# 7 Crown use and acquisition

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| Key points |
| * Crown use and acquisition provisions allow governments to access patents without the owner’s authorisation. Crown use has rarely been invoked and Crown acquisition powers have never been used to the Commission’s knowledge. * Governments will generally find Crown use to be a less costly and time-consuming option than compulsory licensing. For example, governments do not have to apply to the Federal Court. * Crown use can be applied to healthcare-related patents, given governments’ major responsibility for healthcare provision. However, inquiry participants were uncertain about whether: * Crown use can be utilised by non-government healthcare providers, given that it can only be used ‘for the services of’ a government * Crown use can be utilised by State Governments for services outside the state * State Governments have to invoke Crown use individually, rather than coordinate their actions. * To reduce such uncertainty, the *Patents Act 1990* (Cwlth) should be amended so that it is clear that Crown use can be invoked for the provision of a service that the Australian, State or Territory Governments have primary responsibility for providing or funding. * The transparency and accountability of Crown use should be strengthened by requiring (except where it would delay the response to an emergency): * governments to first attempt to negotiate use of a patented invention * a Minister to approve instances of Crown use, and that the patentee be given a statement of reasons no less than 14 days before such use occurs * just and reasonable compensation to be paid to the patentee, on the same basis as for compulsory licences. |
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The terms of reference for this inquiry ask the Commission to consider recommending alternative mechanisms to compulsory licensing. The Crown use and acquisition provisions — set out in ss. 161–170 of the *Patents Act 1990* (Cwlth) (Patents Act) — can be considered to be such alternatives. This chapter examines the functioning of the provisions, and their interaction and potential overlap with compulsory licensing. Reforms are proposed to clarify when Crown use can be utilised, and to strengthen the requirements for transparency and accountability .

## 7.1 Current arrangements

The Crown use and acquisition provisions provide for the Commonwealth or a State Government, or a person or organisation authorised by the Commonwealth or a State, to use a patent with protection from legal action for patent infringement. The legislation allows for these parties to compulsorily acquire a patent (s. 171), have one assigned to them (s. 172), or to use the patent under what is effectively a compulsory licence (s. 163).

### Crown use

Crown use provisions were introduced in Australia with the enactment of the *Patents Act 1903* (Cwlth). The origin of these provisions was English patent law, which provided the template for Australian laws (SLCLAC 2011). England had a history of Crown use of patents, but formal provisions were not adopted there until 1883 (ALRC 2004). Historically, the justifications for Crown use were:

* the Crown should not be impeded by patents (which are, in effect, Crown grants) from acting in the public interest, particularly in relation to matters of national defence
* unlike private traders, the Crown, through its departments and authorities is ordinarily engaged in public services, rather than commercial activities, and therefore should be in a special position in regards to use of patented inventions. (ACIP 2005a, p. 9)

Under ss. 163–170 of the Patents Act, commonly referred to as the Crown use provisions, a patented invention can be used without first seeking the owner’s permission. However, as soon as practicable after an invention has been exploited, the relevant authority must inform the patentee of the exploitation and provide any information about the exploitation that is reasonably required (unless it would be contrary to the public interest to do so). Crown use can only be invoked for the services of the Commonwealth or of a State (s. 163(1)). Where the provisions are invoked, the patent holder is entitled to remuneration under s. 165 of the Act. In the absence of an agreement between the relevant government authority and the patent holder, either party can apply to a prescribed court[[1]](#footnote-2) to determine the terms.

### Crown acquisition

Under s. 71 of the Patents Act, the Crown can acquire a patent. As in the case of Crown use, the legislation allows for court determination of remuneration (s. 171(4)) and requires the Crown to inform the patentee of its actions. The Crown must also publish notice of the acquisition ‘in the *Official Journal* and the *Gazette* unless, in the case of the acquisition of an invention that is the subject of an application for a patent, a prohibition order, or an order under s. 152, is in force in respect of the application’(s. 171(3)(b)).[[2]](#footnote-3) There are no publicly recorded instances of Crown acquisition (LESANZ 2011).

Crown acquisitions of intellectual property can be considered an application of the broader powers of acquisition held by the Australian Government. For example, s. 51(vi) and s. 51(xxxix) of the Constitution provide executive and legislative powers to the Australian Government in situations of national emergency or military operations. Moreover, the Australian Government has the power to enact laws with respect to the acquisition of property on just terms under s. 51(xxxi).

Crown acquisition appears to be an option that would only be invoked when a government wants to exclude others from using an invention. It is not necessary to acquire the property right in its entirety for a government to exploit an invention, given the existence of Crown use. Crown use is also less costly, since the patentee retains ownership of the patent and is able to continue to use the invention in question. As such, the patentee does not have to be compensated for the loss of this use or for the loss of licence fees from third parties. The Commission has hereafter focused its analysis on Crown use.

### Instances of Crown use in Australia

Crown use has been rarely used. In a 1997 report to the TRIPS Council, the Australian Government stated that it expected Crown use to have been minimal (ALRC 2004). The primary difficulty in establishing patterns of use is in uncovering cases of uncontested use. However, there are two reported cases in which Crown use has been contested in court (box 7.1).

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| Box 7.1 Contested cases of Crown use |
| General Steel Industries Inc v Commissioner for Railways (NSW) (1964) 112 CLR 125  The NSW State Commissioner for Railways’ use of an invention for central bearing structures for railway carriage construction was held to be allowed under *s. 125 of the Patents Act 1952 (Cwlth)* (the predecessor to s. 163 of the current Patents Act). It was considered that the use was ‘for the services of the State’, and had regard to the UK decisions in *Pyrene Company Limited v Webb Lamp Company Ltd* (1920) 37 RPC 57 and *Aktiengesellschaft Fur Autogene Aluminium Schweissung v London Aluminium Co. Ltd (No. 2)* (1923) 40 RPC 107.  Stack v Brisbane City Council (1994) 131 ALR 333  Brisbane City Council’s use of a patented invention for water meter assemblies was held to be within the scope of Crown use. It was considered that Brisbane City Council was an authority of a State for the purpose of s. 163. The focus of the case was on whether the functions of Brisbane City Council have the ‘stamp of government’ and whether they have been given the power to direct or control the affairs of others on behalf of the State. |
| *Source*: LESANZ (2011). |
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While the provisions appear to be rarely invoked, submissions to a review of Crown use by the Advisory Council of Intellectual Property (ACIP), claimed that the threat of using the provisions in negotiations was far more prevalent (ACIP 2005a). These submissions reportedly claimed that some IP right owners had ‘been put under considerable pressure by organisations threatening to invoke the provisions in situations where it was not clear whether these organisations had the requisite authority or the legal requirements to qualify as a Crown entity’(ACIP 2005a, p. 8).

### Why are the Crown use provisions seldom used?

Similar to the case of compulsory licences (chapter 6), the limited history of litigation over the Crown use provisions could suggest a variety of things. First, it is likely the provisions are intended to be a safeguard for rare instances in which the patents system is hindering government action to address an urgent issue (for example, providing treatment in an epidemic). It may be that such cases are rare because patent holders are usually willing to license reasonably and widely and/or few instances arise where urgent access is required.

Second, governments may be reluctant to use the provisions, as they involve significant interference with the rights of patent holders. If the provisions were relied upon too readily, confidence in the patents system could be damaged.

Third, it could be the case that there are rarely any problems for governments in securing access to patents. This could be because governments usually offer just terms. Alternatively, it could be that the cost of litigation to challenge Crown use, or the terms offered under Crown use, can force an unwilling licensor to the negotiating table and ensure an acceptable result for the government.

Fourth, it may be that there is a lack of knowledge about the provisions and the appropriate arms of government are unclear on how and when it is appropriate to invoke the provisions.

Finally, it may be that there are a number of problems with the provisions that discourage governments from utilising them.

## 7.2 Assessment of the Crown use provisions

Participants and past reviews have revealed some concerns about aspects of the provisions. This section considers some of these issues in detail.

### Participants’ views

Inquiry participants were generally supportive of the role that Crown use plays, particularly in the case of healthcare:

[Crown use provisions] have a legitimate role to play with regard to domestic issues relating to access to healthcare. (Centre for Law and Genetics, sub. 3, p. 10)

The Department recognises the potential value of the Crown Use provisions in protecting national public health interests. (Department of Health and Ageing, sub. 22, p. 5)

That said, utilising the provisions involves significant interference with the rights of patent holders. As a result, some inquiry participants cautioned that routine use of the provisions could undermine confidence in the patents system, and as such, the provisions should only be invoked in exceptional circumstances:

[The Institute of Patent and Trademark Attorneys and the Australian Federation of Intellectual Property Attorneys] would caution the Crown against use of the Crown use provisions except in cases of extreme urgency in order to preserve the integrity of the patent system so far as patentees and investors are concerned. (Institute of Patent and Trademark Attorneys, sub. 18, p. 7)

Crown Use provisions provide a safeguard to any adverse impact of patent protection on public interest. These provisions should be used cautiously and for exceptional circumstances only since undertaking research and development in biomedicine is risky and expensive. (Walter and Eliza Hall Institute of Medical Research, sub. 13, p. 8)

This would include public health emergencies. A practical example is the US and Canadian Governments’ consideration, in 2001, to invoke their powers to access a treatment for anthrax without the patent owner’s authorisation (box 7.2).

Emergency use of this nature is relatively less contentious in the context of international trade. For example, the United States has been a critic of the use of non‑voluntary licensing provisions (SLCALC 2011). In contrast, emergency use is widely accepted as legitimate. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS agreement) explicitly provides for the emergency use of a patented invention (by the government or a third party authorised by the government) without the authorisation of the patent holder (appendix D).

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| Box 7.2 Emergency use of Bayer’s patent for ciprofloxacin |
| In September of 2001, a series of bioterrorism attacks occurred in the United States with the spreading of anthrax *(Bacillus anthracis)* spores through the mail. The attacks led to the deaths of five people, the infection of 17 others, and many more tested positive for anthrax exposure.  Public fear about the attack led thousands of Americans and Canadians to take antibiotics as a prophylactic measure. A broad spectrum antibiotic made by Bayer A.G. (Bayer), ciprofloxacin (Cipro), became the drug of choice for many. It was believed that Cipro would be effective at treating infections from anthrax since it was chosen by the U.S. Army for use against a potential biological weapons attack from Iraq, during the Gulf War. In the following days, thousands of people sought to obtain the drug and the fear of Cipro shortages became acute.  In order to increase production of Cipro, the United States and Canadian Governments considered overriding Bayer’s patent. Canada, in fact, overrode Bayer’s patent for a few days until Bayer reached a deal with the Canadian government. In the US some politicians urged the enlistment of generic drug companies to manufacture Cipro in order to avoid a shortage. However, such intervention was ultimately not necessary, as by 25 October the United States Government had also reached a deal with Bayer. Bayer agreed to accelerate its production of Cipro to meet the increased demand, and to drop its price. Before October 2001 the average price of Cipro was $US4.25 per tablet, but Bayer cut its prices by more than 70 per cent as a result of its agreements with the United States and Canada. |
| *Source*: Resnick and De Ville (2002). |
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While the Commission agrees that Crown use provisions should not be routinely used, and that they are particularly useful in emergencies, the provisions have a wider application. Like compulsory licensing among private parties, Crown use should continue to be an option, irrespective of whether there is an emergency, if a patented invention is not available to the Australian community on reasonable terms and conditions. That said, in order to avoid undermining the efficiency goal of the patents system, governments using the Crown use provisions should ensure that the benefits of use outweigh the costs.

### Past reviews of Crown use

The most comprehensive review of the Crown use provisions was conducted by ACIP in 2005. The review encompassed the Crown use provisions in the Patents Act and the *Designs Act 2003* (Cwlth). It called for various changes to place greater discipline on use of the provisions and reduce uncertainty about the compensation received by patent holders (box 7.3). The Australian Government did not issue a response to the recommendations on the grounds that there was no substantial evidence that the provisions were being misused (ACIP 2010b). Instead, it wrote to Commonwealth Ministers, and to State and Territory innovation and local government Ministers, outlining governments’ obligations when exercising their rights to Crown use.

The Australian Law Reform Commission (ALRC 2004) also examined Crown use as part of a review of gene patents. It made recommendations aimed at making the Crown use provisions more ‘fit for purpose’ in ensuring access to healthcare. This included amendments that specifically raise healthcare as a rationale for invoking the provisions, and amendments to clarify the remuneration responsibilities of governments in these instances.

The recommendations of the ALRC were endorsed by the Senate Community Affairs References Committee in its review of gene patents (SCARC 2010). It also recommended:

… the Patents Act 1990 be amended to clarify the circumstances in which the Crown use provisions may be employed; and that the Government develop clear policies for the use of the Crown use provisions. (SCARC 2010, p. xviii)

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| Box 7.3 Recommendations from the ACIP review of Crown use |
| In 2005, the Advisory Council on Intellectual Property made the following recommendations to the Australian Government about crown use:  The Need for Prior Consent  The Patents Act should be amended to ensure that, prior to any use of a patent by the Crown, there are genuine efforts to obtain authorisation from the rights holder. Furthermore, the Crown should be required to offer reasonable commercial terms and attempt to reach agreement within a reasonable period of time.  These requirements may be temporarily waived in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use by entities operating solely in the public interest. This would not extend to public/private organisations that predominantly operate for profit.  **Definition of the Crown and Ministerial Approval**  The Patents Act should require organisations using the Crown use provisions to seek Ministerial approval prior to any such use. At the State level, organisations will require the prior approval of the relevant State Attorney General, and at the federal level, require the prior approval of the Federal Minister with portfolio responsibility for the patents legislation. The requirement to obtain Ministerial approval may be temporarily waived for emergency or public non-commercial use.  Remuneration and Processes  The Patents Act should state that patent owners affected by the Crown use provisions are entitled to compensation that is ‘just and reasonable taking into consideration the circumstances of the case’. To facilitate agreement between the parties there should be a prescribed statutory remuneration process in the patents legislation. |
| *Source*: ACIP (2005a). |
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### Definition of the Crown

The ACIP review contended that there was a need for clarity in demarcating the scope of the Crown. Uncertainty surrounds a number of entities that could potentially qualify as the Crown, including, employees, commissions, statutory authorities, statutory corporations, government business entities, government owned corporations and private corporations under contract to the government (ACIP 2005a). Similarly, the ALRC (2004) raised concerns of ambiguity on the issue of whether some research institutes have sufficient government involvement to be considered the Crown. It pointed out that such institutions may be established by state legislation and be affiliated with public sector universities or hospitals, but be self-governing, with their own set of research priorities and sources of funding.

Case law has shown that the definition of the Crown can be broad. *Stack v Brisbane City Council (1994)* 131 ALR 333 interpreted the scope of Crown use to include municipal councils and statutory authorities throughout Australia (ACIP 2005a).

The ambiguous definition of the Crown could result in several issues related to the misuse and misunderstanding of the Crown use provisions.

* Some organisations can be mistaken about whether or not they qualify as the Crown for the purposes of the Crown use provisions. These organisations may believe they have immunity from patent infringement actions, when in fact they do not.
* There may be instances where the provisions are misused, compromising the principles of competitive neutrality. This could occur where bodies gain an unfair competitive advantage in the marketplace, by invoking the provisions, despite the fact that they may not have been intended to have access to the provisions.
* Some patent holders may feel obligated to license their inventions when the person seeking a licence does not in fact have Crown status.
* Some patent holders may not seek infringement remedies that they are in fact entitled to.

#### Should there be Ministerial oversight?

One way to address the uncertainty surrounding the definition of the Crown is to charge an authority with the responsibility for determining when a use of patented material had been ‘impressed with the stamp of government’. ACIP (2005a) proposed that the Ministers charged with this power at the state level should be the relevant Attorney-General, and that the Minister responsible for the Patents Actshould have this power at the federal level.

There are some problems with Ministerial oversight. Critics of the approach cite a danger of politicising access to Crown use, and creating unnecessary bureaucracy (ACIP 2005a). The introduction of Ministerial oversight might also increase uncertainty and inconsistency, as Ministerial decisions may not be based on the system of case law and precedent.

However, ACIP (2005a) reported that a significant majority of the stakeholders it consulted supported the concept of using Ministerial approval for this purpose. These stakeholders indicated that this would help maintain competitive neutrality in the market and provide certainty, accountability and transparency (ACIP 2005a). Additional certainty and transparency would improve the efficiency of the patents system by better defining the property right associated with a patent. The addition of oversight also better aligns the Crown use provisions with the compulsory licensing provisions, which have judicial oversight.

### Consent of the patentee

The current provisions do not require the Crown to obtain consent from, or inform, the patentee of its intentions *before* it has exploited a patent. The Crown can voluntarily seek consent before, during or after it has exploited the patent. However, under s. 169, if the patentee believes that the Crown is exploiting, or has exploited, its patent, it can apply for a declaration from a prescribed court that this is the case. The same section expressly provides that the Crown can respond with a counter‑claim for revocation of the patent.

This contrasts with the compulsory licensing provisions, which require those seeking a compulsory licence to have ‘tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions’ (s. 133(2)(a)(i)). Instituting a requirement to seek consent prior to relying on Crown use would impose on the Crown similar requirements as apply to commercial entities seeking a compulsory licence. As noted in chapter 6, voluntarily negotiated licences will generally generate superior outcomes, and the need to seek prior consent provides an important impetus for achieving this outcome.

It could also be argued that the lack of a requirement to first attempt to reach a negotiated outcome means that the Crown use provisions are inconsistent with the TRIPS agreement (ACIP 2005a). In particular, Article 31(b) of the TRIPS agreement only waives this requirement in cases of ‘national emergency or other circumstances of extreme urgency or in cases of public non-commercial use’ (appendix D).

The Australian Government (1997) noted that it considered all Crown use to be ‘public non-commercial use’. In contrast, ACIP (2005a) observed that the private provision of previously traditional government services, and the quasi-government status of many bodies, may lead to Crown use that is not strictly ‘public non‑commercial’. It was specifically concerned that:

* exploiting the provisions for commercial use has the potential to undermine confidence in the patents system
* unauthorised use has the potential to financially damage patent holders
* the lack of obligations on governments increases uncertainty for businesses.

ACIP (2005a) further argued that:

* a patent holder needs information concerning the exploitation as soon as possible in order to minimise any commercial losses arising from the exploitation, and to ensure other related business decisions can be made with certainty
* Crown entities should be forthright, open and transparent
* patent holders should not be burdened with the expense of costly court proceedings simply to obtain information about whether the Crown is or has been exploiting their patents.

### Remuneration

The existing Crown use provisions do not contain any reference to a standard of remuneration. In other words, the provisions do not contain an express right to ‘adequate’ or ‘reasonable’ remuneration considering the ‘economic value’ of use. However, s. 165(2) states that, when parties fail to come to an agreement, either party can apply to a prescribed court for a determination on any terms of the exploitation, including remuneration. ACIP (2005a) contended that the lack of a remuneration standard can leave patentees disadvantaged and that the lack of an applied standard or criterion to refer to in any negotiations could weaken their bargaining position in seeking to obtain fair and equitable agreement. ACIP (2005a, p. 4) went on to suggest a standard of remuneration that ensures remuneration is paid promptly and is ‘just and reasonable taking into consideration the circumstances of the case’. This is consistent with recommendations made by the ALRC (2004).

The compulsory licensing provisions already have conditions of a similar nature. Section 133(5)(b) requires that a patentee who is subject to a compulsory licence receive remuneration that is ‘just and reasonable having regard to the economic value of the licence’. As is the case with prior consent, adding text to the Crown use provisions to this effect would impose upon the Crown the same conditions as those that face commercial entities in accessing a patent non-voluntarily. It would also help develop jurisprudence over remuneration conditions and harmonise the Patents Act with international agreements such as the TRIPS agreement and the Australia‑United States Free Trade Agreement (AUSFTA). Article 31(h) of the TRIPS agreement and article 17.9.7(b)(ii) of AUSFTA both use language indicative of a standard of remuneration (appendix D).

In addition to a remuneration standard, ACIP (2005a, p. 30) contended that there was ‘no clear reason why there is no formal process of remuneration, at least in non-emergency type situations’. It argued that a structured remuneration process would provide more certainty about respective obligations in negotiations, in addition to addressing the inherent inequality of bargaining power between the patentee and the Crown. This was seen as a particular problem for small to medium enterprises, as they lacked the resources and bargaining power of multinational corporations, for example.

ACIP (2005a) suggested a number of reforms of the remuneration process including:

* if parties fail to agree on the terms of exploitation, then there should be recourse to alternative dispute resolution
* a structured procedure be implemented into the Crown use provisions to guide the parties to reach an amicable outcome
* if the patent holder believes an authority is using a patent without either seeking a commercial licence or notifying the patent holder of such use, the patent holder can seek the assistance of the State or Commonwealth Ombudsman.

The sum of these recommendations is to introduce alternative dispute mechanisms for Crown use. Such mechanisms are discussed in chapter 6 in the context of compulsory licensing. The Commission notes there that the case for adding additional arrangements is weak, and would extend that reasoning to the case of Crown use.

## 7.3 Reforming the Crown use provisions

The Commission considers that reforms are warranted to clarify when Crown use can be utilised — particularly for healthcare — and to strengthen transparency and accountability.

### Clarifying the scope of Crown use

Inquiry participants raised several concerns about the scope of Crown use, particularly in the context of healthcare. Given that Crown use is less costly and more timely to access for a government applicant than a compulsory licence, it will typically be the most cost-effective option for governments to access patents for healthcare purposes. However, inquiry participants were uncertain about whether this could occur in practice for several reasons.

The Law Council of Australia (sub. 32) noted that the scope of Crown use is constrained by s. 165A of the Patents Act. Under this provision, a government can be ordered to cease an instance of Crown use by a court if it ‘is not, or is no longer, necessary for the proper provision of services of the Commonwealth or State’. The Law Council of Australia concluded that it is:

… unlikely that the Crown use exception could be applied in a situation where price negotiations for a voluntary licence are on foot or where the patented product is in fact available, albeit at a higher price. (Law Council of Australia, sub. 32, p. 11)

As discussed below, such limitations may be desirable to make governments accountable for when Crown use is invoked and what compensation is paid.

Some participants were concerned that the courts could interpret the Crown use provisions narrowly to exclude many instances of healthcare. This uncertainty arises because it is open to interpretation what is meant by s. 163(1) of the Patents Act, which limits Crown use to cases where an invention is used ‘for the services of’ a government. It seems unlikely that this would preclude healthcare services provided by governments, given that Crown use has previously been allowed for government-owned railways and domestic water supply (box 7.1).

However, some participants were concerned that the term ‘for the services of’ a government may not extend to the non-government portion of the healthcare sector. For example, the Australian Government Department of Health and Ageing (DOHA) expressed the view that:

There is some lack of clarity as to how far ‘the services of’ the government extend, but it is unlikely it would extend to use of the patent by non-government service providers (such as privately owned medical testing laboratories). (sub. 22, p. 5)

This is important because the Australian health system involves different tiers of government and the non-government sectors (box 7.4).

DOHA suggested that its concern could be addressed by:

… broadening the [Crown use provisions] to allow the Crown to license its access to the patent to a non-government entity, where it would be in the public health interest to extend services beyond those provided directly or indirectly by the Crown. (DOHA, sub. 22, p. 5)

However, this seems unnecessary because s. 163(1) of the Patents Act already allows any ‘person authorised in writing by the Commonwealth or a State’ to exploit the patented invention, at any time, so long as it is ‘for the services of the Commonwealth or the State’. There is no limit to the number of people that can be authorised, or any requirement that the person be a government employee.

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| Box 7.4 Levels of responsibility in Australian healthcare |
| The healthcare system in Australia is complex, involving many funders and healthcare providers. Responsibility for funding and provision is split between different levels of government, and between the public and non-government sectors.  In terms of funding, in 2010-11 the Australian Government provided 43 per cent of the total health funding, State and Territory and Local Governments funded 26 per cent, while non-government sources contributed 31 per cent (AIHW 2012).  The Australian Government operates the Medicare and the Pharmaceutical Benefits Scheme. It also jointly funds a number of aspects of the healthcare system, such as public hospitals and mental health services with the State and Territory Governments, through the National Health Care Agreement. Under this agreement, State and Territory Governments are also responsible for the delivery of a number of other services, including community health, ambulance services and disability services. The non-government sector’s provision of healthcare includes a wide range of services including, private medical practitioners, community and private hospitals, pathology services and pharmacies |
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Another concern raised by participants was that the Crown use provisions are not well suited to cases where coordination is needed across state boundaries.

Under current laws, each state/territory would … need to negotiate recompense to the patent holder individually (or if agreed as joint parties), rather than the Commonwealth negotiating on behalf of all state/territory governments. (DOHA, sub. 22, p. 6)

If a particular State Government invokes Crown use of a gene patent to provide a particular medical genetic test for its citizens, would the provision for Crown use extend to the testing of samples that had been sent from another State for analysis? If not, each State would need to invoke Crown use of that gene patent and develop its own test to meet the needs of the patients in its own jurisdiction. (Royal College of Pathologists of Australasia, sub. 16, p. 2)

… questions exist over *which* Crown must authorise the use. For example, the NSW ‘Crown’ may have to authorise Sydney University to exploit a patented invention, and the Queensland Government authorise exploitation by [University of Queensland]. (Civil Liberties Australia, sub. 12, p. 6)

Conversely, it could be argued that there are no significant barriers to coordinating Crown use because the provisions do not limit its geographic coverage. In particular, s. 163(1) of the Patents Act places no restriction on where a person must reside if they undertake Crown use on a government’s behalf. This should enable a government to authorise Crown use by a healthcare provider in another jurisdiction. Moreover, the Patents Act does not preclude the states and territories from coordinating their actions, including possibly with the Australian Government.

While it is debatable whether the abovementioned issues are indeed barriers to applying Crown use to healthcare, it is evident that there is uncertainty among stakeholders. This could itself be an impediment to the effective utilisation of Crown use. For example, DOHA noted that legal advice it had received led it to the conclusion that it was not viable to apply Crown use to healthcare because:

* the scope of the provisions is unclear
* the ability of the Australian Government to authorise use of a patent by third parties was doubtful and untested
* the required amount of compensation to the patent holder is unclear. (DOHA, Canberra, pers. comm., 30 October 2012)

Some inquiry participants proposed that such uncertainty be addressed by explicitly stating in the Patents Act that Crown use is applicable to healthcare (for example, Centre for Law and Genetics, sub. 3; Civil Liberties Australia, sub 12; DOHA, sub. 22; Matthew Rimmer, sub. 11). The ALRC called for a similar amendment in its review of gene patents.

The Commonwealth should amend the Patents Actto clarify that, for the purposes of the Crown use provisions, an invention is exploited ‘for the services of the Commonwealth or of a State’ if the exploitation of the invention by a Commonwealth or State authority (or by an authorised person) is for the provision of healthcare services or products to members of the public. (ALRC 2004, p. 33)

This was endorsed by the Senate review of gene patents (SCARC 2010). However, the Australian Government rejected this proposal on the grounds that:

The Government does not see a need at present to develop a health-specific policy on the circumstances in which Crown use provisions should be exploited as the provisions are available for all Commonwealth, State and Territory services. The Government agrees that the circumstances in which a patented invention should be exploited pursuant to the Crown use provisions should be considered on a case-by-case basis. (Australian Government 2011a, p. 11)

Identifying healthcare as a special case in the Patents Act would also be contrary to the general approach of having a technology-neutral patents system. Technology neutrality is desirable because it reduces complexity and therefore the overall costs of the patents system. Furthermore, a neutral system has the flexibility to accommodate patenting of new and emerging areas of technology. In contrast, a patents system that differentiates between specific technologies is likely to quickly become out-dated, and so would constantly need updating. Altering the legal status of patents in specific industries could also have unforeseen consequences, possibly making some lines of future research unattractive (SCARC 2010).

Nevertheless, the Commission recognises that stakeholders are likely to remain uncertain about the scope of Crown use, given the lack of jurisprudence, and that this can limit the effectiveness of the provisions. It therefore proposes that the phrase ‘for the services of’ a government be clarified in the Patents Act, while maintaining technology neutrality.

draft Recommendation 7.1

The Australian Government should seek to amend s. 163 of the Patents Act 1990 (Cwlth) to make it clear that Crown use can be invoked for the provision of a service that the Australian, State and/or Territory Governments have the primary responsibility for providing or funding.

### Measures to improve transparency and accountability

This chapter has already explored a number of ways to enhance the transparency and accountability of the Crown use provisions. These included requiring Ministerial approval for the Crown use provisions to be utilised, consent of the patentee to be sought prior to use, and that compensation be just and reasonable, having regard to the economic value of the use. These improvements follow those recommended by ACIP in its 2005 review (box 7.3).

As noted, the Australian Government chose not to implement these requirements because there was no evidence that the provisions were being misused (ACIP 2010b). The Commission is sympathetic to the Government’s reasoning. The costs of initiating reforms solely for the Crown use provisions, given the dearth of evidence that there is a problem, argue for retaining the status quo. In addition, the infrequent utilisation of Crown use suggests that the benefits from reform are likely to be small. However, in light of recommendations requiring changes to the Patents Act made in chapter 6, the Commission considers that several beneficial concurrent changes to the Crown use provisions could be made at relatively low cost.

In addition to the sort of measures proposed by ACIP, the Commission considers that, where a Minister has approved an instance of Crown use, a statement of reasons should be provided to the patentee 14 days before exploitation of the invention. This is similar to requirements in existing administrative review legislation. Applicants for reviews under the *Administrative Decisions (Judicial Review) Act 1977* (Cwlth) and the *Administrative Appeals Tribunal Act 1975* (Cwlth) can request reasons for decisions that are reviewable. Under this legislation the statement of reasons must be provided as soon as is practical, but within 28 days of the request.

A statement of reasons would provide the patentee with an opportunity to have the decision to use their invention properly explained. The patentee could then decide whether to exercise their right to appeal. The notice of 14 days would provide the patentee time to consider the statement before exploitation occurs. Disclosure of reasons would encourage the Minister to reflect more carefully on the decision and be more diligent in authorising instances of Crown use. The reasons could also guide future decisions, help create principles and standards of operation, and over time decrease disputes.

The net effect of these measures is to ensure that governments and their authorised entities meet certain requirements, obligations and responsibilities when seeking to use patents. The measures aim to make the process for their utilisation transparent and accountable to protect against the possibility of misuse. In addition, they have the advantage of harmonising aspects of compulsory licensing and Crown use. For example, requiring just and reasonable compensation, having regard to the economic value of the use, mirrors the pricing principles that the Commission recommended in chapter 6 for compulsory licensing.

While the abovementioned reforms would reduce (but not eliminate) the cost and time advantage of Crown use compared to compulsory licensing, the Commission has concluded that they are warranted because governments should be held to higher standards of transparency and accountability than currently exist. Concerns about timeliness could be addressed by allowing the recommended requirements (except for compensation) to be waived in emergencies.

Draft Recommendation 7.2

The Australian Government should seek to amend the Patents Act 1990 (Cwlth) to:

* require the Crown to attempt to negotiate use of the patented invention prior to invoking Crown use
* require instances of Crown use to be approved by a Minister (the relevant Federal Minister or State Attorneys General), and that the patentee be provided a statement of reasons no less than 14 days before such use occurs
* specify that in instances of Crown use, the patentee is entitled to remuneration determined on the same basis as that for a compulsory licence.

These first two requirements should be able to be waived in emergencies. However, in all cases patentees should be provided with immediate notice that their patents have been used, and a statement of reasons as soon as practical thereafter.

1. A prescribed court is either the Federal Court, the Supreme Court of a State, the Supreme Court of the Australian Capital Territory, the Supreme Court of the Northern Territory, or the Supreme Court of Norfolk Island. [↑](#footnote-ref-2)
2. A prohibition order under s. 173 or an order under s. 152 of the Patents Act allows the Minister or the Commissioner respectively to prohibit/restrict the publication of information about the subject matter of an application for a patent. Section 173 also allows the Minister to prohibit/restrict access to a microorganism deposited for the purposes of s. 41. [↑](#footnote-ref-3)