

***Addressing Vaccine Inequity During the COVID-19 Pandemic:
The TRIPS Intellectual Property Waiver Proposal & Beyond***

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Abstract

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

Keywords: TRIPS Agreement; 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 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 Organisation (WHO) Director Tedros Adhanom Ghebreyesus, a “two tier” pandemic defined by “vaccine apartheid” between high income countries (HICs) and lower- and middle-income countries (LMICs).¹ The transnational intellectual property (IP) framework is implicated in vaccine inequity, as demonstrated by the profound disparities in the production and distribution of COVID-19 health technologies needed to combat the pandemic. The phenomena of COVID-19 corporate secrecy (IP hoarding by companies) and “vaccine nationalism” (vaccine dose hoarding by states) have brought into sharp relief the misalignment of current legal and financial incentives to produce and distribute vaccines equitably.

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

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

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

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

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

operate and to produce COVID-19 vaccines without the fear of infringing another party's IP rights and the attendant threat of litigation.

We develop the argument by first analysing the major COVID-19 vaccines in relation to their development, production, distribution and pricing. Our analysis shows that the IP framework, typified by TRIPS, has enabled IP holders' unfettered monopoly power, resulting in artificial scarcity and iniquitous supply of vaccines. We argue that IP has been central to facilitating an oligopolistic market, entrenching the current inequity. By relying on voluntary licensing and philanthropic donations, the multilateral and multi-institutional efforts to tackle the supply of COVID-19 vaccines, such as COVAX, have maintained IP monopolies, rather than tackling them. This donation model has, thus far, failed to achieve vaccine equity.

In light of this, we examine the TRIPS waiver proposal initially put forward by India and South Africa in October 2020.⁵ As of October 2021, 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 present COVID-19 vaccine context.⁸

We address the key arguments used by opponents of the waiver, which are often presented as a defence of the legal status-quo, namely: (i) that the waiver will not be effective because it is not feasible to boost production capacity in the global south; (ii) that the waiver is not needed because compulsory licensing presents an appropriate alternative to the waiver; and (iii) that the waiver should be opposed because it would

⁵ *ibid.*

⁶ "UK statements during the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council from 13-14 October 2021" available at <https://www.gov.uk/government/news/wto-trips-council-october-2021-uk-statements> (last accessed 19 October 2021). See also E. 't Hoen and P. Boulet, "The EU proposed Covid waivers of certain TRIPS rules are mostly meaningless" (14th October 2021) available at <https://medicineslawandpolicy.org/2021/10/the-eu-proposed-covid-waivers-of-certain-trips-rules-are-mostly-meaningless/> (last accessed 19 October 2021).

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

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.

have a harmful effect on “innovation incentives”. In critiquing these three arguments we reflect on the role of the public interest as a key feature underpinning the development and rationale for IP frameworks.

Finally, we assess the implication of IP rights in the COVID-19 vaccine shortages as a significant inflection point, more than a quarter of a century after TRIPS.⁹ The COVID-19 pandemic has shed light on a deep, existing problem of inequality within the TRIPS system which has kept low and middle-income countries (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 high-income countries (HICs) to realise the promise they made at the time of the TRIPS negotiations in 1994, that by agreeing to the terms of TRIPS, LMICs would benefit from technology transfer and the building of productive capacity.¹¹ As such, the pandemic is revealing not only of inadequacies of how to deal with global emergencies, but also of deficiencies within the international “patent bargain” itself. The article concludes with a discussion of the potential legacy of the waiver debate in addressing these deficiencies.

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 reform under the 2001 Doha Declaration,¹⁴ which focused on

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

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

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

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

balancing IP rights with global health.¹⁵ Although access to generic 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 monopoly rights in the use of a patented invention, precluding or disabling 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. A position of dominance can hinder technology sharing.¹⁸ Patent owners can 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 further bolster this monopoly power.

Crucially, monopoly 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 works, IP must be understood as a key factor when the market produces dysfunctional or inequitable results, as it is doing now during the COVID-19 crisis.

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

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

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

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

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

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

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

The pandemic has exacerbated existing global health inequalities, none more apparent than in vaccine production, distribution and pricing.²¹ Although early in the pandemic the WHO guidelines recommended that health workers and high-risk people in all nations should get vaccinated first, high-income countries (HICs), including the US, UK and EU states, failed to follow through, instead prioritising their own populations, including those at relatively low risk.²² As of October 2021, rich countries such as the UK and many EU member states have double-vaccinated 70-75% of their adult populations; but 92% of Africans have not received even one dose.²³ Furthermore, while Israel, the US, the UK and Germany are administering third “booster” doses to their citizens, billions of people, including vulnerable healthcare workers, in low- and middle-income countries (LMICs) are still waiting for their first dose.²⁴

Insufficient production remains a major source of inequity. Although pharmaceutical companies promised to provide enough doses to vaccinate all adults globally by the end of 2021, their supply has consistently fallen short of targets.²⁵ There has not been enough production to keep up with demand. Moreover, distribution of available vaccines has been highly uneven. The key manufacturing states of the US, UK and EU have stockpiled most of the doses that have been produced - even allowing millions of doses to expire - which has left a vast gap in vaccine access in LMICs.²⁶

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

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

²³ See the map at <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> (last accessed 19 October 2021).

²⁴ “F In Ethics”: UN Chief Grades World On Vaccine Rollout’ *NDTV* (September 21 2021) available at <https://www.ndtv.com/world-news/f-in-ethics-un-chief-antonio-guterres-grades-world-on-vaccine-rollout-2548827> (last accessed 19 October 2021).

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

²⁶ M. Schreiber, “US throws out millions of doses of covid vaccine as the world goes wanting” *The Guardian* (16 October 2021) available at <https://www.theguardian.com/world/2021/oct/16/us-throws-out-millions-doses-covid-vaccine-world-shortages> (last accessed 19 October 2021)

Production of the most effective global vaccines is concentrated in a handful of Western companies, notably Oxford-AstraZeneca, Pfizer-BioNTech, Moderna and Johnson and Johnson (J&J). There are only a limited number of voluntary licensing arrangements aimed at increasing vaccine production capacity, exacerbating the problem of insufficient global production. For example, there is an agreement between J&J and Merck to boost US production of the J&J vaccine, which the US government backed with significant funding, and J&J's "fill and finish" deal with Aspen in South Africa.²⁷ Other voluntary arrangements include AstraZeneca's deals with Serum Institute of India (Serum)²⁸ and Fiocruz in Brazil;²⁹ BioNTech's joint venture with Fosun Pharmaceuticals in China (which is separate from BioNTech's deal with Pfizer);³⁰ Pfizer-BioNTech's limited "fill & finish" agreement with Biovac in South Africa;³¹. These arrangements are certainly positive, but they are inadequate to meet the world's needs for COVID-19.

On vaccine distribution and access, the pandemic has brought a stark realisation into view: regions without vaccine production hubs lack security of supply. In the global south, only India has sufficient local production to ensure supply security during 2021.³² Most other LMICs are far less fortunate. During 2021, very limited production of COVID-19 vaccines has occurred in Africa. Even where vaccine doses have been produced, as under the J&J-Aspen contract in South Africa, many millions of these

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

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

²⁹ "MSF welcomes Fiocruz's step towards transparency of AstraZeneca deal" (November 2020) available at <https://msfaccess.org/msf-welcomes-fiocruzs-step-towards-transparency-astrazeneca-deal> (last accessed 19 October 2021).

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

³¹ Pfizer Press Release (21st July 2021) available at <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac> (last accessed 19 October 2021).

³² S. Findlay, M. Peel and D.P. Mancini, "India's block on vaccine exports deals blow to dozens of nations" *The Irish Times* (26 March 2021) available at <https://www.irishtimes.com/news/world/asia-pacific/india-s-block-on-vaccine-exports-deals-blow-to-dozens-of-nations-1.4520812> (last accessed 19 October 2021).

doses have been exported to the EU.³³ Production in South America has lagged behind that of the US and Europe.³⁴ Overall, a lack of distributed production has created an insecurity of supply in these regions, as vaccine nationalism in the HICs like Canada, US, UK and EU states has seen mass hoarding of the produced doses. Aside from the moral inequity, the failures on production and distribution are short-sighted: without a significant and rapid increase of vaccine production and equitable global distribution, new COVID-19 variants will likely continue to emerge. Such variants may render existing vaccines less effective. In effect, “[v]accine nationalism is not just morally indefensible. It is epidemiologically self-defeating and clinically counterproductive”.³⁵

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

The unit cost of production of a mRNA vaccine dose is less than US\$3, BioNTech-Pfizer priced initially it at US\$19.50.³⁸ Claiming that this is “pandemic pricing” yielding

³³ G. Brown, “The world is making billions of Covid vaccine doses, so why is Africa not getting them?” *The Guardian* (16 August, 2021) available at <https://www.theguardian.com/commentisfree/2021/aug/16/world-billions-covid-vaccine-doses-africa-unprotected> (last accessed 19 October 2021).

³⁴ “Editorial: The World Needs Many More Coronavirus Vaccines” *New York Times* (24 April 2021) available at <https://www.nytimes.com/2021/04/24/opinion/covid-vaccines-poor-countries.html> (last accessed 19 October 2021).

³⁵ T.A. Ghebreyesus, “Vaccine Nationalism Harms Everyone and Protects No One” *Foreign Policy* (2 February 2021) available at <https://foreignpolicy.com/2021/02/02/vaccine-nationalism-harms-everyone-and-protects-no-one/> (last accessed 19 October 2021).

³⁶ R. Robbins, “Moderna, Racing for Profits, Keeps Covid Vaccine Out of Reach of Poor” *New York Times* (9 October 2021) available at <https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html> (last accessed 19 October 2021)

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

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

around 20% gross profit margin, Pfizer stated that in a non-pandemic environment it would be normally be priced between US\$150 and US\$175.³⁹ Indeed, in its most recent sale of “boosters” to the UK and EU, Pfizer actually raised the price, increasing its profits.⁴⁰ Pfizer will generate more than \$26 billion in vaccine revenue in 2021.⁴¹ BioNTech’s share of sales will be at least \$18bn, approximately 0.5% of Germany’s GDP for 2021.⁴² Moderna will earn more than \$18bn in revenue for vaccine sales during 2021.⁴³ The vast majority of the Pfizer-BioNTech and Moderna doses have been sold to HICs. Pfizer-BioNTech and Moderna are the key “beneficiaries” of the status quo.⁴⁴

Only AZ is supplying vaccines at cost.⁴⁵ Despite this pledge, there is evidence of LMICs being charged a higher price than HICs.⁴⁶ Prof. Louise Richardson, Vice-Chancellor of the University of Oxford, defends the Oxford/AZ approach, noting that, unlike AZ, several other pharmaceutical companies “have derived enormous profits from the pandemic”.⁴⁷ Yet, AZ reserves the right to declare an end to the pandemic pricing, stating that the at cost pricing will not last much longer.⁴⁸ Financial markets

³⁹ Pfizer, “Edited Transcript, Q4 2020 Earnings Call” (2 February 2021) available at https://s21.q4cdn.com/317678438/files/doc_financials/2020/q4/PFE-USQ_Transcript_2021-02-02.pdf (last accessed 19 October 2021).

⁴⁰ DP Mancini, H. Kuchler and M. Khan, “Pfizer and Moderna raise EU Covid vaccine prices” *Financial Times* (August 2021) - <https://www.ft.com/content/d415a01e-d065-44a9-bad4-f9235aa04c1a> (last accessed 19 October 2021).

⁴¹ “Pfizer Vaccine revenue is projected to hit \$26bn in 2021 with production surge” *The Washington Post* (4 May 2021) available at <https://www.washingtonpost.com/business/2021/05/04/pfizer-covid-vaccine-revenue/> (last accessed 19 October 2021).

⁴² “BioNTech alone could lift German economy by 0.5% this year – economist” *Reuters* (10 August 2021) available at <https://www.reuters.com/article/germany-economy-biontech-idUSL8N2PH32O> (last accessed 19 October 2021)

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

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

⁴⁵ D.P. Mancini, “AstraZeneca vaccine document shows limit of no-profit pledge” *Financial Times* (7 October 2020) available at <https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686> (last accessed 19 October 2021).

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

⁴⁷ L. Richardson, ‘Time for other vaccine makers to follow Oxford/AstraZeneca’s lead’ *Financial Times* (18 May 2021) available at <https://www.ft.com/content/65856fab-e394-4407-adf9-63edd8acdad3> (last accessed 19 October 2021).

⁴⁸ H. Kuchler, “AstraZeneca reveals strong Covid vaccine sales but warns of US approval delays” *Financial Times* (29 July 2021) available at <https://www.ft.com/content/8e14257f-8bf8-4dc7-9680-9d489654d2b6> (last accessed 19 October 2021)

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 US\$100 million.⁴⁹

Inequities affecting the global public over vaccine access and pricing are all the more glaring given that several vaccines rely on major breakthroughs that occurred at universities and public institutions, including at Oxford University, the University of Pennsylvania (Penn), and the US National Institutes of Health (NIH); as well as the fact that unprecedented amounts of public funding have gone into these private companies' vaccine research and production. The global public sector has spent at least €93 billion on the development of COVID-19 vaccines and therapeutics – including over €88 billion on vaccines.⁵⁰ Detailed analysis shows that 'public funding accounted for 97.1–99.0% of the funding towards the R&D of ChAdOx and the Oxford-AstraZeneca vaccine'.⁵¹ The Moderna vaccine is almost entirely funded by the US government – which provided \$10bn.⁵² BioNTech received more than \$445m from the German government.⁵³

Despite significant public funding underpinning many COVID-19 vaccines, conditions were generally not attached to this funding to secure equitable global access to vaccines. Instead, IP holders exercise largely unfettered power to dictate which country gains access to vaccines and on what terms.⁵⁴ As COVID-19 moves gradually from a pandemic to endemic scenario in HICs, a private market that views vaccines as commodities, and seeks profit maximisation, appears to be incentivising and

⁴⁹ A. Keown, "AstraZeneca Vaccine Collaborator Vaccitech Snares \$110.5 Million IPO" (30 April 2021) available at <https://www.biospace.com/article/vaccitech-raises-110-5-million-in-ipo/> (last accessed 19 October 2021).

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

⁵¹ S. Cross, Y. Rho, H. Reddy, T. Pepperrell, F. Rodgers, R. Osborne, A. Eni-Olotu, R. Banerjee, S. Wimmer and S. Keestra, "Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology" (2021) *medRxiv* preprint doi: <https://doi.org/10.1101/2021.04.08.21255103> – (version 10 April 2021).

⁵² B. Herman, "Biden admin warns Moderna to 'step up' global vaccine supply" *Axios* (13 October 2021) available at <https://www.axios.com/covid-vaccine-moderna-biden-global-supply-covax-ff74663f-8123-40e1-bc91-f91fdbb92f4c.html> (last accessed 19 October 2021)

⁵³ Amnesty, "A double dose of inequality".

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

prioritising production of expensive vaccine booster doses for HICs over first doses for LMICs. Meanwhile, the profit incentive, with the emphasis on maintaining IP restrictions rather than sharing IP or related technology transfer, is clashing with efforts to increase productive capacity for manufacturing vaccines.⁵⁵ In short, the current IP framework is failing to create the right incentives to boost global production sufficiently to resolve vaccine inequity.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. As we outline here, these initiatives have not (at the time of writing) succeeded in delivering global vaccine equity. It is these failings and, in particular, the lack of industry engagement and co-operation with voluntary systems like C-TAP, that have necessitated the TRIPS waiver proposal.

C-TAP and COVAX

The C-TAP scheme originated from Costa Rica’s call for a voluntary pool of IP, data and know-how etc. in March 2020.⁵⁷ 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.⁵⁸ However, the

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

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

⁵⁷ E. Silverman, “WHO is asked to create a voluntary intellectual property pool to develop Covid-19 products” *Stat News* (24 March 2020) available at <https://www.statnews.com/pharmalot/2020/03/24/covid19-coronavirus-costa-rica-intellectual-property/> (last accessed 19 October 2021).

⁵⁸ See: <https://www.who.int/initiatives/covid-19-technology-access-pool> (last accessed 19 October 2021).

pharmaceutical industry has ignored C-TAP.⁵⁹ There are also concerns about a lack of support for a similar vehicle, the mRNA Vaccine Transfer Hub, but WHO and South Africa are going ahead even in the absence of agreement from Moderna and other mRNA vaccine firms.⁶⁰

In contrast to C-TAP, COVAX operates as a public–private initiative, supported by HICs, the UN, GAVI, CEPI and the Gates Foundation.⁶¹ COVAX is designed to meet immediate, rather than systemic needs, with states coming together to purchase and distribute vaccines. Despite some several governance-related problems, COVAX has achieved some success in delivering vaccines to LMICs, with just over 390m doses administered by end October 2021. Yet, this falls far short of the goal to distribute approximately 1.8 billion doses to LMICs by end 2021. This failure is due to vaccine nationalism in HICs and the insufficiency of vaccine production worldwide.⁶² Insecurity of supply to COVAX became evident when the Indian government halted exports from Serum to focus on the crisis in India.⁶³

COVAX has a role to play but a model based on philanthropy and charity will not build sustainable medium- or long-term public health preparedness. The COVAX model of charitable donations “supports the monopolistic model that it is based on”, ignoring the “very real desire of developing and least developed countries to produce for themselves”.⁶⁴

COVAX has failed to provide security of supply to LMICs. LMICs will only be able to attain the kind of security of vaccine supply that countries, such as the UK, US, EU

⁵⁹ E. 't Hoen, “The elephant in the room at the WHO Executive Board” *Medicines Law and Policy* (22 January 2021) available at <https://medicineslawandpolicy.org/2021/01/the-elephant-in-the-room-at-the-who-executive-board/> (last accessed 19 October 2021).

⁶⁰ Aizenman, “Moderna won't share its vaccine recipe”.

⁶¹ See: <https://www.gavi.org/gavi-covax-amc-launch-event-april-2021>

⁶² O. Goldhill, “Naively ambitious’: How COVAX failed on its promise to vaccinate the world” *Stat News* (8 October 2021) – available at <https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/> (last accessed 19 October 2021)

⁶³ S. Findlay and D Pilling, “Indian vaccine maker extends freeze on export of Covid jabs” *Financial Times* (18 May 2021) available at <https://www.ft.com/content/63fbbb79-f657-4e6c-b190-cffd0d630593> (last accessed 19 October 2021).

⁶⁴ “23 February 2021: South Africa’s interventions at the WTO TRIPS Council” KEI (1 March 2021) available at <https://www.keionline.org/35453> (last accessed 19 October 2021).

(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 has put the spotlight on an alternative proposal: the TRIPS waiver.

The TRIPS Waiver

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

work together to ensure that intellectual property [IP] rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat Covid-19.⁶⁵

Justifying the proposal by reference to “exceptional circumstances”, India and South Africa called for a waiver that would “continue until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity”. Although sometimes referred to in shorthand as a “patent waiver”, in both its original and revised forms, the India/South Africa proposal is a broad package extending to all relevant IP, and applicable to diagnostics, treatments and vaccines. After going unheeded at successive WTO meetings, the call received a boost in May 2021 when the US expressed support, albeit for a narrower IP waiver that would apply only to COVID-19 vaccines.⁶⁶

The proposal is currently co-sponsored by over 60 WTO countries.⁶⁷ The waiver would apply “in relation to prevention, containment or treatment of COVID-19”, covering not

⁶⁵ TRIPS Waiver Proposal IP/C/W/669.

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

⁶⁷ Current WTO sponsors are available to view at [https://www.twn.my/title2/intellectual property/trips waiver proposal/W684.pdf](https://www.twn.my/title2/intellectual%20property/trips%20waiver%20proposal/W684.pdf) (last accessed 19 October 2021)

only the temporary waiver of patents (and, where relevant, copyrights) internationally, but also, crucially, the sharing of IP under the umbrella of undisclosed information, such as trade secrets and know-how.⁶⁸

In principle, this kind of ‘sharing’ is not new.⁶⁹ 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.⁷⁰ Since the coming into force of TRIPS in 1995, LMICs’ industrial and pharmaceutical capacity has been hindered by the lack of technology transfer from HICs.⁷¹ 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

⁶⁸ Waiver Revised Text IP/C/W/669/Rev.1.

⁶⁹ A. Kapczynski, “Order without Intellectual Property Law: Open Science in Influenza” (2017) 102 *Cornell Law Review* (2017) 1539.

⁷⁰ P. Erfani, L.O. Gostin and V. Kerry, “Beyond a symbolic gesture: What’s needed to turn the IP waiver into Covid-19 vaccines” *Stat News* (19 May 2021) available at <https://www.statnews.com/2021/05/19/beyond-a-symbolic-gesture-whats-needed-to-turn-the-ip-waiver-into-covid-19-vaccines/> (last accessed 19 October 2021).

⁷¹ S. Humphreys, “Perspective: Technology Transfer and Human Rights: Joining Up the *Dots*” (2009) 2 *Sustainable Development Law & Policy*.

issues are complex, and as we explain in the following section, it is vital to consider both patents and trade secrets.⁷²

IV. Operationalising a TRIPS Waiver – Patents and Trade Secrets

The TRIPS waiver puts into sharp relief the different layers of property rights that often ringfence innovation and operate as assets in the world economy.⁷³ 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).

The patent monopoly on an invention is granted to an inventor/owner by one or more patent offices, with specification documentation made public, and which is protected exclusively under TRIPS for 20 years.⁷⁴ A trade secret under TRIPS is undisclosed information, including know-how.⁷⁵ Such secrets are protected under contract or non-disclosure agreements (NDAs).⁷⁶ For a TRIPS waiver to be effective for COVID-19 vaccines, it would need to comprise not only a patent waiver, but also provide mechanisms by which trade secrets in vaccine manufacturing know-how can be shared by transferring technology and disclosing data.

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. On the other hand, if an invention is genuinely difficult to replicate, it may make more strategic commercial sense to hold

⁷² Other IP issues, such as copyright, and free trade agreement measures, fall outside the scope of this paper, but have been covered in detail elsewhere: see e.g. C.M. Correa, N. Syam and D. Uribe, “Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements” *South Centre Research Paper* 135 (August 2020).

⁷³ H.Y. Kang, “Patents as Assets: Intellectual Property Rights as Market Subjects and Objects” in K. Birch and F. Muniesa (eds.), *Assetization: Turning Things into Assets in Technoscientific Capitalism* (MIT Press 2020).

⁷⁴ Art 33 TRIPS.

⁷⁵ M. Polanyi, *The Tacit Dimension* (Chicago University Press, 1966) at 4.

⁷⁶ Art 39 TRIPS.

that inventive information as a trade secret, and obtain longer protection than the 20 years a patent allows.

Inadequate patent disclosures, combined with trade secrets and tacit know-how, can obscure the theoretically assumed balance between IP restrictions and public interest. Such an overlap of varied IP rights with differential levels of – or no – disclosure is exacerbated in a pandemic, when trade secrets obstruct the sharing of know-how and the technology transfer needed for vaccine manufacturing. For example, although Moderna declared in 2020 that it would not enforce its patents related to COVID-19 vaccines during the pandemic, this did not encompass trade secrets and know-how, and excluded tech-transfer. Moderna admitted that without relevant know-how and technology transfer, others seeking to manufacture their vaccine face significant hurdles, for example, in scaling up manufacturing.⁷⁷ This calls into question the rationale behind Moderna's promise or indeed their good faith in making it. To be effective, the TRIPS waiver must address both patents and undisclosed information.

Patents

Patent law requires the disclosure of information about the invention seeking patent protection with the aim of making this info publicly available. The pandemic has exposed key deficiencies in the level of disclosure within the patent system. There are three specific deficiencies in this context. The first is the insufficiency of disclosure that has developed doctrinally and in practice and that does not necessarily match the requirement of disclosure as a *quid pro quo* for the grant of a patent. The second is the fact that there is a lag in publication of patent applications, either individually, or within patent families. The third is demonstrated by the strategic possibilities created by overlapping patent rights. These three deficiencies make it difficult to disentangle the patent thicket.

⁷⁷ "Moderna sees no impact on COVID-19 vaccine from potential patent waiver" *Reuters* (6 May 2021) available at <https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-raises-2021-sales-forecast-covid-19-vaccine-192-blh-2021-05-06/> (last accessed 19 October 2021).

On the first, patents require inventors to disclose information about their inventions, yet arguably not in significant scientific or technical detail.⁷⁸ The patent system sets up a race – for the first to file an application – meaning that disclosure often occurs early in the process.⁷⁹ In practice, the disclosure requirement underperforms, and speculative filing of merely plausible information is common.⁸⁰ Patent law typically does not mandate further disclosures post-grant, when underlying technologies may become better understood. Details regarding manufacturing processes are not revealed in a patent application, or can be fragmented in multiple applications. Additionally, information generated to fulfil regulatory requirements (discussed below) is not currently linked to the patent disclosure.⁸¹

Second, IP offices are only obliged to publish patent applications within 18 months of filing - during this period the information is inaccessible to the public. In practice, delays can take years.⁸² Therefore, it remains unclear which patents actually exist in the COVID-19 vaccine field.⁸³

Third, the existence of overlapping rights makes it much harder to decipher the IP landscape.⁸⁴ Multiple patent applications with minor modifications from an original application are collated into patent families, with dozens, even hundreds, of patents existing over the same product. This can result in a *de facto* extension of patent protection beyond 20 years.⁸⁵ Companies can amass vast numbers of patents to increase the duration and scope of their monopolies.⁸⁶ As a result, there are already

⁷⁸ H.S. Frost, “The Unique Problem of Inventions Which Are Fully Enabled and Fully Described, But Not Fully Understood (Merrell Dow’s Terfenadine Revisited)” (2007) 20 *Intellectual Property Journal* 369.

⁷⁹ For example: S.B. Seymore, “The Teaching Function of Patents” (2010) 85 *Notre Dame Law Review* 621.

⁸⁰ J.C. Fromer, “Patent Disclosure” (2009) 94 *Iowa Law Review* 539.

⁸¹ W.N. Price and A. Rai, “Are Trade Secrets Delaying Biosimilars?” (2015) 348 *Science* 188.

⁸² USP Application 2021003085.

⁸³ For the most detailed database of known COVID-19 vaccine patents see <https://medicinespatentpool.org/what-we-do/vaxpal/>

⁸⁴ S. Thambisetty, “Patents as Credence Goods” (2007) 27 *O.J.L.S.* 707.

⁸⁵ 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.

⁸⁶ EU Commission, *Antitrust: shortcomings in pharmaceutical sector require further action* (8 July 2009) IP/09/1098.

patent thickets in the mRNA vaccine field.⁸⁷ This hinders the swift sharing of scientific and technical information.⁸⁸

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

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

We define undisclosed information broadly here to include not only trade secrets, but also information about the invention, such as data gathered during the regulatory approval process.⁸⁹

Trade secrets are, by their nature, not disclosed publicly. In normal business practice, holders of IP related to vaccines are not obliged to divulge trade secrets and know-how.⁹⁰ Moreover, there are NDAs in place, for instance, between Pfizer, BioNTech and their suppliers.⁹¹

Undisclosed information may also include information that can be protected separately from the IP framework within TRIPS via “data exclusivity” rights that make clinical trial data proprietary. In the US, complex biologics can have 12 years of data exclusivity,

⁸⁷ See C. Martin and D. Lowery, “mRNA vaccines: Intellectual Property Landscape” (2020) 19 *Nature Reviews Drug Discovery* 578.

⁸⁸ M. Gaviria and B. Kilic, “BioNTech and Pfizer’s BNT162 Vaccine Patent Landscape” *Public Citizen* (16 Nov 2020) available at https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/#_ftnref3 (last accessed 17 May 2021).

⁸⁹ M. Risch, “Why Do We Have Trade Secrets?” (2007) 11 *Intellectual Property Law Review* 1.

⁹⁰ B. Mercurio, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review” (2021, forthcoming) *Virginia Journal of International Law* - https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820 (last accessed 19 October 2021).

⁹¹ See “Supply Agreement Pfizer and BioNTech with TriLink Biotechnologies” (9 October 2020) available at <https://contracts.justia.com/companies/maravai-lifesciences-holdings-inc-11469/contract/137780/> (last accessed 19 October 2021).

and in the EU protection can apply for up to 10 years.⁹² 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).⁹³ Even if technical know-how were shared and patents waived, a new generic manufacturer could struggle to bring a product swiftly to the market, unless regulatory data were shared, because clinical trials would need to be conducted from scratch. Nevertheless, expedited or truncated regulatory pathways are possible.⁹⁴

How the TRIPS Waiver Can Address Both Patents and Undisclosed Information

These specific challenges regarding patents (transparency and disclosure) 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. Instead, 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 vaccine production.

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.⁹⁵

⁹² Medicines Law and Policy, *Data Exclusivity in the EU: A Briefing Document* (June 2019) available at <https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf> (last accessed 19 October 2021).

⁹³ J.S. Sherkow, L.L. Oullette, N. Price and R. Sachs, “Are Patents the Cause of – or Solution to – Covid-19 Vaccine Innovation Problems (No!)?” (4 Mar 2021) available at <https://writtendescription.blogspot.com/2021/03/are-patents-cause-of-or-solution-tocovid.html> (last accessed 19 October 2021).

⁹⁴ Indian Ministry of Health and Family Welfare Press Release, 13 April 2021 GOI - <https://pib.gov.in/PressReleasePage.aspx?PRID=1711381> (last accessed 19 October 2021)

⁹⁵ “Brazil, India denounce Dutch generic drug seizure” *Reuters* (30 Jan 2009) available at <https://www.reuters.com/article/us-davos-generic/brazil-india-denounce-dutch-generic-drug-seizure-idUSTRE50T27O20090130> (last accessed 19 October 2021).

On trade secrets we disagree with some arguments brought forward by waiver sceptics in this context. Hilty et al. argue that it is “highly unlikely that the waiver of trade secret protection could be effectively implemented and enforced to propel companies to disclose all relevant know-how”.⁹⁶ Nevertheless, given the absence of adequate industry co-operation on voluntary sharing of trade secrets, this overly pessimistic and unconstructive view equates to justifying a status quo that is failing LMICs. The circumstances under which entities may be forced to disclose commercially sensitive or tacit technical knowledge may be limited; but they are certainly not without precedent. In fact, governments can utilise the waiver - and, if necessary, bring into domestic law accompanying measures - to incentivise and 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 disclosure 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.⁹⁷ In 2020 the US used the Defense Production Act (DPA), invoking national security concerns to scale up domestic vaccine production (Operation Warp speed).⁹⁸

In relation to incentives (carrots), Love offers a way to “unlock” know-how relevant to manufacturing: it could be bought out by governments.⁹⁹ An example of a potential mandate (stick) is shown with the passing by the Brazilian Senate of a compulsory

⁹⁶ RM Hilty, PHD Batista, S Carls, D Kim, M Lamping and PR Slowinski, “Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021” (7 May 2021) available at https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_07_Position_statement_Covid_IP_waiver.pdf (last accessed 19 October 2021).

⁹⁷ R. Bud, *Penicillin: Triumph and Tragedy* (Oxford University Press 2007) 45.

⁹⁸ See: <https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/> (last accessed 19 October 2021).

⁹⁹ J. Love, “Buying out know-how to scale vaccine manufacturing” *Medium* (20 March 2021) available at <https://jamie-love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36> (last accessed 19 October 2021).

COVID-19 patent and know-how licensing bill in September 2021 aimed at forcing companies to share their trade secrets and data.¹⁰⁰ Moreover, Bernd Lange, a German MEP, proposes that the EU Commission “include a clause on technology transfer in future contracts ... so that companies actively transfer knowledge, also to developing countries”.¹⁰¹ In addition, Art 73 of TRIPS provides grounds for the suspension of normal TRIPS powers and obligations in times of national emergency.¹⁰²

At a practical level, we also observe codification of know-how is common via technology transfer contracts. Aspects of the relevant trade secrets can, and do, leak, as occurred recently when a US NGO released part of the Pfizer-BioNTech mRNA vaccine “recipe” found in a publicly available contract.¹⁰³

Regulatory requirements sometimes force originator and manufacturers to codify and submit some of relevant tacit knowledge. 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.¹⁰⁴ The introduction of a waiver on such data exclusivities (to support the TRIPS waiver) in regions/countries where this is relevant could be efficacious. Domestic legislation could also facilitate the sharing of regulatory data between the relevant medical authorities in one country and those of another, facilitating distributed production.¹⁰⁵ Such measures would not be entirely novel and would certainly not be inappropriate in a pandemic situation. Greater sharing would enable potential manufacturers to connect public IP knowledge (patents) with regulatory knowledge (data and codified know-how).¹⁰⁶

¹⁰⁰ R. Castro de Figueiredo, ‘Brazilian President’s Assent to the bill on the Compulsory Licensing of Covid-19 Vaccines’ Patents’ Kluwer Patent Blog (14 September 2021) - <http://patentblog.kluweriplaw.com/2021/09/14/brazilian-presidents-assent-to-the-bill-on-the-compulsory-licensing-of-covid-19-vaccines-patents/> (last accessed 19 October 2021)

¹⁰¹ See Official Letter sent to the EU Commission by Lange, available at <https://twitter.com/berndlange/status/1394902774832373760> (last accessed 19 October 2021).

¹⁰² F. Abbott, “The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic” *South Centre Research Paper* 116 (August 2020).

¹⁰³ See <https://www.citizen.org/article/a-piece-of-the-covid-vaccine-recipe/> (last accessed 19 October 2021).

¹⁰⁴ E. ’t Hoen, P. Boulet, B. Baker, “Data exclusivity exceptions and compulsory licensing to promote generic medicines in the EU” (2017) 10 *Journal of Pharmaceutical Policy and Practice* 19.

¹⁰⁵ R. Li et al, “Timely access to trial data in the context of a pandemic: the time is now” 10 *BMJ Open* (2020)

¹⁰⁶ P. Krishtel and F. Hassan, “Editorial: Share Vaccine Know-How” 374 *Science* (22 October 2021).

V. Is Boosting Production in the Global South Feasible?

During the COVID-19 pandemic, IP rights, coupled with different regulatory approvals, have resulted in market domination by a small number of vaccine makers. Despite production shortfalls and inequitable distribution, COVID-19 vaccine producers have refused offers to collaborate to boost overall production.¹⁰⁷ That monopolies work against building up production capacity is unsurprising. Transnational IP rights tend to impede new manufacturers from entering and competing in the market.¹⁰⁸ The TRIPS waiver can be utilised to enable new competitors to enter the market to increase vaccine production.¹⁰⁹

Building Production Capacity

A common claim against the TRIPS waiver is that it will not alleviate the current vaccine shortage because it will take a long time to build local manufacturing capacity in LMICs; and in the meantime existing HIC/LMIC facilities may be at, or near, capacity.¹¹⁰ The claim that there is no spare HIC/LMIC production capacity has largely been debunked. 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.¹¹¹ In October 2021 the New York Times published an authoritative study which identified ten production sites in the global south - in Argentina, Brazil, India, Indonesia, and South Africa – that

¹⁰⁷ A. Furlong, “Big vaccine makers reject offers to help produce more jabs” *Politico* (14 May 2021) available at <https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/> (last accessed 19 October 2021).

¹⁰⁸ S. Chandrasekharan et al, “Intellectual property rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: Patent landscaping and perspectives of developing country vaccine manufacturers” (2015) 33 *Vaccine* 6366.

¹⁰⁹ T. Amin, “The Folly of Hoarding Knowledge in the COVID-19 Age: Let Vaccine Producers in Poor Countries Help End the Pandemic” *Foreign Affairs* (29 Jan 2021) available at <https://www.foreignaffairs.com/articles/world/2021-01-29/folly-hoarding-knowledge-covid-19-age> (last accessed 19 October 2021).

¹¹⁰ International Federation of Pharmaceutical Manufacturers and Associations, “Towards Vaccinating the World – Landscape of Current Covid-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible “Solution Space” – A Discussion Document” (9 March 2021) available at https://www.ifpma.org/wp-content/uploads/2021/03/Summit_Landscape_Discussion_Document.pdf (last accessed 19 October 2021);

¹¹¹ Furlong, “Big vaccine makers”.

could begin manufacturing mRNA vaccines within a matter of months.¹¹² This goes against what many industry sources, and even some IP commentators, have argued. Assertions that it would take “four years” to build capacity in a country like Bangladesh lack credibility (see the Incepta example above).¹¹³

Building new capacity quickly is feasible. 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 vaccines in three to four months.¹¹⁴ More companies in the global south could be producing COVID-19 vaccines today if technology had been shared.

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.¹¹⁵ Yet, decades of examples prove vaccines and complex medicines can be produced safely in the global south.¹¹⁶ Tamiflu was produced safely in 2005, despite claims that it involved such a complex process that could not be easily replicated.¹¹⁷ Similarly, Indian company Shantha Biotechnics produced a reliable and safe recombinant hepatitis B vaccine in 2009.¹¹⁸ In 2020, Hetero and CIPLA produced Remdesivir in India after similar claims about safety fears.¹¹⁹ Crucially, the WHO is of

¹¹² S. Nolen, “Here’s Why Developing Countries Can Make the Top Covid Vaccines” *New York Times* (22 October 2021).

¹¹³ See comment of Professor Sir Robin Jacob in H. Kuchler, “Will a Suspension of Covid Vaccine Patents Lead to More Jabs?” *Financial Times* (6 May 2021) available at <https://www.ft.com/content/b0f42409-6fdf-43eb-96c7-d166e090ab99> (last accessed 19 October 2021).

¹¹⁴ M. Cheng and L. Hinnant, “Countries urge drug companies to share vaccine know-how” *AP News* (1 March 2021) <https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92afbc3ea9ed519be007f8887bcf6> (last accessed 20 October 2021).

¹¹⁵ S. Gottlieb, “Covid Lessons from Bush’s Effort Against AIDS” *Wall Street Journal* (28 March 2021).

¹¹⁶ There are several key examples in Brazil, China and India as outlined in R.G. Douglas and V.B. Samant, “The Vaccine Industry” (2018) 41 *Plotkin’s Vaccines* 41, e1.

¹¹⁷ Amin, “The Folly of Hoarding Knowledge”.

¹¹⁸ J. Chakma, H. Masum, K. Perampaladas, J. Heys and P.A. Singer, “Indian vaccine innovation: the case of Shantha Biotechnics” (2011) 7 *Globalization and Health* 9.

¹¹⁹ “Remdesivir: Five Indian and Pakistani firms to make drug to “fight coronavirus” *BBC News* (14 May 2020) available at <https://www.bbc.co.uk/news/world-asia-india-52659052> (last accessed 19 October 2021).

the view that the production of COVID-19 vaccines in the global south can be done in a safe and efficient fashion.¹²⁰

Raw Materials

There has been a related claim that the global shortage of raw materials worldwide is more to blame than IP rights for the lack of COVID-19 vaccine supply.¹²¹ In fact, IP barriers are a factor in shortages of raw materials and consumables, preventing workarounds. For example, plastic single-use bioreactor bags have been scarce due to the global dependency on a few suppliers for these materials; crucially, there are currently 2,800 patents covering them, making entering the market as a new supplier onerous.¹²² The TRIPS waiver would apply not just to vaccine end products but also, potentially, to mechanical equipment and components; moreover, international negotiations over the waiver help co-ordinating the global supply of ingredients.

Profit and Price

On price, the status quo IP legal order upholds a system whereby LMICs, such as South Africa, Bangladesh and Uganda have reportedly been charged a higher price than HICs for vaccines;¹²³ 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.¹²⁴

¹²⁰ Aizenman, "Moderna won't share its vaccine recipe".

¹²¹ A. Bourla, "Today I Sent this Letter to Have a Candid Conversation with our Colleagues about the Drivers of COVID-19 Access and Availability" Open Letter published on LinkedIn (7 May 2021) available at <https://t.co/kkk2NbtKAO?amp=1> (last accessed 17 May 2021)

¹²² M. Stoller and D. Barclay, "Why are there Shortages of Plastic Bags needed for Vaccine Production? Monopolies and Patents" *Substack* (11 May 2021) available at <https://mattstoller.substack.com/p/why-are-there-shortages-of-plastic> (last accessed 19 October 2021).

¹²³ C. Paun and A. Furlong, "Poorer countries hit with higher price tag for Oxford/AstraZeneca vaccine" *Politico* (22 February 2021) available at <https://www.politico.eu/article/astrazeneca-vaccine-cost-higher-in-poorer-countries-coronavirus/> (last accessed 19 October 2021).

¹²⁴ P. Patnaik and H.Y. Kang, "The 'Patent Bargain', Public Good & COVID19" *Healthpolicy Watch News* (26 April 2021) available at

Yet, where there are price inequities it is not enough to focus solely on contracts, as if IP is not a core issue. Hilty et al. state: “In the abstract, there was certainly a risk of excessive prices when the vaccines were still under development. Such risk should have been addressed by governments in the framework of the contracts subsidising research on vaccines ...”¹²⁵ Their argument is offered from 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 a matter of private contractual choices is to selectively ignore how IP facilitates asymmetry.¹²⁶ Hilty et al. fail to offer 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, exclusivity protections around regulatory data, and the legal construction of excessive incentives, from pricing and profiteering; we cannot distinguish a culture of trade secrecy from absent transparency; we cannot rely on the free market to provide equitable distribution of vaccines globally any more than we relied on the free market to fund the necessary R&D, or bear the whole risk of developing such vaccines in the first place.

The TRIPS waiver in the Political-Economic sphere

Rather than merely critiquing the TRIPS waiver proposal in legal formalistic terms, we must locate it within its broader economic and political context: the costs of the status quo are borne disproportionately by the world’s poor.¹²⁷ Until the waiver proposal there

<https://healthpolicy-watch.news/the-patent-bargain-public-good-covid-19/> (last accessed 19 October 2021).

¹²⁵ Hilty et al, “Covid-19” at 3.

¹²⁶ O. Dyer, “Covid-19: Countries are learning what others paid for vaccines” *BMJ* (29 Jan 2021)

¹²⁷ Economist Intelligence Unit, “How much will vaccine inequity cost?” (2021) available at <https://www.eiu.com/n/campaigns/how-much-will-vaccine-inequity-cost/> (last accessed 19 October 2021).

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 envisaged precisely this: utilising the waiver as policy leverage by legal threat.¹²⁸ Although waiver negotiations continue, the proposal has already had several positive impacts in this respect, regarding increased transparency about vaccine manufacturing and pricing.¹²⁹ The waiver proposal has been utilised as a lever to encourage industry co-operation in voluntary deals;¹³⁰ and/or as a demand to mandate knowledge sharing and participation in global measures, such as the WHO-led mRNA hub in South Africa.¹³¹ In light of growing and widespread pressure arising from the waiver, it is not surprising that some companies, such as Merck, prefer a controlled, voluntary transfer of information to enable COVID-19 treatments to be produced widely.¹³²

VI. Does Compulsory Licensing Provide a Viable Alternative to the TRIPS Waiver?

Apart from its political weight, the TRIPS waiver offers substantial practical and legal benefits over the (current) burdensome compulsory licensing system.¹³³ 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

¹²⁸ The Independent Panel, *COVID-19: Make it the Last Pandemic* (May 2021) at 14 https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

¹²⁹ Erfani, Gostin and Kerry, “Beyond a symbolic gesture”.

¹³⁰ See BioNTech-Biovac agreement of July 2021 - “South African firm to help make Pfizer/BioNTech COVID vaccine” Reuters (21 July 2021) available at <https://www.reuters.com/business/healthcare-pharmaceuticals/pfizerbiontech-strike-south-africa-covid-19-manufacturing-deal-with-biovac-2021-07-21/> (last accessed 20 October 2021).

¹³¹ Krishtel and Hassan, “Editorial: Share Vaccine Know-how”.

¹³² See <https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countri/> (last accessed 19 October 2021).

¹³³ J. Bacchus, “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines” (December 2020) available at <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines> (last accessed 19 October 2021);

one such emergency. Yet, the fragmented and complex existing COVID-19 IP landscape means the existing system of compulsory licensing under TRIPS, and the current “TRIPS flexibilities”, are not well suited to addressing vaccine inequity.

In a pandemic context, seeking to use compulsory licensing as a solution to achieving global vaccine equity has six significant drawbacks.¹³⁴ The first is that a CL can only be applied for on a product-by-product, and country-by-country basis. A blanket CL in all states for e.g. COVID-19 vaccines is not possible under TRIPS. Second, the WTO system sets down minimum criteria for a CL under Art 31 (TRIPS), but nation states can impose additional requirements for a CL, meaning the procedures for obtaining a CL 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 a challenge, or of trade sanctions being imposed on them.¹³⁵

Fourth, there are additional obstacles to the use of a CL for vaccines, including regulatory obstacles.¹³⁶ 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. Fifth, when a CL is issued, the rights holder must be provided with “adequate” remuneration, and asymmetrical conflicts can arise this.¹³⁷

Sixth, Art 31(f) of TRIPS states that products made under a CL must be used “predominantly for supply of the domestic market”. Under Art 31 *bis*, in theory a CL for export and import is now possible.¹³⁸ Yet there are obstacles to using Art 31 *bis*, including the fact that some countries/regions (e.g. the EU) have opted out of Art 31 *bis* as importing members.¹³⁹ Conditions for using Art 31 *bis* are onerous. To date this provision has only ever been used effectively once, when Rwanda obtained access to

¹³⁴ 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.

¹³⁵ E. 't Hoen et al., “Medicine procurement and the use of flexibilities in the agreement on Trade-Related aspects of intellectual property rights, 2001–2016” (2018) 96 *Bull World Health Organ* 85.

¹³⁶ 't Hoen, Boulet, and Baker, “Data exclusivity exceptions”.

¹³⁷ H. Wong, “The case for compulsory licensing during COVID-19” (2020) 10 *Journal of Global Health*.

¹³⁸ Amendment of the TRIPS Agreement. WTO Doc. WT/L/641 (Dec. 8,2005) (hereafter Article 31 *bis*).

¹³⁹ See WTO, ‘Annex and Appendix to the TRIPS Agreement (note 3) https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm.

generic HIV TriAvir by importing this from the Canadian company Apotex.¹⁴⁰ Even in that context, Rwanda did not obtain its first shipment of medicines until 15 months after notification.¹⁴¹ In May 2021, Bolivia made a declaration to the WTO that it is seeking supply of the J&J vaccine from the Canadian company Biolyse via a CL under Art 31 *bis*.¹⁴² Bolivia's filing demonstrates that it is difficult to determine which patents and patent applications are relevant for a CL process; and the delays in the processing of the Bolivia/Biolyse application indicate, once again, the limits of Art 31 *bis* when applied in a rapidly evolving technological and heavily patented field.¹⁴³

We must also avoid the error of viewing the TRIPS waiver and compulsory licensing as entirely an either/or situation. There can be reciprocity between the two approaches. COVID-19 has already resulted in some countries modifying compulsory licensing laws to make it easier for CLs to be used at the national level.¹⁴⁴ Recent US support for a TRIPS waiver was accompanied by the use of permissive language on CLs (in the relevant US Trade Representative report).¹⁴⁵ 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. Accordingly, 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).¹⁴⁶ Nonetheless, a TRIPS waiver offers clear benefits that the mere use of CLs under TRIPS simply cannot achieve.

¹⁴⁰ H. Hestermeyer, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines" *ASIL Insights* (10 December 2007).

¹⁴¹ B. Anderson, "Better Access to Medicines: Why Countries are getting "Tripped" up and Not Ratifying Article 31 Bis" (2010) *Case Western Reserve Journal of Law, Technology and the Internet* 165.

¹⁴² "Bolivia outlines vaccine import needs in use of WTO flexibilities to tackle pandemic" (12 May 2021) available at https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm (last accessed 19 October 2021).

¹⁴³ B. Blanco. "With one simple decision, the Canadian government can save lives" *Aljazeera* (28 September 2021) available at <https://www.aljazeera.com/opinions/2021/9/28/the-canadian-government-can-save-bolivian-lives> (last accessed 20 October 2021).

¹⁴⁴ 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.

¹⁴⁵ Office of the US Trade Representative (USTR), *2021 Special 301 Report* (2021) at 34 available at [https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20\(final\).pdf](https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf) (last accessed 19 October 2021).

¹⁴⁶ J.L. Contreras, "US Support for a WTO Waiver of COVID-19 Intellectual Property – What Does it Mean?" (7 May 2021) available at

VII. The TRIPS Waiver and Innovation Incentives – will the Waiver ‘kill innovation’?

Critics of the TRIPS waiver claim the waiver could be weakening the incentives for pharmaceutical innovation.¹⁴⁷ While many scholars have called for a rethink of the dominance of patents and other IP rights in the global innovation ecosystem,¹⁴⁸ others have argued that a TRIPS waiver could sound the death knell of the industry.¹⁴⁹

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.¹⁵⁰ Even so, innovation is often stated as the aim of IP.¹⁵¹ 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.¹⁵²

In the IP context, the term “incentive” is loaded with assumptions.¹⁵³ 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.¹⁵⁴ Landes and Posner

<https://blog.petrieflom.law.harvard.edu/2021/05/07/wto-waiver-intellectual-property-covid/> (last accessed 20 October 2021).

¹⁴⁷ Hilty et al, “Covid-19”.

¹⁴⁸ P. Drahos and J. Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Routledge 2002) at 196-97.

¹⁴⁹ R. Gupta and R. Ramachandran, “A Covid-19 Vaccine IP Waiver won’t kill Pharma innovation” *Bloomberg* (24 September 2021) - <https://news.bloomberglaw.com/ip-law/a-covid-19-vaccine-ip-waiver-wont-kill-pharma-innovation>

¹⁵⁰ F. Machlup & E. Penrose, “The Patent Controversy in the Nineteenth Century” (1950) 10 *The Journal of Economic History* 1-29.

¹⁵¹ J.A. Schumpeter, *Business Cycles: A Theoretical, Historical and Statistical Analysis of the Capitalist Process* (McGraw – Hill Book Company Inc 1939); J Jewkes, *The Sources of Invention* (MacMillan & Co. Ltd 1958); J.A. Allen, *Scientific Innovation and Industrial Policy* (Elsevier 1967).

¹⁵² Allen, *Scientific Innovation*.

¹⁵³ M. Biagioli, “Weighing intellectual property: Can we balance the social costs and benefits of patenting?” (2019) 57 *History of Science* 140.

¹⁵⁴ A. Jaffe and J. Lerner, *Innovation and its Discontents* (Princeton University Press 2007); J. Bessen and M. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton University Press 2009). F. Lévêque and Y. Ménière, “Patents and Innovation: Friends or Foes?” (CERNA 2007).

remark: “[W]hether the benefits exceed the costs is impossible to answer with confidence on the basis of present knowledge.”¹⁵⁵

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.¹⁵⁶ Indeed, Jamie 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 patent incentives from biomedical innovation.¹⁵⁷ Despite this, opposition to the TRIPS waiver often involves the fortification and amplification of IP through heroic innovation narratives.¹⁵⁸ Such mythologies bolster the international IP system and the fluidity of global capital via IP rights.

In light of this we must be wary of the inexact ways in which the terminology is used, especially in rhetoric about COVID-19 vaccines, given the oligopolistic vaccine market.¹⁵⁹ Even if we proceed on the basis that that patent law does create some incentives, we must ask the question: what specific practices is the patent system incentivising?¹⁶⁰

Analysing the Argument That the TRIPS Waiver Will Weaken Incentives

Hilty et al state that a “comprehensive waiver of IP rights will likely have a detrimental effect on incentives for drug innovation” leading IP holders to abandon vaccine innovation.¹⁶¹ 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

¹⁵⁵ W. Landes and R. Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press 2003) 310 (at n 5).

¹⁵⁶ R.C. Feldman, et al. “Negative innovation: when patents are bad for patients” (2021) 39 *Nature Biotechnology* 914.

¹⁵⁷ J. Love, ‘KEI statement in House hearing on Unsustainable Drug Prices (Part III)’ *KEI* (19 May 2021) available at <https://www.keionline.org/36222> (last accessed 19 October 2021).

¹⁵⁸ D. Crow, “Pfizer chief Albert Bourla: ‘We are the most efficient vaccine machine’” *Financial Times* (13 August 2021) – available at <https://www.ft.com/content/97c597dc-03b1-4ece-a302-f9793698ded6> (last accessed 19 October 2021)

¹⁵⁹ Jewkes, *Sources of Invention*.

¹⁶⁰ H.Y. Kang, ‘Patents as Credit – When Intellectual Property Becomes Speculative’ (2015) 194 *Radical Philosophy* 29, at 30–31.

¹⁶¹ Hilty et al, “Covid-19”.

pandemic comes around the pharmaceutical industry may not produce vaccines and treatments. This is a contested claim. Even taken on its own terms it is hardly a ringing endorsement of the status quo.¹⁶² Rather it is an admission that the current system's incentives are misaligned to the extent that pharmaceutical companies can demand patents be kept perpetually strong as a kind of ransom against states.¹⁶³

Notably, in the past the market has not been very good at responding to calls for pandemic preparedness, in part because the way IP incentives operate.¹⁶⁴ There have been prominent examples of market failures with respect to producing vaccines for LMICs.¹⁶⁵ Failures also occurred in the responses to Zika and Ebola.¹⁶⁶ 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.¹⁶⁷

A type of 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".¹⁶⁸ This statement confuses the incentive mechanism of IP with the transactability provided by such rights. The claim seems to be that the TRIPS waiver would remove an incentive of the developers of the original product to provide know-how or trade secrets to manufacturers of biosimilars under non-disclosure agreements (a non-IP measure) on the back of voluntary licences. However, this presumes sufficient incentives already exist to encourage know-how transfer, which is simply not the reality. As detailed above, the IP framework actually encourages a protectionist approach to vaccine IP, including trade secrets.

¹⁶² D.J. Hemel and L Larrimore Ouellette, "Innovation Policy Pluralism" (2019) *Yale Law Journal* 128.

¹⁶³ Z. Rizvi, "Pfizer's Power" *Public Citizen* (19 October 2021) – available at <https://www.citizen.org/article/pfizers-power/> (last accessed 19 October 2021)

¹⁶⁴ A.S. Rutschman, "The Mosaic of Coronavirus Vaccine Development: Systemic Failures in Vaccine Innovation" *Journal of International Affairs* (21 March 2020).

¹⁶⁵ D.C. Kaslow, S. Black, D.E. Bloom, M. Datla, D. Salisbury & R. Rappuoli, "Vaccine candidates to poorer nations are going to waste" (2018) 564 *Nature* 334.

¹⁶⁶ M. Herder, J.E. Graham and R. Gold, "From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine" (2020) 7 *Journal of Law and the Biosciences* 1.

¹⁶⁷ J. Lezaun and C.M. Montgomery, "The Pharmaceutical Commons: Sharing and Exclusion in Global Health Drug Development" (2015) 40 *Science, Technology, & Human Values* 3.

¹⁶⁸ Communication from the EU to the WTO General Council Urgent Trade Policy Responses to the COVID-19 Crisis Brussels (4th June 2021) available at https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159605.pdf (last accessed 19 October 2021).

Even if one accepts the rhetoric of IP as innovation incentive in normal circumstances, the narrative makes very little sense in the extraordinary context of COVID-19-related vaccine IP. This is because, the COVID-19 vaccine market has been created 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 will de-incentivise R&D in science and technology is thus unconvincing. Defenders of the status quo tend to understate the risks of the current pandemic for global public health and overstate the risk to the overall IP system from the temporary, COVID-focused waiver proposal. In fact, there is a tangible risk that privately held IP monopolies and profit maximisation strategies may actually create the *wrong* incentives in the short-term pandemic context, prioritising the production and distribution of HICs’ third (and subsequent) booster doses rather than first doses for LMICs.¹⁶⁹

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

Over the past 26 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, creating fluidity of capital.¹⁷⁰ 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).¹⁷¹ 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:

¹⁶⁹ N. Triggles, “UK orders another 60m from Pfizer” *BBC* (28 April 2021) available at <https://www.bbc.co.uk/news/uk-56921018> (last accessed 19 October 2021).

¹⁷⁰ K. Pistor, *The Code of Capital* (Princeton University Press 2019).

¹⁷¹ S. Oddi ‘TRIPS – Natural Rights and a Polite Form of Economic Imperialism’ (1996) 29 *Vanderbilt Journal of Transnational Law* 415 at 423.

Germany's post-war constitution says that human life is inviolable, I'd say the same about intellectual property ... If the firms were all American I don't think we'd have had this proposal.¹⁷²

Aside from the problematic equation of the right to human life with IP,¹⁷³ it is necessary to unpack this claim regarding "inviolability". In fact, IP rights are historical monopolies that have become socially constructed rights: they are not "discovered" or natural property rights.¹⁷⁴ Oddi states that the "natural right in IP" theory only gained resonance during the negotiations that led to TRIPS.¹⁷⁵ Despite IP's ubiquity, there is still no consensus on its justification.¹⁷⁶ 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.¹⁷⁷

An undifferentiated and uncritical understanding of IP – whether as inviolable property and/or as innovation incentive – tends to ignore that effects of IP rights play out differently 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. Yet, TRIPS fails to account for differential national socio-economic conditions in different states; IP cannot serve differential international public interests equally because there is insufficient space for countries to tailor their design domestically to fit local needs and conditions.¹⁷⁸ TRIPS was not designed to

¹⁷² D. Scally, "Curevac investor sees bright future for German vaccine maker" *The Irish Times* (20 May 2021) available at <https://www.irishtimes.com/business/health-pharma/curevac-investor-sees-bright-future-for-german-vaccine-maker-1.4568758> (last accessed 19 October 2021).

¹⁷³ Committee on Economic, Social and Cultural Rights, *Statement on universal affordable vaccination for COVID-19, international cooperation and intellectual property* E/C.12/2021/1 stated that: '[B]usiness entities should also refrain from invoking intellectual property rights in a manner that is inconsistent with the right of every person to access a safe and effective vaccine for COVID-19 or to the right of States to exercise TRIPS flexibilities.'

¹⁷⁴ M. Biagioli, 'Patent Republic' (2006) 73 *Social Research* 1129.

¹⁷⁵ Oddi, 'TRIPS'.

¹⁷⁶ R. Merges, *Justifying Intellectual Property* (Harvard University Press 2011).

¹⁷⁷ Q. Slobodian, "Are Intellectual Property Rights Neoliberal? Yes and No" (2021) *ProMarket* (18 April 2021) available at <https://promarket.org/2021/04/18/intellectual-property-rights-neoliberal-hayek-history/> (last accessed 19 October 2021).

¹⁷⁸ S. Lall with collaboration of M. Albaladejo, "Indicators of the Relative Importance of IPRs in Developing Countries" *Issues Paper no. 3, UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development* (Geneva, 2003).

meaningfully accommodate such variation despite some favourable language in Articles 7¹⁷⁹ and 66.¹⁸⁰ 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.¹⁸¹ However, when IP rights are couched in "property" terms, often naturalised without a regard for their overall social justification, this important history is lost.¹⁸²

Insights from the pharmaceutical industry in the pre- and post-TRIPS eras are useful here. During the 19th and 20th centuries several major states, including, for example, the Netherlands, abolished patent rights for a period in order to build up domestic industry; while others deliberately weakened IP rights to enhance domestic technological capacities.¹⁸³ 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.¹⁸⁴ 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.¹⁸⁵ These are hard to cede. Nonetheless, amid a pandemic, extraordinary measures such as the TRIPS waiver cannot be viewed as disproportionate to global needs.

¹⁷⁹ Art 7 TRIPS.

¹⁸⁰ Art 66 TRIPS.

¹⁸¹ Commission on Intellectual Property Rights *Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights* (2002).

¹⁸² G.S. Alexander, E.M. Penalver, J. Singer and L. Underkuffler, 'A statement of progressive property' (2009) 94 *Cornell Law Review* 743.

¹⁸³ G. Dutfield, *That High Design of Purest Gold*.

¹⁸⁴ G. Dutfield and U. Suthersanen, *Dutfield and Suthersanen on Global Intellectual Property Law*. (Edward Elgar 2020) 172.

¹⁸⁵ For example, see: PhRMA, 'PhRMA Statement on the WTO TRIPS IP Waiver' (May 2021) available at

<https://www.phrma.org/Press-Release/PhRMA-Statement-on-WTO-TRIPS-Intellectual-Property-Waiver> (last accessed 19 October 2021).

Conclusion: Vaccine Equity and Beyond – What will the Legacy of the TRIPS waiver be?

The history of the TRIPS negotiations and the 2001 Doha Declaration process demonstrates that IP law cannot be separated from global political economy or broader concerns of public interest.¹⁸⁶ 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 abused. The debate has changed the discourse the overall political legitimacy of IP law, and has shifted the way public health concerns are articulated with regard to IP monopolies.

In particular, a global emergency like COVID-19 makes visible the fact that inequities of knowledge governance within capitalism and dysfunctions of the market cannot be separated from IP law. The contested use of “equity” in debates around the TRIPS waiver is one representative expression of the deep inequality transnational IP generates, and of disagreements about the role of law in addressing this injustice. The term “vaccine equity” in this respect takes on a new meaning – equity in this context implies not only fairness, but *wealth sharing*. Vaccine equity does not, and cannot equate to, mere donations. Equity requires technology transfer to enable regional production in the global south, linking the law explicitly to outcomes.

This positive momentum towards change in the political-economic structure around TRIPS must not be allowed to dissipate. Legal scholarship can contribute by interpreting and understanding intellectual property 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.

¹⁸⁶ SK Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003).

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