The IP waiver and COVID-19: reasons for unwavering support

Katarina Foss-Solbrekk

I. Introduction

Inequitable access to coronavirus disease 2019 (COVID-19) products, particularly vaccines, is a pressing problem. Dr Tedros, the Director-General of the World Health Organization (WHO), announced in late April 2021 that only 0.3 per cent of the COVID-19 vaccines administered have reached the citizens living in developing countries. Little has changed since then. On 5 July 2021, Padma reported that, according to recent data, ‘only 1% of people in low-income countries have been given at least one dose.’ This is not surprising when developed countries account for 6 billion of the total 8.6 billion dosages purchased so far. Indeed, most of these were purchased before developing countries could even begin negotiating with pharmaceutical companies. Most higher-income countries were able to pre-order enough vaccines to cover their populations several times over, while others had trouble securing any doses at all, resulting in low-income countries only concluding their first vaccine deals in January of 2021, 8 months after the UK struck its first agreement. Bilateral deals between developing countries and pharmaceutical companies, however, are insufficient to meet current levels of demand, especially now that developed countries will administer booster shots, which will ‘use up roughly 440 million doses of the global supply’.

Many developed countries see COVAX as a convenient solution. COVAX is run by the WHO, Gavi and

The author

- Katarina Foss-Solbrekk is a doctorate (DPhil) candidate in law at Oxford University. Email: katarina.foss-solbrekk@law.ox.ac.uk. I would like to thank Luke McDonagh and the editors of the Journal of Intellectual Property Law and Practice for very helpful comments on earlier versions of this article. Any and all errors are of course my own.

This article

- This article supports India’s and South Africa’s proposal for an intellectual property (IP) waiver on COVID-19 tools at the World Trade Organization.
- Compulsory licencing is not a satisfactory solution to vaccine inequality because it is a drug-specific and country-specific process, with legal and administrative complexities for developing countries.
- An IP waiver, however, would allow developing and least developed countries to have better access to COVID-19 vaccines. Although several hurdles must first be overcome, including tech transfers, data disclosures, investments in production capabilities and an end to exports on raw materials, these are not insurmountable. In addition, because of the unprecedented amounts of public funding allocated throughout the vaccines’ development cycle, a waiver would not harm innovation in the short term or medium term by removing incentives to develop essential pharmaceutical products.

© The Author(s) 2021. Published by Oxford University Press. All rights reserved. For permissions, please e-mail: journals.permissions@oup.com
doi:https://doi.org/10.1093/jiplp/jpab150
Advance Access Publication 11 December 2021
the Coalition for Epidemic Preparedness and Innovations (CEPI); via donations of funds and vaccines from developed countries, the organization aims to ensure that developing countries have equitable access to COVID-19 tools. But COVAX has experienced limited success. Despite lofty targets of 2 billion doses to be shipped by end 2021, currently only 150 million doses have reached those countries most in need. Vaccine nationalism remains a hindrance. India suspended exports on vaccines meant for COVAX amid its own COVID crisis in April–May 2021. High-income countries such Canada even availed itself of dosages secured because of its participation in COVAX. Moreover, as Katz confirms: ‘Wealthier countries did bilateral deals with companies like Pfizer and Moderna to lock up contracts’, while there was also a ‘lack of initial investment to COVAX, meaning it was ‘already too late’ by the time COVAX received funds to order vaccines. Purchasing fuel to transport vaccine doses to clinics, training vaccine administrators and persuading people to get vaccinated in developing countries are also cited as factors that have affected COVAX’s impact. Resolving these issues is vital to ensure that vaccines are properly distributed once produced. Against this background, it is understandable why developing countries should have the possibility to produce their own COVID-19 vaccines. Despite certain production ability concerns, it should be noted that vaccine manufacturers in developing countries currently supply over 50 per cent of the vaccines used in immunization programmes in developing countries, allowing for lower prices and with economies of scale and scope.

Compulsory licencing is touted as one pathway for vaccine autonomy. However, compulsory licencing under Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is poorly understood by many developing countries, is rarely used and has serious administrative drawbacks, requiring governmental implementation by each country for each drug. In addition, the WHO Technology Access Pool that was designed to address COVID-19 medical tools access problems is currently unused.

Adopting the COVID-19 intellectual property (IP) waiver would represent a better route to equal vaccine accessibility and allow drug companies, scientific institutions and relevant government bodies to act immediately, without having to wait for state IP licencing. India and South Africa submitted a proposal to the World Trade Organization (WTO) on 2 October 2020 to waive intellectual property rights (IPRs) for COVID-19 products under TRIPS. Said waiver would allow WTO member countries to circumvent patent, copyright, industrial design and undisclosed information rights normally afforded to products targeting COVID-19. According to the proposal, the waiver would ensure that IPRs ‘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’.

Over 100 countries formally support the waiver, and a global petition signed by more than 900,000 people was submitted to the WTO in December 2020, asking governments, pharmaceutical companies and WTO members to

6 WHO, ‘COVAX: Working for Global Equitable Access to COVID-19 Vaccines’ Available at https://www.who.int/initiatives/acct-acce rator/covax (accessed 31 May 2021).
7 See also The Economist Daily Chart, ‘Covid-19 Vaccine Donations Have yet to Take off’ The Economist (5 May 2021). Available at https://www. economist.com/graphic-detail/2021/05/05/covid-19-vaccine-donations- have-yet-to-take-off (accessed 10 May 2021); Thomas J. Bollyky, ‘Democracies Keep Vaccines for Themselves’ The Atlantic (27 March 2021). Available at https://www.theatlantic.com/ideas/archive/ 2021/03/rich-countries-give-money-keep-vaccines-themselves/618437/ (accessed 2 May 2021).
8 Anthony King, ‘Developing Countries Sidelined in Covid 19 Vaccine Scramble’ Chemistry World (Cambridge, 11 August 2021). Available at https://www.chemistryworld.com/news/developing-countries-sidelined-in-covid-19-vaccine-scramble/4014153.article (accessed 24 August 2021).
9 Tulip Mazumdar, ‘India’s Covid Crisis Hits Covax Vaccine-Sharing Scheme’ BBC News (London, 17 May 2021). Available at https:// www.bbc.com/news/world-57135368 (accessed 18 May 2021); Stephanie Findlay and David Pilling, ‘Indian Vaccine Maker Extends Freeze on Export of Covid Jabs’ Financial Times (London, 18 May 2021). Available at https://www.ft.com/content/63fb6b79-f657-4e6c-b190-cf80d6d30 993 (accessed 20 May 2021).
10 Peter Zimnjoc and Catherine Callen, ‘Canada to Take Covax Vaccines, Won’t Share Doses Until Every Canadian Is Inoculated: Anand’ CBC (Toronto, 5 March 2021). Available at https://www.cbc.ca/news/ politics/covax-anand-vaccine-timetab le-1.5939270 (accessed 1 June 2021).
11 King (n 8).
12 Benjamin Mueller and Rebecca Robins, ‘Where a Vast Global Vaccination Program Went Wrong’ NY Times (New York, 2 August 2021). Available at https://www.nytimes.com/2021/08/02/world/europe/covax-covid- vaccine-problems-africa.html (accessed 3 August 2021).
13 Syarifah Liza Munira et al., ‘A Cost Analysis of Producing Vaccines in Developing Countries’ (2019) 21 Vaccine 1245.
14 Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19. Communication from India and South Africa (2 October 2020) IP/C/W/669. Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:IP/ C/W669.pdf&Open= True (accessed 1 May 2021); a revised version of the waiver was submitted on 21 May 2021. The revisions largely concern the scope of the waiver by focusing the text on ‘health products and technologies’ and its duration; see Knowledge Ecology International, ‘A Revised Version of the Waiver Submitted to WTO’ (accessed 7 June 2021).
15 Agreement on Trade-Related Aspects of Intellectual Property Rights, concluded as Annex 1C of the Marrakesh Agreement Establishing the WTO, 15 April 1994.
16 Ibid.
ensure universal access to COVID-19 treatments.17 The USA now supports the IP waiver for COVID-19 vaccines, as does the European Parliament. High-income WTO members such as Germany, the UK, Norway and the EU, however, remain opposed and have thus far blocked the proposal during numerous TRIPS Council meetings, the most recent being in late July 2021, so little progress has been made.

This article supports the calls for an IP waiver on all COVID-19 tools. This is especially crucial for vaccines, the most important measure to combat the pandemic. Although several hurdles must be overcome for the waiver to take effect, including tech transfers, data disclosures, investments in production capabilities and an end to exports on raw materials, these are not insurmountable problems. All in all, the article demonstrates that a waiver would help enable greater access to COVID-19 vaccines in developing and least developed countries. However, action must be taken quickly.

II. The intellectual property waiver for COVID-19 vaccines

Discussions of the waiver reveal two completely opposite interpretations of the role IPRs play in this pandemic. On the one hand, WTO members supporting the proposal stress that IPRs stand in the way of scaling up vaccine production and that the flexibilities offered under TRIPS, such as import–export compulsory licenses, are too cumbersome to be relied upon as a means of enabling access.18 Opposing WTO members, on the other hand, claim that IPRs are a small and insignificant element impacting vaccine production and allocation.19 Indeed, although adopting the waiver would allow third parties to use COVID-19 IP without fear of being sued, it would not automatically help scale up production and address vaccine inaccessibility in developing countries. If it did, additional companies would perhaps already be producing Moderna’s vaccine, given that Moderna has already publicly announced that it will not be enforcing its patents for COVID-19 related patents against those making vaccines intended to combat the pandemic.20 There are thus additional barriers to consider, namely, technology transfers, data disclosures, production capabilities and sourcing the raw materials needed to produce vaccines. It will be shown that these may be overcome, but first it is important to address why the waiver is needed when pre-existing TRIPS flexibilities exist, such as compulsory licences, and why such licences should not be relied upon as the first line of action to enable greater access to COVID-19 vaccines.

A. Why waive if you ‘can’ licence?

Indeed, an important legal question is why IP needs to be waived in the first place, given that countries already have the right to waive the vaccines’ IPR and manufacture generic alternatives under the compulsory licences route under Article 31 of TRIPS, allowing domestic production. As Thambisetty et al. observe, ‘a common argument which has been raised in opposition to the waiver proposal has been to suggest that the WTO system already allows for compulsory licensing so there is no need for a waiver’.21 As an example, in the position statement ‘Covid-19 and the Role of Intellectual Property’, by the Max Planck Institute for Innovation and Competition, Hilty et al. claim that ‘the TRIPS Agreement contains sufficient flexibilities to prevent negative effects of patents’.22 Article 31 TRIPS permits ‘other use of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government’ provided certain criteria are satisfied. To issue a licence, a state must provide adequate remuneration to the respective right holder; attempt to negotiate a voluntary licence with the right holder prior, although this is not required in the event of a national emergency or other circumstance of extreme urgency; use the patent solely for the purpose of its authorization; authorize the licence ‘predominantly for

---

17 World Trade Organization, ‘WTO Receives Petition Asking for Universally Accessible and Affordable COVID-19 Vaccines’ (9 December 2020). Available at https://www.wto.org/english/news_e/news20_e/trip_09dec20_e.htm (accessed 10 May 2021); Over 100 international IP academics also recently signed an open academic letter supporting the waiver and calling on the governments of the UK, Northern Ireland, Norway, Australia, Brazil, Japan, Switzerland and the EU to drop their opposition; see Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal. July 2021. Available at https://docs.google.com/forms/d/e/1FAIpQLSb497EZSw5oN2k46rzDUAYswsABW91OT91QarsaFtvoBLHvQ/viewform (accessed 1 August 2021).

18 Waiver proposal (n 14).

19 WTO, ‘Members to Continue Discussion on Proposal for Temporary IP Waiver in Response to COVID-19’ (10 December 2020). Available at https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm (accessed 1 May 2021).

20 Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic 8 October 2021. Available at https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19 (accessed 10 May 2021).

21 Siva Thambisetty et al. ‘The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic’ (2021) LSE Legal Studies Working Paper 1, 33. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737.

22 Reto M. Hilty et al. ‘Covid-19 and the Role of Intellectual Property Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021’ at 4–5. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3841349.
the supply of the domestic market’, as well as make the licence non-exclusive and subject it to judicial review. All licences must be assessed on a case-by-case basis. Furthermore, countries have the right to import/export pharmaceutical products under Article 31bis; as such, developing countries with no production facilities would have access to ‘generic’ versions. Article 31bis is a TRIPs amendment, passed in the wake of the HIV/AIDS epidemic in the late 1990s, where countries with little or no local manufacturing capabilities were unable to produce drugs locally and at the same time prohibited from importing medicines under a licence due to Article 31(f). This prompted another round of multilateral trade negotiations, resulting in the Doha Declaration in 2001, which affirmed that TRIPs should be interpreted in a manner ‘supportive of WTO Member’s right to protect public health’ and instructed the TRIPs Council to fix the issue of compulsory licences and local manufacturing capabilities. Accordingly, Article 31bis allows for countries to import drugs under a compulsory licence. Many countries’ domestic law authorizes compulsory licences when clearly in the public interest. Protecting one's citizens from the COVID-19 pandemic is so evidently in the public interest and a matter of public health that Article 31 could not be more appropriate if it tried.

Yet, in practice, compulsory licences come with their own set of problems. As countries are free to determine the grounds in which to grant licences, national procedures may differ. Thambisetty et al. therefore that affirm that compulsory licensing under the TRIPs system has ‘considerable drawbacks’: they can, at the national level, be ‘bureaucratic, uncertain and/or time-consuming’. Despite incorporating compulsory licence provisions in their national laws, government officials are sometimes unaware of licencing possibilities available, as well as how to manage the legal and administrative tasks accompanying licences. This applies to both Article 31 and Article 31bis. This issue is exacerbated because compulsory licences must be issued country-per-country, vaccine-for-vaccine basis: countries cannot issue one compulsory licence covering all vaccines. For COVID-19 vaccines using messenger RNA (mRNA) technology, they would also have to go through a web of patents held and licensed by different stakeholders, including various universities and companies, and license accordingly. Trade agreements further complicate this process as these agreements can restrict the grounds in which developing countries may use TRIPs flexibilities. US free trade agreement (FTAs) with Chile, Morocco, Bahrain and the signatories of the Central American-Dominican Republic FTA, that is Guatemala, El Salvador, Honduras, Costa Rica, Nicaragua and the Dominican Republic, require rightholders to either consent to or be notified of a compulsory licence before it may take effect. This is much more time-consuming than a blanket waiver for all IPRs on every COVID-19 vaccine.

Furthermore, with several developing countries lacking domestic manufacturing capacity, they would have to rely on an import/export licence under Article 31bis. To use Article 31bis, countries must first submit a notification to the WTO secretariat. The importing country must notify of its intent to issue a compulsory licence, with information of the product's name and the quantities to be imported, and enforce measures to prevent re-exportation. The exporting country must likewise inform of its intent to grant a compulsory licence, with information specifying the product, export quantities and the final destination, whereby the products must display distinct features signalling that they are produced under the licence, and post this information on a website. As with regular compulsory licences, the grounds for issuing licences remain at the discretion of states themselves, so additional national criteria may apply. For
example, Indian patent law requires applicants to identify health problems in the importing country, and the Canadian Patent Act specifies which medicines qualify for Article 31bis usage and imposes a 2-year time limit. These requirements encumbered the process when India and Canada attempted to utilize Article 31bis.

Article 31bis has only been used successfully once with the Canada–Rwanda licence, whereas the India–Nepal attempt failed. In the case of the latter, Natco, an Indian generic company, withdrew its application to export 30,000 tablets of Tarceva, a cancer drug originally produced by Roche, from India to Nepal, citing a ‘too cumbersome’ process as the reason, inter alia because the Indian Patent Office allowed Roche and Pfizer to attend the hearing of the licence between Natco and the Patent Office. The Canada–Rwanda licence, albeit executed, experienced limited success. It involved a strenuous 4-year process and assistance from several non-governmental organizations. As TriAvar constituted a new fixed-dose combination drug, the Canadian Patent Act did not list it as a drug eligible for a licence. Canada subsequently amended the Act to include the drug in August of 2006.

Further delays ensued as no country expressed an interest in importing the drug publicly before Rwanda in 2007. Médecins Sans Frontières (MSF) originally discussed testing Article 31bis with another unnamed country who retreated from the project in fear, and Rwanda submitted a notification only after the Clinton Health Access Initiative intervened.

Parties to the licence thus reported of procedural inefficiencies, describing the process as complicated, lengthy and with too few incentives to repeat. Elie Betito, the director of public affairs of Apotex, the Canadian company that exported the drugs to Rwanda, stated that ‘it took us more than four years to get to this point. It’s a huge process, with huge costs involved…we will not be doing this again.’ In another press release, Apotex shared that ‘the delay between approval by Health Canada and issuance of the compulsory license highlights the problems with the process as it exists. It is unnecessarily complex and does not adequately represent the interests of those who require treatment.’ MSF similarly labelled the arrangement ‘unworkable.’ These concerns are not just due to IP. Administrative hurdles, procurement decisions, bureaucracy, regulatory review of the medicine and the Canadian law including additional requirements not mentioned in TRIPs all slowed down the process. Importantly, these concerns are not limited to this licence.

The 2016 Report of the United Nations High-Level Panel on Access to Medicines found that Article 31bis fails to represent an effective solution and needs revising. Abbott describes Article 31bis as saddled with unnecessary administrative hurdles. Tanzania’s High Commissioner to Canada shared insight as to how these hurdles hinder Article 31bis usage when he articulated that ‘it’s not that we don’t want to do it, it’s just that we

38 For an outline of all requirements to issue compulsory licences in India, see N. S. Gopalakrishnan and Madhuri Anand, ‘Compulsory Licence Under Indian Patent Law’ in Reto M. Hilty and Kung-Chung Liu (eds) Compulsory Licensing: Practical Experiences and Ways Forward (Springer 2014) 11.
39 Marumo Nkomo, ‘Rwanda’s New Intellectual Property Law and Compulsory Licensing for Export under the WTO: Not Quite a Panacea’ (2013) 21 Africa Journal of International and Comparative Law 279, 291.
40 Bolivia and Biolyse, a Canadian company, have entered into an agreement to export/import COVID-19 vaccines ‘by way of a Compulsory or Voluntary License or Intellectual Property Waiver’: see ‘Bolivia and Biolyse Sign Landmark Agreement for Export of COVID-19 Vaccines’ Press Release via Cision (12 May 2021). Available at https://www.newswire.ca/news-releases/bolivia-and-biolyse-sign-landmark-agreement-for-export-of-covid-19-vaccines-832670191.html (accessed 1 June 2021).
41 Jean-Frédéric Morin and Mélanie B. Forcier, ‘Pharmaceutical Patent Policy in Developing Countries: Learning from the Canadian Experience,’ in Kenneth C. Shadlen et al. (eds) Intellectual Property, Pharmaceuticals and Public Health (Edward Elgar Publishing 2011) 220.
42 Gopalakrishnan and Anand (n 38) 33.
43 Cynthia Ho, Access to Medicine in the Global Economy (OUP 2011) 214.
44 Padmanabha Ramanujam and Yugank Goyal, ‘One View of Compulsory Licensing: Comparative Perspective From India and Canada’ (2014) 18 Marquette Intellectual Property Law Review 369, 401.
45 Kommerskollegium, ‘The WTO Decision on Compulsory Licensing: Does it Enable Import of Medicines for Developing Countries with Grave Public Health Problems?’ (2008) National Board of Trade Report 1, 31.
46 Canadian HIV/AIDS Legal Network, ‘Delivery Past Due: Global Precedent Set Under Canadian Access to Medicines Regime’ (2008) 13 HIV/AIDS Policy & Law Review 1, 5.
47 Harris (n 33) 391.
48 Quote obtained from International Centre for Trade and Sustainable Development ‘First Generic Drugs En Route to Africa under 5-Year-Old WTO Deal Bridges (2008) 12. Available at https://ictsd.iisd.org/bridges/news/bridges/news/first-generic-drugs-en-route-to-africa-under-5-year-old-wto-deal (accessed 10 May 2021).
49 BioSpace Press Release, ‘Apotex Inc. Life Saving AIDS Drug for Africa Gets Final Clearance’ (21 September 2007). Available at https://www.biospace.com/article/releases/apotex-inc-life-saving-aids-drug-for-africa-gets-final-clearance/ (accessed 5 May 2021).
50 Médecins Sans Frontières, ‘Neither Expendituous, Nor a solution: The WTO August 30th Decision is Unworkable’ (29 August 2006). Available at https://msfaccess.org/neither-expeditious-nor-solution-wto-august-30th-decision-unworkable (accessed 10 May 2021).
51 Nicholas G. Vincent, ‘TRIP-ING Up: the Failure of TRIPS Article 31bis’ (2020) 24 Gonzaga Journal of International Law 1, 19–21.
52 Stacey B. Lee, ‘Can Incentives to Generic Manufacturers Save the Doha Declarations Paragraph 6?’ (2013) Georgetown Journal of International Law 1387, 1401.
53 Final Report of the UN Secretary-General’s High-Level Panel on Access to Medicines, September 2016, 9.
54 Frederick M. Abbott and Jerome H. Reichman, ‘Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions,’ (2007) 10 Journal of International Economic Law 921.
haven't because all bureaucratic, administrative and legal requirements take a lot of time. The system is too complicated.' For instance, the notification requirement, albeit seemingly 'simple', involves two risks. Once the notification is public, the original rightsholder may, as Lee observes, 'undercut the price set by the generic manufacturer and keep the market'. It also exposes countries to political and economic pressure from developed countries, as is discussed further below, which is cited as a possible reason for why countries avoid Article 31bis. Even though TRIPs allows countries to skip negotiations for voluntary licenses with rightsholders before issuing compulsory licences in the event of a national health emergency, which the current pandemic clearly is, not all national laws do the same. Negotiations are still required under Canadian law, meaning that, if used as an exporting country, the applicant must negotiate for at least 30 days prior to applying for a compulsory licence. Article 31bis' cumbersome process therefore dissuades countries from utilizing it. As Article 31bis and corresponding national laws have not been amended since, it is unclear why it would be more workable now. Above all, countries do not have the time to wait years for a potential licence to take effect during a pandemic that has already claimed millions of lives.

It is worth noting that it might be possible to grant a compulsory licence under Article 31bis with multi-country benefits. A 2008 report published by Sweden's National Board of Trade suggests 'pooling through the Regional Trade Agreement (RTA) exception in the [Doha] Decision'. The wording of Article 2(b) of the Doha Declaration technically allows for compulsory licences to deliver products to multiple countries by stating that only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS.

This possibility applies to developing or least developed countries that are signatories to RTAs falling within the scope of Article XXIV of the General Agreement on Tariffs and Trade (GATT), which regulates RTAs. Six African RTAs qualify. Such a pooling arrangement would allow countries to export products imported under Article 31bis to other countries in need and 'form a de facto regional compulsory license', provided each country issues a licence and the countries share the same health problem. Countries not party to an African RTA may also partake in the scheme, as an RTA country may issue a licence encompassing the medical demand for all the countries involved and the exporting party would supply correspondingly. This arrangement is yet to be tested, and for it to operate, several countries would have to coordinate, and different socio-economic, cultural and political variables align. As the national procedures to issue licensees vary for each state, granting multiple ones simultaneously may encounter difficulties. Many African countries have also not accepted the Article 31bis amendment, and it is unclear whether these countries will during the pandemic. Even if they did, it would still not circumvent the administrative issues listed above (if anything, it would require more administration), nor assuage the political and economic pressures developing countries encounter from developed countries while attempting to grant compulsory licences.

Communications published in June 2017 from Brazil, China, Fiji, India and South Africa confirm that this pressure is a reason why many states do not use TRIPs flexibilities. When developing countries have attempted to utilize compulsory licences in the past, many encountered international pressure from developed countries and companies or trade-related repercussions.

55 Médecins Sans Frontières (n 50) 5.
56 Lee (n 52) 1416–1417.
57 Nkomo (n 39) 289–290.
58 Ibid 288.
59 Lee (n 52) 1414–1415; Tolulope A. Adekola, ‘Has the Doha Paragraph 6 System Reached its Limits?’ (2020) 15 JIPLP 525.
60 Kommerskollegium (n 45) 60.
61 The General Agreement on Tariffs and Trade, Marrakesh Agreement Establishing the WTO, Annex 1A, 15 April 1994, 1867, U. N. T.S 187; at least 50% of the countries in the RTA must be least developed countries. For an in-depth explanation, see Adèkola (n 60).
62 The Decision on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (‘Enabling Clause’) 28 November 1979 GATT Doc L/4903 at para 2(c), Kommerskollegium (n 45) 60.
63 For a list of African RTAs, see Kommerskollegium (n 45) 60.
64 Lee (n 52) 1415.
65 Ibid 1416.
66 WTO Members Accepting Amendment of the TRIPS Agreement. Available at https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed 1 June 2021).
67 ‘The Political and Economic Pressure Placed on Governments to Forgo the use of TRIPS Flexibilities Violates the Integrity and Legitimacy of the System of Legal Duties and the Rights Created by the TRIPS Agreement, as Reaffirmed by the Doha Declaration’; see in Full: Communication from Brazil, China, Fiji, India and South Africa, IP/C/W/630. (6 June 2017) para 6. Available at https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_0009-DF.aspx?language=E&CatalogueList=236687,236668,236642,236531,236234,235970,235898,234979&CurrentCatalogueIndex=0&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=False&HasSpanishRecord=False (accessed 1 May 2021).
68 Michael Palmedo and Srividhya Ragavan, ‘The U.S. Posture on Global Access to Medication & the Case for Change’ (May 2021) 1, 5. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3838856 (accessed 1 May 2021).
Thailand issued compulsory licences for two drugs, one authorized to treat HIV/AIDS and the other coronary artery disease; Abbott, the manufacturer, initially withdrew all awaiting registration and refused to register any new drugs in Thailand. 69 Thailand, moreover, received a letter from Peter Mandelson, the European Commissioner for Trade, contesting the need for the licence as a compulsory licence allegedly constitutes an ‘exceptional measure’ that ‘would be detrimental to the patent system’ and ‘could lead to the isolation of Thailand from the global biotechnology community’. 70 The US Trade Representative elevated Thailand’s ranking on the Priority Watch List in its Special 301 Report 71 and withdrew duty-free access on three Thai products. 72 When South Africa attempted to incorporate compulsory licence provisions into its national law in the wake of the HIV/AIDS crisis, 40 pharmaceutical companies, as well as the South African Pharmaceutical Manufacturers Association, sued the South African government. 73 Sir Leon Brittan, then vice-president of the European Commission, asserted in a letter to the South African Vice President Thabo Mbeki that the South African Act appeared ‘to be at variance with South Africa’s obligations under TRIPS’ and disrupted ‘the interest of the European pharmaceutical industry’. 74

In addition to these difficulties, compulsory licences are too narrow in scope to increase the production of COVID-19 vaccines on their own without a waiver. A significant benefit of the waiver compared to compulsory licences is that the waiver concerns all IP, while compulsory licences only apply to patents, which is problematic. As Contreras notes, ‘vaccines are complex and volatile products, so patents alone are generally not sufficient to enable a manufacturer to reproduce another company’s products’, while a waiver could enable countries to use ‘suspend trade secret protection’ without violating TRIPs and ‘incurring international trade sanctions’. 75 Mandatory action is necessary when voluntary initiatives that could achieve the same result as a waiver exist but are not used. The WHO ‘COVID-19 Technology Access Pool’ allows companies to voluntarily share their IPRs, technology transfers and know-how relevant to drugs, vaccines and diagnostic developments in said Pool, which will then be available for free or licensed. 76 None of the vaccine producers have shared their IP via the Pool, meaning it is as of now not a feasible option to improve access. The Open Covid Pledge has also been signed by a large range of companies such as IBM, Facebook and Fujitsu, 77 as well as institutions, committing to ‘making all of their patents freely available to the public for use in the fight against COVID-19’. 78 However, pharmaceutical companies producing vaccines have yet to make a pledge.

This is where the waiver can help. Because voluntary mechanisms are not being utilized, the waiver can incentivize pharmaceutical companies to make use of these initiatives, saving countries from issuing individual compulsory licences. Or, if countries choose to issue compulsory licences, the waiver can give countries the political and international support needed should they encounter any legal, political or trade consequences. More importantly, if adopted, the waiver can enable more IP to be shared and allow developing countries to produce their own vaccines, saving countries from relying on pharmaceutical companies and other countries, provided three additional factors fall into place.

B. Putting the waiver into effect

In terms of practical effect, opponents argue that the main issue with the proposed waiver is that it fails to address three significant issues. 79 First, pharmaceutical companies would still have to share vital technology and data in order for new companies to manufacture the vaccines safely, necessitating a type of technology transfer and disclosure of confidential clinical trial data. 80 Second, there is the practical issue of production capabilities, i.e. finding

69 Dipika Jain and Jonathan J. Darrow, ‘An Exploration of Compulsory Licensing as an Effective Policy Tool for Antiretroviral Drugs in India’ (2013) 23 Health Matrix 425, 450.
70 For Letter, Available at https://www.wlc.american.edu/pijip_static/documents/mandelson07102007.pdf (accessed 1 June 2021).
71 Beatrice Stirner, ‘Learning from Practice: Compulsory Licensing Cases and Access to Medicine’ (2012) 1 Pharmaceutical Patent Analyst 555, 564.
72 Jerome H. Reichman, ‘Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options’ (2009) 23 Journal of Law, Medicine and Ethics 247, 258.
73 ‘t Hoen (n 26) 30.
74 Ibid 31.
75 Jorge Contreras, ‘US Support for a WTO Waiver of COVID-19 Intellectual Property’ (2021) 56 Inter economies 179, 180.
76 The WHO Determines Further Details of Arrangement With the Rightsholder, see WHO, ‘C-TAP: A Concept Paper’ (27 October 2020). Available at https://www.who.int/publications/m/item/c-tap-a-concept-paper (accessed 4 June 2021).
77 Jorge Contreras, ‘Putting Pledged IP to Work — Identifying IP Available Under the Open COVID Pledge’ Open Covid Pledge (12 June 2021). Available at https://opencovidpledge.org/2020/06/12/putting-pledged-ip-to-work-identifying-ip-available-under-the-open-covid-pledge/ (accessed 1 June 2020).
78 Open Covid Pledge, Available at https://opencovidpledge.org (accessed 1 June 2021).
79 Hilty et al. (n 22); Brian Mercurio, ‘WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review’ (February 2021). Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820&dgcid=ejournal_htmlemail_biology:lawejournal_abstractlink (accessed 25 August 2021).
80 John Zarocostas, ‘What Next for a COVID-19 Intellectual Property Waiver’ (2021) 397 The Lancet 1871.
sufficient suitable factories and teams able to produce and storage vaccines.\textsuperscript{81} Third, countries, such as the USA, are de facto blocking vaccine ingredients/equipment from leaving the country: without the requisite ingredients, no vaccines can be produced, whether with or without IP protection. As \textit{Nature} states, ‘these are important arguments, and need to be addressed. But they are not, in themselves, reasons for denying IP relief. If anything, as the pandemic wears on, the reasons to allow a waiver grow stronger.’\textsuperscript{82} Equally, these objections may be overcome, as is shown below.

I. Transferring technology, disclosing data and building production capacity

Technology can be transferred.\textsuperscript{83} Data can be disclosed. Production capacity exists,\textsuperscript{84} or can be built. This is already happening, albeit only in developed countries. Pharmaceutical companies other than the main players who have successfully obtained market authorizations, including AstraZeneca, Moderna, Johnson\&Johnson and Pfizer and their licenced production partners, are well equipped to step up and manufacture extra vaccines. After Sanofi encountered a setback with its own vaccine, they announced in January 2021 that they will help ‘rival’ Pfizer/BioNTech produce 100 million additional vaccines to Europe.\textsuperscript{85} Merck is now helping Johnson\&Johnson produce its vaccine in the USA to amplify supplies.\textsuperscript{86} Moderna entered into a partnership with Lonza on 1 May 2020 so that Lonza’s facilities in the USA and Switzerland could be used to manufacture its mRNA vaccine, stating that the ‘technology transfer is expected to begin in June 2020, and the companies intend to manufacture the first batches of mRNA-1273 at Lonza U.S. in July 2020’.\textsuperscript{87} In September, ‘large-scale production’ had begun in the USA.\textsuperscript{88} In November 2020, it was further reported that Lonza is ‘building out capacity for 400 million doses a year – 300 million from three production lines in Visp, Switzerland and 100 million in New Hampshire’.\textsuperscript{89} If it is possible to complete technology transfers and repurpose factories in Europe and the USA, why should it not be possible to do the same elsewhere?

Companies have transferred vaccine technology to developing countries previously. Fisher, Okediji and Sampath find that ‘in the late 1990s, the technology underlying the recombinant Hepatitis B vaccine was transferred to the Republic of Korea, India and Brazil, resulting in a ‘sharp drop’ in price.’\textsuperscript{90} Transferring mRNA technology is admittedly more difficult given its complexities. To tackle this and to scale up vaccine manufacturing in developing countries, the WHO has announced that they are seeking to create a tech transfer hub that will use a ‘hub and spoke model … to transfer comprehensive technology package and provide appropriate training to interested manufacturers in low- and middle-income countries’, including mRNA technology, which the Pfizer and Moderna vaccines use.\textsuperscript{91} Vaccine technology may also be licensed through the Medicines Patent Pool, that announced on 27 May 2021 that it will increase its mandate to include technology licensing ‘with an initial focus on Covid-19 vaccines’.\textsuperscript{92} The issue is therefore

---

\textsuperscript{81} Ibid.

\textsuperscript{82} Nature Editorial (n 2).

\textsuperscript{83} For examples of tech transfers that have already taken place and estimated timelines, see Zain Rizvi and Peter Maybarduk, ‘A Plan for the People’s Vaccine: How the Biden Administration Can Supply the World’ \textit{Public Citizen Report} (8 December 2020). Available at https://www.citizen.org/article/a-plan-for-the-people’s-vaccine/ (accessed 10 May 2021); \textit{Tech Transfers to Developing Countries Have Also Been Successfully Done Before the Covid-19 Pandemic, See: William Fisher, Ruth Okediji and Padmasree Gehl Sampath, ‘Fostering Production of Pharmaceutical Products in Developing Countries’ (2021) forthcoming 20. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3825165 (accessed 25 August 2021).

\textsuperscript{84} Ibid 20–21 (‘According to the World Health Organisation, of the 84 vaccine manufacturers worldwide, 65 are located outside of the EU and the US’ although the authors note that many produce old or generic vaccines).

\textsuperscript{85} Sanofi to Provide Support to BioNTech in Manufacturing Their COVID-19 Vaccine to Help Address Public Health Needs’ \textit{Press Release} (27 January 2021). Available at https://www.sanofi.com/en/media-room/press-releases/2021/2021-01-27-07-30-00 (accessed 1 May 2021).

\textsuperscript{86} Christopher Rowland and McGinley Laurie, ‘Merck Will Help Make Johnson & Johnson Coronavirus Vaccine as Rivals Team up to Help Biden Accelerate Shots’ \textit{The Washington Post} (Washington, 3 March 2021). Available at https://www.washingtonpost.com/health/2021/03/02/merck-johnson-and-johnson-covid-vaccine-partnership/ (accessed 1 May 2021).

\textsuperscript{87} Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna’s Vaccine (mRNA-1273) Against Novel Coronavirus’ \textit{Press Release} (1 May 2021). Available at https://investors.modernatx.com/news-releases/news-release-details/moderna-and-lonza-announce-worldwide-strategic-collaboration (accessed 3 May 2021).

\textsuperscript{88} Reuters Staff, ‘Lonza Aims to Make Ingredients for 400 Million Doses of Moderna’s COVID Vaccine Annually’ \textit{Reuters} (London, 16 November 2020). Available at https://www.reuters.com/article/us-health-coronavirus-lonza-moderna-idUSKBN27W1N0 (accessed 25 August 2021).

\textsuperscript{89} Naomi Kreuge, ‘Moderna Vaccine Production Is Gearing Up, Partner Lonza Says’ \textit{Bloomberg} (New York, 19 November 2020). Available at https://www.bloomberg.com/news/articles/2020-11-19/moderna-vaccine-production-is-gearing-up-partner-lonza-says (accessed 1 June 2020).

\textsuperscript{90} Fisher, Okediji and Sampath (n 83) 20.

\textsuperscript{91} World Health Organisation, ‘Establishment of a COVID-19 mRNA Vaccine Technology Transfer hub to Scale up Global Manufacturing’ (16 April 2021). Available at https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing (accessed 20 May 2021).

\textsuperscript{92} Medicines Patent Pool, ‘The Medicines Patent Pool Responds to Access Needs for COVID-19 Vaccine Technologies in Low- and Middle-Income Countries’ News (27 May 2021). Available at https://medicinespatentpool.org/news-publications-post/covid-19-vaccine-technologies-mandate-expansion/ (accessed 1 June 2021).
not the actual transfer of technology but motivating companies to transfer. A waiver may help in this regard as the backing of a legally adopted waiver and support of developed countries can give developing countries greater bargaining power during negotiations with pharmaceutical companies in order to compel IP and tech-sharing.

Certain pharmaceutical companies have signed bilateral licences that facilitate tech transfers with manufacturers in developing countries. The Serum Institute of India produces Covishield under a bilateral licence with AstraZeneca, enabling local production, but India suspended vaccine exports headed to developing countries during its own crisis and 'may not export again until the end of this year.' Pfizer/BioNTech announced, on 21 July 2021, that it had signed a letter of intent with Biovac, a South African biotechnology company, to manufacture its mRNA vaccine for distribution within the African Union. However, production will not start before 2022 and the factory will, at full capacity, only produce 100 million finished dosages annually. South Korea is allegedly negotiating whether it may produce mRNA vaccines with Pfizer and Moderna as it has the local capacity to produce '1 billion doses immediately' but how far these talks are and if a deal will be struck remains unclear. Although such agreements are, if executed, a step in the right direction, they are insufficient in terms of aligning supply with global demand.

Scaling up production remains an issue. Indeed, pharmaceutical companies claim that production is 'to blame for vaccine under-supply', as well as 'high-quality standards' and not IP. While it is true that IP is not the only issue for under-supply, it is also true that if the IP and technology was shared, then additional manufacturers could help with production, as factories around the world have publicly shared that they wish to do yet are unable to. Waiving IP means that deciding who may produce vaccines where and when is not a question purely decided by private companies.

On 14 May 2021, Politico reported that certain pharmaceutical companies, including AstraZeneca, rejected offers to help manufacture vaccines from BioLyse in Canada, Incepta in Bangladesh, Teva in Israel and Bavarian Nordic in Denmark. John Fulston, a spokesperson for BioLyse Pharma, a company based in St. Catharines, Ontario, states, 'we have this production capacity and it's not being used [to produce Covid-19 vaccines]. Moreover, that 'if it [BioLyse] had gotten the green light a year ago, it would have taken the company six months to be up and ready to produce vaccines — and now would be halfway through a year's production.' Kapczynski notes that BioNTech used only 6 months 'to turn a cancer antibody factory into a mRNA factory, complete with regulatory approval.'

Repurposing medical factories could potentially curb the production of other essential vaccines and medicines. However, as above with Moderna and Lanzo, it is possible to build new capacity, or, one can, as Moderna did, repurpose an old Polaroid/camera factory to manufacture vaccines. Building new capacity or repurposing non-medical factories is not necessary seeing as several factories wishing to produce vaccines claim that they have available capacity. Relying on reputable, established manufacturers, who already produce many of the world's medicines, also assuages concerns over quality control and vaccine safety, which has been used as a justification for limiting licencing deals and production in developing countries.

Bangladesh's Incepta chairman and managing director, Abdul Muktadir, stated that 'Incepta can manufacture bulk antigen for coronavirus vaccines using almost all of

93 Shruti Menon, 'India Vaccination: Does it Have Enough Doses for all Adults?' BBC Reality Check (2 August 2021). Available at https://www.bbc.com/news/world-asia-india-55571793 (accessed 2 August 2021).
94 Pfizer Press Release, 'Pfizer and Biontech Announce Collaboration With Biovac to Manufacture and Distribute Covid-19 Vaccine Doses Within Africa' (21 July 2021). Available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac (accessed 2 August 2021).
95 Ibid.
96 Sangmi Cha, 'EXCLUSIVE S.Korea in Talks With mRNA Vaccine Makers to Make up to 1 bln Doses -Govt Official' Reuters (Seoul, 5 July 2021). Available at https://www.reuters.com/business/healthcare-pharmaceuticals/exclusive-s-korea-talks-with-mrna-vaccine-makers-make-up-1-bln-doses-govt-2021-07-05/ (accessed 3 August 2021).
97 Ashleigh Furlong, 'Big Vaccine Makers Reject Offers to Help Produce More Jabs' Politico (Brussels, 14 May 2021). Available at https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/ (accessed 21 May 2021).
98 Ibid.
99 Ibid.
100 Sharon Lerner and Lee Fang, 'Factory Owners Around the World Stand Backing of a Legally Adopted Waiver and Support of Developing Nations' (20 March 2021). Available at https://lpeproject.org/blog/how-to-vaccinate-the-world-part-1/ (accessed 1 May 2021).
101 Amy Kapczynski, 'How to Vaccinate the World, Part 1' LPE Project (30 April 2021). Available at https://lpeproject.org/blog/how-to-vaccinate-the-world-part-1/ (accessed 1 May 2021).
102 Charles Clift, 'Scaling up Covid-19 Vaccine Production: What are the Problems and Implications?' The British Medical Journal Opinion (17 March 2021). Available at https://blogs.bmj.com/bmj/2021/03/17/scaling-up-covid-19-vaccine-production-what-are-the-problems-and-implications/ (accessed 20 May 2021).
103 Andrew Dunn, 'How Moderna Plans to Mass- Produce Its Coronavirus Vaccine' Business Insider (19 December 2021). Available at https://www.businessinsider.com/how-moderna-plans-to-mass-produce-coronavirus-vaccine-norwood-factory-2020-12?r=US&IR=T (accessed 20 May 2021).
104 BBC News, 'Covid: Rich States "Block" Vaccine Plans for Developing Nations' (20 March 2021). Available at https://www.bbc.com/news/world/part-1/ (accessed 24 August 2021).
its technology platforms’, including mRNA products if the antigen was provided.\(^\text{106}\) If it was, then ‘production can start immediately as Incepta has several lines sitting idle’ wherein Incepta could likely fill ‘vials for about 500 million doses a year’ with just one line.\(^\text{107}\) Kim Soo-jin, senior vice-president of Hanmi Pharmaceuticals, a South Korean pharmaceutical company, shares that they have ‘a fully ready, GMP, state-of-the-art facility available’ because a clinical trial with Sanofi was discontinued last year.\(^\text{108}\) Using medical factories is the preferable option as it is likely cheaper than building new or repurposing non-medical facilities, although this too comes at an expense, raising the question: where will the money come from?

Philanthropy represents one option. Patrick Soon-Shiong, owner of LA Times, recently committed to donating $213 million to help South Africa with tech transfers for COVID-19 vaccines and other products.\(^\text{109}\) Another is obtaining financing via the World Bank, who approved an ‘envelope of $12 billion for developing countries to finance the purchase and distribution of COVID-19 vaccines, tests, and treatments for their citizens; including financing and technical support so that said countries may prepare to deploy vaccines at scale.’\(^\text{110}\) The World Bank recently increased this funding to $20 billion and, alongside three governments, are investing in a manufacturer based in South Africa to ‘boost production of Covid-19 vaccines on the African continent’.\(^\text{111}\) Said funding includes financing for the entire vaccine production supply chain.\(^\text{112}\) Private–public partnership is another route. Recipharm, global contract development and manufacturing organization, announced in July of 2021 that they have signed a Memorandum of Understanding, with the Moroccan government and a ‘consortium of the country’s leading banks’, both of which have pledged $500 million in funding, in order to build a ‘fill-finish factory’ in Morocco by 2023 in order to produce biologics and vaccines for the African continent and ‘help it gain vaccine sovereignty and access to future biotherapeutics’.\(^\text{113}\) The plant will ‘mirror’ the one Recipharm oversees in France, which is notably used to produce Moderna’s mRNA vaccine.\(^\text{114}\) Whether the factory will be used for COVID-19 vaccines remains unclear. Although it could, waiting until 2023 is too long, meaning the above factories, which may start production immediately, are the best option.

Despite a waiver, it might be difficult to produce vaccines in developing countries as certain countries restrict the exportation of the raw materials used for vaccines. The USA is using its ‘march in’ rights under the US Defence Act to ensure that companies prioritize US procurement orders first, which has impacted India’s vaccine production as they are short of raw materials,\(^\text{115}\) although the USA now exports to India again.\(^\text{116}\) Such restrictions would have to be lifted for all countries for the waiver to have effect, particularly as scaling up vaccine production requires additional raw materials. Those used to produce mRNA vaccines, such as lipid nanoparticles, which are also difficult to manufacture.\(^\text{117}\) There are already shortages. Vaccine production may therefore only be scaled up if the production of raw materials is too. However, the waiver is not limited to vaccines, so it may encompass the raw materials needed to produce vaccines, enabling additional manufacturers to produce raw materials.\(^\text{118}\) Moreover, ‘several world-leading groups working on creating better lipid nanoparticles for the delivery of mRNA.’\(^\text{119}\)

\(^{106}\) Furlong (n 97).

\(^{107}\) Ibid.

\(^{108}\) Cha (n 96).

\(^{109}\) Janice Kew, ‘L.A. Times Owner Pledges $213 Million for COVID-19 Vaccine Work in South Africa’ LA Times (Los Angeles, 13 May 2021). Available at https://www.latimes.com/business/story/2021-05-13/los-angeles-billionaire-pledges-213-million-covid-19-vaccine-work-south-africa (accessed 3 August 2021).

\(^{110}\) World Bank Press Release, ‘World Bank Approves $12 Billion for COVID-19 Vaccines’ (13 October 2020). Available at https://www.worldbank.org/en/news/press-release/2020/10/13/world-bank-approves-12-billion-for-covid-19-vaccines (accessed 3 August 2021).

\(^{111}\) Shabtai Gold, ‘World Bank to Finance Vaccine Production in Africa, Increase Fund to $20B’ Devex (Washington, 1 July 2021). Available at https://www.devex.com/news/world-bank-to-finance-vaccine-production-in-africa-increase-fund-to-20b-100284 (accessed 3 August 2021).

\(^{112}\) Ibid.

\(^{113}\) Recipharm Press Release, ‘Recipharm signs Memorandum of Understanding (MOU) for the Fill Finish of Vaccines and Biotherapeutics in Morocco’ (6 July 2021). Available at https://www.recipharm.com/press/recipharm-signs-memorandum-understanding-mou-fill-finish-vaccines-and-biotherapeutics-morocco (accessed 2 August 2021).

\(^{114}\) Fraiser Kansteiner, ‘With $500M in local pledges, Recipharm Plans Moroccan Factory to help Africa secure Vaccine Sovereignty’ Fierce Pharma (6 July 2021). Available at https://www.fiercepharma.com/manufacturing/recipharm-tees-up-500m-moroccan-factory-to-help-africa-secure-vaccine-sovereignty (accessed 2 August 2021).

\(^{115}\) Aime Williams and Kiran Stacey, ‘Is there a ban on Covid Vaccine Exports in the US?’ Financial Times (London, 1 May 2020). Available at https://www.ft.com/content/82fa86b4-a867-4005-bbc2-a79969139119 (accessed 10 May 2021).

\(^{116}\) Katie Rogers and Sheryl G. Stolberg, ‘U.S. to Send Virus-Ravaged India Vaccines Like Pfizer’s. But we’re Short of Vital Components’ The New York Times (New York, 28 April 2021). Available at https://www.nytimes.com/2021/04/25/us/politics/india-us-corona-virus.html (accessed 4 May 2021).

\(^{117}\) Sarah Matheson AM and Artemis Kirkinis, ‘Compulsory licence and Crown use Provisions in the Covid-19 Pandemic—the Australian Perspective’ (2021) 16 JIPLP 1, 2.

\(^{118}\) Thambisetty et al (n 21) 51–52. The authors also note that patent thickets exist for raw materials so supply chain issued may be partly attributable to IP here too.

\(^{119}\) Archa Fox and Pall Thordarson, ‘The World is Hungry for mRNA COVID Vaccines Like Pfizer’s. But we’re Short of Vital Components’ The Conversation (27 April 2021). Available at https://theconversation.
vaccine hub committee under South Korea’s health ministry, Lee Kang-ho, discloses that South Korean producers are ‘capable of manufacturing and developing such raw materials to help vaccine makers… and the South Korean government is committed to provide all necessary support including financial and administrative aid’.

The raw materials needed to produce vaccines may therefore be more available by the time production starts.

After the tech is transferred and production is set up, the other manufacturers would still require regulatory approval to market their vaccine. Unless originator companies share their clinical trial data, said manufacturers might struggle to show that their generic vaccine is similar enough to the original without conducting their own clinical trials.

As clinical trials are costly and lengthy, relying on this data is vital. There are a few options to consider.

Any trade secrets not included in the waiver could be forcibly disclosed under national law, but this might meet jurisdiction issues as many pharmaceutical companies do not have a presence in developing countries. If forcible disclosure is sought in developed countries, such as the EU, wherein Article (1)(2) of the EU Trade Secrets Directive permits trade secret disclosures on public interest grounds, this would require some multi-jurisdictional data transfer, which would likely take much time, meet much resistance given the EU’s opposition to the waiver and encounter difficulties, particularly in relation to EU data protection laws. Alternatively, countries could enact domestic legislation to enable information sharing between regional/national medicine agencies or with the WHO, which simplified the standard regulatory pathway for vaccine approval when it introduced ‘Emergency Use Listing’, which ‘opens the door for countries to expedite their own regulatory approval processes to import and administer vaccines.

Another option is issuing compulsory licences on top of the waiver. Contreras suggests that a country making use of the waiver ‘could also, presumably mandate that foreign companies disclose their proprietary manufacturing and testing information to local producers under a compulsory license’.

However, compulsory licences may run into issues in this regard if the country is a signatory to an international agreement containing TRIPs-plus provisions that require data to be protected extensively. For instance, Article 18.50 of the TTP ‘requires that, when a party requires approval of a new pharmaceutical product, undisclosed test or other data related to safety and efficacy cannot be used in another party for at least five years from the marketing approval date in the first party.’ This strengthens the case of a waiver on data exclusivities, which is indeed the best alternative, accompanied by, for example, the WHO regulatory approval mechanism to expedite the review basis.

This background shows that competing pharmaceutical companies and/or generic companies may help if know-how is shared and pre-existing factories are used. Equally, if there are no current factories, then it is vital we invest in repurposing old or creating new factories to speed up production. Despite the alternative methods to circumvent IPRs highlighted above, a global IP waiver would help in this regard. This is because no investor or company will invest in repurposing old factories unless they actually have the rights to produce the vaccine. The waiver may likewise give countries the legal basis needed in order to successfully negotiate technology transfers with pharmaceutical companies, which have thus far proved unsuccessful.

Conversely, Hilty et al. claim that ‘waiving IP rights may have detrimental consequences for the firms’ willingness to cooperate’. This is incorrect for two reasons. First, it assumes that firms are willing to cooperate, which is not per se the case. Certain pharmaceutical companies reportedly rejected offers from other companies in Canada, Bangladesh, Israel and Denmark to help manufacture vaccines in May 2021.

Equally, when cooperation has occurred, it has predominantly taken place in high-income countries, while developing countries’ calls for cooperation have been met with silence or rejection. Second, threatening to circumvent IPRs has in pre-pandemic times, as well as during, proved

---

120 Cha (n 96).
121 Vaccine production is also scaling up in Europe despite alleged raw material shortages. On 1 June 2021, the European Medicines Agency recommended the approval of ‘Additional Manufacturing and Filing Lines at Pfizer’s Vaccine Manufacturing Site in Puurs, Belgium’; see ‘Additional Manufacturing Capacity for BioNTech/Pfizer’s COVID-19 vaccine’ (EMA, 1 June 2021). Available at https://www.ema.europa.eu/en/news/additional-manufacturing-capacity-biontechpfizer-covid-19-vaccine (accessed 2 June 2021).
122 Thambisetty et al. (n 21) 28.
123 Directive 2016/943 of the European Parliament and of the Council of 8 June 2016 on the Protection of Undisclosed Know-how and Business Information (Trade Secrets) Against their Unlawful Acquisition, Use and Disclosure, OJ, L 157, 1–18.
124 Thambisetty et al. (n 21).
125 WHO News Release, ‘WHO Issues its First Emergency use Validation for a COVID-19 Vaccine and Emphasizes Need for Equitable Global Access’
126 Contreras (n 75) 180.
127 Vincent (n 51) 27–28.
128 Hilty et al. (n 22) 2.
129 Furlong (n 97).
to be a powerful way to incentivize voluntary action. GlaxoSmithKline and Boehringer Ingelheim granted a voluntary licence after Cosmos, a local manufacturer, applied for a compulsory licence for a HIV/AIDS drug in Kenya. Abbvie waived its patent rights after Israel issued a compulsory licence for its drug, which was thought to be effective for treating COVID-19. A waiver may similarly spark greater voluntarily cooperation. As the New York Times reports: "the Europeans are banking on the notion that the vaccine makers, fearing patent waivers, will eventually agree to the transfers, especially if the world's richest countries throw money their way to make sharing know-how more palatable."

2. What about innovation?
Pharmaceutical companies remain opposed to the IP waiver, claiming it will hurt innovation in the short and long run, well beyond this pandemic, by removing incentives to develop essential pharmaceutical products. Academics, such as Mercurio and Hilty et al., support such claims. This strikes at the heart of IP law, which is built on the presumption that awarding temporary monopolies so companies can charge uncompetitive prices to recoup R&D costs provides an incentive to innovate. This in turn ensures that the innovation cycle continues and new inventions are shared with society, creating a richer quality of life for all.

However, the innovation process behind the COVID-19 vaccines departs from the norm. The vaccines developed by Pfizer, Moderna, Johnson&Johnson and AstraZeneca all benefitted from unprecedented amounts of public funding throughout their development cycle with the public sector taking much of the financial risk usually involved in pharmaceutical development. A recent article in the Lancet shares that each received the following estimates: (i) AstraZeneca $1.7 billion in total from CEPI, as well as the US and UK governments; (ii) Johnson&Johnson, $1.5 billion from the US government; (iii) Moderna, $957 million from CEPI, Dolly Parton COVID-19 Research Fund and US government, and (iv) BioNTech with Pfizer, $445 million from the German government. Pfizer is also predicted to reach $33.5 billion in sales in 2021, with a profit margin percentage of revenue in the high 20s.

Against this background, it is questionable how innovation will be harmed by requesting that publicly funded research be widely available to developing countries during a pandemic, especially after pharmaceutical companies have had much time and many offers to do so voluntarily. Equally questionable is how 'innovation,' which is meant to benefit society, is beneficial if the innovations themselves remain out of reach to those who need them the most.

III. Conclusion

Thanks to international collaboration, public funding and science, pharmaceutical companies have, with the help of governments, universities, and biotechnology companies, developed vaccines in record time. There is finally some light at the end of the tunnel. For some of us. The Economist’s Intelligence Unit estimates that vaccines will be widely available in developed countries between September 2021 and March 2022. The same is not estimated to occur for many developing countries—including most African countries—until April 2022 or 2023. As of late April 2021, Dr Tedros stated that only 0.3 per cent of the vaccines thus far been administered to...
the citizens living in developing countries. With countries such as India reporting of record-breaking deaths per day, and with Nepal expected soon to follow, it is imperative that citizens living in developing countries can access the treatments they need to survive.

While it is true that IP is not the only factor curbing access to COVID-19 vaccines—political nationalism, export bans and production capabilities remain huge issues—it is also true that IP plays a role. Not only does IP mean exclusive production rights, but it means that a couple of commercial pharmaceutical companies effectively decide where to produce vaccines and who to sell them to. In May 2021, it was reported that the pharmaceutical companies producing COVID-19 vaccines rejected offers from companies in Canada, Bangladesh, Israel and Denmark to help. This begs the question: is insufficient production capacity a fact, or a choice?

Although a global waiver of IP for COVID-19 products will not guarantee equal accessibility, it constitutes an important stepping stone towards greater access as it lays the foundation blocks for IPRs to be shared. Indeed, in an interview with Nature, Kiat Ruxrungtham, an immunologist who has, alongside his team, developed another mRNA COVID-19 vaccine that is about to enter human trials, shares that the waiver ‘would allow us to use technologies that are currently unaffordable or inaccessible to us to make our vaccine even better and cheaper’. It may attract the investments needed to repurpose old or build new factories to produce more vaccines.

Moreover, it legitimizes the struggles that developing countries are facing and will continue to face when it comes to securing COVID-19 vaccines wherein developed countries are partly to blame. As Wouters et al. observe, ‘scarcity in supply coupled with the large volumes of pre-orders made by richer countries creates challenges to achieving timely, universal access.’ This is made worse when developed countries are now administering booster shots that will ‘use up roughly 440 million doses of the global supply’, and when countries such as Canada take vaccines destined for developing countries through COVAX. It is not right that developed countries purchased enough vaccines to vaccinate their own citizens multiple times over before developing countries could even secure one dosage, take donated vaccines for themselves and stand in the way of developing countries producing their own vaccines. Something has to give. And that must be developed countries blocking the waiver. Additional issues must indeed be overcome for the waiver to take effect, and further research is needed, particularly when it comes to increasing the production of raw materials. But it is vital that countries and researchers be part of the solution, not the problem.

144 WHO (n 1).
145 Furlong (n 97).
146 Smriti Mallapaty, ‘The COVID Vaccine Pioneer Behind Southeast Asia’s First mRNA Shot’ Nature (26 May 2021). Available at https://www.nature.com/articles/d41586-021-01426-9 (accessed 2 June 2021).
147 Wouters et al. (n 139) 1027.
148 Maxmen (n 5).