

ADDRESSING VACCINE INEQUITY DURING THE COVID-19 PANDEMIC: THE TRIPS INTELLECTUAL PROPERTY WAIVER PROPOSAL AND BEYOND

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ABSTRACT. *This article examines global vaccine inequity during the COVID-19 pandemic. We critique intellectual property (IP) law under the 1994 WTO TRIPS Agreement, and specifically, the role that IP has played 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 should be viewed as offering a necessary and proportionate legal measure for clearing IP barriers that cannot be achieved by existing TRIPS flexibilities. Finally, we reflect on the waiver debate in the wider context of TRIPS and the need to boost global pandemic preparedness.*

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

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¹ “WHO’s Tedros Says COVID-19 Vaccine Inequity Creates ‘Two-Track Pandemic’”, *Reuters*, 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).

phenomena of corporate control of patents and trade secrets (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, distribute and administer vaccines equitably.

The IP legal framework forms an integral part of the multilateral trade regulatory system overseen by the 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 during the period between December 2020, when the first vaccines were administered, and the time of writing, in February 2022.³ We situate the TRIPS waiver proposal within IP law’s substantive and structural shortcomings.⁴ We argue that given the failure of measures seeking vaccine equity by voluntary means, the waiver offers a necessary and proportionate legal measure for clearing IP barriers 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. The waiver offers hope, not just for the immediate term, but to lay the groundwork for building pandemic preparedness in LMICs.

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

² Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO) (1994) (in force since 1995).

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

⁵ Patents create exclusive rights to make, use or sell an invention but do not lead inevitably to market monopoly. Limited market demand, 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.

COVAX, have treated IP exclusivity as sacrosanct. 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 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 inequity we analyse the two different IP rights – patents and trade secrets – which are most relevant to the 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: (1) that the waiver will not be effective because it is not feasible to boost production capacity in the global south; (2) that the waiver is not needed because compulsory licensing presents an appropriate alternative to the waiver; and (3) 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 of, and rationale for, IP frameworks.

Finally, we assess the implication of IP rights in COVID-19 vaccine inequity 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

⁶ The UK and EU are prominent opponents of the waiver proposal. “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”, 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”, available at <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* (Abingdon and New York 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* (Cheltenham and Northampton 2013).

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.

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 rightsholder permission. If the rightsholder 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 the benefit of both

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 (eds.), *International Public Goods and Transfer of Technology Under A Globalised Intellectual Property Regime* (Cambridge 2005), 793.

¹⁶ “Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies”, available at <http://www.unsgaccessmeds.org/final-report/> (last accessed 14 February 2022).

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

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 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 has occurred during the COVID-19 crisis.

A. TRIPS and the COVID-19 Vaccine Market: Inequities 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 per cent of their adult populations; but 85 per cent of Africans have not received even one dose.²³ Furthermore, while Israel, the US, the UK and Germany have administered third or fourth “booster” doses to their citizens, 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, the distribution of available vaccines has

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* (Diemen 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* (Singapore 2020).

²¹ WHO, “WHO Director-General’s Opening Remarks at 148th Session of the Executive Board”, 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 14 February 2022).

²² WHO, “WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply” (Version 1.1) (13 November 2020).

²³ See the map at J. Holder, “Tracking Coronavirus Vaccinations Around the World”, *New York Times*, available at <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> (last accessed 14 February 2022).

²⁴ “‘F in Ethics’: UN Chief Grades World On Vaccine Rollout”, *NDTV*, 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”, available at <https://www.amnesty.org/en/documents/pol40/4621/2021/en/> (last accessed 14 February 2022).

been highly uneven. The key manufacturing states of the US, UK and EU stockpiled most of the produced doses – even allowing millions of doses to expire – which left a vast vaccine access gap in LMICs.²⁶

Production of the most effective global vaccines has been concentrated in a handful of Western companies, notably Oxford-AstraZeneca, Pfizer-BioNTech, Moderna and Johnson and Johnson (J&J). In 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 to a limited “fill and finish” deal with Aspen in South Africa.²⁷ Other voluntary arrangements included the deals made by AstraZeneca (AZ) with Serum Institute of India (Serum)²⁸ and Fiocruz in Brazil;²⁹ BioNTech’s joint venture with Fosun Pharmaceuticals in China (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 been inadequate to meet the global need to combat COVID-19 in an equitable and sustainable fashion.

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 LMICs were, and are, far less fortunate. In 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

²⁶ M. Schreiber, “US Throws Out Millions of Doses of Covid Vaccine as the World Goes Wanting”, *The Guardian*, 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”, 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”, 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, “MSF Welcomes Fiocruz’s Step Towards Transparency of AstraZeneca Deal”, available at <https://msfaccess.org/msf-welcomes-fiocruz-step-towards-transparency-astrazeneca-deal> (last accessed 14 February 2022).

³⁰ A. Liu, “BioNTech, Fosun Pharma Eye 1B Doses of COVID-19 Vaccine Capacity with New China JV”, *Fierce Pharma*, 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*, 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*, available at <https://www.nytimes.com/2021/04/24/opinion/covid-vaccines-poor-countries.html> (last accessed 14 February 2022).

of these doses were exported to the EU rather than used locally.³⁴ Overall, a lack of distributed production led to 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, equitable global distribution and sustainable administration of doses, new COVID-19 variants, such as Omicron, may continue to emerge. Such variants may render existing vaccines less effective. As Dr Tedros Ghebreyesus 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 pandemic has offered significant pecuniary incentives to IP-holding vaccine producers and their shareholders. Data on 2021 sales reveal a perverse incentive for COVID-19 vaccine manufacturers: to prioritise selling vaccines, including booster doses, to countries that could afford to pay the highest price, regardless of other countries’ health needs.³⁶ Financial interests have clashed with global vaccination goals.³⁷

The production of mRNA vaccines by Pfizer-BioNTech and Moderna has been particularly profitable. The unit cost of producing an mRNA vaccine dose is less than US\$3, but Pfizer-BioNTech priced it initially at US \$19.50.³⁸ Claiming this as a form of “pandemic pricing” yielding around 20 per cent gross profit margin, Pfizer stated that in a non-pandemic environment it would be 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,

³⁴ G. Brown, “The World Is Making Billions of Covid Vaccine Doses, So Why Is Africa Not Getting Them?”, *The Guardian*, available at <https://www.theguardian.com/commentisfree/2021/aug/16/world-billions-covid-vaccine-doses-africa-unprotected> (last accessed 14 February 2022).

³⁵ T.A. Ghebreyesus, “Vaccine Nationalism Harms Everyone and Protects No One”, *Foreign Policy*, 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*, available at <https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html> (last accessed 14 February 2022).

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

³⁸ Z. Kis et al., “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”, 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*, available at <https://www.ft.com/content/d415a01e-d065-44a9-bad4-f9235aa04c1a> (last accessed 14 February 2022).

Pfizer generated \$36–37 billion in vaccine revenue in 2021.⁴¹ BioNTech’s share of sales was \$16–17 billion (approximately 0.5 per cent of Germany’s GDP for 2021).⁴² Moderna earned \$15–17 billion 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 has supplied 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 the 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, and the US National Institutes of Health (NIH); as well as the fact that unprecedented amounts of public funding have gone into vaccine research 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

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

⁴² “BioNTech Alone Could Lift German Economy by 0.5% This Year – Economist”, *Reuters*, 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*, 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 M.L.R. 57.

⁴⁵ D.P. Mancini, “AstraZeneca Vaccine Document Shows Limit of No-profit Pledge”, *Financial Times*, available at <https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af1456b86> (last accessed 14 February 2022).

⁴⁶ C. Paun and A. Furlong, “Poorer Countries Hit with Higher Price Tag for Oxford/AstraZeneca Vaccine”, *Politico*, available at <https://www.politico.eu/article/astrazeneca-vaccine-cost-higher-in-poorer-countries-coronavirus/> (last accessed 14 February 2022).

⁴⁷ L. Richardson, “Time for Other Vaccine Makers to Follow Oxford/Astrazeneca’s Lead”, *Financial Times*, 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*, 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”, available at <https://www.biospace.com/article/vaccitech-raises-110-5-million-in-ipo/> (last accessed 14 February 2022).

on vaccines.⁵⁰ Detailed analysis shows that public funding accounted for 97–99.0 per cent of the funding towards the R&D of ChAdOx, the underlying technology of the Oxford-AZ 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 \$10 billion.⁵² BioNTech is a spin-off company of the public Johannes Gutenberg-University Mainz and it received more than \$445 million 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 have exercised largely unfettered power to dictate which country gains access to vaccines and on what terms.⁵⁴ As COVID-19 has moved gradually from a pandemic to an endemic scenario in HICs, a private market that views vaccines as commodities, and seeks profit maximisation, has incentivised and prioritised production of expensive vaccine booster doses for HICs over first doses for LMICs. Meanwhile, the profit incentive, and the concurrent emphasis on maintaining IP restrictions rather than sharing IP or related technology transfer, has clashed with efforts to increase productive capacity for manufacturing vaccines in LMICs.⁵⁵ In short, the current IP framework has failed to create the right incentives to resolve vaccine inequity within an optimal timeframe.⁵⁶

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

⁵⁰ “Governments Spent at Least €93bn on COVID-19 Vaccines and Therapeutics During the Last 11 Months”, *Business Wire*, 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?” (2021) *BMJ Global Health*, doi:10.1136/bmjgh-2021-007321- (last accessed 14 February 2022).

⁵² B. Herman, “Biden Admin Warns Moderna to ‘Step Up’ Global Vaccine Supply”, available at <https://www.axios.com/covid-vaccine-moderna-biden-global-supply-covax-f74663f-8123-40e1-bc91-f91fdbb92f4c.html> (last accessed 14 February 2022).

⁵³ Amnesty, “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) 18 *I.P.Q.* 161.

⁵⁵ N. Aizenman, “Moderna Won’t Share Its Vaccine Recipe: WHO Has Hired an African Startup to Crack It”, *NPR*, 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.

⁵⁷ At the 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 the proposal stage, and it is not clear

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 cooperation with voluntary systems like C-TAP, that have underscored the importance of the TRIPS waiver proposal.

A. C-TAP and COVAX

The C-TAP scheme originated from Costa Rica's call for a voluntary pool of IP, data and know-how 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 Notably, the pharmaceutical industry has ignored C-TAP.⁶⁰ The industry has also failed to support a similar vehicle, the mRNA Vaccine Transfer Hub, although, as discussed further below, the WHO and South Africa have agreed to proceed even in the absence of cooperation from Moderna and other mRNA vaccine firms.⁶¹

In contrast to C-TAP, COVAX was founded as a public-private initiative, supported by HICs, the UN, GAVI, CEPI and the Gates Foundation.⁶² COVAX was 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 800 million doses allocated by the end of December 2021. However, this fell far short of COVAX's goal to distribute approximately 2 billion doses to LMICs by that date.⁶³ Furthermore, more than 100 million 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 the insecurity of supply to

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*, available at <https://www.statnews.com/pharmalot/2020/03/24/covid19-coronavirus-costa-rica-intellectual-property/> (last accessed 14 February 2022).

⁵⁹ See "WHO COVID-19 Technology Access Pool", available at <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", 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".

⁶² See "The Gavi COVAX AMC 2021 Investment Opportunity Launch Event", available at <https://www.gavi.org/gavi-covax-amc-launch-event-april-2021> (last accessed 17 May 2022).

⁶³ O. Goldhill, "'Naively Ambitious': How COVAX Failed on its Promise to Vaccinate the World", *Stat News*, 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*, available at <https://www.aljazeera.com/news/2022/1/13/poorer-nations-dump-close-to-expiry-covid-vaccines-unicf> (last accessed 14 February 2022).

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 played a role, but a model based on philanthropy and charity will not build sustainable medium- or long-term public health preparedness. The inherently insecure COVAX scheme “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.

B. 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 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 (October 2020) and revised (May 2021) 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

⁶⁵ S. Findlay and D. Pilling, “Indian Vaccine Maker Extends Freeze on Export of Covid Jabs”, *Financial Times*, 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”, available at <https://www.keionline.org/35453> (last accessed 14 February 2022).

⁶⁷ TRIPS Waiver Proposal IP/C/W/669.

⁶⁸ “Statement from Ambassador Katherine Tai on the Covid-19 TRIPS Waiver”, 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).

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, copyright) internationally, but also, crucially, the sharing of IP under the umbrella of undisclosed information, such as trade secrets and know-how.⁷⁰

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 a 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 that

⁶⁹ Current WTO sponsors are available to view at: TRIPS Council, “Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19”, IP/C/W/684, available at https://www.twm.my/title2/intellectual_property/trips_waiver_proposal/W684.pdf (last accessed 14 February 2022).

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

⁷¹ A. Kapczynski, “Order Without Intellectual Property Law: Open Science in Influenza” (2017) 102 *Cornell L. Rev.* 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*, 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) 9 *Sustainable Development Law & Policy* 2.

rightsholders can exercise. For the 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 ring-fence inventions 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.

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.

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” (2020) South Centre Research Paper 135; 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” (2022) South Centre Research Paper 133.

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* (Cambridge, MA 2020).

⁷⁶ Article 33 TRIPS.

⁷⁷ Article 39 TRIPS.

⁷⁸ M. Polanyi, *The Tacit Dimension* (Chicago 1966), 4.

⁷⁹ S. Scotchmar, *Innovation and Incentives* (Cambridge, MA 2004).

A. *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 the 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 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

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 I.P.J. 369.

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

⁸² J.C. Fromer, “Patent Disclosure” (2009) 94 Iowa L. Rev. 539.

⁸³ J.C. Fromer, “Dynamic Patent Disclosure” (2015) 69 Vand. L. Rev. 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 “VaxPaL”, available at <https://medicinespatentpool.org/what-we-do/vaxpal/> (last accessed 14 February 2022).

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

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 optimal as a means of making available all the knowledge needed to increase manufacturing capacity for COVID-19 vaccines. A broad IP waiver would be superior.

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

We define undisclosed information broadly here to include not only trade secrets and manufacturing know-how, 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 In the COVID-19 context there are NDAs in place, for instance, between Pfizer, BioNTech and their suppliers.⁹⁴

Undisclosed information may also include knowledge 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

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” (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”, available at https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/#_ftnref3 (last accessed 14 February 2022).

⁹² M. Risch, “Why Do We Have Trade Secrets?” (2007) 11 Intell. Prop. L. Rev. 1.

⁹³ P.K. Yu, “A Critical Appraisal of the COVID-19 TRIPS Waiver” (2021) Texas A&M University School of Law Legal Studies Research Paper No. 21-32.

⁹⁴ See “Supply Agreement Pfizer and BioNTech with TriLink Biotechnologies” (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”, available at <https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharmaceutical-Incentives-Data-Exclusivity.pdf> (last accessed 14 February 2022).

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

C. 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 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 and others argue that it is “highly unlikely that the waiver of trade secret protection could be effectively implemented and enforced to compel companies to disclose all relevant know-how”.⁹⁸ Given the absence of adequate industry cooperation in the voluntary sharing of trade secrets, this overly pessimistic and unconstructive view equates to justifying a status quo that has failed to deliver equity to 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

⁹⁶ Indian Ministry of Health and Family Welfare, “Centre Fast Tracks Emergency Approvals for Foreign Produced Covid-19 Vaccines”, available at <https://pib.gov.in/PressReleasePage.aspx?PRID=1711381> (last accessed 14 February 2022).

⁹⁷ “Brazil, India Denounce Dutch Generic Drug Seizure”, *Reuters*, available at <https://www.reuters.com/article/us-davos-generic/brazil-india-denounce-dutch-generic-drug-seizure-idUSTRE50T27O20090130> (last accessed 14 February 2022).

⁹⁸ R.M. Hilty et al., “Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 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).

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.

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 Warp speed).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 technology-transfer contracts between parties. The fragility of such trade secrets means that they can, and do, leak, as occurred in 2021 when a US NGO released part of the

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

¹⁰⁰ See US Department of Defense, “Coronavirus: DOD Response”, available at <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*, 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”, available at <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 the official letter sent to the EU Commission by Lange: “Clause on Technology Transfer in Future Vaccine Contracts”, available at <https://twitter.com/berndlange/status/1394902774832373760> (last accessed 14 February 2022).

¹⁰⁴ See C.J. Morten, “Publicizing Corporate Secrets for Public Good” (2022) 171 U. Pa. L. Rev. (forthcoming). Article 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.

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 (e.g. 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 diplomatic cover for HICs, such as the US, to share as much knowledge as possible with global south regulators and producers. Greater sharing 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

¹⁰⁵ See Z. Rizvi, “A Piece of the COVID Vaccine Recipe”, available at <https://www.citizen.org/article/a-piece-of-the-covid-vaccine-recipe/> (last accessed 14 February 2022).

¹⁰⁶ A. Durking et al., “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 and B. Baker, “Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the EU” (2017) 10 *J.O.P.P.* 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”, available at <https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2/> (last accessed 14 February 2022).

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

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 be utilised to facilitate LMIC production of vaccines, which would serve immediate needs while also enhancing preparedness for future pandemics.¹¹³

A. Building Production Capacity

A common claim against the TRIPS waiver is that it will not alleviate vaccine inequity 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 Crucially, the claim that there is no spare HIC/LMIC production capacity has 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 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

¹¹¹ A. Furlong, “Big Vaccine Makers Reject Offers to Help Produce More Jobs”, *Politico*, available at <https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jobs/> (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” (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*, available at <https://www.foreignaffairs.com/articles/world/2021-01-29/fully-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”, 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”.

¹¹⁶ S. Nolen, “Here’s Why Developing Countries Can Make the Top Covid Vaccines”, *New York Times*, available at <https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html> (last accessed 14 February 2022).

¹¹⁷ A. Prabhala and A. Alsalthani, “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 14 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*, available at <https://www.ft.com/content/b0f42409-6fdf-43eb-96c7-d166e090ab99> (last accessed 14 February 2022).

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 refrain from enforcing 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 an mRNA vaccine face significant hurdles, for example, in scaling up manufacturing.¹²¹ This calls into question the rationale behind Moderna's promise or indeed their good faith in making it.

Nonetheless, despite Moderna's refusal to cooperate 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 an 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, including at NIH, offered assistance to Afrigen in this effort, though it is unclear whether anyone disclosed information to Afrigen that could be considered a Moderna trade secret.¹²³

That Afrigen had to reverse-engineer the vaccine without Moderna's know-how, data or technology transfer unquestionably delayed the Afrigen 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

¹¹⁹ M. Cheng and L. Hinnant, “Countries Urge Drug Companies to Share Vaccine Know-how”, *AP News*, <https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92affc3ea9ed519be007f8887bcf6> (last accessed 14 February 2022).

¹²⁰ A. Furlong, “Copying Moderna's Jab: The Project to Democratize Vaccine Production”, *Politico*, available at <https://www.politico.eu/article/who-copy-moderna-jab-project-democratize-vaccine-production/> (accessed 14 February 2022).

¹²¹ C. O'Donnell and M. Mishra, “Moderna Sees No Impact on COVID-19 Vaccine from Potential Patent Waiver”, *Reuters*, available at <https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-raises-2021-sales-forecast-covid-19-vaccine-192-blm-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.*

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

Afrigen's achievement proves that companies in the global south can replicate mRNA vaccines. Therefore, despite the claims of IP rightsholders, 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 to licensing deals with LMICs that would be mutually beneficial in the immediate term and would help resolve vaccine inequity, Moderna and Pfizer-BioNTech have prioritised 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 work 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.

B. 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 Nonetheless, 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 Importantly, 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

¹²⁴ As noted earlier, sharing regulatory data, which often includes codified know-how, may assist the mRNA hub to replicate the NIH-Moderna vaccine exactly, further speeding up the trial and rollout process. M. Roy and R. Kasolowsky, "Approval of COVID Vaccine Made in South Africa Could Take 3 Years, WHO Says", *Reuters*, 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.

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*, available at <https://www.wsj.com/articles/covid-lessons-from-bushs-effort-against-aids-11616959045> (last accessed 15 February 2022).

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

¹²⁹ Amin, "Folly of Hoarding Knowledge".

¹³⁰ J. Chakma et al., "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*, 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".

C. Raw Materials

There has been a related claim that the shortage of raw materials worldwide has been more to blame than IP rights for problems of insecure COVID-19 vaccine supply.¹³³ In fact, IP barriers have been 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, positive international negotiations over the waiver could help with co-ordinating the global supply of ingredients.

D. 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 and others 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 on the basis of hindsight, with a lack of critical analysis. Inequalities of pricing and distribution are matters of grave 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 merely a matter of private contractual choices is to selectively ignore how IP facilitates

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”, available at <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”, available at <https://mattstoller.substack.com/p/why-are-there-shortages-of-plastic> (last accessed 14 February 2022).

¹³⁵ Paun and Furlong, “Poorer Countries Hit with Higher Price Tag”.

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

¹³⁷ Hilty et al., “Covid-19”, 3.

asymmetry.¹³⁸ Hilty and others 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 around inventions 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.

E. 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 In this regard, although the waiver negotiations have not, at time of writing, lead to an agreement on a text, the proposal has already had several positive impacts, leading to increased transparency about vaccine manufacturing and pricing.¹⁴¹ The waiver proposal has also been utilised as a lever to encourage industry cooperation 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

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?", 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", 14, available at https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf (last accessed 14 February 2022).

¹⁴¹ Erfani et al., "Beyond a Symbolic Gesture".

¹⁴² See BioNTech-Biovac agreement of July 2021: "South African Firm to Help Make Pfizer/BioNTech COVID Vaccine", *Reuters*, available at <https://www.reuters.com/business/healthcare-pharmaceuticals/pfizerbiontech-strike-south-africa-covid-19-manufacturing-deal-with-biovac-2021-07-21/> (last accessed 14 February 2022).

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

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 Patent Pool licence for its COVID-19 treatment Paxlovid, 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 ARTICLES 31 AND 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 Articles 31 and 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. In spite of this, the fragmented and complex COVID-19 IP landscape means the existing system of compulsory licensing under TRIPS is not well suited to addressing vaccine inequity.

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 Article 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 trade threats, including the possibility of sanctions being imposed on them.¹⁴⁷

¹⁴⁴ See Merck, “The Medicines Patent Pool (MPP) and Merck Enter Into License Agreement for Molnupiravir”, available at <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-countries/> (last accessed 14 February 2022).

¹⁴⁵ See “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”, available at <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).

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 and others, “Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-related Aspects of Intellectual Property Rights, 2001–2016” (2018) 96 *WHO Bulletin* 85.

Fourth, there are additional obstacles to the use of a CL for vaccines, including regulatory barriers.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. Critically, a CL offers no further lever 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, Article 31(f) of TRIPS states that products made under a CL must be used “predominantly for supply of the domestic market”. Under Article 31 *bis*, in theory a CL for export and import is now possible.¹⁵⁰ Yet, there are obstacles to using Article 31 *bis*, including the fact that some countries/regions (e.g. the EU) have opted out of Article 31 *bis* as importing members.¹⁵¹ Conditions for using Article 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 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 Article 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 Article 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

¹⁴⁸ Hoen et al., “Data Exclusivity Exceptions”.

¹⁴⁹ H. Wong, “The Case for Compulsory Licensing During COVID-19” (2020) 10 *Journal of Global Health*, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7242884/> (last accessed 14 February 2022).

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” (2007) 11 *ASIL Insights*, available at <https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and> (last accessed 14 February 2022).

¹⁵³ B. Anderson, “Better Access to Medicines: Why Countries Are Getting ‘Tripped’ Up and Not Ratifying Article 31 Bis” (2010) *J.O.L.T.I.* 165.

¹⁵⁴ WTO, “Bolivia Outlines Vaccine Import Needs in Use of WTO Flexibilities to Tackle Pandemic”, 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*, available at <https://www.aljazeera.com/opinions/2021/9/28/the-canadian-government-can-save-bolivian-lives> (last accessed 14 February 2022).

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.

Finally, Article 73 of TRIPS provides WTO member states with legal cover to suspend the application of normal TRIPS obligations in times of national emergency. While useful, Article 73 is of more limited scope than the TRIPS waiver: Article 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

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”, 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?”, available at <https://blog.petrieflom.law.harvard.edu/2021/05/07/wto-waiver-intellectual-property-covid/> (last accessed 14 February 2022).

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

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 Va. J. Int’l. L. 9.

¹⁶¹ R. Gupta and R. Ramachandran, “A Covid-19 Vaccine IP Waiver Won’t Kill Pharma Innovation”, *Bloomberg*, available at <https://news.bloomberglaw.com/ip-law/a-covid-19-vaccine-ip-waiver-wont-kill-pharma-innovation> (last accessed 14 February 2022).

¹⁶² P. Drahos and J. Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Abingdon and New York 2002), 196–97.

A. 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; 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

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

¹⁶⁴ J.A. Schumpeter, *Business Cycles: A Theoretical, Historical and Statistical Analysis of the Capitalist Process* (New York and London 1939); J. Jewkes, *The Sources of Invention* (London 1958); J.A. Allen, *Scientific Innovation and Industrial Policy* (Amsterdam 1967).

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 2007); J. Bessen and M. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton 2009); F. Lévéque and Y. Ménière, “Patents and Innovation: Friends or Foes?” (2006), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=958830 (last accessed 14 February 2022).

¹⁶⁸ W. Landes and R. Posner, *The Economic Structure of Intellectual Property Law* (Cambridge, MA 2003), 310 (at note 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)’, 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*, available at <https://www.ft.com/content/97c597dc-03b1-4ece-a302-f9793698ded6> (last accessed 14 February 2022).

¹⁷² Jewkes, *Sources of Invention*.

that IP law does create some incentives, we must ask the fundamental question: what specific practices is the IP system incentivising?¹⁷³

B. Analysing the Argument that the TRIPS Waiver Will Weaken Incentives

Hilty and others 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 R&D.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 as 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

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

¹⁷³ H.Y. Kang, “Patents as Credit: When Intellectual Property Becomes Speculative” (2015) 194 *Radical Philosophy* 29.

¹⁷⁴ Hilty et al., “Covid-19”.

¹⁷⁵ Z. Rizvi, “Pfizer’s Power”, 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) *Y.L.J.* 128.

¹⁷⁶ A.S. Rutschman, “The Mosaic of Coronavirus Vaccine Development: Systemic Failures in Vaccine Innovation” (2020) *Journal of International Affairs*, available at <https://jia.sipa.columbia.edu/online-articles/mosaic-coronavirus-vaccine-development-systemic-failures-vaccine-innovation> (last accessed 14 February 2022).

¹⁷⁷ D.C. Kaslow et al., “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 *I.J.B.L.* 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.

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

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 that 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 has little coherence 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 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. India and South Africa proposed the TRIPS waiver in October 2020 precisely because it was foreseeable that a status quo that valorises privately held IP rights and privileges profit maximisation would 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

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.

¹⁸² A. Tong, “Covid-19 Pill Could Add Another \$15-25B to Pfizer’s Already Torrid Pandemic Cash Flow Analyst”, available at <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. Triggler, “UK Orders Another 60m from Pfizer”, *BBC*, available at <https://www.bbc.co.uk/news/uk-56921018> (last accessed 14 February 2022).

VIII. TRIPS AND COVID-19: CONSIDERING THE WAIVER DEBATE IN HISTORICAL PERSPECTIVE

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: “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 an innovation incentive – tends to ignore that the 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. Nonetheless, TRIPS fails to account for

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

¹⁸⁵ S. Oddi, “TRIPS – Natural Rights and a Polite Form of Economic Imperialism” (1996) 29 *Vand. J. Transnat’l. L.* 415, 423.

¹⁸⁶ D. Scally, “Curevac Investor Sees Bright Future for German Vaccine Maker”, *The Irish Times*, 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” (2021) 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* (Cambridge, MA 2011).

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

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 conditions.¹⁹² TRIPS was not designed to accommodate meaningfully 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 nineteenth and twentieth 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 a pandemic, extraordinary measures such as the TRIPS waiver cannot be viewed as disproportionate to global needs.

¹⁹² S. Lall, "Indicators of the Relative Importance of IPRs in Developing Countries" (2003) UNCTAD-ICTSD Project on IPRs and Sustainable Development Issues Paper no. 3, available at https://unctad.org/system/files/official-document/ictsd2003ipd3_en.pdf (last accessed 14 February 2022).

¹⁹³ Article 7 TRIPS.

¹⁹⁴ Article 66 TRIPS.

¹⁹⁵ Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy" (2002), available at http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf (last accessed 14 February 2022).

¹⁹⁶ G.S. Alexander et al., "A Statement of Progressive Property" (2009) 94 Cornell L. Rev. 743.

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

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

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

IX. 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 More recently, 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.

This is not to say that IP is the only issue relevant to the distribution of vaccines. For instance, the provision of adequate funds to LMICs that have low absorption capacity to assist with the administration of doses at the ground level remains essential. Nevertheless, 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. In this respect, the term “vaccine equity” 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 the short-term 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, as well as for related 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 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.

Therefore, 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

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

least in part, by the TRIPS waiver – such as expanding the number of Medicines Patent Pool licences, encouraging the nascent work of Afrigen and the mRNA hub in South Africa, and ensuring the negotiations over the WHO Pandemic Treaty include equity provisions – 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-retroviral drugs (ARVs) in India and Africa. In this respect, the legacy of the waiver debate may be to rebalance the 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.