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Suspend intellectual property rights for covid-19 vaccines

Waivers are essential for global vaccine equity

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The United States caught the world by surprise on 5 May 2021 when it announced its intention to support a World Trade Organization proposal that would temporarily waive intellectual property rights on covid-19 vaccines. While this move is encouraging, the Biden administration's support is the first step of many required.¹

Waiving intellectual property rights is essential to tackle serious inequity in the global distribution of covid-19 vaccines, whereby wealthy countries currently control the lion's share of existing supplies. By the end of April, over 1.3 billion doses had been administered worldwide, but only 0.2% of vaccines had been given in low income countries.²

More than one year into the pandemic, the situation is at a low point globally. The average number of weekly deaths in April was over 36 000 in just India and Brazil,³ and variants are proliferating. Experts fear a devastating second wave across Asia and Africa.⁴

Voluntary action has not worked— whether timely sharing of doses with low and middle income countries or sharing knowledge through the World Health Organization. It's time for mandatory rules and legal commitments that can help put an end to this pandemic.

The proposed intellectual property waiver is appropriate as vaccine manufacturers have relied heavily on publicly funded research into coronaviruses.⁵ Together, companies holding intellectual property rights are estimated to have benefited from government funding of around €93bn (£80bn; \$110bn).⁶ The Moderna vaccine was funded almost exclusively by the US government.⁷

A successfully negotiated intellectual property waiver would ensure manufacturers cannot block production or access to raw materials and finished products for covid-19 technologies worldwide. A waiver would also prevent companies from charging unaffordable prices while insulated from competition.

Lack of competition in the vaccines market has a long history. Previously, the two companies with a duopoly for the human papillomavirus (HPV) vaccine⁸ held patents that prevented competition. According to one estimate, low income countries paid up to 10 times the estimated cost of production for these vaccines.⁹ Millions of girls globally are still unable to access this critical protection against cervical cancer.

Similarly, Pfizer successfully enforced secondary patents on its pneumococcal vaccine through legal proceedings in India¹⁰ and South Korea,¹¹ which delayed competition. Pneumonia remains the leading

cause of death globally among children under 5 years old.¹² Many middle income countries have low coverage because of the high price of the vaccine, often 5-10 times higher than the lowest price available globally.¹³

Inadequate access to essential vaccines is predictable in a system that prioritises monopolies—and this will repeat itself in the absence of an intellectual property waiver for covid-19 vaccines.

Key features

A successfully negotiated waiver would meet four important criteria. The waiver's primary aim should be to save as many lives as possible. The Biden administration wants the waiver to focus on vaccines. This constraint should be removed. The original proposal applies to all medical technologies related to covid-19, including diagnostics, medicines, and ventilators. Many people are likely to become sick even if vaccination rates improve worldwide.

Secondly, negotiations should be completed quickly. Governments should make substantial progress ahead of the WTO meeting on 8 June 2021. Thirdly, any waiver should be straightforward, unambiguous, for a reasonable duration, and limit manufacturers' ability to file legal challenges that impede access.

Finally, negotiating texts should be fully disclosed, with negotiations transparent to ensure all countries negotiate as equals. In the past, powerful nations have used their leverage to extract concessions from less powerful countries behind closed doors.¹⁴

Opponents of a waiver question whether manufacturers in lower income countries have the required capabilities. This argument was also made in the 1980s when Merck and GSK dominated the market for complex recombinant hepatitis B vaccines. It was discredited in 1997, when Indian manufacturer Shantha Biotechnics launched a vaccine that reduced the cost of a dose from up to \$23 to just \$1. Many millions of people worldwide have since been successfully immunised.¹⁵ Manufacturers in low and middle income countries are already critical to overall immunisation efforts worldwide: in 2018, they provided over half of the 2.4 billion vaccine doses procured by Unicef.¹⁶

Suppliers worldwide are gearing up to meet this moment. New mRNA vaccines are under development in India¹⁷ and China,¹⁸ and several companies in middle income countries are already manufacturing covid-19 vaccines.^{19 20} WHO is establishing a technology transfer hub to support local production of mRNA vaccines.²¹ Although follow-on manufacturers can produce complex vaccines without

support from holders of technology, sharing knowledge would save time and lives.

As we enter into a new era of global pandemics, we must fundamentally rethink the global intellectual property system. The ability to respond swiftly to global crises cannot be left to a handful of private companies in a few wealthy countries. We need a more cooperative global response to this and future public health emergencies.

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- 1 Correa CM. Expanding the production of COVID-19 vaccines to reach developing countries. Lift the barriers to fight the pandemic in the Global South. South Centre. Policy brief No 92. 2021. <https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf>.
- 2 Our World in Data. Covid-19 vaccinations. <https://ourworldindata.org/covid-vaccinations>.
- 3 Biller D, Cheng M, Goodman J. Worldwide COVID-19 death toll tops a staggering 3 million. Associated Press 2021 Apr 17. <https://apnews.com/article/ukraine-brazil-caracas-portugal-india-ccad03475cfd5c846f11189a8bfd99c7>.
- 4 WHO coronavirus (covid-19) dashboard. <https://covid19.who.int/>
- 5 Allan A. For billion-dollar covid vaccines, basic government-funded science laid the groundwork. *Scientific American* 2020 Nov 18. <https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/>.
- 6 Hoecklin M. €93 billion spent by public sector on COVID vaccines and therapeutics in 11 months, finds new research. *Health Policy Watch* 2021 Jan 12. <https://healthpolicy-watch.news/81038-2>.
- 7 Stone J. The people's vaccine—Moderna's coronavirus vaccine was largely funded by taxpayer dollars. *Fortune* 2020 Dec 3. <https://www.forbes.com/sites/judystone/2020/12/03/the-peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-dollars/?sh=20d32fab6303>.
- 8 Chandrasekharan S, Amin T, Kim J, et al. IP rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: patent landscaping and perspectives of developing country vaccine manufacturers. *Vaccine* 2015;33:6366-70. doi: 10.1016/j.vaccine.2015.08.063 pmid: 26368398
- 9 Clendinen C, Zhang Y, Warburton RN, Light DW. Manufacturing costs of HPV vaccines for developing countries. *Vaccine* 2016;34:5984-9. doi: 10.1016/j.vaccine.2016.09.042 pmid: 27771183
- 10 Liu A. Pfizer wins Indian patent to Pevnar 13, draws cries of 'monopoly' from MSF. *Fierce Pharma* 2017. <https://www.fiercepharma.com/vaccines/pfizer-gains-indian-patent-to-pevnar-13-draws-monopoly-criticism-from-msf>.
- 11 Chu M. Pfizer Korea wins pneumonia vaccine patent dispute with SK Chemicals. *Korea Biomedical Review* 2017. <http://www.koreabiomed.com/news/articleView.html?dxno=2061>.
- 12 Ghosh A. How pneumococcal vaccine rollout announced in Budget can save 50,000 childrens' lives/year. *The Print* 2021 Feb 10. <https://theprint.in/health/how-pneumococcal-vaccine-rollout-announced-in-budget-can-save-50000-childrens-lives-year/601985/>.
- 13 Unicef Supply Division. Pneumococcal conjugate vaccine: supply and demand update. 2020. <https://www.unicef.org/supply/media/4636/file/Pneumococcal-conjugate-vaccine-supply-update-July2020.pdf>.
- 14 Sell S. Private power, public law: the globalization of intellectual property rights. 2003. <https://www.cambridge.org/core/books/private-power-public-law/A480277793E812D6A1A71C63C3A16C9A>.
- 15 Chakma J, Masum H, Perampaladas K, Heys J, Singer PA. Indian vaccine innovation: the case of Shantha Biotechnics. *Global Health* 2011;7:9. doi: 10.1186/1744-8603-7-9. pmid: 21507259
- 16 Jarrett S, Yang L, Pagliusi S. Roadmap for strengthening the vaccine supply chain in emerging countries: manufacturers' perspectives. *Vaccine X* 2020;5:100068. doi: 10.1016/j.jvax.2020.100068 pmid: 32775997
- 17 Genova. mRNA vaccines. 2020. <https://genova.bio/mma-vaccines/>.
- 18 Pinghui Z. Coronavirus: China's first mRNA vaccine ready for final stage trials overseas. *South China Morning Post* 2021 Apr 13. <https://www.scmp.com/news/china/science/article/3129411/chinas-first-mrna-vaccine-ready-final-stage-trials-overseas>.
- 19 Egypt to produce China's Sinovac covid-19 vaccine in June. *Xinhua* 2021 May 10. http://www.xinhuanet.com/english/2021-05/10/c_139934954.htm.
- 20 Sguazzin A. Covid-19 to serve as platform for South African vaccine industry. *Bloomberg* 2021 Mar 19. <https://www.bloomberg.com/news/articles/2021-03-19/immunity-bio-to-have-covid-19-vaccine-made-in-south-africa>.
- 21 World Health Organization. Establishment of a covid-19 mRNA vaccine technology transfer hub to scale up global manufacturing. 2021. <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>.

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