

Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal

July 2021

The temporary TRIPS waiver¹ - as proposed by India and South Africa and supported by more than 100 countries - is a necessary and proportionate legal measure towards the clearing of existing intellectual property barriers to scaling up of production of COVID-19 health technologies in a direct, consistent and effective fashion. We call on the governments of the United Kingdom of Great Britain and Northern Ireland, Australia, Brazil, Japan, Norway, Switzerland and the European Union to drop their opposition to the TRIPS Waiver proposal at the World Trade Organisation and to support the waiver.

Intellectual Property (IP) rights - including patents, copyrights, trade secrets and other undisclosed information - are not, and have never been, absolute rights and are granted and recognised under the condition that they serve the public interest. IP rights must not be allowed to stand in the way of measures designed to make accessible the health technologies needed to fight the COVID-19 pandemic, where universal global access is essential for the global public good. We acknowledge that legal factors beyond IP, such as trade and export restrictions, also shape the ability to produce and access COVID-19 vaccines and therapeutics. Nonetheless, it is the case that IP rights, and monopolies over tacit and informal information, are also implicated in the current lack of global capacity for vaccine production and other health technologies, as well as in enabling their inequitable distribution.

Current strategies to address the vast inequity in the distribution of COVID-19 vaccines have focused on solutions which build on the existing IP system, such as the World Health Organisation (WHO) COVAX initiative or voluntary licensing provisions. Such proposals have had limited and insufficient success to date at providing vaccines to low- and middle-income countries. We note that as of June 2021 the voluntary COVAX donation scheme has delivered only 90m out of a promised 2bn doses.² Pharmaceutical companies who hold relevant IP rights have also failed to engage with the WHO's voluntary COVID-19 Technology Access Pool (C-TAP) of IP and know-how.³ Meanwhile, several

¹ 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 <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>> (accessed 14 May 2021). See also revised TRIPS waiver text of 21 May 2021 at <<https://www.keionline.org/wp-content/uploads/W669Rev1.pdf>>.

² The WHO COVAX scheme has fallen drastically short of its initial aim to provide 2 billion doses. See details at <<https://www.who.int/news/item/27-05-2021-covax-joint-statement-call-to-action-to-equip-covax-to-deliver-2-billion-doses-in-2021>>

³ The WHO's proposed COVID-19 Technology Access Pool (C-TAP) C-TAP is aimed at increasing the production of COVID-19 vaccines and other health-technologies globally whilst compensating the IP right

solicitations of collaboration to produce vaccine by companies, such as from Teva in Israel, Biolyse in Canada, Bavarian Nordic in Denmark, and Incepta in Bangladesh, have not engendered a positive response from vaccine IP holding companies.⁴ Moreover, the shortcomings of vaccine production are not the only problem: distribution of existing vaccine supply has been profoundly unequal, with pre-purchasing and hoarding of doses by several high-income countries. This has underlined the need for globally distributed, local vaccine manufacturing hubs in low and middle-income countries in order to guarantee sustainable supply.⁵

Given the ongoing absence of sufficient voluntary engagement by the pharmaceutical industry with proposed global mechanisms to share IP rights, data and know-how to address the pandemic, the ability to suspend rules under the TRIPS Agreement is crucial to enable a radical increase in manufacturing capacity, and thus supply, of COVID-19 vaccines. This will facilitate a globally coordinated and transparent pathway to achieve global equitable access. The proposed TRIPS waiver would provide more companies with the freedom to operate in order to produce COVID-19 vaccines and other health technologies without the fear of infringing another party's IP rights and the attendant threat of litigation.

Furthermore, in light of the considerable public financing of COVID-19 vaccine research, development, production and purchase, claims of inviolability of private IP monopoly rights cannot be justified.⁶ The IP system has failed in the past to create market incentives for vaccine development - a finding that is acknowledged and analysed by scholars in the field.⁷ In the case of COVID-19 vaccines, such a market failure has been mitigated with unprecedented public funding and de-risking of R&D costs through advance market commitments by governments.⁸ These tailored public interventions addressed the

holder. C-TAP has attracted no IP-rightsholder engagement to date since its launch in May 2020. See details at <<https://www.who.int/initiatives/covid-19-technology-access-pool>>

⁴ S Thambisetty, A McMahon, L McDonagh, HY Kang and G Dutfield, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic' *LSE Legal Studies Working Paper* 6/21 (2021) -

<https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737>

⁵ The WHO recently announced a new mRNA hub in South Africa but as yet no pharma companies have agreed to take part - <<https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub>>

⁶ 'Global Health Centre COVID-19 Vaccines R&D Investments' Graduate Institute of International and Development Studies (21 May 2021) <knowledgeportalia.org/covid19-r-d-funding>

⁷ S Chandrasekharan, T Amin, J Kim, E Furrer, A-C Matterson, N Schwalbe and A Nguyen, 'Intellectual property rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: Patent landscaping and perspectives of developing country vaccine manufacturers' 33 *Vaccine* (2015) 6366; J Lezaun and CM Montgomery, 'The Pharmaceutical Commons: Sharing and Exclusion in Global Health Drug Development' 40 *Science, Technology, & Human Values* (2015) 3 doi:<[10.1177/0162243914542349](https://doi.org/10.1177/0162243914542349)>.

⁸ For example, on the public funding of the Oxford-AstraZeneca vaccine, see S Cross, Y Rho, H Reddy, T Pepperrell, F Rodgers, R Osborne, A Eni-Olotu, R Banerjee, S Wimmer and S Kestra, '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' *medRxiv* (2021) preprint doi: <https://doi.org/10.1101/2021.04.08.21255103> – this version posted 10 April 2021. NB: ChAdOx refers to the specific viral vector technology developed at Oxford.

pressing need for vaccine development, and in doing so compensated for the failure of IP incentives on their own to promote vaccine research and development.

The TRIPS waiver is necessary at this time because the existing provisions within the TRIPS Agreement are not sufficient in a pandemic context, whereby global access to vaccines produced at speed and scale is in all our interests. For example, compulsory licence provisions under Art. 31 and Art. 31bis of TRIPS are insufficient to tackle already existing and emerging patent thickets and data exclusivity rules that impede production by manufacturers other than the IP rightsholders.⁹ Furthermore, compulsory licences do not address the need for technology transfer and the sharing of know-how needed to build local and regional manufacturing capacity. Building such capacity would enable sustainable solutions for this and future pandemics by increasing domestic/regional manufacturing capacity for vaccine production.

Governments must work with IP holders to make available and incentivise the disclosure of information held as trade secrets (and other undisclosed information) on grounds of Art. 73 (b)(iii) TRIPS, as well as through the strengthening of domestic public interest provisions under Art. 39(3) TRIPS. There are precedents for this, including US production of penicillin in WWII in which the US government oversaw the necessary pooling of technology and knowledge by companies and universities to rapidly increase penicillin production. Last year, the US government used the Defense Production Act to prioritise the production of components for national supply as needed to combat COVID-19.¹⁰

The proposed TRIPS waiver will enable the temporary suspension of the relevant TRIPS rules for the duration of the COVID-19 pandemic, allowing freedom to operate. It is thus a necessary ingredient as part of a multi-pronged approach to combat the pandemic. This approach must also encompass other steps, including: global co-ordination of supply chains; streamlining regulatory approval processes and sharing exclusive data from regulatory dossiers; and investment in the WHO's C-TAP and the mRNA technology transfer hub in South Africa.¹¹ The TRIPS waiver will thus facilitate the technical resilience of lower- and middle-income countries in view of present and future pandemic action and preparedness. This is in line with the commitment in the TRIPS Agreement to balance the rights of IP holders in high-

⁹ See VaxPal, *COVID-19 vaccines patent landscape*. Available at <<https://medicinespatentpool.org/what-we-do/disease-areas/vaxpal/>>. For analyses of existing patents and license agreements on mRNA-based COVID-19 vaccines, see C Martin and D Lowery, 'mRNA vaccines: Intellectual Property Landscape' 19 *Nature Reviews Drug Discovery* (2020) 578 and M Gaviria and B Kilic, 'A network analysis of COVID-19 mRNA vaccine patents' 39 *Nature Biotechnology* (2021) 546.

¹⁰ S Thambisetty, A McMahon, L McDonagh, HY Kang and G Dufield, 'The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic' *LSE Legal Studies Working Paper* 6/21 (2021) - <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737>

¹¹ The Independent Panel for Pandemic Preparedness and Response, *Access to Vaccines, Therapeutics and Diagnostics: Background Paper 5* (May 2021) 1–7 <<https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-5-Access-to-vaccines-Therapeutics-and-Diagnostics.pdf>>

income countries with the promise of technology transfer to lower- and middle-income countries. It is time to fulfil this promise and, in so doing, to end the pandemic.

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