Compulsory licence and Crown use provisions in the Covid-19 pandemic—the Australian perspective
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I. Introduction

Australia, like many sovereign states, has compulsory licence and Crown use (also known as government authorization) provisions in its domestic legislation, which are derived from historical bases and standards set in international agreements. In the context of the ongoing global COVID-19 pandemic, there has been considerable speculation that the pressures facing governments and manufacturers could lead to these provisions being invoked. For governments, the pressures include the need to guarantee the supply of vaccines or treatments and medical equipment, while for manufacturers it is the pressure to meet demand simultaneously in multiple jurisdictions. Yet, in the quest to develop and produce vaccines and treatments, the COVID-19 pandemic has, at least to date (at the time of writing), been characterized by collaboration and cooperation between industry partners and with governments. Some intellectual property rights holders have adopted unconventional approaches to their intellectual property, while governments are adopting a facilitative approach to accelerate the development, and domestic and international distribution, of vaccines or treatments.

In this context, this article contends that, at least in relation to the Australian context, neither the compulsory licence nor the Crown use regimes ultimately provide the optimal measure to ensure supply of vaccines or treatments in this pandemic. Rather, the current collaborative approach is more effective to achieve this objective. In light of these considerations, this article concludes that the primary utility of the compulsory licence and Crown use provisions is not their deployment but their potential to drive collaboration.

II. The Covid-19 pandemic

A. Demand and factors affecting supply of vaccines or treatments

A powerful combination of health and economic factors are influencing the demand for prophylactic vaccines against and therapeutic treatments for COVID-19.

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This article

- In the global COVID-19 pandemic, there has been considerable speculation that global pressures facing governments, including the need to guarantee the supply of a vaccine or treatments (when available) and medical equipment, could lead to the compulsory licence or Crown use (otherwise known as government authorization) provisions being invoked.
- However, to date, collaborative approaches have prevailed; there have been some unconventional approaches to intellectual property rights, and considerable efforts to repurpose existing technology that shows any promise of application in the present context.
- Despite a pandemic being the very type of emergency that could trigger the use of these coercive powers, it may be that patented technology can be accessed without the need to invoke them. Instead, the mere fact of their existence may encourage an otherwise reluctant patentee to reach a timely arrangement for access to patented technology or products. In this way, compulsory licence and Crown use provisions serve an important role as safeguards to ensure the appropriate balance between a patentee’s reward for its investment, and the need for access to patented technology during a public health crisis.
On 11 March 2020, the World Health Organisation (WHO) declared the COVID-19 outbreak a global pandemic.\(^1\) COVID-19 has had, and continues to have, devastating health consequences, and enormous economic repercussions globally. The two are very much linked. The economic impact is a direct result of many jurisdictions adopting necessarily stringent public health measures to stop the spread of the virus. The physical distancing restrictions, which have manifested in periods of complete or partial lock down of cities, regions and even whole countries, has presented one of the few available measures to attenuate the rate of transmission of COVID-19. These restrictions have seen border closures, restrictions on travel, restrictions on movement (in some cases beyond the home) and prohibitions on public gatherings. The human toll (at the time of writing: 54.3 million confirmed cases worldwide, and over 1.3 million deaths)\(^2\) and the economic impact (conservatively estimated as being a 5.2 per cent contraction in global GDP)\(^3\)—have translated into unprecedented urgency to combat the virus.

Generally, vaccine development—from discovery to commercial availability—takes around 10–20 years (or even longer) and has an average 94 per cent chance of failure.\(^4\) Failure can occur at any stage from drug discovery to pre-clinical evaluation, at the clinical evaluation stage, or at the point of regulatory approval. Reasons for the high failure rate include the unpredictability of human immune system reactions to antigens as they relate to immunogenicity and/or safety.

In the context of the current pandemic, there are number of factors that are expediting the development and availability of safe and effective vaccines and treatments. First and foremost is the sheer volume of effort directed to this end. There is an extraordinary number of vaccine candidates under investigation by many different groups of researchers. As of November 2020, WHO reported 164 candidate vaccines in preclinical evaluation and 48 candidate vaccines in clinical evaluation.\(^5\) In November 2020, Pfizer,\(^6\) AstraZeneca\(^7\) and Moderna\(^8\) announced each of their candidate vaccines met primary efficacy endpoints of phase III clinical trials. Secondly, around the world, many governments are doing all they can to facilitate this research, including removing regulatory hurdles to accelerate development efforts. For example, in the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA) granted a temporary authorization under Regulation 174, permitting the supply of Pfizer/BioNTech’s COVID-19 vaccine without marketing authorization. Similarly, in the USA, on 11 December 2020, the FDA issued its first emergency authorization for Pfizer-BioNTech’s COVID-19 vaccine allowing the vaccine to be distributed to the USA.\(^9\) Australia’s regulator, the Therapeutic Goods Administration (TGA), is prioritizing the processing of notifications relating to COVID-19 clinical trial activities,\(^10\) and in October 2020 it granted a provisional determination to AstraZeneca, Pfizer and BioNTech, in relation to each of their COVID-19 vaccines, which speeds up the registration of new medicines with preliminary clinical data.\(^11\)

Due to the unprecedented global scale of the COVID-19 pandemic, there is not only enormous demand for safe and effective vaccines, but intense pressure to meet that demand simultaneously in many

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1. World Health Organisation (WHO), ‘WHO Director-General’s Opening Remarks at the Media Briefing on COVID-19 – 11 March 2020’ (Media Briefing, 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> accessed 8 August 2020.
2. Worldometer, ‘Coronavirus Death Toll’ (15 November 2020) <https://www.worldometers.info/coronavirus/coronavirus-death-toll/> accessed 15 November 2020.
3. The World Bank, ‘Global Economic Prospects’ A World Bank Group Flagship Report (Washington, June 2020) 3.
4. See, eg D Douglas and others, ‘Estimating the Cost of Vaccine Development Against Epidemic Infectious Diseases: A Cost Minimisation Study’ (2018) 6(12) The Lancet 1386.
5. WHO, ‘Draft Landscape of COVID-19 Candidate Vaccines – 12 November 2020’ (12 November 2020) <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> accessed 12 November 2020.
6. Pfizer, ‘Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints’ (18 November 2020) <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine> accessed 22 November 2020.
7. AstraZeneca, ‘AZD1222 Vaccine Met Primary Efficacy Endpoint in Preventing COVID-19’ (29 November 2020) <https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222hr.html> accessed 29 November 2020.
8. Moderna, ‘Moderna’s COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study’ (16 November 2020) <https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy> accessed 22 November 2020.
9. U.S. Food and Drug Administration (FDA), ‘FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine’ FDA News Release (11 December 2020) <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19—> accessed 24 December 2020.
10. Therapeutic Goods Administration (TGA), ‘Clinical Trial Processes’ (31 March 2020) <https://www.tga.gov.au/clinical-trial-processes> accessed 30 June 2020.
11. TGA, ‘TGA grants provisional determination for COVID-19 vaccine’ (9 October 2020) <https://www.tga.gov.au/tga-grants-provisional-determination-covid-19-vaccine> accessed 9 April 2021; TGA, ‘TGA grants second provisional determination for COVID-19 vaccine’ (14 October 2019) <https://www.tga.gov.au/tga-grants-second-provisional-determination-covid-19-vaccine> accessed 9 April 2021.
jurisdictions. This pressure on the development phase flows through to manufacture and the supply chain. Compounding this pressure, is not only manufacturing capacity, but also manufacturing constraints, which affects supply. Vaccines are extremely complex biological products. The many different candidates under investigation, or vaccines that have been, or are being, developed, each rely variously on a range of different technological platforms, involving RNA, DNA, protein subunits, peptides, non-replicating viral vectors, replicating viral vectors, inactivated virus, live-attenuated virus or virus-like particles. It is often the case that production of biological products requires purpose-built manufacturing facilities which may not be readily adaptable to manufacture products for which such facilities were not originally designed without significant modifications. For example, a manufacturing facility that utilizes recombinant technology may have the capability to make protein-subunit vaccines but not an RNA or DNA-based vaccines without modifications. Challenges may include production capability, technical barriers, existing commitments, and access to relevant know-how absent a licence. Furthermore, manufactures need to establish manufacturing consistency across production and this often requires additional information, expertise and processes.

As vaccines or treatments are developed and become generally available, the volume required to meet global demand is also unprecedented. If correlated to the world’s total population, 7.65 billion doses are required. This presents an enormous manufacturing challenge to meet global demand in a short timeframe even when, as has been occurring, manufacturing capacity is being reserved ahead of the availability of trial results.

B. Unprecedented levels of collaboration and cooperation

Globally, governments, industry and academia are working towards the common goal of accelerating the development of vaccines and treatments for COVID-19, on multiple projects and in parallel. The volume and scale of these efforts has led to unprecedented levels of collaboration and some unconventional approaches to intellectual property rights.

Some companies have elected not to enforce their intellectual property rights, or are at least suspending enforcement of their rights for now. Others are forgoing their rights to market exclusivity. This enables a complete focus on working towards solutions, and the manufacture and supply of critical products as solutions are found, without the immediate risk of patent infringement. This may be altruism, pragmatism, or a mixture of both. The first reported instance seems to have occurred in Israel in the early days of the pandemic. Following Israel’s Attorney General authorizing a compulsory licence to provide for the importation of generic versions of AbbVie’s combination HIV treatment comprising lopinavir and ritonavir (marketed as Kaletra), AbbVie reportedly gave notice to the United Nations-backed public health organization, Medicines Patent Pool, that it would not enforce its global patent rights to Kaletra. In the USA, Gilead rescinded the orphan drug designation for the investigational antiviral remdesivir, thereby forgoing seven years of marketing exclusivity in that country. In October 2020, the FDA approved use of remdesivir for the treatment of COVID-19 requiring hospitalization. In October, Moderna announced that it would not enforce its patents in relation to its mRNA-based COVID-19 vaccine.

While there is nothing new in the pharmaceutical sector and academia in collaborating to progress drug development, or pharmaceutical companies engaging in cross licensing arrangements to commercialize products, the COVID-19 pandemic has seen new models of sharing of intellectual property. In March 2020, Medtronic announced that it was publicly sharing the intellectual property for its ventilators to help doctors and patients dealing with COVID-19. In April 2020, an Open COVID Pledge was established, which invites organizations around the world to make their patents and copyright freely available through the grant of temporary licences ‘in the fight against COVID-19’. These licences begin no later than 1 December 2019 and end...
no earlier than one year after the WHO declares the end of the COVID-19 pandemic. A number of organizations have joined the pledge and made COVID-19 related technology available including the New Jersey Institute of Technology, NASA’s Jet Propulsion Laboratory, Fujitsu and SAP.

In other cases, companies have elected to forgo anticipated profits from any COVID-19 vaccine. For example, it has been reported that AstraZeneca and Johnson & Johnson have said that they will sell their vaccines at cost price at least for a temporary period.

Notwithstanding that co-operative supply and distribution arrangements between companies are part of an established model of commercialization, the pandemic has also encouraged unprecedented levels of collaboration amongst would-be competitors in relation to drug discovery and the development of manufacturing know-how, which might in other circumstances be fiercely protected trade secrets or patented technology. For example, Sanofi and GlaxoSmithKline, traditional competitors in the influenza vaccine market, are collaborating in drug discovery, establishing a joint venture whereby Sanofi contributes its S-protein COVID-19 antigen (based on recombinant technology) and GlaxoSmithKline contributes its proven pandemic adjuvant technology.

Pfizer has jointly developed BioNTech’s mRNA-based vaccine candidate to prevent COVID-19 infection and BioNTech has been expanding, throughout the course of 2020, its manufacturing capacity in order to supply their vaccine quickly worldwide. CSL has contracted with AstraZeneca to manufacture 30 million doses of the AstraZeneca/Oxford University vaccine in Australia.

Competition regulators have long held concerns that the collaboration between pharmaceutical companies has the potential to lead to unsustainably high prices for products. However, it has been widely recognized in the current pandemic that collaboration, including between competitors, is a necessary means to accelerate essential drug development and manufacturing capacity. Traditional concerns around possible anti-competitive conduct are being balanced with the recognition of the enormous public benefits that COVID-19 vaccines and treatments will provide. In Australia, collaboration between competitors is being facilitated by the pandemic-specific approach taken by the competition watchdog, the Australian Competition and Consumer Commission (ACCC). Parties wishing to engage in conduct that would otherwise risk contravening Australia’s competition laws may seek advance authorization from the ACCC on public benefit grounds. Since the commencement of the pandemic, this authorization process for coordinated conduct between competitors has sped up significantly and the ACCC has granted significantly more authorizations, including in the healthcare sector, than it would ordinarily grant.

There is not only collaboration between government and industry but also between governments. Notably, the COVAX Facility, led by Gavi, the Coalition for Epidemic Preparedness Innovations, and WHO, has the aim of accelerating the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country around the world. This involves upper-middle-income and high-income countries contributing to a facility which is pooled to secure doses for contributing countries and the Gavi Covax Advanced Market Commitment involves the use of official development assistance funds from governments to incentivise manufacturers through guarantees to ensure global capacity is installed before vaccines are licensed.

III. Compulsory licences and Crown use

As noted, in the COVID-19 pandemic, the objective of governments to guarantee the supply of vaccines or treatments and medical equipment has led to the

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19 Open COVID Pledge, ‘Info About the Licences’ (2020) <https://opencovidpledge.org/> accessed 10 June 2020.
20 The Guardian, ‘UK Faces Calls to Drop Opposition to Patent-free Covid Vaccines’ (20 November 2020) <https://www.theguardian.com/world/2020/nov/19/uk-faces-calls-drop-opposition-patent-free-covid-vaccines-wto> accessed 24 November 2020.
21 GlaxoSmithKline, ‘Sanofi and GSK to Join Forces in Unprecedented Vaccine Collaboration to Fight COVID-19’ (14 April 2020) <https://au.gsk.com/en-au/media/press-releases/2020/sanofi-and-gsk-to-join-forces-in-unprecedented-vaccine-collaboration-to-fight-covid-19/> accessed 13 August 2020.
22 Pfizer, ‘Pfizer and BioNTech to Co-develop Potential Covid-19 vaccine’ (17 March 2020) <https://investors.pfizer.com/investor-news/press-release-details/2020/Pfizer-and-BioNTech-to-Co-Develop-Potential-COVID-19-Vaccine/default.aspx> accessed 30 June 2020.
23 European Commission, ‘Coronavirus: Commission Approves Contract with BioNTech-Pfizer Alliance to Ensure Access to Potential Vaccine’ (11 November 2020) <https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2081> accessed 22 November 2020.
24 Gavi, ‘Gavi COVAX AMC Explained’ (13 October 2020) <https://gavi.org/vaccineswork/gavi-covax-amc-explained/> accessed 28 November 2020.
speculation that the compulsory licence and Crown use provisions will be invoked. Part III of this article explores compulsory licence and Crown use provisions in the Australian context. Given that such provisions are derived from international standards and that corresponding provisions are also found in the domestic legislation of other jurisdictions, key international treaties are analysed, and some high-level comparisons between the corresponding provisions in Australia and other jurisdictions are drawn.

A. Underlying rationale

The grant of a patent provides the patentee with a time-limited statutory monopoly as the reward for investment in, and ongoing incentive to continue to develop, new products and processes. During the term of this monopoly, the patentee has the exclusive right to decide whether and how the patented invention will be commercialized, who will be permitted to use the technology and, subject to the dictates of the market, what remuneration it will accept in exchange for its return on investment. At the end of the term of the patent, the invention is effectively given to the world in that anyone is free to use the technology.

The underlying rationale of both the compulsory licence and Crown use regimes is to benefit the public. Broadly, a compulsory licence requires a patentee to grant a licence to a third party, so as to prevent the patentee from restricting others from exploiting a patented invention in circumstances where the patentee has failed to do so. Otherwise, if a patentee does not exercise its rights, yet others are prevented from exploiting the invention during the term of the patent, the public derives no benefit in return for the temporary monopoly enjoyed by the patentee.

Government authorization (or Crown use) allows governments to exploit patented technology without the authorization of the patentee. This provides a safeguard where access to a technology is necessary to respond to an emergency or other public interest need.

Any use of a patent without the authorization of the patentee is a significant curtailment of the patentee’s exclusive rights. The grant of a compulsory licence or Crown use necessarily interferes with those rights by permitting any third party (in the case of a compulsory licence) or a government (in the case of Crown use) to exploit a patented invention not only without the patentee’s authorization but also dictating the remuneration payable to the patentee. Compulsory licensing and Crown use are seen as justified impositions on those rights as part of the balance between the patentee’s temporary monopoly and public access to the benefits of innovation.

B. International agreements

Many jurisdictions have compulsory licence and government authorization provisions in their domestic legislation which are derived from standards set in international agreements. The Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) provides a framework for compulsory licences. With 177 contracting states, it is one of the most widely adopted treaties in the world.

Effective 1 January 1995, the Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS), to which all World Trade Organization (WTO) members are parties, is the most comprehensive multilateral agreement on intellectual property. Article 31 provides a framework for compulsory licences and government authorization, but also recognizes that use of the subject matter of a patent without the authorization of the patentee is a significant curtailment of the patentee’s rights. Specifically, under Article 31(b), a proposed unauthorized user must first make efforts to obtain authorization from the right holder on reasonable commercial terms and conditions within a reasonable period of time, unless that requirement is waived in the case of a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use.

In Australia, ratified international treaties such as TRIPS and the Paris Convention are not automatically incorporated into Australian domestic law. Rather, legislation must be introduced into the Federal Parliament and approved by both Houses of Parliament and the Governor-General and even then, as is the case with TRIPS, the treaty may not be adopted co-extensively, as explored further below. Notwithstanding this, Australia’s adoption of TRIPS means that it maintains certain minimum standards in relation to its domestic intellectual property regime.

Contracting states may enter into bilateral agreements which set more restrictive standards than the parameters set by multilateral agreements. For example, Article 17.9.7 of the Australia–US Free Trade Agreement (AUSFTA) permits the use of non-voluntary licensing to remedy a practice determined by a judicial or administrative process to be anti-competitive; or in cases of public non-commercial use or other circumstances of extreme urgency, provided that the patent...
owner is compensated and such use is limited to the government or third persons authorized by the government.\textsuperscript{30} Importantly, the parties are not permitted to require the patent holder to provide undisclosed information or technical know-how related to the patented invention.\textsuperscript{31}

TRIPS originally envisaged that compulsory licence and government authorization provisions would be deployed in the domestic context of a Member State. Article 31(f) provides that use without authorization of the patent holder shall be ‘predominantly’ for the supply of the domestic market of the Member authorizing such use. However, in 2003, concerns around the equitable and affordable supply of pharmaceutical products to developing countries led the WTO to implement paragraph 6 of the Doha Declaration on the TRIPS agreement and public health\textsuperscript{32} which permits the waiver of Article 31(f). Accordingly, ‘pharmaceutical products’ can be exported to an ‘eligible importing Member’, being a country that lacks the relevant manufacturing capability to address a public health problem. A number of jurisdictions, including Australia, have implemented the Doha Declaration,\textsuperscript{33} the effectiveness of which has been the subject of much debate which is investigated in the literature.\textsuperscript{34}

C. Compulsory licences in Australia

While one of the main objectives of TRIPS was to introduce compulsion into the international arena, compulsory licences provisions have been included in Australia’s patent legislation since 1903, long before TRIPS. Despite that history, a compulsory licence request has only ever been litigated in three instances.\textsuperscript{35} To date, no compulsory licence has yet been granted by an Australian court.

A recent public consultation on compulsory licensing posited a number of reasons for this.\textsuperscript{36} First, it was suggested that compulsory licences may be a safeguard that is rarely needed. Secondly, it could be that the existence of a compulsory licence regime acts as a deterrent against refusal to license on voluntary terms, and there have been reported instances where threats of a compulsory licence have led to a negotiated outcome.\textsuperscript{37} Thirdly, the language of the provisions was said to create significant uncertainty, thereby deterring their use.

Under the Australian Patents Act 1990 (Cth) (Patents Act), as amended following this consultation, a person may apply to the Federal Court of Australia (FCA) for an order requiring the patentee to grant a licence to exploit a patented invention.\textsuperscript{38} The FCA may only make such order if the patentee has engaged in anti-competitive conduct in connection with its patent\textsuperscript{39} or provided that the following conditions are satisfied:\textsuperscript{40}

- demand in Australia for the original invention is not being met on reasonable terms;
- authorization to exploit the invention is essential to meet that demand;
- the applicant has tried for a reasonable period, without success, to obtain authority from the patentee to exploit the original invention on reasonable terms and conditions;
- the patentee has given no satisfactory reason for failing to exploit the patent to the extent necessary to meet the demand for the original invention in Australia;
- it is in the public interest to provide the applicant with authorization to exploit the original invention; and
- if the applicant is the patentee of another invention (the dependent invention) and is seeking authorization for the purpose of exploiting that invention, the dependent invention cannot be exploited without the applicant exploiting the original invention and the dependent invention involves an important technical advance of considerable economic significance on the original invention.

The patentee thus has the onus of showing that it has a satisfactory reason for failing to exploit the patent.\textsuperscript{41} The applicant for a compulsory licence bears the onus of proving the other requirements.

These preconditions establish a high threshold for an applicant for a grant of a compulsory licence to satisfy.

\textsuperscript{30} ibid, art 17.9.7(b)(i)–(ii).
\textsuperscript{31} ibid, art 17.9.7(b)(iii).
\textsuperscript{32} Declaration on the TRIPS agreement and public health (14 November 2001) WT/MIN(01)/DEC/2 <https://www.wto.org/english/tratop_e/minist_e/min01_e/minedc_trips_e.htm>.
\textsuperscript{33} See Patents Act 1990 (Cth), Ch 12, Pt 3.
\textsuperscript{34} See, eg TA Adekola, ‘Has the Doha Paragraph 6 System Reached its Limit?’ (2020) 15(7) IJLP 525.
\textsuperscript{35} Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp (1969) 119 CLR 572; Amrads Operations Pty Ltd v Genelabs Technologies Inc [1999] FCA 653; and Wisen Pty Ltd v Kenneth Mervyn Lown (1987) 9 IRP 124.
\textsuperscript{36} IP Australia, Public Consultation: Compulsory Licensing of Patents (Public Consultation, 2017).
\textsuperscript{37} See Law Council of Australia, Submission to the Productivity Commission’s inquiry into Compulsory Licensing under the Patents Act 1990 (Submission, 2012) 3.
\textsuperscript{38} Patents Act 1990 (Cth), s 133(1) for a standard patent, s 133(1A) for an innovation patent.
\textsuperscript{39} ibid, s 133(2)(b).
\textsuperscript{40} ibid, ss 133(2)(b), 133(3).
\textsuperscript{41} Amrads Operations Pty Ltd v Genelabs Technologies Inc [1999] FCA 633, [10].
Relevantly, as foreshadowed above, Australia has not adopted TRIPS in all respects. In particular, Australia’s compulsory licence regime does not waive the requirement that the applicant must first try to obtain the authority from the patentee to exploit the invention on reasonable terms in situations of national emergency or other circumstances of extreme urgency.

The Patents Act requirement that the grant of a compulsory licence be ‘in the public interest’ is not found in Article 31 of TRIPS. Prior to the recent amendments to the regime, the FCA had to be satisfied that the ‘reasonable requirements of the public’ were not being met. This test was considered to be uncertain, and open to conflation with the interests of Australian trade or industry, thus inconsistent with promoting community-wide welfare. In the Fastening Supplies case, the Court ultimately declined to grant a compulsory licence because it was not satisfied that the applicant had the skill, knowledge, experience or resources to develop the patented invention in Australia. In addition, the Court considered that the exclusive licensee had provided a satisfactory reason for not exploiting the relevant invention—the patentee had encountered substantial difficulties in designing a tool which could be made economically in Australia.

D. Crown use in Australia

Australia’s Crown use provisions are also rarely used. In contrast to the compulsory licence regime, no court process is required. The Crown use provisions permit the Commonwealth, or a State or Territory government, or a person authorized by one of them, to use an invention without infringement of the relevant patent. The Commonwealth government can also compulsorily acquire a patent for exclusive use, provided that the Commonwealth compensates the original patentee. However, according to the Federal Register of Legislation, there has been no government gazette recording an executive decision relating to the government’s power to compulsorily acquire a patent.

The circumstances in which a patent may be exploited under the Crown use provisions of the Patents Act have recently been clarified such that in non-emergency situations, the following steps must occur:

42 Revised Explanatory Memorandum to Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019, [205].
43 Patents Act 1990 (Cth), s 133(3)(e).
44 (1969) 119 CLR 572.
45 ibid, 575.
46 ibid, 582.
47 ibid, 579.
48 Australian Government Productivity Commission, Compulsory Licensing of Patents (Productivity Commission Inquiry Report, No 61, 2013), 60.
49 See Patents Act 1990 (Cth), ch 17.
50 Australia is a federation of States and Territories. Some State and Territory laws cover areas where there is no federal law, or their laws may be in line with federal law. If there is a clash between federal and State or Territory laws, the federal law prevails.
51 Patents Act 1990 (Cth), ss 160A and 163.
52 ibid, s 171(1).
53 ibid, s 171(4).
54 ibid, s 163(3).
the relevant Minister considers that the relevant authority has tried for a reasonable period without success to obtain authorization from the patentee to exploit a patented invention on reasonable terms;

- that Minister provides written approval for the exploitation for Crown purposes; and

- at least 14 days before such exploitation commences, the relevant authority must give the patentee a copy of the Ministerial approval and written reasons for approving the exploitation.

However, in emergency situations, the steps are modified such that:

- the relevant Minister considers that exploitation of a patented invention is required due to an emergency, and provides prior written approval for exploitation of that invention for Crown purposes;

- a person authorized by the relevant authority is authorized to exploit the patented invention before that exploitation starts.

The circumstances that unify Crown use in both non-emergency and emergency situations are that authorization must be a decision of the relevant Minister and that the invention is to be exploited for a ‘Crown purpose’. The requirement for Ministerial approval is the result of the recent amendments which are intended to provide greater comfort to patent owners that the result of the recent amendments which are intended to pose. The requirement for Ministerial approval is that the invention is to be exploited for a ‘Crown purpose’. This expressly includes provision of services’ of the government. Now, exploitation must be for a ‘Crown purpose’. This expressly includes provision of services that are primarily government funded, making it clear that the Crown use regime can be accessed by non-government healthcare providers. For example, where the government is responsible for providing or funding genetic tests, the relevant government authority may, with approval from the relevant Minister, authorize private providers to undertake patented diagnostic genetic testing for private patients. Crown may also be likely to expand to the provision of healthcare services that are primarily government funded including implementation of the national immunisation programme.

It is open to a relevant government authority to apply to the FCA for a compulsory licence. However, invoking Crown use is a more efficient pathway for a government to exploit a patent lawfully without the patentee’s authorization. Rather than applying to the FCA, a decision of the executive is all that is required. Furthermore, by reason of the recent amendments, the Crown use provisions may now be invoked in an emergency without the requirement for prior negotiation, and nor does the Minister have to provide reasons for authorizing the exploitation.

Thus, the legislative intention that the provisions be sufficiently flexible to cover any situation, such as a pandemic, where the government must act quickly, recognizing that emergencies are inherently unpredictable.

Despite this relatively more straightforward route, the Explanatory Memorandum introducing the recent amendments to the Crown use regime confirms that, similar to compulsory licences, Crown use is a rarely used safeguard. However, unlike the public process of a court mandated procedure for a compulsory licence, the frequency (or otherwise) of Crown use can only be inferred, primarily from challenges to such use. The fact that Crown use has only been contested in two reported instances in Australia suggests that these provisions are not frequently invoked. In those cases, the relevant government authority was permitted to exploit a patented invention in respect of services relating to railways and domestic water supplies. There are no reported instances of any challenges to Crown use in a health setting.

E. Other jurisdictions

Many jurisdictions have compulsory licence and government authorization provisions reflecting the standards set in the Paris Convention and Article 31 TRIPS or otherwise in accordance with historical bases. As is the case in Australia, a number of them have not adopted TRIPS in all respects.

In particular, in relation to compulsory licences, a number of other Member States have opted not to waive the requirement that the proposed user seek

55 ibid, s 163A(3).
56 Revised Explanatory Memorandum to Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019, [68]–[70].
57 ibid, [35].
58 Patents Act 1990 (Cth), ss 163(3) and 163A.
59 ibid, s 163A(3).
60 Revised Explanatory Memorandum to Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019, [79].
61 ibid, [38].
62 General Steel Industries Inc v Commissioner for Railways (NSW) (1964) 112 CLR 125; and Stack and Others v Brisbane City Council and Others (1995) 131 ALR 333.
authorization from the right holder on reasonable commercial terms and conditions in a national emergency of extreme urgency or in cases of public non-commercial use. For example, the Patents Act 1977 (UK) provides that a person may apply to the Comptroller General of Patents for a compulsory licence of a patent that is owned by a WTO Proprietor any time three years from the grant of the patent. The Comptroller may grant a compulsory licence on the terms that the Comptroller thinks fit if satisfied that the relevant grounds are established. The grounds include that the applicant has made efforts to obtain a licence from the WTO Proprietor on reasonable commercial terms and conditions. Some jurisdictions contemplate a negotiation requirement in a national emergency of extreme urgency or in cases of public non-commercial use. The USA might arguably be said to the outlier with a compulsory licence regime permits the US government to ‘march in’ and license or demand licensing of government-funded patent inventions to third parties without any negotiation requirement.

As in Australia, a number of jurisdictions have also incorporated a public-interest test in relation to compulsory licences that is not contemplated by TRIPS, including Canada, Germany, South Africa and Japan. Similarly, in the UK, the applicant is also required to demonstrate public interest-type grounds: hindrance or prevention of the exploitation of an invention which involves an important technical advance of economic significance, thus unfairly prejudicing the development of commercial or industrial activities in the UK.

In relation to government authorization, TRIPS requires that Members allow use of the subject matter of a patent without authorization of the right holder, including use by the government or third parties authorized by the government. Government authorization provisions are incorporated into the domestic legislation of a number of jurisdictions in accordance with TRIPS, Article 31, or otherwise in accordance with historical bases, including the USA, Canada, Germany, South Africa and India. Most of these jurisdictions do not adopt TRIPS co-extensively, and the grounds or reason by which such provisions can be invoked vary from jurisdiction to jurisdiction. In Canada, the Commissioner has discretion to authorize government use; in the USA, the provisions effectively permit the government to use an invention as long as it pays compensation; in Germany such provisions can be invoked for the interest of public welfare; in South Africa for public purposes; and in India for the purposes of the government.

In the UK (as in Australia), the basis for the concept of Crown use lies in historical concepts relating to the derogation of a Sovereign’s prerogative right. Section 55(1) of Patents Act 1977 (UK) provides that any government department and any person authorized in writing by a government department may, ‘for the services of the Crown’, exploit a patented product or product made in accordance with a patented process. Examples of ‘services of the Crown’ include: the production or supply of specified drugs or medicines; the supply of anything for foreign defence purposes; and purposes relating to the production or use of atomic energy or research into matters connected therewith. These examples are not exhaustive. In the seminal case of Pfizer Corp v Minister of Health, the House of Lords upheld the decision of the lower court that supply by the Ministry of Health of the antibiotic tetracycline to National Health Services hospitals was use for the services of the Crown. The majority of the Law Lords held that an act is for the services of the Crown if it is done for the purpose of performing a duty or exercising a power which is imposed upon or invested in the executive government by statute or by prerogative. More
recently, in *IPCOM v Vodafone*,\(^8^7\) it was held that exploitation of a system providing priority access to mobile phone networks to organizations involved in responding to emergencies was for services of the Crown. This was both because the system benefited the Crown directly and members of Crown services used it in the exercise of their duties.\(^8^8\)

The extent to which a Member State adopts TRIPS but incorporates additional requirements for the grant of a compulsory licence or exercise of Crown use (or government authorization) may impact the extent to which those provisions are invoked. However, it seems that, in general, these provisions are infrequently relied upon.\(^8^9\) For example, similar to the position in Australia, the UK Crown use provisions are rarely invoked and infrequently contested. Unlike Australia, compulsory licences have in fact been granted in the UK, albeit seemingly infrequently.\(^9^0\)

Sparked by the COVID-19 pandemic, some governments have sought to strengthen the coercive measures relating to government authorization and compulsory licence for a specified period of time. For example, in Canada, section 19.4 of the Patents Act was enacted, which authorized the Government of Canada and any person specified in the relevant application to construct, use and sell a patented invention to the extent necessary to respond to the public health emergency.\(^9^1\) In Germany, the Act on the Protection of the Population in the Event of an Epidemic Situation of National Importance amended the Act for the Prevention and Control of Infectious Diseases in Humans now allows the Federal Ministry of Health (and not just the German Federal Patent Court) to authorize the use of patents in the interest of public welfare. These pandemic related amendments, while time-limited, increase the reach and extent to which these coercive measures may be invoked in an emergency public health crisis. However, perhaps unsurprisingly, for the reasons explored in Section IV of this article, there are so far no reported instances of such newly enacted provisions being invoked during this COVID-19 pandemic.

**IV. Ensuring supply of Covid-19 related vaccines or treatments**

**A. Are compulsory licences a necessary or effective means to ensure supply?**

As explored in Section II of this article, since the COVID-19 pandemic was first declared, the emerging picture is one of collaboration rather than coercion. As the efforts to identify and develop candidates for vaccines or treatments have intensified, it seems that any company with existing technology which shows any promise is already deploying considerable efforts to explore its application in the present context. Thus, it seems unlikely, given the extensive research efforts taking place, that any relevant patented technology will be left ‘unworked’, which is the fundamental prerequisite for the grant of a compulsory licence.\(^9^2\)

However, the expected volume of demand for COVID-19 vaccines and treatments has been placing great pressure on governments to guarantee supply when any supply is possible. This could lead to situations which prevent a patented invention being ‘worked’ in all of the jurisdictions in which a corresponding patent has been filed. Many governments have already contracted with manufacturers to ensure priority supply of COVID-19 vaccines or treatment candidates. Notably, Operation Warp Speed has seen the US Department of Health and Human Services (HHS) fund the manufacturing effort of several companies in exchange for priority supply of doses of each investigational vaccines.\(^9^3\) Australia has agreements with the University of Oxford/AstraZeneca, Novavax, and Pfizer/BioNTech for the supply of vaccines conditional on such vaccines proving safe and effective.\(^9^4\)

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\(^{8^7}\) [2020] EWHC 132.

\(^{8^8}\) ibid, [209], [210].

\(^{8^9}\) Australian Government Productivity Commission, *Compulsory Licensing of Patents* (Productivity Commission Inquiry Report, No 61, 2013) 4.

\(^{9^0}\) See, eg, *Kalle v Co AG’s Patent* [1966] FSR 112; *In the Matter of an Application by McKechnie Bros Ltd’s for a Compulsory Licence in respect of certain Letters Patent* (1934) 51 RPC 461; *In the Matter of an Application by A. Hanson & Son (London) Limited for a Licence under No 653,123* [1985] RPC 88; *Penn Engineering and Manufacturing Corp’s Patent* [1972] FSR 535; *Allen & Hanbury’s Limited (Sulbutamol) Patent* [1987] RPC 327.

\(^{9^1}\) Patents Act (Canada) s 19.4.

\(^{9^2}\) Note that an application to the Court for a compulsory licence, in respect of a standard patent, can only be made after three years have elapsed since grant; see section Patents Regulations 1990 (Cth), reg 12.1; Patents Act 1990 (Cth) s 133(1).

\(^{9^3}\) See, eg US Department of Health & Human Services, ‘HHS, DOD Collaborate with Novavax to Product Millions of COVID-19 Investigational Vaccine Doses in Commercial-Scale Manufacturing Demonstration Projects’ (7 July 2020) <https://www.hhs.gov/about/news/2020/07/07/hhs-dod-collaborate-novavax-produce-millions-covid-19-investigational-vaccine-doses-commercial-scale-manufacturing-dem onstration-projects.html> accessed 12 July 2020. See also Pfizer, ‘Pfizer and Biontech Announce an Agreement with US Government for up to 600 million doses of mRNA-based Vaccine Candidate against SARS-COV-2’ (22 July 2020) <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-govern ment-600> accessed 14 August 2020.

\(^{9^4}\) Australian Government Department of Health, ‘Australia’s Vaccine Agreements’ (9 December 2020) <https://www.health.gov.au/australias-vaccine-agreements> accessed 9 December 2020.
A manufacturer that has exhausted its total production capacity may not be able to ‘work’ its patents in all jurisdictions where it has corresponding patent rights. As national or regional governments rush to secure supply arrangements for their own citizens, it is not unreasonable to speculate that the existence, if not the threat, of compulsory licence regimes may be playing a role in the various negotiations taking place in multiple jurisdictions.

However, in Australia, even if patented technology risks being left ‘unworked’ locally, the inherent constraints of the compulsory licence regime may nonetheless dictate limited practical application in the current pandemic. Once a COVID-19 vaccine or treatment is widely available, supply will be time-critical. In those circumstances, seeking a compulsory licence is not the most efficient avenue to pursue. First, a compulsory licence for a standard patent can only be sought three years after the date of granting the relevant patent.95 Where securing the supply of newly developed vaccines is time-critical in this pandemic, this requirement presents a practical limitation on the utility of the compulsory licence regime. Secondly, the applicant for a compulsory licence has to meet a high evidentiary burden to have any prospect of persuading the court to grant a compulsory licence, including running the gamut of appeal rights. Assuming, the applicant is successful, it is then at the mercy of the court as to the terms of the licence, the FCA having a broad discretion to dictate any terms of a compulsory licence as it thinks fit.96 Furthermore, in the absence of the applicant and the patentee reaching agreement on remuneration, the FCA will impose such remuneration as it considers just and reasonable.97 Thus, the prospective licensee may find itself subject to licence conditions not of its choosing.

Despite these limitations, the mere existence of the compulsory licence provisions, together with the threat (express or implied) they may be invoked, may prompt any recalcitrant patentee to license any ‘unworked’ patent technology on appropriate terms. Australia’s public consultation preceding the recent amendments to its compulsory licensing regime concluded that the very existence of the regime may deter patentees from refusing to license their patented technology. In examples cited,98 the commencement of proceedings for a compulsory licence led one patentee to grant a licence over its bauxite processing technology, and another to grant a licence over its hepatitis E assay kits.

At least to date in the current pandemic, similar factors seem to be at play more broadly. As noted above, Israel’s authorization of a compulsory licence to provide for the importation of generic versions of AbbVie’s Kaletra reportedly led AbbVie to decide not to enforce its global patent rights. It is not unreasonable to hypothesize that the mere threat of invoking available compulsory licence regimes may be sufficient to incentivise manufacturers to do what is necessary to ‘work’ relevant inventions. This could include licensing arrangements to access additional manufacturing capability where a manufacturer lacks or has insufficient capacity to scale up its own facilities to the extent necessary to supply multiple geographies. Alternatively, we may see instances of rights holders electing not to enforce their intellectual property rights extending into the manufacturing and supply phase, at least during the global efforts to bring the pandemic under control.

B. Other emergency measures and responses may be more appropriate than Crown use

(1) Limitations of Crown use

As noted, it is assumed in the Australian context that governments would be inclined to rely on Crown use rather than pursue a compulsory licence route. However, the Crown use provisions also have limitations. First, there is a risk that the relevant patentee or exclusive licensee will use legal means such as judicial review or patent infringement proceedings to contest or resist a decision under the Crown use provisions.99 Secondly, the Crown use regime does not empower the government to require a manufacturer to divulge undisclosed information or know-how associated with the patent. This may present a practical limitation on ‘working’ a patented invention as governments may simply lack the required skills, knowledge, experience, resources or information to do so. Absent cooperation from the patentee, this constraint could theoretically be resolved by a government authorizing a third-party manufacturer to exploit the relevant patent. However, as previously noted, pharmaceutical inventions are complex biological products. Without the transfer of technical manufacturing information and know-how, or access to purpose-built manufacturing facilities, it

95 Patents Act 1990 (Cth), s 133(1). Patent Regulations 1991 (Cth) reg 12.1(1).
96 Patents Act 1990 (Cth), s 133(3C).
97 ibid, s 133(5)(a)–(b).
98 See Law Council of Australia, Submission to the Productivity Commission’s inquiry into Compulsory Licensing under the Patents Act 1990 (Submission, 2012) 3.
99 See, eg Stack and Others v Brisbane City Council and Others (1995) 131 ALR 333; and General Steel Industries Inc v Commissioner for Railways (NSW) (1964) 112 CLR 125.
may not be possible for an unrelated third-party manufacturer to deploy the patented technology effectively or at all, potentially thwarting the practical efficacy of the Crown use provisions.

(2) Other available powers and responses

Thus far, this article has explored the options available to governments to compulsorily access technology through patent specific regimes. However, in many countries, governments also have broader powers which may ultimately be better suited to secure the supply of any COVID-19 vaccine, treatment and necessary medical supplies during this pandemic.

In Australia, the Biosecurity Act 2015 (Cth) (Biosecurity Act) gives the Australian government broad powers to impose measures to manage the risk of infectious diseases that potentially harm the Australian population, its food security or the economy, thereby providing scope for deploying measures to ensure supply. A human biosecurity emergency may be declared to exist if the Health Minister is satisfied that:

- a listed human disease is posing severe and immediate threat, or is causing harm, to human health on a nationally significant scale; and
- the declaration is necessary to prevent or control the listed human disease from entering, emerging, establishing or spreading in Australian territory.

Relevantly, on 21 January 2020, COVID-19 became a listed disease in Australia, with a human biosecurity emergency being declared in March that year. This has since been extended to December 2020, with the possibility of further extensions. This gives the Health Minister extremely wide powers to determine any requirement or issue any direction considered necessary to:

- prevent or control the entry, emergence, establishment or spread of COVID-19 in any part of Australian territory;
- prevent or control the spread of COVID-19 to another country; or
- give effect to any recommendation made by the WHO in relation to COVID-19.

These expansive powers are targeted and time-limited to the declared emergency, and the Health Minister must be satisfied that any requirements or directions will be effective and are not more restrictive or intrusive than the circumstance require. Non-compliance can result in criminal sanctions.

These powers have been deployed in this pandemic, providing the basis for Australia’s lock-down orders and prevention of gatherings of individuals. The breadth of these powers raises the possibility of the Australian government seeking to rely upon them to compel a manufacturer domiciled in Australian territory to produce and supply vaccines, medical treatments or other supplies to meet local demand, should the necessary capability exist within Australia.

Other national governments have also invoked their pre-existing emergency powers during this pandemic. In the USA, the Defense Production Act 1950 (US) (DPA) has been used to ensure the critical supply of COVID-19 related medical equipment. The DPA can be used to compel businesses to perform contracts for materials deemed necessary or appropriate to promote national defence, in priority to performance of any other contract or order. In March 2020, former President Trump issued an executive order that defined ventilators and protective equipment as ‘essential to the national defense’ and has since invoked the DPA to require:

- General Motors to accept, perform and prioritize contracts to make as many ventilators as determined to be appropriate;
- 3M, General Electric and Medtronic to increase production of protective masks.

Given the extent of the manufacturing and pharmaceutical capability in the USA, the DPA is potentially a very powerful tool to ensure supply of a vaccine, treatment or medical supplies. Deployment of the DPA to date suggests that broad emergency-type powers is an effective measure where there is a significant public health threat.

C. The advantages of collaboration and reaching an agreement

Coercive measures such as compulsory licences, Crown use and the use of government emergency powers each have their limitations. To that end, reaching a negotiated agreement with a patentee or manufacturer is a
preferenceable approach to secure the supply of any promising COVID-19 vaccine or treatment, or necessary medical supplies. This avoids the risk that a patentee will seek to contest the relevant, measure, thereby delaying or even thwarting the outcome sought to be achieved in the name of public health.

A negotiated licence is also a more effective means to facilitate the sharing or transfer of technical information and know-how, access to which may be necessary to optimize the exploitation of the patented technology where it is necessary or desirable to involve third parties. For example, Oxford University has licensed its front-runner vaccine candidate, AZD1222, to AstraZeneca, which has entered into supply agreements with various governments or coalitions, including, for example, the US government, the UK government, Europe’s Inclusive Vaccines Alliance, the Coalition for Epidemic Preparedness Innovations and Gavi the Vaccines Alliance and Serum Institute of India and the Australian government. In November 2020, AstraZeneca announced that its manufacturing capacity for its candidate vaccine is three billion doses. To meet this extraordinary level of demand, it is contracting with several other manufacturers and distributors and is building a comprehensive manufacturing supply chain. A notable example is the agreement between CSL and AstraZeneca and Australian Government, to manufacture 30 million doses of the AstraZeneca/Oxford University vaccine which required close collaboration between CSL’s and AstraZeneca’s technical experts. Perhaps by reason of the unprecedented impact that it has had on the global economy and on health outcomes, the COVID-19 pandemic has to date been characterized by cooperation and collaboration to expedite the discovery of vaccines and treatments. If industry and governments can continue the collaborative approach adopted to date during this pandemic, implementing instruments such as Crown use and compulsory licences may ultimately be unnecessary.

However, as some countries secure priority supply of promising candidates, where others may fail to reach such arrangements, the pandemic landscape that has to date promoted collaboration may be at risk of devolving into something less cooperative. In a move which may be a portent of such concerns, in October 2020, discussions amongst WTO members saw India and South Africa submit a proposal that would temporarily waive certain obligations under TRIPS enabling the availability of a COVID-19 vaccines and new technologies in poorer nations. The response from the USA, UK, Canada, Australia and the European Union was that there was no indication that intellectual property rights have been a barrier to accessing COVID-19 related medicines and technologies, and that such proposal would undermine the collaborative efforts that are underway. In any event, TRIPS arguably provides sufficient measures to protect public health: the very existence of compulsory licences and government use may play a role in persuading, if not compelling, patentees to negotiate acceptable contractual supply arrangements with governments. Thus, the compulsory licence and Crown use regimes may not be entirely nugatory in the current context. Their true utility in this pandemic may lie not in the fact that they are actually invoked, but that they could be should the current levels of cooperation deteriorate.

V. Conclusion

Compulsory licences and Crown use provisions have a long and distinguished pedigree, enshrined in important intellectual property treaties. However, the finer points of these regimes are more often the purview of theoretical debate amongst intellectual property lawyers and policy-makers. It is well recognized that the enormity of the global health and economic challenges of the current pandemic will only ultimately be resolved by safe and effective vaccines that will assist populations to build herd immunity and provide a basis for developments that can meet the challenges of the mutations of COVID-19 virus. This thwarts the debate around access to the technology needed to do this into the spotlight of mainstream debate, raising the spectre that global efforts will stall if access is delayed or denied. To date, a collaborative approach has prevailed. Despite a pandemic being the very type of emergency for which
coercive access to patented technology is designed, it may be that it is not necessary that compulsory licence and Crown use provisions are actually invoked. The one early instance seen in Israel seems to have driven an arguably better outcome with AbbVie deciding to forgo enforcing its patent rights more broadly.

This in fact demonstrates that the compulsory licence and Crown use regimes do have utility. Their existence, with the attendant possibility they may be invoked, may operate to encourage what may otherwise be reluctant patentees to negotiate and reach a timely arrangement for access to relevant technology. They therefore continue to serve as safeguards to ensure the appropriate balance between a patentee’s reward for its investment, and the need for access to patented technology during a public health crisis.