Australian Government

Department of Health and Ageing

Submission to the Productivity Commission Inquiry into Compulsory Licensing

September 2012

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1 Introduction

The Department of Health and Ageing (the Department) welcomes the opportunity to make a submission to the Productivity Commission's Review of Compulsory Licensing (the Review).

As noted in the Government's response to Community Affairs References Committee's *Gene Patents Report 2011* (the Senate Gene Patents Report), the Government supports a review of the operation of the Compulsory Licensing provisions to ensure that the provisions are achieving their intended purpose as a safeguard to facilitate access to innovations where the reasonable requirements of the public are not being met.

The Department delivers outcomes to promote and support the Australian Government's 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.

In discharging its portfolio responsibilities in the healthcare sector, the Department regularly encounters issues relating to intellectual property (IP) interests (such as patents, designs, trademarks and copyright). Compulsory Licensing or Crown Use provisions may potentially apply in delivering policies and programs relating to medical and pharmaceutical benefits, in directly funding research activities, or in providing services.

There have been numerous reviews and inquiries in recent years examining aspects of the IP rights system in Australia. This submission is consistent with those made by the Department to previous reviews and inquiries, and with the Australian Government's response to the *Report of the Senate Community Affairs Committee Inquiry into Gene Patents* (the Senate Inquiry Report), which constituted a combined Government response to:

- The 2010 Senate Gene Patents Report;
- The 2010 Advisory Council on Intellectual Property's Patentable Subject Matter Report (ACIP PSM Report);
- The 2004 Australian Law Reform Commission's Report No. 99, *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99 Report); and
- The review of Australia's patent system by IP Australia.

In responding to the matters raised in the Issues Paper, the Department aims to accommodate a balance of interests to both support the healthcare needs of the Australian public and to encourage commercial health sector interests to maintain investment in effective healthcare innovations.

The Government Response to the Senate Inquiry Report accepted, in principle, the ALRC99 Report recommendation that governments should consider exercising legal options (including Crown Use) to facilitate access to patented inventions, where particular patents have an adverse impact on medical research or cost-effective healthcare. This submission is consistent with that recommendation.

2 Gene patents

One of the specific matters raised in the Issues Paper is the patenting of isolated, naturally-occurring genes and the extent to which Crown Use or Compulsory Licencing provisions could potentially address the risk that such patents could adversely affect access to affordable healthcare. Numerous and complex IP issues surround genetic testing and associated health services. The rate of discovery and the potential application of new knowledge calls for careful consideration of whether current ways of managing intellectual property, and associated diagnostic and treatment services, are congruent with community needs and values. Careful and prudent assessment of the issues and consequences are needed, within frameworks that rigorously assess the costs and benefits for commercial interests, individuals and society.

The Senate Inquiry heard evidence of a number of cases where gene patents have impeded the provision of healthcare or the conduct of medical research.

The validity of patenting isolated human gene sequences will remain unsettled until the question is decided by an Australian court. The Department is supportive of a balanced approach that:

- Encourages the development of new genetic technologies;
- Ensures the availability of, or access to genomic and personalised medicine; and
- Provides for corroborative medical testing, or allowing patients to obtain a second opinion on results;
    - for example, it is good medical practice to independently confirm a test for genetic susceptibility to a certain illness, where possible by using a different method.

If the statute and case law do not exclude the granting of patents on gene sequences, the monopoly rights preventing access to gene sequences could be addressed through some form of compulsory licensing.

The Department notes that Australia's obligation under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is to maintain technology-neutral patentability criteria.

3 Crown Use

The Department recognises the potential value of the Crown Use provisions in protecting national public health interests. However, the Department recommends broadening the provision 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.

a. Definition

Crown Use provisions are a limited form of Compulsory Licensing contained in section 163 of the *Patents Act 1990*, which allow, under strict conditions, patent use without the authorisation of the patent or design owner so long as the use is 'for the services' of the Commonwealth, a State or a Territory. Crown Use provisions ensure that Commonwealth and State Government agencies are protected from infringement actions when such agencies need to exploit a patent or design in the public interest. If the Commonwealth obtained an assignable license under Crown Use, this would allow the Department to grant others access to the patented technology, as long as such access relates to services provided on behalf of the Commonwealth or a state.

b. Issue

Crown use rights are presently restricted and would apply only in limited circumstances where the patent is to be used by the government or someone it authorises 'for the services' of the Crown. 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).

The public and private health sectors do not operate in isolation. For example, co-located hospitals can share resources, and medical staff work across both sectors. Both sectors are an integral part of the national health system. However, under current law, it is unlikely that Crown use would extend to any healthcare service which is expected to be supplied for the good of all Australians, irrespective of whether it was provided by the public or private health sector.

The *Discussion Paper on the Review of the Funding Arrangements for Pathology Services* (DoHA, March 2011) suggested that about 26% of all genetic tests are currently performed by private national medical testing laboratories. While these laboratories could apply for a compulsory licence (where, for example, the patent holder restricted access to a nominated laboratory) this would need to be on an individual basis and would involve further costs and delays through negotiations and court proceedings.

The Department agrees with the conclusion of the ACIP PSM Review and the ALRC 99 Report 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. However, with respect to the above questions, the Department believes that any Crown use rights should enable the government to intervene in any case where access to healthcare is being restricted or denied, including non-government healthcare facilities.

c. Discussion

In addition to the value of these provisions for providing access to necessary patents for governments, the Crown Use provisions may also constitute an important negotiating tool and public safeguard. The existence of the provisions assists in negotiating with patent owners and ensuring that the government is able to achieve acceptable results for the public interest.

The Department is not aware of any circumstances in which the Crown Use provisions have been used in the healthcare context. While Crown Use provisions appear potentially useful for dealing with issues of access to affordable genetic tests raised by some existing patents on human DNA, the Commonwealth is rarely involved in the direct provision of health services. Use of these provisions would most likely be a decision of the relevant state/territory, noting that most genetic tests currently performed are funded by the states/territories. Under current laws, each state/territory would then 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.

The option to use Crown Use provisions has been considered by the Department, for example, in the following theoretical scenarios:

- Preparations during an emerging pandemic in which international trade was disrupted for an extended period and where essential pharmaceuticals may need to be manufactured locally;
- Where a genetic test that has been patented is available for use in a limited number of private laboratories only and this is considered to hinder the Government's ability to deliver on health outcomes through public health facilities;
- In times of war or emergency;
    - for example, a situation such as when the governments of both the US and Canada considered utilising compulsory use of a Bayer AG-patented antibiotic following the anthrax bio-terror attacks in the US in 2001; or
- Other public health emergencies.

The costs of compensation to the patent holder are likely to be significant and may be substantial depending on the number of patents acquired or licensed. Costs may be disproportionate to the benefits achieved, for example, by reason of low rates of usage of patent licenses or post-hoc compensation to the patent holder. The other significant impact is the legal process to settle the compensation price; though this should not impact on the practical process of ensuring access in emergencies.

Given the infrequent use of Crown Use provisions, it is difficult to comment on whether these provisions are adequate to protect the public interest. The Department is concerned that a strict reading of the statement "for the services of the Crown" may unduly restrict the ability of governments to act in an emergency, as it may prevent the Commonwealth and state governments from quickly acting in an area where the Crown provides no direct health services. For this reason, the Department believes that the Productivity Commission should consider the merits of explicitly extending Crown Use provisions to allow the Crown to license its Crown Use access to a patented technology to (one or more) private third party entities when the situation warrants.

4 Compulsory Licensing provisions

The Department supports consideration of easing the barriers to invoking the Compulsory Licensing provisions in situations where it would be in the public interest to do so. This is particularly important in situations where Crown Use provisions may not be available to the Commonwealth for use.

a. Definition

Section 133(2)(a) of the *Patents Act 1990* provides that a person may apply to a prescribed court for a compulsory license for a patent 'after trying for a reasonable period to obtain authorisation' to use the patent; where the 'reasonable requirements of the public' with respect to the patented invention have not been satisfied; and the patent holder has not given a satisfactory reason for 'failing to exploit the patent'.

Section 133(2)(b) of the *Patents Act 1990* provides (in the alternative) that a person may apply for a compulsory license where it is established that the patentee has contravened or is contravening Part IV of the *Competition and Consumer Act 2010* or an application law in connection with that patent.

b. Issue

The Commonwealth is able to pursue the use of patents and designs by applying for a compulsory license through the Federal Court. However, given that a compulsory licence cannot be assigned or "rented" to more than one entity it is unlikely that this approach would be taken. While the Crown may benefit from non-government entities obtaining a licence, each private entity (eg, health provider) would need to apply for, and obtain, a separate licence. The costs to those seeking access to the patent are likely to be substantial and a considerable disincentive.

c. Discussion

Acquiring a license in this manner is a drawn out and likely very expensive process. It requires either accumulating good evidence of a history of a patentee denying use to others, and non-use by the patent holder, together with proof that the 'reasonable requirements' of the public are not being met, and that the patentee has given no satisfactory reason for failing to exploit the patent itself. Alternatively it is necessary to establish a contravention of Part IV of the *Competition and Consumer Act 2010,* in itself a formidable undertaking. It is then followed by an application to the Federal Court seeking a court order, which may or may not be granted.

Generally, due to the length, cost and uncertainty of achieving a desired outcome, the Department does not consider Compulsory Licensing to be a practicable solution to a patent holder's unreasonably impeding access to patented inventions.

The benefits of the Compulsory Licensing provisions have been considered by the Department, for example, in response to legal action associated with laboratory testing for BRCA1 and BRCA2 genes (but for the reasons outlined above the Department chose not to pursue that course of action).

- BRCA 1 & 2 genes have been patented in Australia by Myriad Genetics Incorporated (Myriad). Mutations of these genes have been linked to the development of breast, ovarian and prostate cancer. Genetic Technologies Limited (GTL) obtained an exclusive license to perform BRCA 1 & 2 genetic testing in Australia. In 2002 and again in 2008, GTL sought to enforce its exclusive right to the patents by requiring others it considered to be infringing on its rights to cease testing.

    - The actions of GTL raised concern amongst healthcare professionals, researchers, and the broader community about access to affordable genetic testing. In both 2002 and 2008, public outcry led GTL to declare its patents a 'gift to the people of Australia' and cease attempts to enforce its monopoly rights. Myriad is currently a party to lawsuits in both Australia and the US regarding the validity of their patent claims over genes. A decision in Australia is pending.

  Efforts by GTL to restrict genetic testing for BRCA 1 & 2 genes to their labs are concerning to the Department for two major reasons:

    1) that the enforcement of these patents may restrict access to genetic tests or technologies, both economically and geographically; and

    2) that restricting a specific test to one lab does not allow for corroborative testing by other labs, which is not consistent with good medical practice.

The scope for Compulsory Licensing provisions to expedite or enhance access to new medicines for Australian consumers is unknown, but believed to be minimal, noting that a pharmaceutical company would most likely need to apply on the basis that demand was not being met. However, the Department does consider that as well as balancing access to healthcare technologies with innovation, Australia, as a net importer of pharmaceuticals, needs to manage the risk associated with global pharmaceutical companies deciding not to bring new and innovative medicines to the Australian market if they perceive a risk to their intellectual property.

The Department suggests that the Productivity Commission consider the merits of simplifying the use of Compulsory Licensing, accompanied by establishment of an independent Tribunal to consider applications. Such a body would offer a cost and time effective alternative to expensive court processes.

5 Alternative licensing

A different form of compulsory licensing may be effected through the establishment of a collecting society[1] where healthcare technologies including gene patents are compelled to be licensed under the auspices of a collecting society to users for a specific purpose. The collecting society would license users, set prices, collect royalties and distribute these to the patent holders. A similar mechanism (the Copyright Agency Limited, or CAL) is presently operating in relation to copyright.

[1] The concept of a collecting society is known, and already exists in the *Copyright Act 1968.*

This would provide a means to access the latest patented medicines, notably patented gene sequences, for the specific purpose of screening, testing and diagnosis, and may allow licensing of multiple patents by one entity. Such a mechanism could allow much quicker, cheaper and less cumbersome access to patents which need to be utilised in a health or broader context. However, there may be insufficient demand to justify the establishment and maintenance of such a body by Government.

6 Pharmaceutical Benefits Scheme (PBS)

The PBS has been cited by industry groups as a policy regime that guarantees government access to patented technologies. The Department wishes to address this view.

The PBS Schedule lists all of the medicines available to be dispensed to patients at a Government-subsidised price. The Schedule is part of the wider Pharmaceutical Benefits Scheme managed by the Department of Health and Ageing and administered by the Department of Human Services.

The Scheme is available to all Australian residents who hold a current Medicare card. Overseas visitors from countries with which Australia has a Reciprocal Health Care Agreement (RHCA) are also eligible to access the scheme to cover treatment that is medically essential[2].

Where there are two or more brands of the same drug on the Schedule, the Government subsidises each brand to the same amount - up to the cost of the lowest priced brand.

a. Guarantee of Supply provisions

Under the guarantee of supply provisions contained in the *National Health Act 1953*, suppliers of newly listed products on the Pharmaceutical Benefits Scheme (PBS) which are bioequivalent or biosimilar to existing PBS listed products are required to guarantee the supply of their products for a period of 2 years following listing. These provisions apply only in situations where a patent on a medicine has expired and generic competition has commenced.

The guarantee of supply provisions deter suppliers from entering the Australian market without a viable business model able to support their long term participation in the market. Interruptions to supply are disruptive for patients, prescribers and pharmacists. The provisions also ensure that the government has as much notice as possible about supply failures so that the impact on patients, prescribers and pharmacists can be minimised. The Guarantee of Supply requirements and sanctions for failing to comply with the requirements are set out in Division 3C of Part VII of the *National Health Act 1953*.

The Department strongly considers that the Guarantee of Supply provisions should not be cited as reason to remove or place limits on Crown Use or Compulsory Licensing provisions.

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[2] This means any ill-health or injury which occurs while in Australia and requires treatment before the visitor returns home.

Guarantee of Supply provisions:

- apply only in situations where a patent on a medicine has expired and generic competition has commenced;
- rely on the ability of the company to maintain manufacture and supply lines;
- would be inadequate in the event of a severe pandemic, or indeed, any major event affecting supply chains; and
- have failed in the past.

For these reasons, guarantee of supply provisions have no relation to Crown Use or Compulsory Licensing provisions and can neither affect, nor be affected by them.

7 Research exemptions

A key policy issue is to ensure that patent protection, which is intended to encourage and disseminate research, does not impede access to basic health research, or render treatments founded on genetic technologies inaccessible by reason of cost to those who might require it.

Both the ALRC Genes and Ingenuity report and the ACIP Patents and Experimental Use report recommended codifying the research use exemption. Amendments to introduce an exemption from infringement for acts done for experimental purposes are contained in the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*. The various changes encoded under *Raising the Bar* will serve to increase the quality of patents that are granted and to allow others to freely conduct research on gene sequences set out in patents granted and published by IP Australia without infringing those patents.

However, the Department has reservations about the extent to which the research exemption will permit all research. While this will permit health related research to be conducted it does not address the problem of patent holders using monopoly rights to block access to an individual's own health information, for example through screening and diagnostic testing involved in research.[3]

The National Health and Medical Research Council (NHMRC) will provide a separate submission to the Commission. This submission will more broadly address any concerns relating to the research exemptions on behalf of the Health portfolio.

[3] Stakeholders have raised concerns that the exemption from patent infringement for experimental (i.e. research) activities introduced by amendment to the *Patents Act 1990* may be insufficient to protect researchers in situations where there may be an intersection between experimental and clinical purposes relating to a patented invention.
For example, in clinical trials a researcher may be required to make available the results of a genetic test undertaken as part of the trial to a participant in accordance with NHMRC's National Statement on Ethical Conduct in Human Research. There is concern that this type of research may be seen as involving a screening service and therefore may not be protected from claims of patent infringement under the research exemption.

8 Relevance to international treaties

Australia is a signatory to multiple international treaties, under which the Commonwealth has made certain commitments in relation to intellectual property rights. A brief outline of the agreements and obligations from a health perspective is as follows.

When entering into international arrangements or agreements the Australian Government seeks to avoid provisions, including IP provisions, which would adversely affect Australian healthcare policy or constrain the Government's ability to regulate legitimately on public policy matters such as the Pharmaceutical Benefits Scheme (PBS), or to the health system more generally, including tobacco control measures.

However, any moves to amend legislation or clarify the meaning of terms under legislation would need to be informed by a more detailed analysis of the impact on Australia's international obligations by the Department of Foreign Affairs and Trade (DFAT), and the Attorney-General's Department.

DFAT leads negotiations on Free Trade Agreements. DFAT's website notes those in place and currently under negotiation http://www.dfat.gov.au/fta/index.html.

8.1 Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The World Trade Organization (WTO), the international body managing TRIPS, describes compulsory licensing as "when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement."[4]

Article 31 of TRIPS allows compulsory licensing and government use of a patent without the authorisation of its owner. The patent owner still has rights over the patent, including a right to be paid for the government authorized copies of the products.

Article 31 of the TRIPS Agreement enables a country that is experiencing a serious epidemic to ensure that its own population is supplied with a patented treatment. It provides that a patented product may be used without the authorisation of the patent owner, but only under certain conditions. Under this provision, a court may compel a patent owner to grant to a third party a license to manufacture and supply a pharmaceutical and ensure that the patent owner is compensated accordingly. The TRIPS Protocol provides for compulsory licenses to be granted for the export of patented products. Australia is a signatory to the TRIPS Agreement and the TRIPS Protocol.

Some countries have exercised Compulsory Licensing provisions to enable manufacture of pharmaceuticals for export to least-developed nations. For example, Canada allowed anti-retroviral drugs to be produced by Apotex in 2007 under compulsory licensing provisions, for export to

[4] https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

Rwanda. IP Australia is consulting on the feasibility of similar amendments to Australian patent law, to allow for compulsory licensing of pharmaceuticals for export to developing countries. Similar provisions have been exercised for domestic use by Brazil and Thailand. However, these countries are both considered 'developing' countries under international agreements, and as such have greater scope for use of Compulsory Licensing provisions under TRIPS.

8.2 Australia-United States Free Trade Agreement (AUSFTA)

Australia and the United States have a trade agreement which does not disturb the integrity of the PBS, Medicare Benefits Scheme or the Pharmaceutical Benefits Advisory Committee process in Australia. Any further international trade negotiations should not exceed the obligations previously agreed as a part of the Australia-US Free Trade Agreement (AUSFTA). Any contemplation of changes to the national intellectual property laws in Australia should have regard for this agreement.

AUSFTA came into force on 1 January 2005. The obligations in this agreement in relation to the PBS relate to issues of timeliness, transparency and process. These obligations have been fully implemented.

The PBS pricing and listing arrangements that ensure access to quality medicines that are affordable for Australian consumers and the community were not altered as a result of the AUSFTA.
The commitments made under the AUSFTA do not inhibit Australia's ability to protect critical elements of public policy, or deliver fundamental policy objectives in pharmaceuticals.

Article 17 of AUSFTA contains provisions relating to intellectual property. Of note, Australia is required to provide measures in its marketing approval process to prevent a person from entering the market with a generic version of a patented medicine before a patent covering that product has expired.

8.3 International / alternative dispute resolution mechanisms

Traditionally national governments had to bring about dispute settlements under international agreements, through a government to government arrangement. Investor State Dispute Settlement (ISDS) provisions provide 'foreign investors' with a direct means for redress against national government for breaches of treaties/agreements.

The Gillard Trade Policy Statement published April 2011[5] states that Australia will not accept ISDS provisions in trade agreements that would limit the Government's capacity to put health warnings or plain packaging requirements on tobacco products, or limit its capacity to continue the Pharmaceutical Benefits Scheme (PBS).

[5] http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.pdf

9 Conclusion

In summary the Department recommends that the Productivity Commission note the following:

- The Compulsory Licensing and Crown Use provisions should provide an appropriate balance of interests to both support the healthcare needs of the Australian public and to encourage commercial health sector interests to maintain investment in effective healthcare innovations.
- Simplifying the use of the Crown Use and Compulsory Licensing provisions would improve the ability of governments to take action in the event of access to patented inventions being withheld. This would be of benefit, particularly considering the IP complexity of emerging technologies, such as genetic technologies and to facilitate research.
- While these provisions have never been used in a healthcare setting (to the best of the Department's knowledge), they are potentially an important safeguard for governments to be able to ensure access to a patented technology in the event that this is required to provide equitable access to affordable healthcare.
- Any amendments to Compulsory Licensing or Crown Use provisions should not significantly affect the ability of governments to respond to national medical emergencies (for example, an outbreak of a pandemic).
- Broadening the Crown Use provision to allow the Crown to license its use of a patent to a non-government entity, where it would be in the public health interest to do so, may help to ensure that health services of a high quality are available to all Australians.
- Ways of making Compulsory Licensing more workable in terms of costs, timeframes and likely outcomes should be considered, for example by establishing an independent Tribunal to consider applications.
- A different form of compulsory licensing may be effected through the establishment of a collecting society where patents over healthcare technologies, including genetic materials, are compelled to be licensed under the auspices of a collecting society to users for a specific purpose.
- Crown Use and Compulsory Licensing provisions are consistent with the legal protection and enforcement of intellectual property systems in comparable countries, notably the US, the UK and Canada. Any proposal to limit the scope of these provisions in Australian law may significantly reduce the ability of companies and governments to negotiate access to patented technologies, and needs to consider Australia's commitments under its international agreements.