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**THE PROPOSED TRIPS WAIVER AND PHARMACEUTICAL INDUSTRY'S
CONCERNS ABOUT COUNTERFEIT COVID-19 VACCINES**

Submission to the Australian Parliament's Joint Committee on Law Enforcement Inquiry into
Vaccine Related Fraud and Security Risks



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Executive Summary

Corporations are expected to pursue profit-maximising strategies. They do not like competition and look for strategies to extract maximum revenue from their patent-protected products. They like to dominate markets by having exclusive rights and by extending their exclusive rights. It is duty of the Australian government to intervene through policy and legislative measures when the public interest is actually or potentially undermined, especially in times of emergencies.

The COVID-19 crisis exposed vulnerabilities of supply chains and put global healthcare systems under critical strain. The Australian government's policy and legislative response is required to address the imbalance between the corporate interest and the public interest in the context of equitable access to COVID-19 vaccines. There is a pressing need to consider policy initiatives that are aimed at expanding equitable access to COVID-19 related health technologies, especially vaccines. Patent rights should not be allowed to stand in the way of saving human lives. Australia needs to support the proposal of temporarily waiving intellectual property protections to scale up production and supply of vaccines and other COVID-19 related treatments and diagnostics.

Brand-name pharmaceutical industry's claim that the proposed TRIPS waiver will result in proliferation of counterfeit vaccines and treatments is not supported by empirical evidence. If there is a tangible risk of counterfeit vaccines, governments have mechanisms in place to curb any malpractices. Governments can further strengthen their existing mechanisms to deal with any issues hypothetically raised by brand-name pharmaceutical industry.

Recommendations

1. To safeguard the public interest, Australia needs to support the proposal of temporarily waiving intellectual property protections to scale up production and supply of vaccines and other COVID-19 related treatments and diagnostics.
2. Australia needs to learn from others' mistakes, in tackling with the HIV/AIDS crisis, and refrain from siding with brand-name pharmaceutical corporations in the middle of a pandemic.
3. Australia needs to question the validity of hypothetical claims made by brand-name pharmaceutical industry in terms of proliferation of counterfeit vaccines and treatments potentially resulting from the proposed TRIPS waiver.
4. Australia needs to strengthen its anti-counterfeit mechanisms in order to address any hypothetical concerns of brand-name pharmaceutical industry.
5. Australia needs to make policy interventions to make it binding for brand-name pharmaceutical corporations to share knowhow with generic manufacturers of vaccines and treatments, in a health emergency, in order to address the safety concerns as raised by these corporations.

Biography

Dr. Muhammad Zaheer Abbas, Member of the Australian Centre for Health Law Research (ACHLR), is a Postdoctoral Research Fellow at Faculty of Business and Law, Queensland University of Technology (QUT), Brisbane, Australia. In this role, he is working with Professor Matthew Rimmer on his Australian Research Council Discovery Project 'Inventing the Future: Intellectual Property and 3D Printing' (Project ID: DP170100758). In March 2020, he completed PhD in Law at QUT as a recipient of QUT Postgraduate Research Award. Previously, he studied Law at International Islamic University (IIU), Islamabad, Pakistan, and obtained LLB (Hons) with distinction in 2010. He also obtained LLM in International Law, with distinction, from the same university in 2012. He served as a Lecturer in Law at Faculty of Law, IIU, and has nearly 10 years of teaching and/ or research experience. He also served as Associate Editor of '*Islamabad Law Review*', a peer reviewed open-access research journal of IIU. He has published 26 peer-reviewed research papers, mostly related to intellectual property protection and the public interest. He has also presented 35 conference papers on related topics.

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I. INTRODUCTION

Monopolistic ownership of proprietary rights is key concern of brand-name manufacturers of pharmaceutical drugs and vaccines. Patents, which are considered the strongest form of intellectual property protection, 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 which allow patent holders to control whether or not, and on what terms, the protected items can be used by third parties. Patent protection conflicts with reverse-engineering and manufacturing of pharmaceutical drugs and vaccines, if such activities are carried out without the right holder's consent.

It can be foreseen that most of the developing countries will have to wait for several years to have widespread access to COVID-19 vaccines if business-as-usual approach is adopted in terms of enforcing intellectual property protections. India and South Africa, along with other developing countries, proposed in October 2020 that certain TRIPS rules should be waived for COVID-19 for a limited time period in order to remove intellectual property barriers to widespread vaccination across the globe. This submission calls upon the Australian government to support the proposal of temporarily waiving certain provision of the TRIPS Agreement in order to remove intellectual property barriers in accessing COVID-19 vaccines, treatments, and diagnostics.

II. PHARMACEUTICAL INDUSTRY'S POSITION ON THE TRIPS WAIVER

To downplay the importance of the proposed TRIPS waiver, brand-name pharmaceutical corporations are raising safety concerns. They claim that 'illicit and counterfeit products [resulting from TRIPS waiver] can pose real health and financial risks to individuals who unknowingly purchase these products'.¹ Without any empirical evidence to support their claim, brand-name pharmaceutical corporations are trying to convince policymakers at national and international levels that temporarily waiving certain provisions of the TRIPS Agreement in the current health emergency will undermine the public interest as it will 'further weaken already

¹, Anne Harris 'Vaccine related fraud and security risks Submission 11' (2011) *Committee Secretary-Parliamentary Joint Committee on Law Enforcement*, 2.

strained supply chains and foster the proliferation of counterfeit vaccines'.² There is no empirical evidence to suggest that prior to adoption of the TRIPS Agreement the western markets were flooded with counterfeit drugs and vaccines manufactured by generic manufacturers.

Brand-name pharmaceutical industry also raises concerns about safety of all individuals who take COVID-19 vaccines if such vaccines are manufactured by generic manufacturers without having the requisite knowhow to manufacture the same. As noted by Pfizer Australia in its submission to this inquiry, 'the waiver would increase the risk that patients around the world could be exposed to unsafe products; since it may invite copycat medicines from suppliers that lack the knowhow to manufacture vaccines safely'.³

One can ask brand-name pharmaceutical corporations what is stopping them from sharing the knowhow with authorized and capable generic manufacturers to manufacture vaccines safely if they are genuinely concerned about the safety and wellbeing of patients across the globe. Perhaps, they are prioritising secrecy and profits over saving human lives even in the middle of an unprecedented pandemic situation. Corporations are expected to pursue profit-maximising strategies. They do not like competition and look for strategies to extract maximum revenue from their products. They like to dominate markets by having exclusive rights and by extending their exclusive rights. It is duty of the Australian government to intervene through policy and legislative measures when the public interest is actually or potentially undermined, especially in times of emergencies.

Brand-name pharmaceutical industry understandably considers intellectual property protection as a necessary tool for supply chain resilience. As noted by Pfizer Australia in its submission to this inquiry:

A robust intellectual property (IP) policy environment that includes, for example, a strong patent system and regulatory data protection is critical to incentivise and drive the extensive investments and risk-taking involved in the development of innovative medicines and vaccines ... A strong IP system will also be critical to provide certainty for industry to be able to respond to future pandemics ... The IP system has also enabled an unprecedented number of

² PhRMA, 'PhRMA Statement on WTO TRIPS Intellectual Property Waiver', (May, 2021) *PhRMA*, <https://www.phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver>

³ Anne Harris 'Vaccine related fraud and security risks Submission 11' (2011) *Committee Secretary-Parliamentary Joint Committee on Law Enforcement*, 3.

collaborations between biopharmaceutical innovators and governments, universities and other research partners to speed up progress on finding solutions.⁴

Brand-name pharmaceutical industry claims that their extensive investments and risk-taking involved in the development of innovative vaccines was purely driven and incentivised by a strong patent system. This claim is, however, not well supported by evidence. As a matter of fact, despite the excellent public health value of vaccines, producing and selling vaccines is considered unattractive from a commercial perspective. The patent-based innovation model failed to respond to the emergence of diseases like Ebola (the Ebola virus is known since the 1970s), Zika, and yellow fever. Pharmaceutical companies are not interested in investing in such diseases because of limited commercial market opportunities.⁵ Innovation in new infectious diseases is questionable and highlights failures of the patent-based innovation model in the critical area of developing innovative vaccines. Moreover, there are issues of public funding of vaccine development projects. Public funding contributions are generally not reflected in the pricing and licensing decisions of corporations. Brand-name pharmaceutical industry questionably avoids mentioning the substantial public funding that went into development of COVID-19 vaccines. It is beyond the scope of this submission to go into further details of these lengthy discussions.

Brand-name pharmaceutical industry opposes the TRIPS waiver proposal for obvious reasons. As noted by Pfizer Australia in its submission to this inquiry, ‘The waiver proposal at the WTO incorrectly portrays IP as a barrier to rapid innovation, R&D collaboration and access to COVID-19 vaccines and other products ... Eliminating IP protections would not speed up vaccine production’.⁶ Medicines Australia holds a similar view: ‘Some individuals, organizations, and governments have called for suspending IP protections to improve access, including compulsory licensing via section 31 of the TRIPS waiver. Yet the current IP system has increased access to COVID-19 products’.⁷ Pfizer Australia’s and Medicine Australia’s viewpoint is in line with the IFPMA (International Federation of Pharmaceutical

⁴ Ibid.

⁵ Muhammad Zaheer Abbas, ‘Conflicting Interests, Competing Perspectives and Policy Incoherence: COVID-19 Highlights the Significance of the United Nations High-Level Panel Report on Access to Medicines’, (2020) 31 *Australian Intellectual Property Journal*, 32.

⁶ Anne Harris ‘Vaccine related fraud and security risks Submission 11’ (2011) *Committee Secretary-Parliamentary Joint Committee on Law Enforcement*, 3.

⁷ Medicines Australia, ‘Medicines Australia updated position on Intellectual Property (in light of TRIPS Waiver)’ (6 May 2021) *Medicines Australia* <https://www.medicinesaustralia.com.au/media-release/medicines-australia-updated-position-on-intellectual-property-in-light-of-trips-waiver/>

Manufacturers and Associations) statement on the TRIPS waiver: ‘Waiving patents of COVID-19 vaccines will not increase production nor provide practical solutions needed to battle this global health crisis’.⁸

This position – that intellectual property is not a barrier to scale production of vaccines and other COVID-19 related health technologies - obviously suits brand-name pharmaceutical industry, keeping in view its corporate interests linked with market exclusivity. This position, however, is not backed by empirical evidence and logical reasoning. The global community is fully cognizant of implications of adopting a business-as-usual approach to enforcing intellectual property protections during a health emergency.

The TRIPS Agreement purposefully included public health flexibilities, like compulsory licensing,⁹ to deal with situations like the current COVID-19 crisis when business-as-usual approach to intellectual property protection seriously undermines the public interest. The Doha Ministerial Declaration on the TRIPS Agreement and Public Health 2001 reaffirmed these public health flexibilities.¹⁰ In response to COVID-19, countries like Canada, Chile, Ecuador, Germany, Hungary, and France have taken enabling legislative measures to consider the use of compulsory licensing provisions to secure access to COVID-19 related health technologies.¹¹ Israel actually issued a compulsory license in March 2020 to secure access to AbbVie’s drug Kaletra.¹² Thus, intellectual property protection does pose barriers to access and countries do consider policy options to overcome these barriers in the real world situations.

The Bolivia-Biolyse case, in Canada, is the most recent example where patent protection is posing serious barriers and even the TRIPS Agreement’s public health flexibilities are failing to overcome these barriers. Since March 2021, Biolyse Pharma – a Canadian company having the potential to produce up to 20 million COVID vaccine doses per year - has been trying to use the TRIPS Agreement’s Article 31bis or Doha Declaration’s paragraph 6 mechanism to manufacture COVID vaccines. In May 2021, Biolyse signed an agreement with Bolivia to provide COVID vaccines subject to grant of compulsory licenses under the Article 31bis

⁸ International Federation of Pharmaceutical Manufacturers & Associations, ‘IFPMA Statement on WTO TRIPS Intellectual Property Waiver’ (2021) *International Federation of Pharmaceutical Manufacturers & Associations* <https://www.ifpma.org/resource-centre/ifpma-statement-on-wto-trips-intellectual-property-waiver/>

⁹ *The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) 1994*, Art. 31.

¹⁰ *Doha Ministerial Declaration on TRIPS Agreement and Public Health 2001*, Para 5.

¹¹ VM Tellez, ‘The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines’ (2020) *73 Policy Brief*, 2.

¹² *Ibid.*

mechanism.¹³ There is no progress despite Biolyse Pharma's eagerness to help countries lacking vaccine manufacturing capacity of their own. Patent law stands in the way as Johnson & Johnson has refused a voluntary license and Canada is not willing to issue an export-oriented compulsory license, possibly because of pressure of brand-name pharmaceutical industry. This case highlights the importance of negotiating the proposed TRIPS waiver to avoid unnecessary delays and substantial barriers in accessing COVID-19 vaccines, treatments and diagnostics.

III. AUSTRALIA'S POSITION ON THE TRIPS WAIVER

Shortage of COVID-19 vaccines is an urgent global crisis. Economically advanced high-income countries are no exception. Australia has been facing shortages in COVID-19 vaccine supply. Among developed countries, Australia has one of the lowest rates in terms of fully immunizing its population.¹⁴ COVID-19 vaccine production and licensing arrangements are questionable if economically advanced countries, like Australia, are struggling to get sufficient vaccine supply.

Prior to May 2021, Australia had been opposing the TRIPS waiver on COVID related intellectual property.¹⁵ In May 2021, the 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.¹⁶ Trade Minister Dan Tehan wrote to Amnesty Australia in June 2021 that the Australian government is 'not opposed' to the TRIPS waiver proposal.¹⁷ The Australian government has not announced or indicated its support for the TRIPS waiver. Australia is yet to hold a clear publicly-announced position on the TRIPS waiver. The Australian government, despite itself experiencing the fallout of COVID-19 vaccine shortages, is silent on a key policy issue concerning the entire global population.

Siding with the brand-name pharmaceutical industry in a pandemic situation is an extremely risky policy option for any representative government. If we look at President Biden's decision

¹³ Luis Gil Abinader, 'Bolivia seeks to import COVID-19 vaccines from Biolyse, if Canada grants them a compulsory license' (May 11, 2021) *Knowledge Ecology International* <https://www.keionline.org/36119>

¹⁴ 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>

¹⁵ Commonwealth of Australia, *Proof Committee Hansard Senate, Foreign Affairs, Defence and Trade Legislation Committee- Estimates*, (3 June 2021) 77).

¹⁶ *Ibid.*

¹⁷ 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/>

- to support the TRIPS waiver - in a historical context, the democrats in the U.S. have learned their lessons from their past experience of siding with brand-name pharmaceutical industry during HIV/AIDS crisis. In 1998, Pharmaceutical Manufacturers Association of South Africa (a group of 39 pharmaceutical companies including U.S.-based Bristol-Myers Squibb, Eli Lilly and Merck) challenged the constitutional legality of Amending s 15C of the South African Medicines and Related Substances Control Act, which authorized pro-health measures like parallel importation and compulsory licensing.¹⁸ The group of pharmaceutical companies - faced with unprecedented public outcry and widespread condemnation - withdrew the suit before judgment was reached.¹⁹ The Clinton Administration in the U.S. not only supported brand-name pharmaceutical industry's actions but also exerted direct trade pressure on South Africa through the United States Trade Representative (USTR).²⁰ The timing of these actions coincided with the presidential election campaign in the U.S. Democrat's Presidential candidate Al Gore's support for the brand-name pharmaceutical industry, while ignoring the right to health, led to the 'erection of such politically-damaging banners as 'Gore's Greed Kills''.²¹

Instead of making its own mistakes, a much wiser approach for Australia would be to learn from others' mistakes and experiences. Siding with brand-name pharmaceutical industry in the middle of a pandemic and quietly witnessing millions of preventable deaths might not be the best policy option for Australia if it wants to be on the right side of the history.

IV. CONCLUDING COMMENTS

Intellectual property is an important area when it comes to affordable and equitable universal access to COVID-19 vaccines, treatments, and diagnostics. It is critically important to consider practical implications of adopting a business-as-usual approach to enforcing intellectual property protections in a pandemic situation. The TRIPS waiver proposal should be supported by Australia in order to safeguard the public interest. Siding with brand-name pharmaceutical corporations, at the expense of saving human lives, is an extremely risky approach for any democratic government. Australia should learn lessons from the history and choose to be on

¹⁸ Flint, A. and Payne, J., 2013. Intellectual Property Rights and the Potential for Universal Access to Treatment: trips, acta and HIV/aids medicine. *Third World Quarterly*, 34(3), 507.

¹⁹ Sundaram, J., 2018. *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines*. Routledge, 176.

²⁰ Ibid, 175. See more Muhammad Zaheer Abbas, 'Parallel importation as a policy' (2021) *Journal of Generic Medicines* 3,4.

²¹ Yu, P.K., 2008. Access to medicines, BRICS alliances, and collective action. *American journal of law & medicine*, 34(2-3), 355.

the right side of the history by supporting policy initiatives that are aimed at upholding the right to health and reducing inequality in accessing health technologies in a health emergency.

The concerns raised by brand-name pharmaceutical corporations in terms of proliferation of counterfeit vaccines and treatments are not backed by evidence. Australia needs to question the validity of these hypothetical claims. Australia needs to make policy interventions to make it binding for brand-name pharmaceutical corporations to share knowhow with generic manufacturers of vaccines and treatments, in a health emergency, in order to address the safety concerns as raised by brand-name pharmaceutical corporations.