

**AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING –  
Response to Advisory Council on Intellectual Property – Review of Crown Use  
Provisions in Patents and Designs Legislation Discussion Paper.**

**Executive Summary**

The Australian Government Department of Health and Ageing (Health and Ageing) enthusiastically supports the sustainable promulgation of new scientific discoveries and useful innovations to improve healthcare for the Australian public. Health and Ageing delivers outcomes to promote and support the Australian Government healthcare vision for better health and healthier ageing for all Australians through a world class system that:

- Meets people’s needs, throughout their life;
- Is responsive, affordable and sustainable;
- Provides accessible, high quality service including preventative, curative, rehabilitative maintenance and palliative care; and
- Seeks to prevent disease and promote health.

Health and Ageing portfolio responsibilities involve a variety of diverse and valuable intellectual property (IP) interests to which Crown use provisions may apply. The Pharmaceutical Benefits Scheme (PBS), the Medical Benefits Scheme (Medicare) and continued support for state funded hospital systems are key areas in which Health and Ageing is a major funder and purchaser of services, devices and procedures, all of which involve significant IP. These ensure that quality healthcare services remain accessible, and affordable to the Australian public. Consequently Health and Ageing regularly encounters issues relating to patents, designs and copyright in the healthcare sector.

Crown use provisions allow the Australian Government or a State to exploit a patented invention for the services of the Australian Government or State (hereafter the Crown). The Crown can do this without permission but must advise the patent holder of their use of the patent and provide compensatory payment on agreed terms. If terms cannot be agreed the courts can step in to set the level of remuneration. The overall aim of the Crown use provisions is to ensure that Governments in Australia can balance the temporary monopoly rights that patents provide with the needs of the Australian public.

Health and Ageing is not aware of any examples where Crown use provisions have been invoked in the Australian healthcare sector, though this potential is strongly indicated from overseas experience in relation to pharmaceutical and healthcare benefits programs and in dealings with patent owners. For this reason Crown use provisions are considered an important safeguard or fall-back position in possible negotiations.

In responding to the issues raised in the Discussion Paper, Health and Ageing is concerned to represent a balance of interests to protect the healthcare needs of the Australian public and in supporting commercial health sector interests to exercise responsibility in managing patents and designs.

However, Health and Ageing is not convinced that the examples and arguments raised in the Discussion Paper demonstrate a strong enough case that a significant problem exists with the current Crown use provisions. Therefore at this stage, Health and Ageing is unable to support any changes to the patents or design legislation that may result in a narrowing of accessibility to Crown Use provisions.

## **Introduction**

Crown use provisions are rarely used, usually as a tool of last resort. This lack of use should not be equated with irrelevance, as the provisions' mere existence provide an important background deterrent to prevent patent holders engaging in unreasonable conduct. Such conduct could include charging high prices for their patented technology or refusing to licence on reasonable terms to ensure access to an important technology. For Health and Ageing this is particularly important.

The ACIP Discussion Paper suggests proposals that, if actioned, would have the effect of narrowing existing access to Crown use provisions. The Health and Ageing submission to the Australian Law Reform Commission (ALRC) *Inquiry into Gene Patenting and Human Health* requested that the Inquiry analyse the Crown use provisions and propose reforms so as to *expand* access to them. This was on the basis that the Crown use provisions appeared potentially useful for dealing with the serious issues of access and affordability to genetic technologies raised by some existing patents on human DNA.

Until Health and Ageing has considered the final report of the *ALRC Inquiry into Gene Patenting and Human Health*, it would not support any change to the Crown Use provisions, particularly any narrowing of the provisions. The ALRC recently released proposals for review in its discussion paper and Health and Ageing would be pleased to provide further information about its response to the final report of the ALRC Inquiry which is expected in June 2004.

The ACIP Discussion Paper proposes a number of specific options that may serve to limit access to Crown Use provisions. These include a requirement that Crown Use provisions be accessed only with ministerial approval or only in a time of national emergency, such as may arise in the defence and health contexts. The Discussion Paper alternatively proposes the development of an exclusive list of organisations that may attract Crown use provisions, which is also not supported by Health and Ageing.

Health and Ageing views that any recommendations arising from this review should enhance rather than adversely affect the Australian Government's health care objectives. There will need to be an appropriate balance between the interests of protecting commercial development of technology and the public interest in high quality, accessible and affordable healthcare.

## **Definition of the Crown**

*What is an appropriate definition of the 'Crown' as applied to the Crown use provisions. In particular:*

- *Has the definition been applied too broadly?*
- *Should the application of Crown use provisions be limited in some way, like, for example, requiring Ministerial approval?*

Health and Ageing does not have a reason to understand that the definition of 'Crown' has been applied too broadly. The application of the right of Crown in Commonwealth rights has never been in doubt in the context of administering Health and Ageing portfolio responsibilities (in its various administrative arrangements). Health and Ageing continues to have available to it the application of Crown use provisions.

Health and Ageing acknowledges that Crown use provisions are rarely used<sup>1</sup>. In any event, the Department is reluctant to endorse calling into question the exercise of its own powers in administering public interest and accountability considerations on behalf of programs delivered by this portfolio. Restricting the basis by which Crown use provisions may be invoked in patent and design legislation may have a significant adverse effect in the Health and Ageing sector.

Health and Ageing therefore does not support the proposal in the Discussion Paper that the Crown use provisions only be accessed with ministerial approval<sup>2</sup>. Such a process may be seen as overly politicising access to the Crown use provisions and may expose the government to claims of introducing avoidable bureaucracy.

### **Specific Proposals to Limit Crown use provisions**

*ACIP would welcome views on the range of entities to which Crown use arrangements should appropriately extend. In particular:*

- *Should the availability of such provisions be limited or denied to certain organisations and/or functions of organisations?*
- *If so, on what basis?*

Health and Ageing would not support any limitation or denial of access to Crown use arrangements as this would seriously interfere with the functions of the Health and Ageing. Crown use provisions are called into use on exceptionally few occasions so prematurely anticipating restrictions on any further use is inappropriate.

Current references to Crown use provisions are adequate for protecting the long term interests of Health and Ageing. Specifically these interests include the delivery of Medicare and PBS services, support funding for hospital and aged care services, and in respect of supporting genetic health technologies. Health and Ageing therefore considers that any review of Crown Use provisions in patents and designs should support and enhance its ability to deliver its program objectives.

While there are very few examples of the Department of Health and Ageing relying on the Crown use provisions, the existence of those provisions have proved extremely useful in supporting negotiation of access rights with owners of intellectual property. The knowledge that access is assured under legislation, most often leads to a successfully negotiated contract or licence on commercially acceptable terms.

The Discussion Paper suggests limiting access to Crown use provisions to declarations of national emergencies<sup>3</sup>. This option is not supported by Health and Ageing. Such a limitation would prevent strategic planning in the health arena. A requirement to limit access rights to times of emergency comes too late to allow for effective response. For example, the avoidance of an influenza pandemic requires up to 24 months forward planning and access to relevant technologies. Most strategic planning in Health and Ageing focuses on avoidance and prevention rather than just treatment.

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<sup>1</sup> Discussion Paper pgs. 8 & 9

<sup>2</sup> Discussion Paper pg. 6

<sup>3</sup> Discussion Paper p. 8.

## **Circumstances enabling Crown use of Patents and Designs**

*ACIP would welcome views on whether the current Crown use arrangements are achieving an appropriate balance between the needs of IP right holders and the Crown. In particular:*

- *Is the current test for Crown use exploitation (ie. ‘is necessary for the proper provision of those services within Australia’) appropriate and/or is it appropriately applied?*
- *Under what circumstances should Crown use of patents and designs be allowed?*
- *Should there be restrictions to particular types of patents and designs that are subject to Crown use?*
- *Would it be advantageous to categorise and/or restrict the range of circumstances in which the Government can invoke the provisions?*

The current test for Crown use exploitation is appropriate for the purposes of Health and Ageing and this has been applied appropriately in the context of fulfilling portfolio policy and program objectives.

Section 163 of the Patents Act states that Crown use provisions should be accessed where ‘this is necessary for the proper provision of those services within Australia’<sup>4</sup>.

The following excerpt from the *Australian Law Reform Commission Report No.74 – Designs* is indicative of the responses received from Commonwealth departments on whether they were likely to use Crown use provisions:

*(1)... While the powers may not have been expressly and formally utilised, it may be that their very existence has acted as a lever in negotiations for ensuring co-operation from design owners.*

*(2)... The possible lack of use of these powers may be explained on the basis that there may be little knowledge within the Department of the existence and the scope of the powers available to it under Part VIA. This does not mean however, that those powers are of no use and should be abolished. (Submission 226, 2)*

In the case of Health and Ageing, specific inclusion of Crown use provisions provides the Department with an important negotiating lever without necessarily having to invoke the provisions.

Health and Ageing contend that there should not be restrictions as to types of patents and designs for application of Crown use provisions as it is not feasible to anticipate the relevance of developing sciences and technologies and the impact these may have in the Health and Ageing arena. The existing limitation on the scope of Crown use arrangements is sufficient to protect the interests of current and future owners of intellectual property.

The suggestion in the Discussion Paper of restricting Crown use provisions to a list of possible technological applications would erode the effective protection offered by current patent law. It can be argued that patent and design law is sufficiently open to encourage the protection and delivery of a range of innovations using combinations of scientific and technological discoveries. The suggestion to restrict Crown use provisions to particular types of patents and designs and not others would threaten existing rights of protection, and risk establishing a reversal of the current government policy of encouraging commercial innovation.

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<sup>4</sup> Discussion Paper p. 8

The National Health and Medical Research Council (NHMRC) enter into Deed of Agreements with Administering Institutions, in which the intellectual property generated by NHMRC support is vested in the Administering Institutions. In signing Deed of Agreements any Administering Institutions agree to put in place and administer appropriate policies and procedures relating to intellectual property (IP) management.

This establishes a delegation of rights and responsibilities for the sustainable management of possible flow-on patents and designs by Administering Institutions. The National Principles of Intellectual Property Management for Publicly Funded Research guide the implementation of such IP management policies.

The Principles set out to assist researchers, research managers and research institutions in using best practices for the identification, protection and management of IP and to maximise the national benefits and returns from public investment in research. They also highlight the need for IP owners to consider the best way to use the knowledge gained from publicly funded research.

The Principles reaffirm the practice of NHMRC and the Australian Research Council (ARC) not having a stake in the direct ownership of IP. The intention of the National Principles is to improve the commercial outcomes from publicly funded research where a commercial outcome is appropriate. To a large extent this minimises the need to exercise Crown use provisions since NHMRC research funding takes appropriate account of and is sympathetic to potential downstream protection of commercially viable IP in the right of the researcher.

At this stage the NHMRC is not supportive of possible changes that would impact on its current approach to the ownership of IP as generated by its investments in medical research.

Current limitations on the scope of Crown use arrangements provides sufficient control and limits on Government action. Rather than restricting Crown rights, perhaps guidance and training on the scope of those provisions and more streamlined and cheaper avenues for review could address concerns.

### **Compensation**

*ACIP would welcome views on whether the current remuneration provisions are a fair and equitable arrangement for IP right holders, and especially for individuals and SMEs. In particular:*

- *Does the IP right holder have sufficient bargaining power to negotiate a fair, equitable and just remuneration with the Crown?*
- *Is the process adequate for informing the IP right holder that exploitation has occurred or is intended to occur? Should some specific time limit (or similar mechanism) be introduced in which the IP right holder must be advised of the exploitation?*
- *Is the process for assessing and settling remuneration and terms for exploitation an appropriate arrangement?*
- *Given the financial capacity of the Crown, is it unduly onerous for individuals or SMEs with limited financial capacity, to be required to take court actions, if terms cannot be agreed?*
- *Are there any cost effective and time alternatives to seeking redress from expensive court adjudication?*

Health and Ageing supports the understanding that Section 165 of the Patent Act 1990 makes provision for the Crown to seek agreed terms of exploitation, including to fulfil obligations for compensation with the patent owner either before, during or after the exploitation. Under these arrangements the Crown is obliged by Section 171 of the Patents Act 1990 and Section 106 of the Designs Act 2003 to offer appropriate compensation for the proposed use of IP rights. The IP right holder can always seek a review of any remuneration to test that it is fair and equitable.

If an agreement is not reached then either party may apply to a court for a determination of an appropriate payment amount<sup>5</sup>. These legal requirements provide the Australian Government with appropriately unfettered access to Crown use with fair and equitable conditions. The current process for agreement with the IP owner on settling remuneration and terms for exploitation is appropriate. However, Health and Ageing would support the introduction of any cheaper and more streamlined methods for review of adequate compensation in the event that agreement cannot be reached.

In terms of informing the IP holder the current process is adequate (although in respect of copyright it can be difficult at times to identify and/or locate owners). The obligation to inform the owner is 'as soon as practicable'. This provides a stringent obligation for prompt action on the part of the Crown and is sufficient to protect the rights of the owner.

Health and Ageing understand that the Crown is under an obligation not to use its financial capacity in oppressive ways in respect of litigation. (See Legal Services Directions.) However, Health and Ageing would support the introduction of any cheaper and more streamlined methods for review that may be better suited to the needs of individuals or small to medium enterprises (SMEs).

In the instance of possible unfair exercise of Crown use provisions, existing processes of review are available to bring public decisions to account. For example, processes may be instigated with the Australian Government Ombudsman and the Offices of the Ombudsman in each state, the Australian National Audit Office and the Administrative Appeals Tribunal, as well as accessing to documents through Freedom of Information legislation. In addition to this, it is possible for individual project activities to be scrutinised by Parliamentary Committees or separately as a public inquiry.

Health and Ageing suggest an independent tribunal representing expertise in IP would offer a cost and time effective alternative to expensive court processes. However, such a proposal would need to demonstrate a streamlined process for redress. For example the Federal Court of Australia established the Copyright Tribunal under Part VI of the *Copyright Act 1968*. A similar tribunal system could be introduced for patents and designs.

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<sup>5</sup> Discussion Paper p. 9

## **Crown use and re-sale of exploited patents**

*ACIP would welcome views on whether the current Crown use arrangements contain sufficient safeguards. In particular:*

- *Should the sale of patented or design protected products, to particular members of the public, still be characterised as 'use necessary for the proper provision of Commonwealth or State services'? Please elaborate on the reasons for or against.*
- *Is the Crown's power limited in any way when seeking to sell an exploited patent or design? If not, should it be?*

Health and Ageing are major purchasers of essential medications and medical treatments. Current forums such as the Pharmaceuticals Benefits Advisory Committee offer opportunities to extend accessibility of essential medicines and medical treatments. In addition, the Australian Government is a model contractor and purchases of services fairly in interest of the public and the healthcare sector more broadly.

If seeking to sell or sublicense patented or design protected products to the public it will be an appropriate requirement for the Crown use test to be satisfied. The support of the public interest inherent in the wording 'necessary for the proper provision of Commonwealth or State services' should be preserved.

Addressing the question of whether '...the Crown's power is limited in any way when seeking to sell an exploited patent or design' may duplicate the efforts of the ALRC Inquiry into Gene Patenting and Human Health. Health and Ageing's submission to the Inquiry requested the ALRC investigate the potential application of Crown use provisions to deal with the issue of gene patents.

Reference in the Discussion Paper to the *Pfizer* case supports retaining existing access to Crown use provisions in Australia<sup>6</sup> possibly for the administration of drugs used in the treatment of diseases.

## **Alternatives to Crown use provisions**

*ACIP would welcome views on the relative relevance of the current Crown use provisions. In particular:*

- *Are the provisions appropriate in the current commercial environment as it relates to Crown activities?*
- *Are there any alternatives to the Crown use provisions?*
- *Would these alternatives be sufficiently flexible for the Commonwealth?*
- *What are the advantages in retaining the Crown use provisions?*

The current provisions are, in the experience of Health and Ageing, appropriate to the current commercial environment in which the Department operates and Crown activities.

In terms of possible alternatives to the application of Crown use provisions, the ability to reach a commercial accommodation can pre-empt any reference to the Crown use provisions, and to that extent offer an alternative (but not a replacement for those rights).

Possible alternatives may include the adoption by agencies of Crown use provisions guidelines arrived at through consultative arrangements and subject to the unique and specific

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<sup>6</sup> Discussion Paper p. 11

requirements of each agency. Such guidelines would need to account for the Crown use provisions as they currently exist.

Program delivery areas in Health and Ageing are operating in the same sphere of activity as pharmaceuticals, health software and medical devices. In many cases they pay either directly or indirectly for the equitable availability of such goods or services or for new innovations. These program areas effectively manage IP, including rights for specific funding that result in patents and designs, in a manner that is appropriate to their specific requirements.

The current Crown use provisions are relevant to Health and Ageing. Even though there have been no instances of this power being invoked in a healthcare setting the fact that the provisions exist in their current form is a sufficient safeguard.

### **Conclusion**

Crown use provisions may be used in negotiating a fair and equitable position in the interest of the Australian public. However, it is a power that is rarely used. The fact that the provisions exist in their current form as a type of reserve power for the Crown is the most likely reason why so few problems are ever encountered.

In administering its responsibilities Health and Ageing is not aware of any problems with Crown use provisions in patent and design legislation. The Discussion Paper does not sufficiently demonstrate that the current provisions have any less relevance in supporting the needs of the Australian public and it does not sufficiently disprove the rationale behind the current IP system in terms of any imminent threat from existing application of Crown use provisions.

In addition, potentially changing Crown use provisions in patent and design legislation may risk exposing Health and Ageing to limits on its ability to maintain equitable Medicare and PBS services, and for continued support for human genetic health technologies.

There is no information in the Discussion Paper that suggests changes to the current application of Crown use provisions will provide any benefits to the delivery of healthcare services. Health and Ageing concludes that, from the information presented in the Discussion Paper, there is at this stage no clear policy or program imperative to support changes to existing Crown use provisions but there is a strong risk that changes to Crown use provisions may be likely to have an adverse effect in some key areas of portfolio activity.