

# **REGULATION IMPACT STATEMENT**

## **Invoking the Crown Use Provisions for a Patented Invention**

### **PROBLEM**

#### **Role of patents**

A patent is a legally-enforceable right to exclude others from commercially exploiting a device, substance, method or process that is new, inventive, and useful at the time the patent was granted. Patents rights are of limited duration, generally a maximum of 20 years.

The patent system serves three roles: to provide incentives to innovate; to encourage dissemination of knowledge; and to facilitate technology transfer and commercialisation. The patent system benefits society by promoting innovation that would not otherwise occur and public access to, and diffusion of, new technologies. The system benefits patentees by giving them certain exclusive rights for a limited period that facilitates investment in invention. In order to enhance the net welfare of Australian society, the patent system is structured to provide an appropriate balance between the interests of different stakeholders.

#### **Crown Use provisions**

The *Patents Act 1990* (the Act) contains a number of mechanisms that allow exploitation of a patented invention without the patentee's authorisation. These mechanisms are essential safeguards to be invoked in exceptional cases where the outcome associated with a patent would not serve the best interests of the community as a whole. These mechanisms include the compulsory licensing provisions (sections 133-140 of the Act), research and regulatory approval exemptions (sections 119B and 119C of the Act) and the Government use and acquisition provisions (sections 163-171 of the Act).

The compulsory licensing provisions allow a person to obtain a non-exclusive licence to 'work' a patented invention under specific circumstances. There are two grounds for the granting of a compulsory licence. An applicant must satisfy either a 'reasonable requirements of the public' test or demonstrate certain offences under competition law have, or are going to, occur.

The Crown use provisions (sections 163-170 of the Act) allow governments to access patented inventions under specific circumstances. Such provisions have been part of Australian law since the first Commonwealth Patents Act of 1903 and were derived from earlier English law. The reasons for Crown use provisions generally include:

- 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.

Crown use can only be invoked for the services of the Commonwealth or of a State (section 163(1)). Where the provisions are invoked, the patent holder is entitled to remuneration under section 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 court to determine the terms.

Most foreign patent systems include mechanisms for the government to make use of patented inventions under appropriate circumstances.

Crown use has rarely been used in Australia. There are only two cases reported where Crown use has been contested before the courts, otherwise data are difficult to obtain as uncontested use is not normally reported. While the provisions appear to be rarely used their availability may facilitate agreement in negotiations of other types of licensing.

## **Productivity Commission inquiry**

The Productivity Commission Inquiry into Compulsory Licensing of Patents was commissioned by the Assistant Treasurer in June 2012. The Inquiry arose from a number of reviews of ‘gene patents’ and was tasked to review the operation of the compulsory licensing provisions of the *Patents Act 1990*, but also any alternative mechanisms “deemed necessary to ensure that the balance between incentives to innovate and access to technology” is appropriate. The Productivity Commission considers that Crown use will be a more efficient and cost effective way for governments to make use of patented inventions than compulsory licensing.

The Productivity Commission viewed Crown use provisions as likely to be effective and appropriate when ‘a potential licensee would not be able to earn a sufficient return on the licence, compared to the benefits that the licence will create for the broader community’<sup>1</sup>.

Based on submissions received from inquiry participants the Productivity Commission considered that reforms to the Crown use are warranted in two main areas. Firstly, the scope of what types of entities can actually make use of the Crown use provisions is unclear, particularly in the healthcare field. Secondly changes to improve transparency and accountability around such use.

The issues are inter-related and the problems identified with Crown use concern the low levels certainty. Certainty of the scope of exercise of Crown use presupposes certainty of what constitutes the Crown. Certainty of the scope of the exercise of Crown use presupposes certainty that it has been used and why it has been used (as Crown use is rare and voluntary licensing is routine). Certainty of the impact of Crown use relates to the structure of the remuneration process for it.

### Lack of clarity about Crown Use

The Productivity Commission notes that ‘it is evident that there is uncertainty among stakeholders’ concerning Crown use. They stated that:

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<sup>1</sup> Chapter 7: *Compulsory Licensing of Patents Productivity Commission Inquiry Report, No. 61, 28 March 2013*

The Patents Act states that Crown use can only be used 'for the services of' a government, which the courts could interpret narrowly to exclude healthcare. Conversely, it could be argued that this is unlikely, given that Crown use has previously been allowed for railways and domestic water supply.

Healthcare services are sometimes provided by non-government organisations, such as privately owned testing laboratories, which some participants considered to be outside the scope of Crown use. An alternative view is that non-government providers can be included because the Patents Act allows a government to authorise other parties to undertake Crown use on its behalf.

Genetic samples taken in one state are sometimes tested by a laboratory in another state. Some participants questioned whether states can apply Crown use outside their borders in such cases. Some were also concerned that states have to invoke Crown use individually, rather than coordinate their actions. An alternative view is that the Patents Act does not limit the geographic location of Crown use, or interjurisdictional coordination.

The Australian Law Reform Commission (ALRC) and the Advisory Council on Intellectual property (ACIP) appear to view the scope of the Crown and hence the scope of Crown use as unclear to many. The Productivity Commission stated:

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.

Submissions to the inquiry that viewed the current scope of the Crown and hence the scope of exercise of Crown use as unclear were included in the Productivity Commission Draft Report.

The Department of Health and Ageing 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).

Royal College of Pathologists of Australasia expressed the view that 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.

Civil Liberties Australia had questions regarding 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 a University in Queensland.

The effect was stated by the Productivity Commission as:

- 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.

Also that:

- 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.

The Productivity Commission stated in its draft report that ‘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.’

The Productivity Commission report also stated:

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.

Need to improve transparency and accountability

The Productivity Commission considered that there was insufficient transparency and accountability in Crown use in three main areas:

- insufficient certainty in the definition of the Crown and that there was the need for Ministerial oversight (dealt with above);
- insufficient certainty regarding the exercise of Crown use and its relationship to patentee negotiation (including knowing when and why it was used); and
- insufficient certainty regarding remuneration structures for Crown use.

The current provisions do not require the Crown to attempt to negotiate or provide reasons for invoking Crown use.

The problems with this approach are that:

- it can significantly disadvantage the patent holder, is inconsistent with notions of natural justice and could place the patent holder in a situation where threat of Crown use could be used as a negotiating tactic to reduce licence fees;
- it means that the opportunity for a better outcome through negotiation is forgone;
- it is not consistent with the practice applying to compulsory licences; and
- in the view of ACIP it is inconsistent with the TRIPS agreement.

These issues are explored further below.

ACIP<sup>2</sup> 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; and
- 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.

The Productivity Commission viewed voluntarily negotiated licences as generally generating superior outcomes to non-voluntary mechanisms. In support of this, the Law Council of Australia, in evidence to the Productivity Commission, has argued that a voluntary outcome was superior for the licensee, because the agreement could incorporate other knowledge of the patentee and thus be better adapted to the licensee's needs than a narrow compulsory licence 'to work the patented invention'.

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<sup>2</sup> ACIP (Advisory Council on Intellectual Property) 2005, *Review of Crown Use Provisions for Patents and Designs*, Australian Government, Canberra

Commercial entities seeking a compulsory licence are required to negotiate. Requiring the Crown to adopt a similar practice would seem to be a reasonable requirement with potential beneficial outcomes for both the Crown and patent holder.

ACIP<sup>3</sup> has expressed a view 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. In particular, Article 31(b) of the TRIPS agreement only waives this requirement in cases of ‘national emergency or other circumstances of extreme urgency’.

## **OBJECTIVE OF GOVERNMENT ACTION**

There are two key objectives of Government action:

- maintain the appropriate balance of the interests of patent holders and the broader community allowing governments to intervene in the market if the needs of the community are not being met; and
- have efficient and effective Crown use provisions that have the appropriate levels of transparency, accountability and flexibility in the rare cases Crown use is needed.

## **OPTIONS THAT MAY ACHIEVE THE OBJECTIVE**

Options may be broadly grouped as follows:

- **Option 1: Status Quo - No changes to the Act.**

Under this option, no action would be taken and the existing provisions relating to Crown use would be unchanged.

- **Option 2: Implement Recommendations 7.1 and 7.2 of the Productivity Commission’s Report “Compulsory Licensing of Patents”, March 2012.**

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

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<sup>3</sup> ACIP (Advisory Council on Intellectual Property) 2005, *Review of Crown Use Provisions for Patents and Designs*, Australian Government, Canberra

The second and third requirements could be waived in emergencies. However, in all cases patentees would be provided with immediate notice that their patents have been used, and a statement of reasons as soon as practical thereafter.

The requirement to attempt to negotiate use of the patented invention prior to invoking Crown use may lead to unacceptable delays in the availability of the patented technology. This will be alleviated through legislative provisions which will clarify expectations, and limit the scope for vexatious legal action.

These two options are considered in more detail below.

## ***IMPACT ASSESSMENT***

### **Who would be affected by each option?**

The groups which would be impacted by each of these options are, broadly speaking:

- Patent holders (This group will be taken to include applicants for patent rights whose applications have not yet been determined.)
- The Commonwealth Government and State and Territory Governments
- The broader community, including consumers.

### **Impacts of each option**

The anticipated impacts of the options are outlined below.

#### **Option 1: No change**

Under this option, no action would be taken and the existing provisions relating to Crown use would be unchanged. In this scenario, the lack of clarity identified by the Productivity Commission about what entities can actually invoke Crown use would continue. Furthermore there would be no requirements for any approval of Crown use or for governments to negotiate with patentees prior to invoking Crown use. No further guidance on remuneration would be given to the patentee other than that currently provided in section 165 of the Act, which requires terms to be negotiated between the parties or determined by a prescribed court.

##### *Patent Owners*

The current level of uncertainty and the perception of lack of transparency around Crown use will remain. These uncertainties may mean that the threat of Crown use could be used in negotiations to obtain favourable terms during negotiation of other sorts of licensing.

##### *Governments*

Maintaining the status quo will preserve the government's ability to access patented inventions where necessary. This could include access to healthcare technology that is required to treat a pandemic.

The uncertain scope of the Crown may mean some entities mistakenly believe that they are able to invoke Crown use. Others could be reluctant to invoke Crown use on the mistaken belief that it does not apply to them.

#### *Broader Community*

The status quo allows governments to provide services to the public by using patented inventions when justified.

The possibility of over use of Crown use could lead to a lack of supply of patented technologies in Australia. In reality the low level of Crown use historically means that this is an unlikely outcome.

## **Option 2: Implement the Productivity Commission's recommendations 7.1 and 7.2**

Under this option, the *Patents Act 1990* would be amended to clarify that the Crown use provisions can be invoked for the provision of services that the Australian, State and/or Territory Governments have the primary responsibility for providing or funding.

Currently, non-government bodies require authorisation by the Commonwealth or a State to undertake Crown use. The authorisation must be in writing, but may be given before or after any act for which the authorisation is given has been done. Option 2 clarifies the circumstances in which Crown use can be invoked, but requires Ministerial approval.

This is likely to lead to a more effective application of Crown use. Providers of Government services will be clearer that Crown use is a potential remedy to inappropriate patent holder behaviour. Ministerial consideration will ensure that Crown use is only invoked where the benefits outweigh the costs and will help avoid vexatious actions.

The Act would also be amended to require:

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

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

The legislative requirement for the Crown to attempt to negotiate with patentee prior to invoking Crown use improves transparency and accountability. This would impose on the Crown similar requirements as those that apply to commercial entities seeking a compulsory licence.



The new requirements allow increased oversight ensuring that Crown use is invoked appropriately. It may increase administrative burden to government bodies and departments, but the increased clarity and transparency regarding Crown use is likely to enhance the Crown's ability to meet the needs of the public in the rare circumstances Crown use is invoked.

Providing clarification that reasonable remuneration will apply should reduce the likelihood that the matter will need to be resolved in court proceedings which could be expensive for both parties.

#### *Patent Owners*

A legislative requirement to negotiate with the patentee prior to invoking Crown use means that a patent holder can negotiate a reasonable outcome in relation to their interests using the required statement of reasons in addition to any outcome resulting from routine negotiations with the Crown. As argued by ACIP<sup>4</sup>, some of the benefits of the requirement to negotiate are 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; and
- 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.

A requirement to provide a statement of reasons provides 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 have their decision reviewed. The notice of 14 days provides the patentee time to consider the statement before exploitation occurs.

In emergencies the Crown is not obliged to attempt to negotiate or issue a statement of reasons prior to intended use. However in all cases the patentee will be issued with immediate notice that their patents have been used, and will be entitled to pursue their review rights available under the law, albeit after the Crown has exploited the relevant invention.

The requirement for Ministerial approval provides an important check on vexatious claims and provides the Crown with the opportunity to consider the costs and benefits of invoking Crown use. Patent owners are also not exposed to the threat of crown use arising from lack of clarity of its application or the approval process.

Amendments that specify in instances of Crown use the patentee is entitled to remuneration determined on the same basis as that for a compulsory license are designed to apply a standard of remuneration to Crown use and align it with that for compulsory licensing. Providing clarification that reasonable remuneration will apply should reduce the likelihood that the matter will need to be resolved in court proceedings, which could be expensive for both parties. The Productivity Commission considered that aligning the

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<sup>4</sup> ACIP (Advisory Council on Intellectual Property) 2005, *Review of Crown Use Provisions for Patents and Designs*, Australian Government, Canberra

remuneration requirements for Crown use with those for compulsory licensing would ensure the patent owner obtained a return on investment commensurate with the regulatory and commercial risks involved. It would also help develop jurisprudence over remuneration conditions and harmonise Crown use with international agreements such as the TRIPS Agreement and the Australia-United States Free Trade Agreement.

### *Governments*

The requirement to negotiate with the patentee prior to invoking Crown use could mean a superior outcome for government because the agreement could incorporate other know-how of the patentee.

There is a risk that this could lead to unacceptable delays in the availability of the patented technology. This risk can be ameliorated by drafting legislative provisions to make expectations clear and to limit the scope for vexatious legal action. In addition, in the case of emergencies, the requirement for negotiation is waived. While there would be some small costs involved in a negotiation, any costs would be inconsequential compared to those resulting from a protracted legal dispute.

The requirement to provide a patentee with a statement of reasons could benefit government by guiding future decisions, helping create principles and standards of operation, and over time decreasing disputes. This would also ensure that Governments carry out due diligence before implementing Crown use.

The requirement for Ministerial approval will enable the Government to consider the costs and benefits of invoking Crown use. This may add some administrative burden for governments departments. However, this will not impact on the ability of the Crown to address the needs of the public. The low historical use of Crown use provisions indicates that the benefits from Ministerial approval will outweigh any additional administrative burden.

The requirements in relation to remuneration should help avoid the involvement of courts in reaching agreement on just terms which could be costly to both parties.

There is a concern that the Crown use provision may be invoked by Governments after the patented invention has been utilised without awareness of an existing patent. In these circumstances, there would be no prior negotiation with the patentee, nor would a notice of intended use be provided to the patentee. Such cases are likely to be rare and most likely to only arise in emergencies where there is strong public benefit.

### *Broader Community*

The clarification of Crown use provisions ensures that it can be invoked when there is a public need in rare cases where patents lead to Australians being denied reasonable access to technologies. The clarification also better adapts Crown use to increasingly diverse delivery models of government services.

The requirement to negotiate with the patent owner prior to use, and any potential disputes arising from this process, could delay access to the patented invention to the broader community. This can be mitigated by legislative provisions which clarify expectations on both sides and which limit the prospect of vexatious legal action. In addition, in the case of emergency the requirement to negotiate is waived enabling the

Crown to act quickly to respond to emergency public health concerns such as pandemics.

In summary, the Productivity Commission's recommendations concerning this option attempt to strike a balance between the public interest requirement and the interests of patent owners to be able to exploit their patented inventions. The improved clarity around the application of Crown use and greater transparency and accountability when it is applied should lead to a more effective use of the Crown use provisions.

## **CONSULTATION**

### **The consultation process**

There has been extensive consultation on the issue of Crown use through the Productivity Commission's Inquiry into the Compulsory Licensing of Patents.

On 29 June 2012, the Assistant Treasurer asked the Productivity Commission to undertake an inquiry into the compulsory licensing provisions in the *Patents Act 1990*. The purpose of the inquiry was to assess, advise and recommend on the impacts and mechanisms of compulsory licensing invoked by the Patents Act's public interest and anti-competitive safeguard. In undertaking the inquiry, the Commission was to have regard to recent changes to the intellectual property system reflected in the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cwlth), and the range of international approaches.

Following receipt of the terms of reference, the Commission placed notices in the press and on its website inviting public participation in the inquiry. Information about the inquiry was also circulated to people and organisations likely to have an interest in it.

The Commission released an issues paper in August 2012 to assist inquiry participants with preparing their submissions. The Commission received 35 submissions from organisations and individuals representing the legal and patent attorney profession, the medical and pharmaceutical sector (including manufacturers of generic pharmaceuticals), the research sector, academia, public interest groups, large public companies, and government organisations.

The Commission then released a draft report on 14 December 2012, and further submissions were invited. The Commission received 16 post-draft submissions.

The Commission held public hearings in Melbourne on 20 February 2013. Representatives from the Public Health Association of Australia, Medicines Australia and academia attended the hearings.

The final report was sent to Government on 28 March 2013.

### **Views expressed during the consultation process**

The Productivity Commission noted that inquiry participants were generally supportive of the role that Crown use plays, particularly in the case of healthcare. Nevertheless, some participants were concerned that routine use of the provisions could undermine

confidence in the patents system, and that they therefore should only be invoked in exceptional circumstances.

The Productivity Commission's draft recommendation 7.2 addressed transparency and accountability issues around Government use of Crown use provisions, specifically by amending the *Patents Act 1990* to require that:

- the Crown should attempt to negotiate use of the patented invention prior to invoking Crown use;
- instances of Crown use should be approved by a Minister and the patentee be provided with a statement of reasons no less than 14 days before such use occurs; and
- the patentee is entitled to remuneration determined on the same basis as that for a compulsory licence.

Alphapharm (a major generic drug manufacturer) disagreed with this proposal on the basis that mandating negotiation with the patentee prior to invoking Crown use:

- could have significant military and security implications that have not been fully considered;
- could significantly elevate the obligations on Commonwealth and State governments above those stipulated in the Australia-US Free Trade Agreement; and
- could encourage the patentee to introduce delaying tactics and litigation.

In contrast, Medicines Australia (the peak body representing non-generic medicines suppliers in Australia) indicated that they were very comfortable with the draft recommendation.

### **How stakeholders' views have been taken into account**

The Productivity Commission took account of stakeholder views in its report, but noted that 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. At the same time, the Commission noted that governments using the Crown use provisions should ensure that the benefits of use outweigh the costs.

In relation to its recommendation 7.2, the Commission noted that 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. In addition, the measures in recommendation 7.2 would harmonise aspects of compulsory licensing and Crown use.

The Commission concluded its arguments by stating that the measures are warranted because governments should be held to higher standards of transparency and accountability than currently exist.

Issues such as compliance with treaty provisions have been taken into account through standard governmental processes.

## ***CONCLUSION AND PREFERRED OPTION***

In contrast to option 2, option 1 does not provide certainty about what Crown use can be used for, that is 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; and
- State Governments have to invoke Crown use individually, rather than coordinate their actions.

Nor does option 1 provide the desired transparency and accountability. Therefore option 1 would not meet the Government’s objective of maintaining an appropriate balance of the interests of patent holders and the broader community and allowing governments to intervene in the market if the needs of the community are not being met.

The proposed option 2 provides clarity concerning the application of Crown use and strengthens transparency and accountability around the exercise of Crown use provisions.

Under option 2, the requirement to negotiate with the patent owner prior to use, and any potential disputes arising from this process, could delay access to the patented invention to the broader community. This can be mitigated by legislative provisions which clarify expectations on both sides and which limit the prospect of vexatious legal action. In addition, in the case of emergencies the requirement to negotiate is waived enabling the Crown to act quickly to respond to situations such as pandemics.

Option 2 maintains the appropriate balance of patent holder and broader community interests. It also allows governments to intervene in the market if the needs of the community are not being met, with appropriate levels of transparency, accountability and flexibility in the rare cases Crown use is needed.

It is therefore recommended that option 2 be endorsed.

## ***IMPLEMENTATION AND REVIEW***

Amendments to the Act would be required to implement the preferred option for invoking the Crown use provisions for a patented invention.