COMMONWEALTH GOVERNMENT COVID-19 RESPONSE INQUIRY

AUSTRALIA'S COVID-19 RESPONSE: INTELLECTUAL PROPERTY AND PUBLIC HEALTH



Universities Allied for Essential Medicines, Free the Vaccine Campaign

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SUMMARY

The purpose of the Commonwealth Government COVID-19 Response Inquiry (the Inquiry) is to identify lessons learned to improve Australia's preparedness for future pandemics.

There has been a growing literature on COVID-19 law and policy – looking at the responses of international institutions, national governments, and judicial systems to the public health crisis. This submission focuses upon the role of intellectual property in terms of Australia's COVID-19 response. The Federal Government has responsibility for intellectual property law and policy – both under the intellectual property power and the external affairs power of the *Australian Constitution*. So this submission does concern the 'role of the Commonwealth Government' in terms of 'key health response measures' and 'international policies to support Australians at home and abroad.'

This submission focuses on the intellectual property dimensions of Australia's response to the COVID-19 crisis – which both has national and international dimensions. Part 1 of the submission considers Australia's position in debates over international intellectual property and access to essential medicines. Part 2 addresses questions in respect of patent law and access to essential medicines in the COVID-19 public health emergency. Part 3 explores the diverse role of other forms of intellectual property during the COVID-19 crisis.

1. INTERNATIONAL INTELLECTUAL PROPERTY

This submission focuses upon intellectual property, access to essential medicines, and COVID-19. It considers the Australian Government's response to legal issues in respect of the COVID-19 pandemic relating to intellectual property, public health, and international trade. This submission considers the challenges and obstacles presented by vaccine nationalism and commercial profiteering during the COVID-19 crisis.

TRIPS Waiver. There was a call by COVID-19 crisis. This call was taken up by civil society organisations, health groups, and developing countries. In international debates over intellectual property, trade, and public health, India and South Africa proposed a TRIPS Waiver to enable nation states to suspend the operation of the TRIPS Agreement 1994 insofar as it related to technologies needed to combat the COVID-19 crisis. The Australian Government vacillated on the topic of a TRIPS Waiver. At first, the Morrison Government was unwilling to support the TRIPS Waiver proposal. The Australian Labor Party and the Australian Greens were critical that the Morrison Government was non-committal about the TRIPS Waiver. The Morrison Government then changed its position, and expressed limited support for a TRIPS Waiver confined to vaccines. This switch of position coincided with a diplomatic change of position by the Biden Administration – which expressed a willingness to support a TRIPS Waiver for vaccines. However, the proposal for a TRIPS Waiver did not reach consensus support. The European Union, the United Kingdom, and Switzerland were obstinate in their opposition to a TRIPS Waiver (whatever form that might take). Arguably, a full endorsement of the TRIPS Waiver by the Australian Government would have helped boost domestic biomanufacturing of vaccines, treatments, diagnostics, and health-equipment, as well as assist our near neighbours in the Asia-Pacific.

Ministerial Decision. In 2022, the Ministerial Conference of the World Trade Organization agreed to the Ministerial Decision on the TRIPS Agreement 2022. This limited decision allowed for the broader use of compulsory licensing of patents for the purpose of exporting vaccines. Minister for Trade argued that the decision sent 'a powerful signal of global solidarity in fighting COVID-19 and reaffirming the role the WTO can play in responding to urgent global issues'. In insisted that the decision 'will support equitable access to vaccines for developing countries, including across the Indo-Pacific region.' However, many civil society organisations in Australia were disappointed by the Ministerial Decision on the TRIPS Agreement 2022. In practice, the decision has had no influence on the distribution of vaccines to deal with the COVID-19 crisis.

Pandemic Treaty. The Australian Government is involved in negotiations in the World Health Organization over the foundation of a Pandemic Treaty, ¹⁵ and discussions on changes to International Health Regulations. ¹⁶ The Federal Department of Health has observed that a number of principles guide Australia's approach to the negotiations. ¹⁷ The Australian Government wants to 'maintain Australia's sovereignty to make and implement decisions to protect the health of Australians. ¹⁸ It hopes to 'promote fairness, advance gender equality, and uphold human rights'. ¹⁹ At the same time, the Australian Government has vowed to 'uphold intellectual property rights'. ²⁰ There has been discussion as to whether a Pandemic Treaty should include text on intellectual property, and, if so, what form that text should take.

There has been a call from civil society and developing nations to recognise intellectual property flexibilities in a Pandemic Treaty, as well as alternative models of research and development, such as open innovation.²¹

2. PATENT LAW

There has been a longstanding debate over the relationship between patent law and access to essential medicines.²² There have been controversies over the role of patent law and the provision public health in relation to HIV/AIDS, malaria, and tuberculosis. There have been patent races in relation to new emerging infectious diseases, such as the SARS virus,²³ avian influenza, the Zika virus. The COVID-19 crisis provided a new context in which there have been tensions in respect of intellectual property and access to essential medicines.

Patent Litigation. There have been patents filed around in respect of COVID-19 related technologies – including vaccines, diagnostics, treatments, and health equipment. The patent landscape is a very messy one with thickets of patents around key technologies designed to address COVID-19. There has been increasing patent disputes over key technologies related to COVID-19 vaccines. and have challenged COVID-19 vaccine patents at the US Patent Office.²⁴ has brought patent infringement action against and over its patents in lipid nanoparticle technology.²⁵ No doubt there will be Australian patent disputes over key COVID-19 vaccines, diagnostics, and treatments in the future. The ultimate patent ownership and control of COVID-19 vaccinees, diagnostics, treatments, and health equipment will have ramifications for Australia's public health.

Patent Flexibilities. During the COVID-19 crisis, there was debate in the Australian Parliament as to whether the Australian Government should make use of patent flexibilities – such as Crown Use and compulsory licensing.²⁶ The Hon. of the Australian Labor Party questioned the Morrison Government as to whether it would use patent flexibilities to address public health concerns.²⁷ The Australian Government should make use of domestic compulsory licensing flexibilities under patent law in order to ensure fair competition, boost public health, and enable technology transfer. Australia should enable the use of compulsory licensing for the purposes of the export of essential medicines – particularly to developing countries and least developed countries in the Asia-Pacific. If need be, the Australian Government should deploy Crown Use provisions and government acquisition powers in the case of market failure in the production and distribution of COVID-19 technologies.

Patent Licensing. The Medicines Patent Pool expanded its mandate and jurisdiction so that it could cover the COVID-19 crisis.²⁸ The organisation seeks to overcome intellectual property barriers through voluntary licensing Australia should reinforce the work of the Medicines Patent Pool in the distribution of COVID-19 related technologies. Public sector research organisations, philanthropic entities, and private companies should contribute to the Medicines Patent Pool.

The World Health Organization established the C-TAP – the Coronavirus Technology Access Pool – building upon a proposal from Costa Rica.²⁹ The Australian Government, public sector research organisations, philanthropic entities, and private companies should contribute to C-TAP.

The Universities Allied for Essential Medicines argued that there should also be scope for public sector licensing – particularly where there has been public sector funding of COVID-19 related technologies.³⁰

The Open COVID Pledge was a useful means of allowing intellectual property owners to signal that they would decline to engage in IP litigation during the COVID-19 crisis.³¹ There has been much interest in the development of open innovation models to help the development of new vaccines, diagnostics, and treatments for COVID-19. The COVID Moonshot project is an example of an Open Science project.³²

3. OTHER FORMS OF INTELLECTUAL PROPERTY

Copyright Law and Access to Knowledge. COVID-19 had an impact upon access to knowledge, education, and learning – particularly during lockdown periods. In this context, a number of digital libraries sought to make materials more widely available during the public health emergency.

In response, publishers sued the Internet Archive in the United States for copyright infringement over its digital lending scheme and its National Emergency Library.³³ The Internet Archive argued that its actions were protected by

the defence of fair use – and various copyright exceptions. The publishers have prevailed at first instance – but the matter is under appeal.

It would be worthwhile considering the operation of Australia's copyright law and its exceptions during a public health emergency. The current purpose-specific fair dealing provisions under copyright law are not necessarily well-adapted to deal with the exigencies of a public health epidemic.

Designs Law and the Right to Repair. During the COVID-19 crisis, the Productivity Commission was conducting an inquiry into the right to repair.³⁴ This investigation looked at intellectual property (including designs law); consumer law and competition policy; and environmental stewardship and sustainable development. The Productivity Commission made a number of recommendations to support a right to repair in Australia.³⁵ However, the Productivity Commission recommended that there should be a separate inquiry into the topic of the medical right to repair. The question of the medical right to repair was highlighted by the COVID-19 crisis – in which there was a need to repair and fix medical equipment and supplies in the middle of lockdowns. There has been a call for a recognition of the medical right to repair – particularly in the context of public health emergencies.³⁶

Trade Marks. During the COVID-19 pandemic, there was a rush to register COVID-19 related trade marks in relation to a wide range of goods and services. IP Australia took a hard line against trade mark applications containing references to COVID-19.³⁷ IP Australia rejected many applications on the basis that the registration of COVID-19 Marks would be scandalous or offensive to ordinary Australians in view of the detrimental impact of the pandemic in Australia. IP Australia was also reluctant to grant trade marks in respect of descriptive uses of the term of COVID-19.

Consumer Protection. Consumer law is often conceived as an important supplement to trade mark law. The ACCC took action in respect of false and misleading representations about COVID-19 made by companies. Notably, the ACCC brought litigation against in the Federal Court of Australia over its false 'anti-virus activewear' claims. The ACCC also initiated action against for misleading representations about government approval of products – during public concern about COVID-19. The Therapeutic Goods Administration (TGA) also took action over illegal advertising related to COVID-19. The TGA issued infringement notices to company over the promotion of a device. There were also larger problems in respect of fraudulent claims relating to COVID vaccinations – and a larger increase in fraud during the COVID-19 lockdown period. The control of the covided with the covided vaccinations and a larger increase in fraud during the COVID-19 lockdown period.

Trade Secrets and Data Protection. Trade secrets have played an important role in vaccine development, and the creation of diagnostics and treatments during the COVID-19 pandemic.⁴² There have been a number of instances in which COVID-19 vaccine developers have brought action for breach of trade secrets (not always with success).⁴³ National governments have also taken action in respect of trade secrets theft of COVID-19 technologies directed by foreign principals.⁴⁴ Some scholars have called for compulsory licensing of trade secrets to ensure access to COVID-19 vaccines.⁴⁵ There has been discussions of the use of data protection in respect of COVID-19 related information and knowledge.

CONCLUSION

The Commonwealth Government COVID-19 Response Inquiry should seek to investigate Australia's position in international intellectual property debates during the COVID-19 crisis – in particular, looking at the *TRIPS Waiver* proposal, the *Ministerial Decision on the TRIPS Agreement* 2022, and the *Pandemic Treaty*. Clearly, there needs to be better articulated intellectual property flexibilities to deal with public health emergencies. There should be a review of Australia's patent law, policy, and practice to see whether it was well-adapted to deal with the public health emergency of the COVID-19 crisis. Likewise, there is a need to consider other fields of intellectual property, and their role during the COVID-19 pandemic. Copyright law had a significant impact in relation to access to education, knowledge, and learning during COVID-19 lockdowns. Intellectual property and the medical right to repair were an important issue during the COVID-19 crisis. Trade mark law and consumer protection played an important role in dealing with misleading and deceptive representations about COVID-19. Trade secrets and data protection also played a significant role as supplementary forms of intellectual property protection in relation to COVID-19 technologies. Intellectual property law and policy has also had a bearing in respect of COVID-19 recovery plans. Australia should conduct a full review of its intellectual property system to see whether it is well prepared for future pandemics.

Biography

Dr Matthew Rimmer is a Professor in Intellectual Property and Innovation Law at the Faculty of Business and Law, at the Queensland University of Technology (QUT). He has published widely on copyright law and information technology, patent law and biotechnology, access to medicines, plain packaging of tobacco products, intellectual property and climate change, Indigenous Intellectual Property, intellectual property and trade, and 3D printing regulation. He is undertaking research on intellectual property and sustainable development (including the debate over the right to repair); greenwashing; intellectual property, access to essential medicines, and public health (particularly looking at the COVID-19 crisis), and tobacco endgame policies. His work is archived at QUT ePrints, SSRN Abstracts, Bepress Selected Works, and Open Science Framework.

Rimmer has published four major research monographs. Rimmer is the author of a research monograph, *The Trans-Pacific Partnership: Intellectual Property and Trade in the Pacific Rim* (Edward Elgar, 2020), *Intellectual Property and Climate Change: Inventing Clean Technologies* (Edward Elgar, 2011), *Intellectual Property and Biotechnology: Biological Inventions* (Edward Elgar, 2008), and *Digital Copyright and the Consumer Revolution: Hands off my iPod* (Edward Elgar, 2007). His PhD Dissertation is on *The Pirate Bazaar: The Social Life of Copyright Law* (UNSW, 2001).

Rimmer has also edited a number of collections. In collaboration with Bita Amani and Caroline B. Ncube, Rimmer is the editor of the Elgar Companion on Intellectual Property and the Sustainable Development Goals (Edward Elgar, 2024). Along with Dinusha Mendis and Mark Lemley, Rimmer is the editor of the collection, 3D Printing and Beyond: Intellectual Property and Regulation (Edward Elgar, 2019). Rimmer is the editor of the collection, Intellectual Property and Clean Energy: The Paris Agreement and Climate Justice (Springer, 2018). Rimmer has edited a special issue of the QUT Law Review on the topic, The Plain Packaging of Tobacco Products (2017) - which featured a foreword by former Minister for Health and Attorney-General Nicola Roxon. Rimmer is the editor of the collection, Indigenous Intellectual Property: A Handbook of Contemporary Research (Edward Elgar, 2015). Rimmer is also a coeditor of Intellectual Property and Emerging Technologies: The New Biology (Edward Elgar, 2012), and Incentives for Global Public Health: Patent Law and Access to Essential Medicines (Cambridge University Press, 2010). Rimmer edited the thematic issue of Law in Context, entitled Patent Law and Biological Inventions (Federation Press, 2006).

Over the past two decades, Rimmer's research has been supported by a number of nationally competitive research grant applications. Rimmer has been a chief investigator in an Australian Research Council Discovery Project, 'Gene Patents In Australia: Options For Reform' (2003-2005), an Australian Research Council Linkage Grant, 'The Protection of Botanical Inventions' (2003); an Australian Research Council Linkage Grant, 'Unlocking IP' (2006-2008) and an Australian Research Council Discovery Project, 'Promoting Plant Innovation in Australia' (2009-2011). He was an Australian Research Council Future Fellow, working on Intellectual Property and Climate Change from 2011 to 2015. Rimmer was a Chief Investigator on an ARC Discovery Project on 'Inventing The Future: Intellectual Property and 3D Printing' (2017-2021). He is a chief investigator of the NHMRC Centre of Research Excellence on Achieving the Tobacco Endgame (CREATE) (2020-2025). Rimmer has experience in directing large-scale collaborative research projects on intellectual property and global challenges.

Rimmer is a chief investigator in the QUT Centre for Behavioural Economics, Society, and Technology (QUT BEST); and the QUT Australian Centre for Health Law Research (QUT ACHLR). He is a chief investigator in the NHMRC Centre of Research Excellence on Achieving the Tobacco Endgame (CREATE) (2020-2025) - a transnational research network. Rimmer was previously the leader of the QUT Intellectual Property and Innovation Law Research Program from 2015-2020 (QUT IPIL). He was also a member of the QUT Digital Media Research Centre (QUT DMRC), the QUT Centre for the Digital Economy, the QUT Centre for Justice, the QUT Centre for Clean Energy Technologies and Processes, and the QUT International Law and Global Governance Research Program.

Dr Matthew Rimmer holds a BA (Hons) and a University Medal in literature (1995), and a LLB (Hons) (1997) from the Australian National University. He received a PhD in law from the University of New South Wales for his dissertation on *The Pirate Bazaar: The Social Life of Copyright Law* (1998-2001). Dr Matthew Rimmer was a lecturer, senior lecturer, and an associate professor at the ANU College of Law, and a research fellow and an associate director of the Australian Centre for Intellectual Property in Agriculture (ACIPA) (2001 to 2015). He was an Australian Research Council Future Fellow, working on Intellectual Property and Climate Change from 2011 to 2015. He was a member of the ANU Climate Change Institute.

The Australian Centre for Health Law Research

The Australian Centre for Health Law Research (ACHLR) is a research centre based at the Faculty of Business and Law at the Queensland University of Technology (QUT).

ACHLR is celebrating ten years of making a difference to health law. Health law is critical to support and regulate health systems, the delivery of health services and positive health outcomes for individuals and society. ACHLR is internationally recognised as a leading health law research centre, with 38 academic members, 20 PhD students and 20 esteemed Adjunct Professors in the field of health law from across the globe. ACHLR researchers undertake innovative interdisciplinary research into current and emerging health law challenges in Australia and globally to produce an evidence base to properly address complex problems in the field of health and inform reforms to health law, policy and practice in the context of constant societal change.

ACHLR's research critically evaluates the legal, ethical, policy and regulatory frameworks, both conceptual and practical, which support and regulate the delivery of health services in diverse contexts. It distils the links between historical and current law, and its informing ethical and social realities and principles. We employ a range of research methods, including doctrinal, ethical, and empirical approaches. Our research explains for academic, professional and community audiences why the law takes its current form, how it can be critiqued, and how it might be reformed.

During its ten-year history, ACHLR researchers have published 784 articles and book chapters; 25 books or edited collections; produced 82 reports/policy briefings and submissions to government enquiries or royal commissions; and graduated 30 PhD students. ACHLR researchers have been awarded \$56 million in grant funding during this time.

ACHLR's health law researchers draw on disciplines including ethics, philosophy, medicine, nursing, psychology, economics, sociology and social work to address practical problems that arise in the health context. Our researchers have a strong track record of undertaking high impact research in health law, policy, ethics, and regulation. Our focus is not only on quality scholarship, but generating new knowledge, evidence, and insights to enhance health and legal policy and practice, and to improve health outcomes. This research serves the interests of the individuals, communities, and institutions that deliver and benefit from health services and other interventions that aim to improve health locally and globally.

Our research has had significant impact: our recommendations have been adopted by parliaments, courts and tribunals, and law reform commissions. Our work has also influenced state and national policy, prompting changes to clinical education in universities, hospitals and health departments. ACHLR has a strong international focus and presence. We actively continue to build and maintain relationships with external partners to facilitate opportunities for research collaborations, funded and unfunded, and to build and maintain our profile as a leading health law centre globally.

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