has changed the discourse on the overall political legitimacy of IP law, and has shifted the way public health concerns are articulated with regard to IP.

A global emergency like COVID-19 makes visible the fact that dysfunctions of the market and inequities of knowledge governance in capitalism cannot be separated from IP law. The contested use of “equity” in debates around the TRIPS waiver is one representative expression of the deep inequality transnational IP generates, and of disagreements about the role of law in addressing this injustice. The term “vaccine equity” in this respect takes on a new meaning – equity in this context implies not only fairness, but *wealth and knowledge sharing*, creating a level playing field. Vaccine equity does not, and cannot equate to, mere donations – it is not enough to transfer some vaccine doses to satisfy short-term immediate needs of some of the populations in LMICs. Equity requires technology transfer to enable regional production in the global south, to facilitate a long-term sustainable supply of vaccines in LMICs for this and future pandemics and health needs, linking the law explicitly to outcomes.

This positive momentum towards change in the political-economic structure around TRIPS must be maintained. Legal scholarship can contribute by interpreting and understanding IP law in its original broader public purpose, rather than insisting on a

²⁰⁰ S.K. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003).

narrow legal formalism. Patents, after all, are not ends in themselves, they are a means to an end: a public good. In the midst of a pandemic, if that good can be better served globally by waiving patents and other IP rights, there are compelling academic and ethical reasons to support this. Unlike human life, IP rights are not inviolable.

Beyond the WTO negotiations, one legacy of the waiver debate must be a renewed focus on efforts to share IP, knowledge and technology globally. It is possible that the material developments inspired, at least in part, by the TRIPS waiver – such as the the work of Afrigen and the mRNA hub in South Africa and the ongoing negotiations over the WHO Pandemic Treaty – may outlive the waiver debate (and any eventual text). It is worth recalling that the abiding legacy of the Doha Declaration 2001 was not the legal measure itself, but the expansion of production of generic anti-retrovirals (ARVs) in India and Africa. In this respect, the legacy of the waiver debate may be to rebalance global production of medicines towards regional hubs in the global south. This would go some way to fulfilling the broken technology-transfer promise of TRIPS.