PATENTS AND THE PANDEMIC

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INTRODUCTION

The global COVID-19 pandemic has dominated almost every aspect of daily life throughout the world during 2020. In addition to the significant impact on public health, the way people work, socialise and learn has been impacted by the pandemic to a greater or lesser extent depending on their circumstances and geographic location. So far, 2020 has been filled with daily headlines regarding the origin, spread and economic impact of the virus. There is extensive coverage of the significant global efforts to develop and distribute treatments and vaccines, which has sparked greater interest and debate as the pandemic continues.

The global intellectual property ("IP") regime is only a small part of the complex matrix of factors playing into solutions (and for some, perceived problems) related to the global pandemic. However, the race to develop effective treatments and vaccines has resulted in considerable discussion about the potential impact IP, and in particular patents, may have on the ability to produce and distribute medications for the billions of individuals who will require access.

Whether the current patent system will inhibit the common goal of treating and, ideally eradicating, the COVID-19 virus has been the subject of commentary and debate amongst activists, government leaders and in the corporate world. Concerns have been expressed from the perspective of developing countries that more advanced economies, which are at the forefront of scientific development, will leverage the legal and regulatory environments, including the existing patent regime, to ensure their citizens have priority access to vaccines. Further, there is concern that commercial outcomes will become paramount and prevail over those of public health.

Advocates for access to vaccines and other health-related products are also apprehensive about the fact that large private corporations in the life sciences industry may seek to optimise profits at the expense of universal access to treatments or vaccines. These innovators, who make high-risk investments in relation to sophisticated and complicated science, tend to uphold the patent regime as one essential pillar in the overall policy, regulatory and research framework that enables advances in medical science.

The debate about the appropriateness and efficacy of the patent system is not new. Its capacity to achieve the objective of enhancing innovation has been repeatedly challenged over time, including at the height of the HIV/AIDS epidemic in the 1980s.

Given the unprecedented scale and impact of the present pandemic from both health and economic standpoints, it is understandable that the surrounding discourse has become emotive and polarising. It is also understandable, given the subject matter, that some of the well-intended commentary is driven by a misunderstanding of some of the theoretical nuance of patent law, and its operation in practice.

The debate

The two main sides of the argument are clearly drawn. On one side, industry stakeholders and some patents scholars articulate a belief in the system that seeks to incentivise innovation via the bargain at the heart of the regime. This will be dealt with in this article in more detail further; suffice it to state briefly here that it involves a limited monopoly for the patentee in exchange

for the ultimate disclosure of the invention at issue, to the benefit of society as a whole.[1]

In contrast, valid concerns around broad access to medical and therapeutic "solutions" or forms of assistance in the wake of such a health crisis have been put forward by some academics and activists who are worried that the patents system will prove to be restrictive, and its beneficial outcomes not shared broadly amongst society, because it may seem to function around the incentive of profit, through the mechanism of the limited monopoly.[2] These opposing assessments actually reflect the critical balance that the patent regime is intended to achieve — encouraging innovation for the benefit of the broader community on the one hand, while rewarding the risks undertaken by innovators in order to achieve that outcome, on the other.

An assessment of the arguments and evidence to date reveals that there is no need for an immediate, fundamental overhaul of the patent system in order to facilitate an effective response to COVID-19. The potential of the patent system to create friction in terms of the universal and equitable distribution of COVID-19 treatments and vaccines are balanced by:

(a) the incentives offered by the patent system to encourage development of new treatments;

(b) provisions in patent regimes to facilitate mandatory access to patented technologies in certain circumstances;

(c) the economic, social and governmental pressures on organisations to act ethically and in accordance with their broader obligations to society; and

(d) the fact that universal distribution of an effective vaccine is essential in order for all countries to be confident that the virus has been controlled.

HISTORY: A BARGAIN

Following on from the description of the main arguments, above, the patent system can be described as a contradictory union of principles whereby a balance is struck between monopoly and liberty, public disclosure and ownership of ideas, and economic gain and the common good.[3] This balance is deeply embedded in the origins of the regime and is intended to function as a primary motivator for research and innovation, thereby improving the state of technology.

The origins of Australia's patent system pre-date the COVID-19 pandemic by some 400 years. Our regime traces its beginnings to the United Kingdom ("UK"), where, as Ricketson et. al. put it, "the system is of considerable antiquity".[4] Scholars generally point to 1623 and the Statute of Monopolies as the first formal codification of the patents system in England.[5] In general terms, the underlying rationale of the system is to encourage investment in research and innovation by providing the innovator with a time-limited monopoly, after which the invention is in the public domain and may be freely accessed and used. The mechanism of disclosure that effectuates the release of the patent to the public, the specification, is discussed in more detail in this article further on.[6]

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[1] Gary Cox et al, *Patents, Trade Marks & Related Rights* (LexisNexis Australia, October 2020) 15,000. And, see eg, Sam Ricketson et al, *Intellectual Property: Cases, Materials, Commentary*, (LexisNexis Butterworths 6th ed 2020) 659-667.

[2] Dorothy R Auth, 'COVID-19 Update: Patent Rights in the COVID-19 Pandemic: How will Industries and Governments Respond?' (2020) X (311) *National Law Review* 309 <https://www.natlawreview.com/article/covid-19-update-patent-rights-covid-19-pandemic-how-will-industries-and-governments>.

[3] Australian Law Reform Commission, *Genes and Ingenuity: Gene patenting and human health (ALRC Report 99)* (Report 2 August 2010) <https://www.alrc.gov.au/publication/genes-and-ingenuity-gene-patenting-and-human-health-alrc-report-99/2-the-patent-system/an-outline-of-the-patent-system/> .

[4] Sam Ricketson et al, *Intellectual Property: Cases, Materials, Commentary*, (LexisNexis Butterworths 6th ed 2020), 647.

[5] Section 6 famously reads: "Provided also and be it declared and enacted that any declaration before mentioned shall not extend to any letters patent and grants of privilege for the term of fourteen years or under, hereafter to be made, on the sole working or making of any manner of new manufactures within this realm, to the true and first inventor and inventors of such manufactures which others at the time of making such letters patent and grants shall not use, so as also they be not contrary to the law, mischievous to the state, by raising prices of commodities at home, or hurt at trade, or generally inconvenient; the said fourteen years to be accounted from the date of the first letters patent or grant of such privilege hereafter to be made, but that the same shall be of such force as they should be if this Act had never been made, and of none other." See Sam Ricketson, et al, *Intellectual Property: Cases, Materials, Commentary*, (LexisNexis Butterworths 6th ed 2020), 648-651 (and reference to K Boehm, *The British Patent System, Vol I: Administration* (Cambridge University Press, Cambridge, 1967), 14-26. And, William van Caenegem, *Intellectual and Industrial Property Law*, (LexisNexis Butterworths 3rd ed, 2019), 147-150.

[6] See page 10 of this article.

One way of understanding the character of the patent system is to think of it as a contract or "bargain" with the state, in Australia's case, the Commonwealth. In exchange for an inventor delivering up a new and useful technology, the state will grant that inventor a limited monopoly of up to 20 years. During that period, the patentee may exercise exclusive rights, or control, over their invention; in other words, no other person can exploit the technology without the patent owner's permission. In theory, this gives the patentee significant economic power. In effect, they have no competition, which, in turn, enables them to generate a return on their investment. Thus, the promise of a monopoly for a limited time is intended to encourage investment in innovation, and profits realised during the monopoly period will ideally be re-invested in further innovation, to the advantage of both the economy at large, and society's 'innovativeness' overall. The theory suggests that without this incentive, there is no reason for innovators to take the substantial risk of investing in a new technology if, once it goes to market, others can supply competing products and reap the rewards of the innovator's risk and effort.

In the life sciences space, it often takes numerous attempts and significant financial investment to develop and test a new pharmaceutical product or treatment. However, such products are often relatively easy and inexpensive to replicate or copy if one knows how. Therefore, there is a need for an in-built economic mechanism to redress the imbalance between the significant investment of the original developer or innovator, and the concomitantly significant ease of replication and consequent reward. Patents are such a mechanism.[7]

The patentee's contribution

The innovator's side of the bargain is met by their obligation to publish a detailed patent specification describing their invention in full.[8] The specification enables anyone, at the conclusion of the patent term, to freely use, or put the invention into practise.[9] Thus, the whole of society ultimately benefits from the innovator's risk and investment — following the expiry of the patent term the invention is "gifted" to the public.

Patent specifications are published on broadly accessible databases and constitute a vast store of scientific and technical literature which, following expiry, is freely available for exploitation.[10] Even while patents are in force, competitors and/or imitators are entitled to review specifications in order to build on what has been disclosed and, if necessary, work around the scope of the specification to provide an alternative, and potentially improved, technology.[11]

Illustrating this, according to the IP Australia database, there are nearly 900,000 lapsed or expired patents published in Australia alone.[12] This amounts to a very substantial, searchable, categorised database of innovation that anyone is free to mine and exploit.

Throughout its history, there has been debate about whether the patent system in fact achieves its goals. It has always been notoriously difficult to quantitively measure the effectiveness of the system. One of the problems is temporal — a patentee is granted a monopoly today and any broader flow-on benefit to society may not become apparent until years later. The conundrum or debate is often most prevalent in the area of the life sciences because of the importance of the subject matter and its effect on individuals' wellbeing, as well as the substantial commercial returns that can be generated in the industry. Further, sophisticated players in the life sciences have been very successful at leveraging the patent system to achieve commercial outcomes. Patents have become a key strategic plank of their business model and a

[7] Hon MK Ohlhausen, 'Patent Rights in a Climate of Intellectual Property Rights Skepticism' (2016) 30(1) *Harvard Journal of Law & Technology* 15.

[8] Gary Cox et al, *Patents, Trade Marks & Related Rights* (LexisNexis Australia, October 2020) 15,005 – 15,030.

[9] Gary Cox et al, *Patents, Trade Marks & Related Rights* (LexisNexis Australia, October 2020) 15,000.

[10] By way of example, see "AusPat", IP Australia's Australian patent search engine that allows, inventors, industry and researchers to access patent applications (lodged and granted in Australia) < http://pericles.ipaustralia.gov.au/ols/auspat/faqs.html>. The World Intellectual Property Organization's equivalent is "Patentscope" < https://patentscope.wipo.int/search/en/search.jsf>.

[11] In Australia, fewer than half of all patents filed are still in force after 10 years (ie, half their potential life): see s 68, *Patents Act 1990* (Cth) for terms of innovation patent as 8 years from the date of the patent. Most are allowed to lapse during their term for failure to pay renewal fees and therefore, most patented technologies will become freely available to the broader community well before their full term: see IP Australia, 'Maintaining your patent', (Web Page, 30 May 2016) <https://www.ipaustralia.gov.au/patents/managing-your-patent/maintaining-your-patent>.

[12] IP Australia, 'Search Patents', "AusPat" (Search Engine) <http://pericles.ipaustralia.gov.au/ols/auspat/quickSearch.do>.

critical factor in the "race" they run to develop treatments as noted recently by Justice Burley.[13]

International obligations

This article is focused on the Australian context. However, given that the underlying rationale and key aspects of the patent system are common to most jurisdictions, the arguments may be of general application.

One of the issues with which jurisdictions such as Australia have to grapple is the fact that they have entered into multilateral treaties which impose obligations on them in relation to the scope and implementation of domestic IP laws. For example, Australia, along with some 150 other countries, is a party to the World Trade Organization's Agreement on Trade Related Aspects on Intellectual Property Rights ("TRIPS") Agreement.[14] Designed to harmonise and facilitate trade and protection of IP, under TRIPS Australia is obliged to maintain certain minimum standards in relation to its domestic IP regime. In addition, Australia has in place a number of bi-lateral agreements with key trading counterparts that impact on our domestic IP regime including, by way of example, treaties with the USA,[15] Japan,[16] and the Trans Pacific Partnership.[17]

IS IT BROKEN?

Following the calls of scholars like Stoianoff,[18] Clark,[19] Thampapillai,[20] and noting that IP Australia, for instance, is compiling the Patents Analytics Hub to assist researchers in identifying know-how, supply and manufacturing resources required during the COVID-19 pandemic,[21] a question arises: does the existing patent system require change in view of COVID-19?

CONCERNS WITH THE CURRENT SYSTEM

Pandemics past and public health

Communicable diseases have existed throughout history. Increasing urbanisation has accompanied the growth and spread of disease. Recent examples include the "Spanish Flu" in 1918 (resulting in 50 million deaths worldwide);[22] "Asian Flu" in 1957 (resulting in 14,000 deaths in six months);[23], human immunodeficiency virus ("HIV/AIDS") in 1981 (resulting in 33 million deaths worldwide since discovery),[24] Severe Acute Respiratory Syndrome ("SARS") in 2003 and currently the COVID-19 pandemic.

The HIV/AIDS global epidemic highlighted the ambiguities between the terms of the TRIPS Agreement and the need for governments to

[13] See *Merck Sharp & Dohme Corporation v Wyeth LLC* (No 3) [2020] FCA 1477 8, [1]: *It is perhaps not inappropriate that, at a time when the world is affected by the COVID-19 pandemic, the present dispute concerns attempts to improve disease immunity. Two pharmaceutical companies are in the race to develop better forms of immunisation against Streptococcus pneumoniae, which is a leading cause of meningitis, pneumonia and severe invasive disease in people, especially infants and young children, throughout the world. These proceedings concern an aspect of that race.*

[14] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C Marrakesh Agreement Establishing the World Trade Organization (15 April 1994) is an international legal agreement between all the member nations of the World Trade Organization.

[15] *Australia-United States Free Trade Agreement* (1 May 2019) <https://www.dfat.gov.au/trade/agreements/in-force/ausfta/Pages/australia-united-states-fta>.

[16] *Japan-Australia Economic Partnership Agreement* (15 January 2015) < https://www.dfat.gov.au/trade/agreements/in-force/jaepa/full-text/Pages/full-text-of-jaepa>.

[17] *Comprehensive and Progressive Agreement for Trans-Pacific Partnership* (30 December 2018) Signed by 11 countries, the CPTPP recognises challenges facing small and medium sized enterprises in establishing export markets and includes outcomes to make this an easier task in the CPTPP region <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/Pages/comprehensive-and-progressive-agreement-for-trans-pacific-partnership>.

[18] Natalie Stoianoff, 'Whoever invents a coronavirus vaccine will control the patent – and, importantly, who gets to use it' *The Conversation* (online, 29 May 2020) <https://theconversation.com/whoever-invents-a-coronavirus-vaccine-will-control-the-patent-and-importantly-who-gets-to-use-it-138121>.

[19] Helen Clark and Winnie Byanyima, 'The world needs a 'people's vaccine' for coronavirus, not a big-pharma monopoly' *The Guardian* (online, 23 July 2020) < https://www.theguardian.com/commentisfree/2020/jul/23/world-needs-coronavirus-vaccine-big-pharma-monopoly-astrazeneca-patent-pandemic>.

[20] Dilan Thampapillai, 'The controversy to come? Patent law and a Covid-19 vaccine' (Web Page, 10 June 2020) < https://law.anu.edu.au/research/essay/covid-19-and-international-law/controversy-come-patent-law-and-covid-19-vaccine>.

[21] IP Australia, 'Patent Analytics Hub' (Web Page, 2 July 2020) < https://www.ipaustralia.gov.au/tools-resources/patent-analytics-hub>.

[22] Douglas Jordan, 'The Deadliest Flu: The Complete Story of the Discovery and Reconstruction of the 1918 Pandemic Virus' *Centers for Disease Control and Prevention* (Web Page, 17 December 2019) < https://www.cdc.gov/flu/pandemic-resources/reconstruction-1918-virus.html.>.

[23] Claire Jackson, 'History lessons: the Asian Flu pandemic' (2009) 59(565) *British Journal of General Practice* 622.

[24] World Health Organization, 'World Health Data Platform' The Global Health Observatory (Web Page) < https://www.who.int/publications/data/gho/data/themes/hiv-aids>.

apply principles of public health.[25] Concerns emerged that patent rights might restrict access to affordable treatments for developing countries. In response, the Doha Declaration on the TRIPS Agreement, referenced above, was created.[26]

Notably, developing countries have experienced the greatest mortality and morbidity rates in relation to public health crises, with the highest prevalence rates recorded in sub-Saharan Africa.[27] Although there is no cure for HIV/AIDS, the development of antiretroviral treatment, supported by the patent law system, has greatly reduced the toll of AIDS-related deaths, however, *access* to the treatment is not universal. Importantly, it was only following the agreement of global trade rules in 1994 that developing countries began to offer patents on medicines.[28]

The Doha Declaration on TRIPS and Public Health acknowledged the difficulty in the balance between patent protection and compulsory licensing; the need to ensure access to medication for all versus the need to encourage research and medical development.[29] As a means of attempting to address this balance, Article 31 of TRIPS required consultation and negotiation with a patent owner before compulsory licensing and manufacturing of a drug can take place.[30] Despite such existing provisions within international law, in reality and as a matter of practicality, such provisions are time-consuming to implement and are therefore ill-suited to pandemics, and other health emergency situations.

On the other hand, the development of a vaccine is a risky, complex and costly venture, with no guarantee of success or of any return on investment. Pharmaceutical companies will typically spend many millions of dollars in developing, trialing, testing and manufacturing any viable treatment prior to production (often required on a mass scale), and distribution. In the absence of some capital return on their investment, from the perspective of such companies, it would make little commercial sense to engage in such a venture.

Perhaps for as long as the patent regime has existed, people have questioned whether an appropriate balance is being met or whether, as critics assert, the scales are tipped in the favour of "innovators", which are generally perceived to be large, well-resourced corporate entities, usually from developed countries. Critics consider that the present regime is open to misuse and enables private entities to improperly leverage the patent system for their own commercial interests. These outcomes are unsurprising given the health and life sciences industries' reliance on the patent system to support their very significant growth and commercial reach, particularly over the last half century.[31]

The current situation

A substantial body of commentary during 2020 reflects legitimate anxieties related to patents and the pandemic. Several non-governmental organisations ("NGOs"), governments and individuals have expressed uneasiness about the application of the patent system during the COVID-19 pandemic. Concerns include that:

(a) the patent system will result in restrictions on supply of COVID-19 treatments including vaccines;[32]

[25] World Health Organization, 'The Doha Declaration on the TRIPS Agreement and Public Health' (Web Page) <https://www.who.int/medicines/areas/policy/doha_declaration/en/>.

[26] See discussion of TRIPS on p. 11 of this article.

[27] Paul M Sharp and Beatrice H Hahn, 'Origins of HIV and the AIDS Pandemic' (2011) 1(1) *Cold Spring Harbor Perspectives in Medicine* (Web Page) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3234451/>.

[28] Ellen Hoen et al, 'Driving a decade of change: HIV/AIDS, patents and access to medicines for all' (2011) 14 *Journal of the International Aids Society* 14.

[29] *Declaration on the TRIPS Agreement and Public Health,* WT/MIN(01)/DEC/2 (20 November 2001). See also: World Health Organization, 'The Doha Declaration on the TRIPS Agreement and Public Health' (Web Page) <https://www.who.int/medicines/areas/policy/doha_declaration/en/>.

[30] See Article 31 of TRIPS: "*Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected… (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.*"<https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf >.

[31] Richard E Gold et al, 'Are Patents Impeding Medical Care and Innovation' (2010) 7(1) *Plos Medicine* (Web Page) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2795161/>..

[32] Organisation for Economic Co-operation and Development (OECD) 'Treatments and a vaccine for COVID-19: the need for coordinating policies on R&D, manufacturing and access' (29 May 2020) <http://www.oecd.org/coronavirus/policy-responses/treatments-and-a-vaccine-for-covid-19-the-need-for-coordinating-policies-on-r-d-manufacturing-and-access-6e7669a9/>.

(b) that the developers of treatments including vaccines will use the patent system to inflate prices in order to maximise profits and that these pricing strategies will put essential treatments beyond the reach of much of the global population;[33] and

(c) early innovators will use the exclusivity provided by patents to restrict or constrain the development of follow on or derivative treatments, thereby limiting the range of products available and restricting the breadth of treatments and undermining the fight against the virus.[34]

In response, critiques, inquiries and calls for action have emerged along the following lines:

+ Criticism of global patent regimes and calls for open access systems, such as the Open COVID Pledge, to facilitate the sharing of research and knowledge to develop safe and effective medical treatments and vaccines to combat COVID-19.[35]

+ Moral challenges to the phenomenon of "treatment nationalism" whereby developed countries' secure "bulk treatments" and therapeutic advantages by using its dominant economic position to monopolise drug supply. Given the global effects of the pandemic, calls to challenge these positions are heightened as reinfection is a possibility.[36]

+ Calls for the creation of a patent pool in which researches and patent holders make available their research results and relevant intellectual property, usually for a royalty, to allow third parties to further develop the information, thereby accelerating the development of multiple treatment and vaccine options.[37]

+ Calls for a "cash prize" for any firm that develops a successful vaccine (this suggestion, or argument responds to the need to generate private-sector interest in vaccines precisely because pharmaceutical companies are concerned that they will face significant pressure to make a vaccine available too cheaply in light of their costs and we need additional mechanisms or incentives to bring such initiatives to market).[38]

International imbalance

Those fortunate enough to live in countries with advanced health systems can take comfort in the knowledge that they will likely have access to the best available treatments and vaccines if and when they become available. Australia is such a country. Indeed, the Australian Federal Government has already announced that it has entered into a number of arrangements with developers and potential suppliers of vaccines.[39] The Government says it will ensure these treatments are available to every person in Australia, without charge.[40] At the time of writing, reports abound about the Australian Government securing 50 million more potential coronavirus vaccine doses as a result of two new agreements.[41] This demonstrates the

[33] Kenneth Shadlen, 'Will patents stop Covid drugs from saving lives' (Blog Post, 12 June 2020) <https://blogs.lse.ac.uk/internationaldevelopment/2020/06/12/will-patents-stop-covid-drugs-from-saving-lives/>.

[34] Enrico Bonadia et al, 'COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health' (2020) 11 *Cambridge University Press Public Health Emergency Collection* (Web Page) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7156563/>.

[35] Natalie Stoianoff, 'Whoever invents a coronavirus vaccine will control the patent – and, importantly, who gets to use it' *The Conversation* (online, 29 May 2020) <https://theconversation.com/whoever-invents-a-coronavirus-vaccine-will-control-the-patent-and-importantly-who-gets-to-use-it-138121>.

[36] Graham Dutfield, 'Coronavirus: it is morally indefensible for a nation to keep life-saving drugs for itself' *The Conversation* (online, 2 July 2020) <https://theconversation.com/coronavirus-it-is-morally-indefensible-for-a-nation-to-keep-life-saving-drugs-for-itself-141734>.

[37] Anja Lunze, 'Patent pools: an easy licensing option for COVID-19 drugs and SARS CoV 2 vaccines?' *TaylorWessing* (online, 22 April 2020) <https://www.taylorwessing.com/en/insights-and-events/insights/2020/04/patent-pools---an-easy-licensing-option-for-covid-19-drugs-and-sars-cov-2-vaccines>.

[38] See Lisa Larrimore Ouellette and Daniel Hemel, 'Want a Coronavirus Vaccine, Fast? Here's a solution', Ideas, COVID-19, *Time* < https://time.com/5795013/coronavirus-vaccine-prize-challenge/>; and, prior to the COVID-19 context, see Lisa Larrimore Ouellette and Daniel Hemel, 'Beyond the Patents-Prizes Debate' (2013) 92 (2) *Texas Law Review* 303.

[39] Prime Minister, Minister for Health, Minister for Industry Science and Technology, 'Australia secures onshore manufacturing agreements for two COVID-19 vaccines' (Media release, 7 September 2020); Minister for Health, 'Australia now eligible to purchase COVID-19 vaccine doses through COVAX' (Media release, 23 September 2020).

[40] Prime Minister, Minister for Health, Minister for Industry Science and Technology, 'New deal secures potential COVID-19 vaccine for every Australian' (Online, Media release, 19 August 2020) <https://www.pm.gov.au/media/new-deal-secures-potential-covid-19-vaccine-every-australian>; Paul Jarp, 'Australian government announces Covid vaccine deals to provide 84.8m doses' *The Guardian* (online, 6 September 2020) < https://www.theguardian.com/australia-news/2020/sep/06/australian-government-announces-covid-vaccine-deals-to-provide-848m-doses>.

[41] For example, see Rob Harris, 'Australia signs two more COVID-19 vaccine agreements', *The Sydney Morning Herald*, 4

Government's commitment to securing a vaccine, and the enduring public interest in the issue.

Universal, free access to a vaccine is not without recent precedent in Australia. The HPV vaccine was developed in Australia from patented technology, [42] and is freely available under the National Immunisation Program.[43]

However, the concerns expressed above are legitimate in relation to people who live in what the World Trade Organization ("WTO") designates "Least Developed Countries" ("LDCs").[44] Unlike Australia or some of our key trading partners, many countries around the world would not have the financial resources or health infrastructure in place to fund, distribute and administer treatments or vaccines if they are subject to the same economic models implemented in relation to ordinary medicines. That is especially the case if the treatments are subject to the usual supply and distribution models which innovators regularly implement in reliance on the patent system.

WHAT STEPS HAVE BEEN PROPOSED TO MITIGATE THE PERCEIVE NEGATIVE EFFECTS OF THE PATENT SYSTEM?

There have been a number of initiatives put forward by both the private and public sectors in relation to patent rights and the fight against COVID-19.

Representatives of India and South Africa have been behind a push to modify obligations under TRIPS to enable the development and dissemination of COVID-19 treatments and vaccines.[45] The proposal, which has subsequently been supported by a number of other countries, would allow signatories to the relevant treaties to waive certain enforcement rights including in relation to patents. A substantial number of NGOs such as Medecins Sans Frontieres, Oxfam and dozens of regional groups from Europe Latin America and Africa supported this proposal.[46] The proposal was similar to implementations around the turn of the millennium in response to the HIV aids epidemic, which resulted in modification to TRIPS to enable ready availability of treatments during health emergencies.

Some of the calls for patent reform led to the "OPEN COVID PLEDGE" advocated by Professor Stoianoff and others above.[47] While many organisations have signed up to the pledge, support at a government level and by the key players in life sciences and biotech industries appears to have been less forthcoming.

The "OPEN COVID PLEDGE"

The Pledge calls for immediate action to halt the COVID-19 pandemic and treat those that it has affected. The Pledge calls on organisations to make their IP available free of charge for use in ending the COVID-19 pandemic and minimising the impact of the disease.

The impetus behind it is obviously the devastation that the pandemic has wrought on both developing and developed nations worldwide, affecting as it has, the lives of many millions of people such that life is unlikely to return to normal without effective and sustainable treatment and preventative measures including a vaccine. Calls for an open pledge system are animated by the rationale that with shared resources and innovation without fear of infringement, organisations can work together to develop treatment and vaccine options at an unparalleled pace (and, it follows, this pace may be hampered by patents).

November 2020 <https://www.smh.com.au/politics/federal/australia-signs-two-more-covid-19-vaccine-agreements-20201104-p56biy.html>.

[42] AusBiotech, 'Cervical cancer vaccine' (Web Page) < https://www.ausbiotech.org/about-us/30-success-stories/5-cervical-cancer-vaccine>.

[43] Department of Health, 'Human papillomavirus (HPV) Immunisation service' (Webpage, 26 September 2019) < https://www.health.gov.au/health-topics/immunisation/immunisation-services/human-papillomavirus-hpv-immunisation-service#do-i-need-to-pay-for-hpv-immunisation>.

[44] World Trade Organization, 'Least-developed countries' < https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm >; see World Trade Organization 'Members discuss intellectual property response to the COVID-19 pandemic' (Media release, 20 October 2020).

[45] World Trade Organization, 'Waiver from certain provisions of the TRIPS Agreement for the prevention, containments and treatment of COVID19: communication from India and South Africa' <https://docs.wto.org/ >.

[46] Dianne Nicol and Olasupo Owoeye, 'Using TRIPS flexibilities to facilitate access to medicines' *Bulletin of World Health Organization* (18 April 2013) <https://www.who.int/bulletin/volumes/91/7/12-115865/en/>; J Saunders, 'Covid-19 and Human Rights' (Oxfam Discussion Paper, 7 July 2020) 9.

[47] See page 7 of this article.

The Pledge came about after the expression of concerns around the impact of patent protection and perceived lack of access to technology on the development of a vaccine.[48] The movement calls on organisations to make their existing IP, including but not limited to patents, copyright and designs for medical devices associated with medical treatment or vaccine research, available to an open patent pool to allow collaboration and cross-use of resources in an effort to halt this global problem. To make the pledge, organisations publicly commit to making their IP relevant to the fight against COVID-19 freely accessible.

The Pledge has attracted a great deal of attention internationally, and significant and well-resourced organisations (such as Facebook, Amazon and Microsoft as Founding Adopters, among others), have supported the initiative.[49] Although not signatories to the Pledge, several organisations have heeded the call for open access to technologies and know-how that may assist in combatting the pandemic, and have promised not to enforce their COVID-19 related patents.

Amongst these is Cambridge-based Biotech company Moderna Inc. ("Moderna") which pledged not to enforce its COVID-19 related patents and also expressed a willingness to license its intellectual property for COVID-19 vaccines to others after the pandemic. Moderna holds seven US patents covering aspects of an mRNA-based candidate vaccine which is currently in Phase 3 clinical trials. Earlier this year, US firm AbbVie announced that it would not enforce its patent on Kaletra, a HIV medicine tested for effectiveness in the treatment of COVID-19,[50] with other biotech companies entering into collaborate partnerships to jointly develop vaccine candidates.[51]

COVAX

An example of an organisation informed by the concept underlying the Pledge is the COVID-19 vaccine global access facility ("COVAX"). COVAX consists of two parts. First, the COVAX advance Market Commitment ("AMC") is intended to enable the purchase and delivery of vaccines for developing countries based on donor funds in developed nations.[52] The AMC aims to provide guarantees to manufacturers to create global production, purchase the vaccines and help deliver them to developing nations. The second mechanism aims to set up a fund function as insurance to ensure that, should a vaccine candidate in which a country has invested in fail, it will have access to other vaccines for a portion of its population.[53] Australia has joined the COVAX Facility which will allow the Australian government to access a greater range of vaccine candidates and purchase vaccine doses once available.[54]

Current state of development - is a vaccine imminent?

The worldwide race for a vaccine and medical treatments and devices for the COVID-19 virus began in earnest the moment the World Health Organization ("WHO") declared it a pandemic.[55] Since then, work has proceeded at a hectic pace to meet the unprecedented demand for medical treatment and devices that could provide relief and treat patients diagnosed with the disease. As the global socioeconomic effects of the pandemic have worsened, the push for a vaccine has grown. Production of a vaccine typically

[48] Following concerns expressed about patent protection and access to the technology in the face of the pandemic, an international group of scientists and lawyers joined together to establish the pledge: See Natalie Stoianoff, 'Whoever invents a coronavirus vaccine will control the patent – and, importantly, who gets to use it' *The Conversation* (online, 29 May 2020) <https://theconversation.com/whoever-invents-a-coronavirus-vaccine-will-control-the-patent-and-importantly-who-gets-to-use-it-138121>.

[49] Other 'Founding Adopters' include: Intel, IBM, Hewlett Packard Enterprise, Sandia National Laboratories, Unified Patents, apheris AI and Fabricatorz Foundation: see <https://opencovidpledge.org/partners/>.

[50] Enrico Bonadio, 'Drug companies should drop their patents and collaborate to fight coronavirus' *The Conversation* (online, 1 April 2020) <https://theconversation.com/drug-companies-should-drop-their-patents-and-collaborate-to-fight-coronavirus-135241>.

[51] For example, the partnership between Pfizer and BioNTech see Pfizer, 'Pfizer and BioNTech announce further details on collaboration to accelerate global COVID-19 vaccine development' (Online, Media Release, 9 April 2020) <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-further-details-collaboration>.

[52] Fabrice Delaye, 'A COVID-19 vaccine would pay for itself in 5-6 days' *Health Policy Watch* (online, 10 August 2020) <https://healthpolicy-watch.news/76270-2/>.

[53] Fabrice Delaye, 'A COVID-19 vaccine would pay for itself in 5-6 days' *Health Policy Watch* (online, 10 August 2020) <https://healthpolicy-watch.news/76270-2/>.

[54] Department of Health, 'Australia's vaccine agreements' (Web page, 23 October 2020) <https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/vaccines-and-treatments/australias-vaccine-agreements>.

[55] Tedros Adhanom Ghebreyesus, 'WHO Director – General's opening remarks at the media briefing on COVID-19' (Speech, 11 March 2020) <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.

requires years of research and testing before clinical trials begin, however, the hope for an effective and safe vaccine has thus far involved 49 vaccines in clinical trials on humans, with at least 11 of those in the final stages of testing.[56]

Given the tremendous amount at stake in terms of human health and economic outcomes, it is not surprising that people are intently following any updates or developments regarding vaccines. Events which would normally be unremarkable, such as a pause of a vaccine trial due to patient illness for instance, are having significant impacts on public health decision making regarding management of the virus and even causing fluctuations in global financial markets.[57] Of these vaccines, the AstraZeneca/Oxford vaccine has attracted global attention after clinical trials were paused because one participant suffered an adverse reaction. Following a safety review, trials have resumed.[58] The results from trials of the AstraZeneca/Oxford vaccine suggest that the vaccine produces the same type of immune response in older adults as in younger volunteers, giving hope for those most vulnerable to the COVID-19 virus.[59]

Both in China and Russia, six vaccines have been approved for early or limited use.[60] Chinese company CanSino Biolgics in partnership with the Institute of Biology at the Academy of Military Medical Sciences have approved a vaccine based on an adenovirus called Ad5 and later began running Phase 3 trials.[61] Clinical trials of other vaccines, such as Russia's Gam-Covid-Vac and Sinovac's CoronaVac, have been expedited, with some receiving early use approval prior to completion of Phase 3 trials.[62] Experts have warned that rushing the development of vaccines and approving their use before the results of Phase 3 clinical trials are properly assessed is "really risky".[63] Now more than ever there is a need for public confidence in the effectiveness and safety of any vaccine that is to be produced and distributed globally.

THE EXPERIENCE TO DATE

So, with the benefit now of almost 12 months since COVID-19 first came to light, a picture is emerging in terms of the threat or otherwise of the patent system to the rapid development and dissemination of COVID-19 treatments.

It is important to keep in mind that, notwithstanding the significance IP advocates and lawyers place on the patent system, it is only one small part of a very complex puzzle in terms of achieving the common goal of effective management or eradication of the virus. The technical, safety, logistical and philosophical challenges of developing, trialling, testing and disseminating a safe and effective virus to over 7 billion individuals, are for more significant than any debate about IP.

Aside from the incredibly complex science involved in effectively developing a vaccine, the challenge of global distribution is enormous. [64] [65]

[56] Jonathan Corum, Sui-Lee Wee and Carl Zimmer, 'Coronavirus Vaccine Tracker' *The New York Times* (online, 3 November 2020) <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>.

[57] Johnson & Johnson's vaccine trial paused due to adverse reaction in a volunteer see BBC, 'Johnson & Johnson Covid vaccine trial paused due to ill volunteer' *BBC News* (online, 13 October 2020) <https://www.bbc.com/news/health-54521527>.

[58] David Cyranoski and Smriti Mallapaty, 'Scientists relieved as coronavirus vaccine trial restarts – but question lack of transparency' *Nature* (online, 14 September 2020) <https://www.nature.com/articles/d41586-020-02633-6>.

[59] Sarah Boseley, 'Oxford Covid vaccine works in all ages, trials suggest' *The Guardian* (online, 27 October 2020) <https://www.theguardian.com/world/2020/oct/27/covid-vaccine-uk-oxford-university-astrazeneca-works-in-all-ages-trials-suggest>.

[60] Jonathan Corum, Sui-Lee Wee and Carl Zimmer, 'Coronavirus Vaccine Tracker' *The New York Times* (online, 3 November 2020) <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>.

[61] Jonathan Corum, Sui-Lee Wee and Carl Zimmer, 'Coronavirus Vaccine Tracker' *The New York Times* (online, 3 November 2020) <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>.

[62] Conditional approval given on the basis of positive results from Phase 3 trials - see Andrew E Kramer, 'Russia Approves Coronavirus Vaccine Before Completing Tests' *The New York Times* (online, 11 August 2020) <https://www.nytimes.com/2020/08/11/world/europe/russia-coronavirus-vaccine-approval.html>.

[63] Carl Zimmer, 'This is all beyond stupid'. Experts worry about Russia's rushed vaccine' *The New York Times* (online, 11 August 2020) <https://www.nytimes.com/2020/08/11/health/russia-covid-19-vaccine-safety.html>.

[64] Anna Nagurney described the subzero temperatures required to effectively store vaccines, which are highly perishable, "just like a piece of fish", noting that logistics companies are investing in storage facilities for cold chain management. See Anna Nagurney, 'Keeping coronavirus vaccines at subzero temperatures during distribution will be hard, but likely key to ending pandemic', *The Conversation* (online, 18 September 2020) < https://theconversation.com/keeping-coronavirus-vaccines-at-subzero-temperatures-during-distribution-will-be-hard-but-likely-key-to-ending-pandemic-146071>.

[65] Julia Kollewe, 'Covid vaccine: "8,000 jumbo jets needed" to deliver doses around world' *The Guardian* (online, 10 September 2020) <https://www.theguardian.com/world/2020/sep/10/we-have-too-

Add to this the fact that in one recent survey only a minority of citizens of the United States said they would be prepared to have a vaccination[66], navigating the patent system would seem to be a relatively simple hurdle to overcome.

COLLABORATION AND SCIENTIFIC ADVANCES

It is clear that, notwithstanding the perceived constraints imposed by patents, there has been a substantial degree of collaboration and information sharing at the coalface of research. One celebrated example is the Australian researcher who published the gene sequence for the COVID-19 virus in early 2020.[67] As *Nature* noted, there has been a free flow of information and exchange between a range of private and public research institutions across numerous countries including China, the UK and the United States of America ("US"), enabling, in a matter of months and sometimes weeks, advances that might otherwise have taken years to be achieved. It is clear the scientific community has embraced the challenge of staving off the global threat the pandemic represents.[68]

Even anecdotally, important advances have been made in a very short space of time in a wide range of health-related disciplines. For instance, in Australia, the science of contact tracing has taken huge leaps forward. Rapid advances in diagnostic testing and analysis have been attained in incredibly short time frames and public health education has become much more sophisticated.[69] There appears to be no concrete evidence any of these advances have been hampered in anyway by the patent system.

Lack of IP reform

However, at government level, particularly in developed economies, there has been a clear reticence to embrace or adopt proposals for wholesale change to existing IP laws and the relevant international treaties that govern global trade. The UK, China, Singapore, and others have declined to adopt wholesale changes to the law.[70]

In what could be described as a "throwing the baby out with the bath water" approach, the leaders of developed, IP-rich economies have been slow to embrace any significant changes to patent law. One possibility is that they have simply not directed attention to it. It is fair to say that Australian governments at both State and Federal level have been pre-occupied by the day-to-day battle to contain the virus while trying to preserve a balance in terms of economic activity. This has been an all-encompassing job for government leaders and ministers, particularly those involved in public health.[71] Not surprisingly, the intricacies of the patent system have to date not been a topic of concern amongst Australian policy makers.[72]

In any event, it appears the leaders of the world's largest economies as well as IP advocates, including at the leading life sciences companies, would argue that changes to the patent system to combat COVID-19 are unnecessary for a number of reasons.

JUSTIFICATIONS FOR THE STATUS QUO

few-planes-to-deliver-any-covid-19-vaccine-warns-aviation-group>.

[66] Shannon Mullen O'Keefe, 'One in Three Americans Would Not get COVID-19 Vaccine' *Gallup* (online, 7 August 2020) <https://news.gallup.com/poll/317018/one-three-americans-not-covid-vaccine.aspx >.

[67] Rob Harris, 'Australia commits $500m for COVID-19 vaccine for the Pacific and south-east Asia' *Sydney Morning Herald* (31 October 2020) <https://www.smh.com.au/politics/federal/australia-commits-500m-for-covid-19-vaccine-for-the-pacific-and-south-east-asia-20201030-p56a8v.html>.

[68] Sara Frueh, 'Enlisting Science and Technology in the Fight Against COVID-19 – and the Ongoing Struggle for Sustainable Development' (20 May 2020) *The National Academies of Sciences, Engineering, Medicine*. (Web Page) <https://www.nationalacademies.org/news/2020/05/enlisting-science-and-technology-in-the-fight-against-covid-19-and-the-ongoing-struggle-for-sustainable-development>.

[69] Olivier Vandenberg et al, 'Consideration for diagnostic COVID-19 tests' *Nature Review* (online, 14 October 2020) <https://www.nature.com/articles/s41579-020-00461-z>.

[70] World Intellectual Property Organization, 'COVID-19 Policy Tracker' (Web Page) < https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access>.

[71] The Premier of Victoria, Daniel Andrews, gave a press conference for 122 days running (media commentary noted this at different points, e.g. Patrick Wood, 'Daniel Andrews hits his 50th straight coronavirus update today – is it time he took a break?' *ABC News* (blog, 21 August 2020) < https://www.abc.net.au/news/2020-08-21/daniel-andrews-hits-50-daily-coronavirus-updates-for-victoria/12565048>; and, Margaret Simons, 'One hundred days of Andrews' press conferences: What do they tell us about journalism?', *The Age*, (online October 11, 2020) < https://www.theage.com.au/national/victoria/one-hundred-days-of-andrews-press-conferences-what-do-they-tell-us-about-journalism-20201009-p563lt.html>.

[72] It is worth noting that no Premier or Minister of Health has commented on patent issues relating to Covid-19 in 2020.

(a) The bargain theory underlying the patent system is working well.

As set out above it is notoriously hard to asses in any quantitative way whether the patent system effectively achieves the goal of stimulating innovation. However, there is some suggestion that the evidence which supports that theory is most persuasive in the life sciences space.[73]

The leading organisations at the forefront of innovation in life sciences have always relied heavily on the patent system to generate returns and fund future research. They argue that the patent system continues to work effectively in motivating organisations to take risk in seeking to identify and develop treatments and vaccines in relation to COVID-19.

There can be no argument that huge sums and very significant resources have been invested and prioritised in the search for a vaccine. Some of the world's leading life sciences companies have made it their paramount objective.[74] Many would argue that without at least having the option of obtaining patent protection for any breakthrough developments, those sums would not be committed, and the development of treatments delayed.[75]

(b) There are enough inbuilt mechanisms in the patent system to prevent misuse such that access to treatments and vaccines is ensured.

The patent regimes of most countries, including signatories to TRIPS and other multilateral treaties, include compulsory licencing and or State use exemptions that ensure patented technologies are not suppressed.

The following analysis focusses on Australia.

Crown use

Crown use provisions enable the Commonwealth and State governments to exploit a patented invention without authorisation where the exploitation is necessary for the proper provision of services of the Commonwealth or State. The rationale behind the provision is it allows the government to take necessary actions to deal with urgent concerns to the public without the hindrance by the patent regime.

Recent amendments to the *Patents Act* 1990 (Cth) ("Patents Act") have reduced uncertainty and improved transparency and accountability by requiring governments to seek a negotiated outcome with a patent owner first, unless in an 'emergency' situation.[76] The amendments introduced a new section 163 which provides that exploitation of an invention is not an infringement if the relevant authority has tried to obtain authorization, the relevant Minister approves of the exploitation, the invention is exploited for Crown purposes, the authorisation occurs before the exploitation starts and at least 14 days prior to exploitation, the relevant authority gives the patentee a copy of the written approval and statement of reasons for approving exploitation.[77] Although there is no statutory definition of "emergency", the explanatory memorandum provides:

> *[80] An emergency would include an unforeseen occurrence or a sudden and urgent occasion for action. It could include a public health crisis such as a plague or*

[73] Jorge L Contreras et al, 'Patents: pledging intellectual property for COVID-19', *Nature* (online, 5 October 2020) < https://www.nature.com/articles/s41587-020-0682-1>.

[74] BIO, 'Biopharmaceutical Innovators Lead the Charge in Fight Against Coronavirus' (Web Page) <https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus>.

[75] Stephen Haber, for example, argues that "there is a causal relationship between strong patents and innovation" (deploying analyses from economic history and empirical microeconomics), in 'Patents and the Wealth of Nations', *George Mason Law Review* (2016) 23 (4), 834 < http://georgemasonlawreview.org/wp-content/uploads/Haber-FINAL.pdf>. Somewhat less stridently, Eric Budish, Benjamin N. Roin, and Heidi Williams contend there is need for "understanding heterogeneity in the relationship between patents and research investments across industries" in their article, 'The Design and Use of Patents: Patents and Research Investments: Assessing the Empirical Evidence': see Eric Budish, Benjamin N. Roin, and Heidi Williams, 'The Design and Use of Patents: Patents and Research Investments: Assessing the Empirical Evidence', *American Economic Review: Papers & Proceedings 2016*, (2016) 106(5) 183, 187; and, they point to a positive relationship between patent terms and investment in medical research and development in 'Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials', see: Eric Budish, Benjamin N. Roin, and Heidi Williams 'Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials', *American Economic Review* (July 2015) 105(7), 2044-85.

[76] *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020* sch 2, pt 1.

[77] *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act* 2020 (Cth) sch 2, pt 1 [7].

> ***epidemic**, or a medical emergency such as a pandemic. It could also include war, national security situations, perceived threats to law and order, natural disasters and other situations of urgency. It includes, but is not limited to, situations where a state of emergency has been declared by a government. The amendments do not specify any considerations as to what constitutes an emergency, as the nature of emergency situations is inherently unpredictable, and in such situations, it is important that a government can act quickly and that all possible situations are covered by the legislation.*
>
> *[81] It is expected that this would be a rarely exercised power, particularly given that there have only been two reported cases in which Crown use has been contested in court…*[78]

The current COVID-19 pandemic fits the definition of an emergency situation, meaning Crown use provisions may be invoked to aid in the quest for medical treatment and potential vaccines.

Further considerations arise when examining the Crown use provisions and amendments in light of the COVID-19 pandemic, including the meaning of "relevant authority" as described in new section 160A. Section 160A describes that an invention is exploited for Crown purposes if the invention is exploited for the services of a relevant authority and the exploitation is by the relevant authority or a person authorised. Although there is little judicial consideration of "authority of the Commonwealth or of a State", the meaning of "authority" and "public authority" has been considered. Essentially, the characteristic of a "public authority" is that it is constituted under a statue and given powers to be exercised for public objectives. An invention is taken to be exploited for the services of a "relevant authority" if the exploitation is necessary for the proper provision of those services, including services primarily provided by the relevant authority alone or in conjunction with one or more of the States or Territories or the Commonwealth. The relevant authority must notify the applicant or patentee as soon as practical following exploitation of the invention and provide information about the exploitation as reasonably required under section 164. The amendments also provided guidance for the terms of exploitation, including agreement and timing of renumeration and the involvement of the Court.

Compulsory licensing

The provisions as found in Chapter 12 of the Patents Act provide an alternative to invoking Crown use provisions.

Although both the Crown use and compulsory licence provisions have been embedded in the patent system as remnants of the Sovereign's ownership of inventions and granting of rights, the amendments following the COVID-19 outbreak have made the usage of such provisions more easily accessible and guided.

Globally

Compulsory licences have been granted in other jurisdictions on various grounds, including to facilitate access to patented medicines in the public interest.[79] In jurisdictions such as New Zealand,[80] Brazil and China,[81] compulsory licensing and crown use provisions allow governments to use patented inventions for service of the government in a health emergency. Although compulsory licence and crown use provisions may have been in existence, the unprecedented global effect of the COVID-19 pandemic saw nations re-examine their intellectual property regimes to create easier government accessibility to medical devices and treatments. At the height of the pandemic, Canadian parliament passed legislation that amended the patent legislation to

[78] *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020No. 9, 2020 Explanatory Memorandum* <https://www.legislation.gov.au/Details/C2020A00009>.

[79] *Australian Law Reform Commission, Genes and Ingenuity: Gene patenting and human health (ALRC Report 99)* (Report 2 August 2010) <https://www.alrc.gov.au/publication/genes-and-ingenuity-gene-patenting-and-human-health-alrc-report-99/2-the-patent-system/an-outline-of-the-patent-system/> "compulsory licensing"

<https://www.alrc.gov.au/publication/genes-and-ingenuity-gene-patenting-and-human-health-alrc-report-99/27-compulsory-licensing/compulsory-licensing/>.

[80] Jessica Lai, 'How patent law and medicine regulations could affect New Zealand's access to a COVID-19 vaccine' *The Conversation* (online, 12 October 2020) <https://theconversation.com/how-patent-law-and-medicine-regulations-could-affect-new-zealands-access-to-a-covid-19-vaccine-147653>.

[81] Justin Culbertson and Jason Jardine, 'Compulsory patent licensing in the era of pandemic' *International Bar Association* (online, 30 June 2020) <https://www.ibanet.org/Article/NewDetail.aspx?ArticleUid=36a60309-5a33-4891-8624-86a6d89a251e#_ftn3>.

allow the Minister of Health to direct the Patents Commissioner to authorise the use of a patent for a public health emergency.[82] Other jurisdictions such as Germany[83] and France[84] have amended legislation to aid governmental use and access to treatment and medical devices, highlighting the ability of governments to ensure access to public health during emergency public health crises.

Experimental use

In Australia, the patent system also provides an avenue for organisations to continue to research, develop, experiment and modify the subject matter of a patented invention without infringing the patent at issue.[85] The 'experimental purposes' exemption, contained in section 119 C of the *Patents Act* works in parallel with the rationale underlying the patent system in that it allows for an act to be performed that would otherwise infringe a patent if it is undertaken "for experimental purposes relating to the subject matter of the invention", and thus aims to encourage innovation and knowledge sharing by allowing research and development to be undertaken on patented technology. Experimental purposes are defined as including (but are not limited to), determining the properties, scope of a claim, validity of a patent or claim and whether the patent would be or has been infringed through the doing of an act relating to an invention, as well as for improving or modifying the invention.[86]

The effect of this provision in the current COVID-19 climate is that it removes barriers to conducting research and experiments on relevant patented technology so long as the relevant activity is contained within the scope of experimental purposes, thereby allowing researchers and organisations to continue in their quest for a COVID-19 vaccine.

Similar provisions exist in other jurisdictions, including the US patent laws which similarly provide a safe harbour for research and development efforts relating to diagnostics, vaccines and treatments.[87] Although calls for collaboration and open access have gained momentum throughout the pandemic, the existence of internal mechanisms within the patent regimes arguably function to protect researchers, facilitate experimentation and foster innovation.

COMPETITION LAW RISING (AND CURBING PATENT RIGHTS)

Recent developments in Australia's competition law introduce further limits on the misuse of patents.[88] While some argue these are an overreach and another example of competition policy encroaching on IP, they are a further mechanism to ensure ready access to COVID-19 technologies is not unlawfully constrained.

The overall theme of provisions described above is that they ensure access to patented technologies in return for reasonable compensation to the patent owner. One can see that this results in a degree of fairness. Undoubtedly, it is hard to argue that patented technologies should be compulsorily acquired without some form of compensation, even in the extreme circumstances of the current pandemic.

THE APPROACH TO PATENT ISSUES BY LEADING STAKEHOLDERS TO DATE HAS MITIGATED CONCERNS

[82] World Intellectual Property Organization, 'COVID-19 Policy Tracker' (Web Page) < https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access>.

[83] Which passed the "Act for the protection of the population in case of an epidemic situation of national importance" to amend previous legislation to authorise the Federal Ministry of Health to use patents to secure the manufacture/delivery of pharmaceuticals and/or medical devices see: WIPO, 'COVID-19 Policy Tracker' (Web Page) < https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access>.

[84] Which introduced Emergency law No, 2020-290 to authorise the Prime Minister to order the seizure of all goods and services necessary to fight against the disaster, temporarily control the price of such products and take any measures to ensure appropriate medicines are available to patients to eradicate the health disaster, see WIPO, 'COVID-19 Policy Tracker' (Web Page) <https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access>.

[85] *Patents Act* 1900 (Cth) s.119C.

[86] *Patents Act* 1900 (Cth) s.119C.

[87] Jorge L Contreras, 'Research and repair: expanding exceptions to patent infringement in response to a pandemic' (2020) 7(1) *Journal of Law and the Biosciences.*

[88] Recent amendments led to the repeal of subsection 51(3) of the *Competition and Consumer Act 2010* (Cth) which, prior to amendment, provided a limited exemption for certain anti-competitive conduct prohibitions in Part IV of the Act in relation to intellectual property (IP) rights: see ACCC, *Guidelines on the repeal of subsection 51(3) of the Competition and Consumer Act 2010 (Cth)* (Online, August 2019) <https://www.accc.gov.au/system/files/1619RPT_Guidelines%20on%20the%20repeal%20of%20subsection%2051_FA1.pdf>.

Private organisations

While of course there will always be exceptions, it appears that many of the key global life sciences stakeholders are, in fact, "playing fair". In addition to those who have signed the COVID-19 pledge discussed above, there have been numerous examples of private entities indicating their preparedness to waive strict compliance with patent rights. For example, US company Moderna, which is at the forefront of vaccine development, has recently pledged to make its IP freely available. There have been numerous Australian examples as well including heavyweight biotech players CSL Behring, ResMed and Cochlear. CSL Behring is one of the largest and fastest growing providers of in-licensed vaccines, and as part of the fight against COVID-19, is one of the founding members of the CoVIg-19 Plasma Alliance.[89] The Alliance is an industry partnership dedicated to developing a potential plasma-derived therapy treatment for COVID-19,[90] and, notably is developing an anti-coronavirus medicine which is currently undergoing Phase 3 clinical trials. Other large biotech companies such as ResMed, who have allowed the Australian Government to oversee distribution of critical ventilators and respiratory care devices,[91] and BioCurate who have entered agreements with other large biotech companies to accelerate medicinal developments,[92] have pooled resources and established agreements and protocols to facilitate the effective and accelerated development and access to treatment.

Given the exceptionally high-profile nature of the pandemic and the running commentary on the development of treatments and vaccines, it could be argued that it would be commercially very dangerous for any leading organisation to adopt an unreasonable approach in relation to access and pricing of any treatment. Such an approach would likely lead to shareholder, public and government criticism. While this in itself may be insufficient to ensure that all participants behave ethically and equitably, together with the patent access regimes set out above that provide a backstop, what may be regarded as the 'public relations' concern may prove to be effective.

Patents governance

Notably, even though they are traditional IP powerhouses, nations such as Israel, Germany and Canada have signaled they will not press patent protection for COVID-19 vaccines given the current global health emergency.[93]Australia has recently committed to AU$500m in funding to aid Pacific Islands response to the crisis.[94]

While these government responses are largely driven by philanthropic goals, there may be another agenda at play — self-preservation. It is in every nations' interest that an effective vaccine be universally distributed. Without a high level of successful vaccination globally — the virus will not be controlled. Though percentages differ according to different sources, it seems to be generally accepted that 60-70 per cent of the global population need to be immune to the coronavirus in order that it cease spreading. This amounts to billions of people worldwide, even if the vaccine functions perfectly, otherwise, the goal of eradication will not be reached.[95] If it is not, the only way developed countries can effectively protect their citizens is to take the unpopular and economically damaging step of closing their borders for extended periods of time. Consequently, there is a significant motivation on the part of all governments to ensure widespread distribution and ready, economical access to a vaccine *for all*. It is likely that this motivation will supersede any apparent hurdles or friction created by the patent system.

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[89] CSL Behring, 'CSL's Global Role in Battling COVID-19' (Media Release, 8 October 2020) <https://www.csl.com/news/2020/covid-19-csl-facts>.

[90] The Alliance includes industry members Biotest, BioProducts Laboratory, LFB, Octapharma and Takeda see CoVIg-19 Plasma Alliance (Web page) <https://www.covig-19plasmaalliance.org/en-us#recruitment>.

[91] ResMed, 'COVID-19:ResMed is ready to respond' (Web Page) <https://www.resmed.com/au/en/healthcare-professional/covid-19-our-response.html>.

[92] BiotechDispatch, 'BioCurate inks new MoU with AbbVie' (Media Release, 29 October 2020) <https://biotechdispatch.com.au/news/biocurate-inks-new-mou-with-abbvie>.

[93] Dilan Thampapillai, 'The controversy to come? Patent law and a Covid-19 vaccine' (Web Page, 10 June 2020) < https://law.anu.edu.au/research/essay/covid-19-and-international-law/controversy-come-patent-law-and-covid-19-vaccine>.

[94] Rob Harris, 'Australia commits $500m for COVID-19 vaccine for the Pacific and south-east Asia' *Sydney Morning Herald* (31 October 2020) <https://www.smh.com.au/politics/federal/australia-commits-500m-for-covid-19-vaccine-for-the-pacific-and-south-east-asia-20201030-p56a8v.html>.

[95] See for instance, Anthea Rhodes et al, 'Intention to vaccinate against COVID-19 in Australia', *The Lancet*, (online, September 14, 2020) < https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30724-6/fulltext> and, news sources such as the BBC, for example: James Gallagher, 'Coronavirus vaccine: When will we have one?' *BBC News* (online, 27 October 2020): <https://www.bbc.com/news/health-51665497>.

CONCLUSIONS AND THE "PUDDING TEST"

From the literature available to date, it is difficult to glean any determinative evidence for the proposition that the patent system is creating friction in terms of the speed or cost of development of COVID-19 treatments and vaccines.[96]

Revelatory of the enduring concerns of WTO member states about IP and trade and their relationship with public health outcomes, and arguably reflective of governance within the institution itself, it is also worth noting that, whilst the proposal by India and South Africa for a waiver of certain TRIPS obligations, in front of the WTO in October, was rejected,[97] the organisation is committed to continuing discussion and exchange about COVID-19-related IP; to this end, it has compiled a list of measures.[98] The World Intellectual Property Organization ("WIPO"), and IP Australia, for instance, have also compiled databases of COVID-19-related IP resources, demonstrating attendance amongst peak and IP-administrative bodies to concerns raised in the field about access to technologies and knowledge related to public health.[99]

Certainly, the patent system does not seem to have hampered progress towards the objective of a vaccine and related developments to date given the rapid and extensive scientific response so far. In fact, it is arguable that the system itself has catalysed the rate of development and has bolstered objectives that will, ideally, benefit all. The pace of education about and research into COVID-19 has surpassed anything we have seen in history. In any case, there are much more significant hurdles (scientific and logistical) to be overcome in developing a vaccine than anything that could be imposed by the patent system.

Perhaps it will only be with the benefit of hindsight that a true assessment can be made in terms of which side of the argument ultimately triumphs. Clearly, those holding the reins of power and therefore the legislative control will prevail for now. Certainly, it appears that wholesale change to the patent regime in Australia or within any of our major trading counterparts is unlikely in the immediate future.

It may sound trite, but, the proof will be in the pudding. If, and when, an effective treatment or vaccine reaches the market, the extent to which patent holders engage in litigation to constrain supply or seek to profiteer will be some indicator of the extent to which the patent system has hindered the common goal. At the time of writing, the authors have been unable to find any reference to patent litigation relating to COVID-19 specific treatments to date.[100]

If the developers of such technologies can disseminate their products and technology and attain a fair return for the risk they have undertaken and the resources they have invested, that will reflect a patent system functioning harmoniously.

In summary, the COVID-19 crisis has had an immeasurably significant impact on the world in 2020 and its effects will continue well into 2021 and beyond. Unsurprisingly debate has flourished across the globe around the need to balance economic interests with public health outcomes. Discussions about the role of the patent system, which is a small but essential aspect of that overall balance, are reflective of the broader concerns. The debate may in itself have reached its goal, as to date there is no concrete evidence the patent system is hindering the fight against COVID-19 or that it requires immediate review.

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[96] See the summary of 20 October 2020 in 'News' on the World Trade Organization website, "Members discuss intellectual property response to the COVID-19 pandemic" <https://www.wto.org/english/news>.

[97] Mentioned above in this article.

[98] See World Trade Organization 'COVID-19: Measures regarding trade-related intellectual property rights' < https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm>.

[99] IP Australia, 'Patents Analytics Hub' <https://www.ipaustralia.gov.au/tools-resources/patent-analytics-hub>.

[100] The authors of this article consulted relevant sources of case law most recently on 5 November 2020.