

Proposals to waive intellectual property rights for pandemic response products in the World Health Organization pandemic accord need Australia's support

The Australian Government should review its position and support intellectual property waivers in the pandemic accord

Throughout the coronavirus disease 2019 (COVID-19) pandemic, inequities in access to COVID-19 vaccines, diagnostics and therapeutics have been vast and persistent. By the end of 2022, only 26% of people in low income countries had received a COVID-19 vaccine dose.¹ Less than one in 50 of the three billion diagnostic tests administered globally by March 2022 were performed in low income countries.² Further, low and middle income countries have had very little access to therapeutics, particularly antivirals such as nirmatrelvir–ritonavir (Paxlovid, Pfizer) and molnupiravir (Lagevrio, Merck Sharpe & Dohme).²

Unless action is taken quickly, the gap in access to antivirals between high and low income countries seems set to repeat the inequities in distributing COVID-19 vaccines. The cost of antivirals is prohibitive for low and middle income countries. While Pfizer has agreed to provide 10 million Paxlovid courses at lower prices to low income countries through UNICEF and the Global Fund,³ this represents only a small fraction of Pfizer's production. Both Pfizer and Merck Sharpe & Dohme have entered licensing agreements with the Medicines Patent Pool to enable future generic manufacture of their treatments for low and middle income countries.⁴ However, these agreements exclude many middle income countries that would struggle to pay the higher prices set by Pfizer and Merck Sharpe & Dohme.

The exercise of intellectual property rights is at least partly to blame.⁵ Intellectual property rights, while intended to incentivise innovation, create monopolies which can work against equitable access to the resulting products.⁶ Systematic reviews of the evidence of their impact on access to medicines have found negative effects on medicine prices, affordability, consumer welfare, and costs to consumers and governments.^{7,8}

Efforts to relax the intellectual property rights covering COVID-19 vaccines, diagnostics and therapeutics to enable more widespread manufacturing and equitable access have been unsuccessful to date. It took 20 months for member states of the World Trade Organization (WTO) to agree on a narrow, temporary waiver of export restrictions for COVID-19 vaccines, which is not expected to make any significant difference.⁹

The negotiation of a pandemic prevention, preparedness and response accord among World Health Organization (WHO) member states presents

an opportunity to respond differently in future pandemics. The Australian Government should support promising proposals for providing equitable access to pandemic response products in the pandemic accord, including language supporting time-bound waivers of intellectual property protections.

Intellectual property rights: a barrier to access

Intellectual property rights can affect equitable access to COVID-19 vaccines, diagnostics and treatments in various ways.¹⁰ For example, a single rapid antigen test may have copyright, trademarks, trade secrets and patents attached. The latter two can significantly impede equitable access. The value of trade secrets is just that — they are secret. Unless inside knowledge about vaccine production is shared, manufacture by others will be a matter of trial and error. In contrast, the grant of a patent requires that the invention and the best method of performing it are disclosed, but the disclosed invention cannot be used by others for the life of the patent (usually 20 years).

In 1994, governments negotiating the establishment of the WTO agreed that intellectual property was a form of international trade and should be included in the WTO package. Hence the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was born. TRIPS requires WTO members to provide certain minimal standards for intellectual property protection in their domestic laws, including patent and trade secrets.¹¹ TRIPS requires that patents are made available for all inventions provided they satisfy certain criteria.

There are flexibilities in TRIPS, which WTO members can include in their domestic legislation. For example, members can provide for uses of patents without authorisation by the patent owner.¹² This allows members to include compulsory licensing and government use in their domestic patent laws. What this means in practice is that a generic manufacturer might be able to obtain a court order to allow it to manufacture a pharmaceutical without the risk of being sued for patent infringement, without needing prior approval from the patentee. However, TRIPS includes several complex rules that make it practically difficult to use compulsory licensing.¹³ Even though there has been an amendment to TRIPS to allow high income countries to enact domestic legislation to allow them to export medicines under compulsory licence to low and middle income countries during pandemics, there is little evidence that it has been

Deborah Gleeson¹



James Scheibner²

Dianne Nicol³



¹ La Trobe University, Melbourne, VIC.

² Flinders University, Adelaide, SA.

³ University of Tasmania, Hobart, TAS.

d.gleeson@latrobe.edu.au

successfully utilised. For example, Australia has enacted this provision, but there are no reports of its use.

There is no equivalent compulsory licensing for trade secrets. As such, existing intellectual property arrangements, both domestically and internationally, offer limited pathways to remove intellectual property blocks to equitable access to COVID-19 vaccines, diagnostics and therapies.¹⁴

The TRIPS waiver: too little, too late

Owing to concerns about the impact of intellectual property rights on COVID-19 vaccine distribution, India and South Africa co-sponsored a TRIPS waiver proposal to the WTO in October 2020. This proposal sought to temporarily waive all intellectual property rights over COVID-19 inventions, including unregistered rights such as trade secrets.

However, many high income countries opposed the initial proposal, and it lacked sufficient support to achieve WTO consensus. The final Ministerial Decision approved in June 2022¹⁵ was significantly narrower than the initial proposal. Rather than waiving intellectual property rights as such, the Ministerial Decision merely permits a developing country member to export any proportion of vaccines it manufactures to other developing countries, rather than having to predominantly supply its domestic market as stipulated by TRIPS article 31(f).¹⁶

Further, the Ministerial Decision only covers vaccine technology and not therapeutics and tests. Paragraph 8 of the Ministerial Decision,¹⁵ which permits WTO member states to extend its scope to therapeutics and diagnostics has not yet been activated, with many high income countries still resolutely opposed. Second, the Ministerial Decision only applies to vaccine patents and not know-how and trade secrets, which are also essential to increasing manufacturing.¹⁷ Accordingly, the Ministerial Decision has been widely condemned for failing to meet its stated objectives of encouraging additional production of pandemic response products. Therefore, the focus has now shifted to new legal avenues, such as the pandemic accord, to help remove barriers imposed by intellectual property rights.

The pandemic prevention, preparedness and response accord

Following the failure to equitably distribute COVID-19 products and technologies, and the disappointing outcome of negotiations over a TRIPS waiver at the WTO, attention has now turned to negotiations over a new legal instrument being developed under the purview of the WHO as an opportunity to design systems that will serve the world better in future pandemics. In December 2021, the 194 WHO member states established an intergovernmental negotiating body to “draft and negotiate a convention, agreement or other

international instrument under the Constitution of the World Health Organization to strengthen pandemic prevention, preparedness and response”,¹⁸ with the aim of adopting the agreement at the World Health Assembly in May 2024.

A zero draft released in February 2023 as the starting point for negotiations¹⁹ included several promising proposals that meet many recommendations put forward by academic and civil society experts,²⁰ and which could increase equitable access to pandemic response products if ultimately adopted. Among other measures to improve access to technology, the zero draft commits the parties to, in future pandemics, “take appropriate measures to support time-bound waivers of intellectual property rights that can accelerate or scale up manufacturing of pandemic-related products during a pandemic, to the extent necessary to increase the availability and adequacy of affordable pandemic-related products”.¹⁹ Importantly, this clause does not narrow the range of products eligible for intellectual property waivers, or the types of intellectual property that can be waived, in the manner in which the WTO Ministerial Decision did. However, whether this broad language will be retained — and whether any language at all about intellectual property waivers survives what are likely to be intense negotiations — remains uncertain.

Including language affirming WHO members’ commitments to support intellectual property waivers in the pandemic accord would not automatically ensure that such waivers are realised, as any waiver of TRIPS obligations would need to be negotiated at the WTO. However, its inclusion in the pandemic accord signals an important normative commitment for states to support such waivers — which could be crucial to achieving more meaningful outcomes on intellectual property waiver negotiations in future.

To ensure an equitable distribution of lifesaving products in future pandemics, it is critical that the pandemic accord deals effectively with the barriers that intellectual property presents.²⁰ Including a commitment to waive intellectual property protections is an important strategy — particularly if trade secrets are included in the scope of the waiver and if the obligation is binding. However, reports of the December 2022 intergovernmental negotiating body meeting suggest that Australia is currently taking the position that intellectual property matters should be left to the WTO.²¹ Given the WTO’s failure to negotiate a comprehensive and effective TRIPS waiver for COVID-19, the Australian Government should review its position and support the inclusion of language relating to intellectual property waivers in the pandemic accord.

Open access: Open access publishing facilitated by La Trobe University, as part of the Wiley - La Trobe University agreement via the Council of Australian University Librarians.

Competing interests: Deborah Gleeson holds an honorary role in the Public Health Association of Australia (PHAA) and often represents the PHAA on matters related to trade agreements and public health. The views expressed in this article are those of the authors and do not necessarily represent those of the PHAA.

Provenance: Not commissioned; externally peer reviewed. ■

© 2023 The Authors. *Medical Journal of Australia* published by John Wiley & Sons Australia, Ltd on behalf of AMPCo Pty Ltd.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

- 1 Our World in Data. Coronavirus (COVID-19) vaccinations. <https://ourworldindata.org/covid-vaccinations> (viewed Dec 2022).
- 2 Balakrishnan VS. 2 years of the access to COVID-19 Tools-Accelerator. *Lancet Infect Dis* 2022; 22: 948.
- 3 Pfizer. Pfizer to supply Global Fund up to 6 million PAXLOVID™ treatment courses for low-and-middle-income countries [press release]. 22 Sept 2022. <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-supply-global-fund-6-million-paxlovid-treatment> (viewed Dec 2022).
- 4 Medicines Patent Pool. Licences. <https://medicinespatentpool.org/progress-achievements/licences> (viewed Dec 2022).
- 5 Herder ME, Gold R, Murthy S. University technology transfer has failed to improve access to global health products during the COVID-19 pandemic. *Healthc Policy* 2022; 17: 15-25.
- 6 Hensher M, Wann Arachchige Dona S. COVID-19 vaccines, boosters and mandates: building a mission economy, not a rentier paradise. *Med J Aust* 2022; 216: 556-558. <https://www.mja.com.au/journal/2022/216/11/covid-19-vaccines-boosters-and-mandates-building-mission-economy-not-rentier>
- 7 Tenni B, Moir HVJ, Townsend B, et al. What is the impact of intellectual property rules on access to medicines? A systematic review. *Global Health* 2022; 18: 40.
- 8 Islam MD, Kaplan WA, Trachtenberg D, et al. Impacts of intellectual property provisions in trade treaties on access to medicine in low and middle income countries: a systematic review. *Global Health* 2019; 15: 88.
- 9 Médecins Sans Frontières. Lack of a real IP waiver on COVID-19 tools is a disappointing failure for people. 17 June 2022. <https://www.msf.org/lack-real-ip-waiver-covid-19-tools-disappointing-failure-people> (viewed Dec 2022).
- 10 Gold ER. What the COVID-19 pandemic revealed about intellectual property. *Nat Biotechnol* 2022; 40: 1428-1430.
- 11 Reichman JH. Universal minimum standards of intellectual property protection under the TRIPS component of the WTO agreement. *Int Lawyer* 1995; 29: 345-388.
- 12 Nicol D, Owoeye O. Time for rich countries to enact TRIPS-compliant legislation to facilitate access to medicines by poorer countries? *Bull World Health Org* 2013; 91: 533-539.
- 13 Urias E, Ramani SV. Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. *J Int Bus Policy* 2020; 3: 367-384.
- 14 Scheibner J, Nielsen J, Nicol D. An ethico-legal assessment of intellectual property rights and their effect on COVID-19 vaccine distribution: an Australian case study. *J Law Biosci* 2022; 9: Isac020.
- 15 World Trade Organization. Ministerial Decision on the TRIPS Agreement: adopted 17 June 2022. WT/Min(22)/30 WT/L/1141. Geneva, WTO, 2022. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True> (viewed May 2023).
- 16 Correa CM, Syam N. The WTO TRIPS decision on COVID-19 vaccines: what is needed to implement it? Geneva: South Centre, 2022. https://www.southcentre.int/wp-content/uploads/2022/11/RP169_The-WTO-TRIPS-Decision-on-COVID-19-Vaccines_EN.pdf (viewed Dec 2022).
- 17 Gurgula O, Hull J. Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer. *J Intellectual Property Law Practice* 2021; 16: 1242-1261.
- 18 World Health Organization. Third meeting of the Intergovernmental Negotiating Body (INB) for a WHO instrument on pandemic prevention, preparedness and response. 5-7 December. Geneva: WHO, 2022. [https://www.who.int/news-room/events/detail/2022/12/05/default-calendar/third-meeting-of-the-intergovernmental-negotiating-body-\(inb\)-for-a-who-instrument-on-pandemic-prevention-preparedness-and-response](https://www.who.int/news-room/events/detail/2022/12/05/default-calendar/third-meeting-of-the-intergovernmental-negotiating-body-(inb)-for-a-who-instrument-on-pandemic-prevention-preparedness-and-response) (viewed Dec 2022).
- 19 World Health Organization. Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting (A/INB/4/3). Geneva: WHO, 2023. https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf (viewed Apr 2023).
- 20 Perekhodoff K, 't Hoen E, Mara K, et al. A pandemic treaty for equitable global access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology. *BMJ Global Health* 2022; 7: e009709.
- 21 Ravelo JL, Byatnal A. Devex CheckUp: the coming pandemic treaty fight over equitable access. 8 Dec 2022. <https://www.devex.com/news/devex-checkup-the-coming-pandemic-treaty-fight-over-equitable-access-104609> (viewed Dec 2022). ■