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**AUSTRALIA MUST SUPPORT A TEMPORARY WAIVER OF INTELLECTUAL  
PROPERTY PROTECTIONS IN RESPONSE TO A FUTURE PANDEMIC**

Submission to the Commonwealth Government COVID-19 Response Inquiry

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**Executive Summary**

In times of pandemics, the Australian government must intervene through policy and legislative measures to protect the public interest. In response to the COVID-19 pandemic, the Australian government failed to take a clear position on intellectual property (IP) and access to vaccines, therapeutics, and diagnostics. Instead of fully supporting the TRIPS Waiver proposal aimed at addressing vaccine inequity, Australia remained non-committal in times of serious public health crisis. In response to a future pandemic, the Australian government must take a clear and strong position on IP in favour of equitable and universal access to vaccines, diagnostics, and therapeutics.

**Recommendations**

1. To safeguard the public interest, Australia needs to appreciate the importance of temporarily waiving IP protections to scale up production and supply of vaccines, diagnostics, and therapeutics in response to a pandemic.
2. In the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (Pandemic Accord), Australia needs to fully support temporary waivers of IP protections.

**I. AUSTRALIA'S NON-COMMITTAL POSITION**

Initially, in 2020, there was some virtue signalling by the Scott Morrison government in relation to fair and equitable distribution of COVID-19 vaccines. Mr Morrison said, "Whoever finds the vaccine must share it. This is a global responsibility, and it's a moral responsibility, for a vaccine to be shared far and wide".<sup>1</sup> This virtue signalling was not followed by concrete measures to achieve the goal of universal access to COVID-19 vaccines.

In October 2020, India and South Africa, along with other developing countries, proposed that certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) should be waived for COVID-19 for a limited time period in order to remove IP barriers to widespread vaccination across the globe.<sup>2</sup> Australia should have clearly supported the TRIPS Waiver proposal to fulfil its global and moral responsibility towards vaccine equity to save human lives. However, at the World Trade Organization (WTO), Australia

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<sup>1</sup> David Lipson, 'Scott Morrison urges sharing of COVID-19 vaccine in his United Nations speech' (26 September 2020) *ABC News* <https://www.abc.net.au/news/2020-09-26/scott-morrison-urges-sharing-covid-19-vaccine-united-nations/12706792>.

<sup>2</sup> World Trade Organization, '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.

preferred to maintain a non-committal position and questioned the necessity of the Waiver.<sup>3</sup> Downplaying the importance of the Waiver proposal, Australia stated at the WTO that “the TRIPS Agreement’s public health flexibilities offer practical support for all countries responding to the grave challenges posed by COVID-19”.<sup>4</sup>

Australia’s statement at the WTO suggested that a business-as-usual approach could be adopted in terms of enforcing patent protections to safeguard the profits of patentee corporations in the middle of a pandemic. Patents provide the desired tool to manufacturers of pharmaceutical drugs and vaccines to dominate the market and derive maximum profits by excluding others. Patents are private exclusive rights that allow patent holders to control whether or not, and on what terms, the protected items can be used by third parties.

COVID-19 vaccine production and licensing arrangements were not adequate, mainly because of IP barriers. Even economically advanced countries, such as Australia, faced shortages in COVID-19 vaccine supply. Among developed countries, Australia had one of the lowest rates in terms of fully immunizing its population.<sup>5</sup> Despite an insufficient supply of COVID-19 vaccines, Australia was opposing the Waiver proposal.<sup>6</sup>

In May 2021, U.S. President Biden announced his support for the proposed TRIPS Waiver. The Prime Minister of Australia welcomed this important move by the U.S. Trade Minister Dan Tehan wrote to Amnesty Australia in June 2021 that the Australian government is “not opposed” to the TRIPS Waiver proposal.<sup>7</sup> The Australian government, however, did not announce its support for the TRIPS Waiver. Australia remained hesitant in holding a clear publicly announced position on the TRIPS Waiver. The Australian government, despite experiencing the fallout of COVID-19 vaccine shortages, remained non-committal, let alone co-sponsor the Waiver proposal.

## II. INTELLECTUAL PROPERTY IS A KEY FACTOR

The brand-name pharmaceutical industry vigorously argued during the COVID-19 pandemic that IP was not posing barriers to access.<sup>8</sup> However, empirical evidence suggested exactly the opposite. A patent landscape report of the World Intellectual Property Organization (WIPO) found that by the end of September 2021, there were “5,293 patent filings on technologies related to COVID-19 in general, including 1,465 patent filings about therapeutics and 417 about vaccine development”.<sup>9</sup> IP has been a major barrier to scale production of vaccines and other COVID-19 related health technologies because corporate interests are linked with market exclusivity.

To downplay the importance of the Waiver, opponents of the proposal asserted that “life-sciences innovators extensively voluntarily licensed IP rights to produce COVID-19 vaccines and

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<sup>3</sup> TRIPS Council, ‘Questions on Intellectual Property Challenges Experienced by Members in relation to COVID-19: Communication from Australia, Canada, Chile and Mexico’ (27 November 2020) IP/C/W671.

<sup>4</sup> World Trade Organization, ‘Minutes of Meeting’, *Council for Trade-Related Aspects of Intellectual Property Rights* (30 July 2021) IP/C/M/99/Add.1.

<sup>5</sup> Sophie McNeill, ‘Australia Should Back Covid-19 Waiver of Intellectual Property Rules Waive TRIPS Amid Delta Outbreak, Vaccine Shortages’ (25 July 2021) *Human Rights Watch* <https://www.hrw.org/news/2021/07/25/australia-should-back-covid-19-waiver-intellectual-property-rules>.

<sup>6</sup> Commonwealth of Australia, *Proof Committee Hansard Senate, Foreign Affairs, Defence and Trade Legislation Committee- Estimates* (3 June 2021) 77.

<sup>7</sup> Amnesty International Australia, ‘Everything You Need To Know About The Trips Waiver’ (6 May, 2021) *Amnesty International Australia* <https://www.amnesty.org.au/everything-you-need-to-know-about-the-trips-waiver/>.

<sup>8</sup> Anne Harris ‘Vaccine related fraud and security risks Submission 11’ (2021) *Committee Secretary-Parliamentary Joint Committee on Law Enforcement* 3.

<sup>9</sup> WIPO, ‘Patent Landscape Report COVID-19-related vaccines and therapeutics’ (2022) *WIPO* 5.

therapeutics”.<sup>10</sup> Voluntary licenses do not have a global impact because of “geographic restrictions, resulting in market fragmentation and gaps in access, particularly for upper middle-income countries”.<sup>11</sup> For instance, [REDACTED]’s voluntary licensing agreement with the Medicines Patent Pool (MPP) in relation to Paxlovid did not include most of Latin America.<sup>12</sup> Technology-holding corporations were able to dictate terms and conditions as they were empowered to control their bilateral voluntary licensing deals with manufacturing partners.

Opponents of the proposal argued that the Waiver would undermine innovation by disincentivising future R&D activity.<sup>13</sup> Relatedly, the brand-name pharmaceutical industry claimed that their extensive investments and risk-taking involved in the development of innovative vaccines were purely driven and incentivised by a strong patent system. This claim is, however, not well supported by evidence. Brand-name pharmaceutical industry questionably avoided mentioning the substantial public funding that went into the development of COVID-19 vaccines. The development of mRNA technology involved billions in government funding for R&D over decades.<sup>14</sup> The argument that investments in R&D would not be recouped is baseless because the market for COVID-19 vaccines is literally the entire world.

Another key argument against the Waiver was that the TRIPS Agreement already allowed compulsory licensing as a flexibility to deal with a health emergency. The compulsory licensing mechanism, as set out in Article 31 of the TRIPS Agreement, is loaded with restrictions and challenges and does not provide a streamlined route to promote access. This mechanism is too slow to be effective in an emergency and does not provide a global solution because patents are territorial in nature and compulsory licenses are granted under national laws within each country. Export-oriented compulsory licensing under Article 31bis of the TRIPS Agreement is even more problematic.<sup>15</sup>

### III. CONCLUDING COMMENTS

IP is a key factor in terms of affordable and equitable universal access to vaccines, diagnostics, and therapeutics. Adopting a business-as-usual approach to enforcing IP protections in a pandemic situation seriously undermines the public interest and results in the preventable loss of human life. Siding with brand-name pharmaceutical corporations, at the expense of saving human lives, is not a value-based approach for any democratic government. In a future pandemic, Australia must support policy initiatives that are aimed at upholding the right to health and reducing inequality in accessing health technologies.

Australia must question the validity of the hypothetical claims of the brand-name pharmaceutical industry. Australia needs to make policy interventions to make it binding for brand-name pharmaceutical corporations to share IP and know-how with generic manufacturers of vaccines, diagnostics, and treatments in a future pandemic. In the WHO Pandemic Accord, Australia needs to fully support temporary waivers of IP protections.

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<sup>10</sup> Information Technology & Innovation Foundation, ‘COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities’, *Post-Hearing Comments of Stephen Ezell Before the U.S. International Trade Commission Washington, D.C.* FR Doc. 2023-02466 (May 5, 2023) 6.

<sup>11</sup> Public Citizen, ‘RE: Written Comments for Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics and Flexibilities Under the TRIPS Agreement’, *Public Citizen* (May 5, 2023) 1.

<sup>12</sup> *Ibid.*, 15.

<sup>13</sup> Peter J Pitts, Robert Popovian, and Wayne Winegarden, ‘Waiving COVID-19 Vaccine Patents: A Bad Idea and a Dangerous Precedent’ (2021) 26(2) *Journal of Commercial Biotechnology*.

<sup>14</sup> Lori Wallach, ‘U.S. International Trade Commission Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities’ (2023) *Rethink Trade. American Economic Liberties Project* 5.

<sup>15</sup> Muhammad Zaheer Abbas and Shamreeza Riaz, ‘WTO ‘Paragraph 6’ System for Affordable Access to Medicines: Relief or Regulatory Ritualism?’ (2018) 1–2 *Journal of World Intellectual Property* 32–51.