Public Health Association
AUSTRALIA

Public Health Association of Australia submission to the Productivity Commission – Compulsory Licensing of Patents Inquiry

Second submission

Compulsory Licensing of Patents Inquiry
Productivity Commission
Locked Bag 2, Collins St East
MELBOURNE VIC 8003

Fax: (03) 9653 2182
Email: patents@pc.gov.au

Contact for PHAA
Michael Moore
CEO
mmoore@phaa.net.au

4 March 2013

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

Contents

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

Introduction

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles.

Public Health

Public health includes, but goes beyond the treatment of individuals to encompass health promotion, prevention of disease and disability, recovery and rehabilitation, and disability support. This framework, together with attention to the social, economic and environmental determinants of health, provides particular relevance to, and expertly informs the Association's role.

The Public Health Association of Australia

PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups concerned with the promotion of health at a population level.

Key roles of the organisation include capacity building, advocacy and the development of policy. Core to our work is an evidence base drawn from a wide range of members working in public health practice, research, administration and related fields who volunteer their time to inform policy, support advocacy and assist in capacity building within the sector. PHAA has been a key proponent of a preventive approach for better population health outcomes championing such policies and providing strong support for the Australian Government and for the Preventative Health Taskforce and National Health and Medical Research Council (NHMRC) in their efforts to develop and strengthen research and actions in this area across Australia.

PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups the Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

Advocacy and capacity building

In recent years PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of Government and agencies, and promoting key policies and advocacy goals through the media, public events and other means.

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

Summary of our first submission and testimony at the public hearing

- Compulsory licensing is a critical safeguard for protecting public health and the utmost flexibility should be preserved for national governments to use it as they deem necessary to meet public health goals and ensure access to medicines and other health technologies.
- Australia's existing trade agreements already impose some constraints on the effective use of compulsory licensing. Australia is now negotiating a new trade agreement, the Trans Pacific Partnership (TPP) which could impose additional constraints.
- Protection of pharmaceutical test data (commonly known as 'data protection') constitutes an impediment to the effective use of compulsory licensing, because even where a compulsory license has been granted, the Therapeutic Goods Administration cannot evaluate or approve an application for marketing approval for a generic product that relies on these data until the expiration of the patent protection period. The impediment this presents to compulsory licensing has not yet been tested in the courts, but there have been cases in the US and the EU where compulsory licenses were rejected due to data protection periods being in place.
- In the TPP, the US is seeking to extend both the duration and the scope of data protection, including:
    - At least five years of data protection for new pharmaceuticals;
    - An additional three years for new uses of existing products;
    - Data protection covering not just undisclosed data , but also data that is already in the public domain (this is often referred to as 'data exclusivity'); and
    - The US pharmaceutical industry is also pushing for longer periods of data exclusivity – up to twelve years – for therapeutic biologics (Note: this is actually a longer period than in the US, where there is currently 12 years of market exclusivity but only four years of data exclusivity. In effect this means the TGA would not be able to even begin to evaluate an application until the end of the twelve year period, meaning that it may take up to 14 years before the product enters the market if this provision is adopted in the TPP).
- The Productivity Commission should consider recommending that Australia not accept any provisions in future trade agreements that could prevent the effective use of compulsory licensing. Provisions such as those proposed for the TPP would prevent the effective use of compulsory licensing and it would be consistent with the Inquiry's terms of reference for such a recommendation to be made.

The recommendations of our first submission were:

- **The Productivity Commission should carefully review the implications of the current data protection provisions of S25 of the Therapeutic Goods Act 1989 to ensure that they do not preclude the effective use of compulsory licensing of medicines in Australia.**
- **The Productivity Commission should also carefully examine the implications of the existing provisions of Chapter 17 of the Australia US Free Trade Agreement (AUSFTA) for the effective use of compulsory licensing of medicines in Australia. Consideration should be given to re-negotiating the data protection provision in AUSFTA with a view to removing it to facilitate future use of compulsory licensing in Australia.**

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

- **The Productivity Commission should carefully consider the potential implications of the proposed intellectual property provisions of the TPP for the future use of compulsory licensing of medicines in Australia.**

This second PHAA submission to the Productivity Commission Compulsory Licensing of Patents Inquiry

The Public Health Association of Australia (PHAA) made an earlier submission in September 2012 in response to the Productivity Commission's Issues Paper of August 2012. This second submission responds to certain draft recommendations in the Productivity Commission's Draft Report released in December 2012 and to questions raised by the Commissioners at the public hearing on 20 February 2013.

Specifically, we respond to:

- **Draft Recommendation 6.3**, which proposes that the Australian Government should seek to repeal s.136 of the Patents act 1990 (Cwlth) and that current and future international treaty obligations should be incorporated directly into the Patents Act 1990 (Cwlth) or its subordinate legislation;
- **Chapter 7 of the Draft Report (Crown use and acquisition)**, including the proposed reforms to Crown use provisions (Draft Recommendations 7.1 and 7.2) and the Commissioners' query regarding whether the amended Crown use provision would address the public health concerns raised in our earlier submission;
- The request of the Commissioners for information about **cases in the US and EU where compulsory licenses were not issued due to data exclusivity** being in place; and
- Other queries made by the Commissioners during the public hearing.

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

1. Response to Draft Recommendation 6.3 – international treaty obligations

The commissioners asked us to comment on Draft Recommendation 6.3 which proposes that the Australian Government should seek to repeal s. 136 of the Patents act 1990 (Cwlth) and that current and future international treaty obligations should be incorporated directly into the Patents Act 1990 (Cwlth) or its subordinate legislation.

Section 136 of the *Patents Act 1990 (Cwlth)* states that 'An order must not be made under Section 133 or 134 that is inconsistent with a treaty between the Commonwealth and a foreign country.' Sections 133 and 134 deal with compulsory licensing and the revocation of a patent after the grant of a compulsory license.

The advantage of this recommendation, from our perspective, would be that international treaty obligations would need to be subject to parliamentary scrutiny. This may also mean greater transparency and the opportunity to exercise parliamentary discretion where such flexibility exists in treaties.

However, the Commissioners should be aware that Article 17.9.7 of the Australia-US Free Trade Agreement (AUSFTA) limits the circumstances in which a CL may be granted (see Box 1 below).

Box 1: Australia-US Free Trade Agreement, Article 17.9.7

7. A Party shall not permit the use[17-[22]] of the subject matter of a patent without the authorisation of the right holder except in the following circumstances:

(a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party's laws relating to prevention of anti-competitive practices;[17-[23]] or

(b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that:

(i) the Party shall limit such use to use by the government or third persons authorised by the government;

(ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and

(iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph.

[17-[22]] "Use" in this paragraph refers to use other than that allowed under paragraph 3 and Article 30 of the TRIPS Agreement.
[17-[23]] With respect to sub-paragraph (a), the Parties recognize that a patent does not necessarily confer market power.

Source: Australia-United States Free Trade Agreement, Chapter Seventeen: Intellectual Property Rights. Available at: http://www.dfat.gov.au/fta/ausfta/final-text/chapter_17.html

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

Incorporating the wording of AUSFTA Article 17.9.7 directly into the Patents Act may increase the clarity about the circumstances in which compulsory licenses can be issued but it would also limit the circumstances in which a compulsory license can be issued to remedy an anti-competitive practice, or 'in cases of public non-commercial use, or of national emergency, or of other circumstances of extreme urgency'. AUSFTA provision 17.9.7 limits the effective use of the compulsory licensing provisions and should not be incorporated directly into Australian domestic law.

If international treaty obligations with respect to compulsory licensing were to be incorporated directly into the Patents Act 1990, it would be critically important, from a public health perspective, to include language from the Doha Declaration on the TRIPS Agreement and Public Health affirming the right of countries to use compulsory licenses for any reason they see necessary for public health. The application of compulsory licensing should not, for example, be narrowed to specific diseases or circumstances of extreme urgency. Box 2 sets out the relevant parts of the Doha Declaration. 5(b) is particularly important.

Box 2: Excerpt from the Doha Declaration on the TRIPS Agreement and Public Health

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Source: Doha WTO Ministerial 2001: TRIPS. Declaration on the TRIPS agreement and public health. Available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

We support Recommendation 6.3 in principle, but the utmost care needs to be taken in incorporating international treaty obligations into domestic legislation. We suggest that the Productivity Commission final report recommends against incorporating the wording of AUSFTA Article 17.9.7 directly into the Patents Act, instead recommending that the AUSFTA obligations are re-interpreted carefully with regard to their implications for the circumstances in which compulsory licensing can be used. We recommend that relevant wording from the Doha Declaration on the TRIPS Agreement and Public Health be incorporated to protect domestic flexibility in the use of compulsory licensing.

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

2. Crown use provisions and public health

Crown use should not be relied on as an alternative compulsory licensing

PHAA appreciates the Commissioners' intention to make the Crown use provisions more useable. However, we caution against relying on the Crown use provision as an *alternative* to compulsory licensing. The Crown use provisions have rarely been used and, while it is important to retain this safeguard in the legislation, there is no evidence that it will in every case provide a feasible alternative. Furthermore, Crown use does not provide a pathway for third parties such as non-government organisations or generic manufacturers to seek a license. There may be many situations where this would be important.

Data protection presents an impediment to both compulsory licensing and Crown use

Section 25A of the Therapeutic Goods Act (1989) prevents the Therapeutic Goods Administration from using information about safety and efficacy (ie clinical trial data) provided to the TGA by the originator when evaluating a generic equivalent for registration, for a period of five years following the registration of the original product. This is commonly referred to as 'data protection' (the data being protected are referred to as 'protected information' in s 25A of the Therapeutic Goods Act).

It is well known that data protection can impede compulsory licensing. Our first submission addressed this and we provide specific examples in section 3 below.

The Commissioners have suggested that the Crown use provisions might not be subject to the same problems with respect to data protection. However, we have closely examined the Patents Act and the Therapeutic Goods Act and can see no means by which the protection of pharmaceutical test data ('data protection') would not create a similar barrier to Crown use as it would to compulsory licensing. Section 25A of the *Therapeutic Goods Act (1989)* prevents the TGA from evaluating a generic marketing application during the five year period of test data protection, and there does not appear to be any mechanism in either the compulsory licensing or Crown use provisions of the *Patent Act (1990)* that would enable this to be waived.

To ensure that data protection does not prevent the effective use of either compulsory licensing and Crown use provisions, the Commission should recommend the inclusion of a mechanism that deals with the constraints presented by test data protection to both compulsory licensing and Crown use, such as an amendment to s25A of the Therapeutic Goods Act (1989) or a mechanism within the compulsory licensing and Crown use provisions of the Patents Act (1990) specifying that s25A of the Therapeutic Goods Act would not apply when a compulsory license is issued or when the Crown use provisions are invoked. We recommend that the Productivity Commission consults with the TGA regarding an appropriate mechanism.

Such an exemption has been implemented in Malaysia. The Malaysian Ministry of Health issued a Directive on Data Exclusivity on February 28, 2011 specifying that the provisions relating to protection of test data would not apply where a compulsory licence is issued. Article 5(i) of the Directive states: 'Nothing in the Data Exclusivity [Directive] shall: (i) apply to situations where compulsory licenses have been issued or the implementation of any other measures consistent with the need to protect public health and ensure access to medicines for all'. (1)

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

Response to Draft Recommendation 7.1

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.

We support the Productivity Commission's intention to clarify and broaden the scope of what is defined as 'Crown use'. However, in our view the scope of Crown use in Draft Recommendation 7.1 is still too narrow. We note that the Department of Health and Ageing has suggested broadening the provisions to permit the Crown to license access to the patent to third parties (2). Adopting the Department of Health and Ageing's recommendation would make the Crown use provisions far more useable.

It is also unclear how the courts would interpret the words 'primary responsibility for providing or funding'. This phrase does not reflect the complexity of funding relations within the Australian health care system and may be too limiting.

Response to Draft recommendation 7.2

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 license.*

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.

This recommendation appears to only benefit patent holders in a context where the Crown use provisions are already extremely difficult to use.

While it is commendable that the requirement should be able to be waived in cases of emergencies, the meaning of the term emergencies should be defined clearly, otherwise the potential for disputes over the meaning of 'emergencies' may act as a deterrent to the effective and timely application of the Crown use provisions. 'Emergencies' should be broadly defined and any references to circumstances in which compulsory licensing or Crown use can be implemented should draw on the language of the Doha Declaration (see Box 2 above).

Introducing a requirement to attempt to negotiate the use of a patent (particularly where there is no time limit to such negotiations specified) is inadvisable as it could introduce perverse incentives to

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

delay the process. If a requirement to negotiate must be included, then a time limit to such negotiations should be specified and the period should be as short as possible.

3. Cases where compulsory licenses were not issued due to the protection of pharmaceutical test data

The Commissioners have asked for examples where a compulsory license was not issued due to a data protection period being in place. There are two such cases we are aware of. Both have been documented by Knowledge Ecology International (KEI) and both involved situations where there was a genuine public health emergency in the context of a drug shortage (3, 4, 5).

The first of these cases occurred during a shortage of Tamiflu in the Europe in 2006. This was a situation in which there was an emergency and the patent holder was unable to meet the demand for Tamiflu (3). A compulsory license was not granted by the European Union's Enterprise and Industry Directorate-General due to there being "no provision allowing the waiver of the rules on data exclusivity and marketing protection periods […] in the case of a national or an EU-wide emergency" (4).

The second case occurred in the United States in 2010 during a severe worldwide shortage of the drug Fabrazyme (used to treat Fabry disease, a very serious inherited disease leading to severe morbidity and foreshortened life expectancy in the absence of treatment). A license to permit manufacture of this drug was requested by the National Institutes of Health, however the request was rejected on the grounds that granting the license "would not overcome other barriers, including the exclusive rights in test data" (5).

4. Further comments regarding data protection

The following comments address further queries raised by the Commissioners during the public hearing (recorded on pages 7 and 8 of the transcript).

Dr Mundy raised the issue of compulsory licensing for export (page 7). The Commissioners should be aware that while the data protection provision in s25A of the Therapeutic Goods Act do not present an impediment to compulsory licensing for export, this is because marketing approval is the responsibility of the importing country rather than the exporting country. The TGA would not be responsible for providing marketing approval for drugs exported to other countries and so s25 would not apply. However s25A does present an impediment to compulsory licensing in the domestic context.

Dr Mundy also asked (page 8) whether data protection might be more appropriately dealt with elsewhere rather than through the compulsory licensing and Crown use sections of the Patents Act. Data protection of course does present other problems beyond the impediment to compulsory licensing and Crown use, as it can delay the entry of generic medicines, even in circumstances where a patent has expired, and we agree that this should be addressed. Data protection periods should certainly not be extended further. **However, s25A of the Therapeutic Goods Act as it currently**

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

stands presents an impediment to the effective use of both compulsory licensing and Crown use provisions and if this impediment is not removed, either by amending s25A of the Therapeutic Goods Act to specify that it would not apply to compulsory licensing or Crown use or by including a waiver of s25A of the Therapeutic Goods Act in the compulsory licensing and Crown use sections of the Patents Act, both compulsory licensing and Crown use provisions will be unusable during the five year period of pharmaceutical test data protection.

Conclusion

PHAA supports the aims of the inquiry to strengthen the compulsory licensing and Crown use provisions of the Patent Act (1990). However, we are keen to ensure that these provisions are further strengthened in line with this submission. We are particularly keen that the following points are highlighted (along with the recommendations from our first submission):

- While we support Recommendation 6.3 in principle, the utmost care needs to be taken in incorporating international treaty obligations into domestic legislation. AUSFTA Article 17.9.7 imposes restrictions on the use of compulsory licensing to achieve public health goals. **We suggest that the Productivity Commission final report recommends against incorporating the wording of AUSFTA Article 17.9.7 directly into the Patents Act, instead recommending that the AUSFTA obligations are re-interpreted carefully with regard to their implications for the circumstances in which compulsory licensing can be used. We recommend that appropriate wording from the Doha Declaration on the TRIPS Agreement and Public Health be incorporated to protect domestic flexibility in the use of compulsory licensing for public health purposes.**
- Section 25A of the Therapeutic Goods Act prohibits the TGA from using non-publicly available test data in the evaluation of an application for a generic equivalent for registration for five years from the first registration of the originator product. This provision presents an impediment to the effective use of both compulsory licensing and Crown use provisions as there appears to be no mechanism in either the Patents Act or the Therapeutic Goods Act to deal with this constraint. **To ensure that data protection will not prevent the effective use of both compulsory licensing and Crown use provisions, the Commission should recommend the inclusion of a mechanism that deals with the constraints presented by test data protection to both compulsory licensing and Crown use, such as an amendment to the s25A of the Therapeutic Goods Act (1989) or a mechanism within the compulsory licensing and Crown use provisions of the Patents Act (1990) specifying that s25 of the Therapeutic Goods Act would not apply when a compulsory license is issued or when the Crown use provisions are invoked.**
- **Draft Recommendations 7.1 and 7.2 should be reviewed to ensure that the scope of what is defined as 'Crown use' is as broad as possible (Rec. 7.1) and to remove the requirement to negotiate the use of the patented invention prior to invoking Crown use, or at least to strictly limit the time frame for such negotiations (Rec 7.2).**

The PHAA appreciates the opportunity to make this submission and to respond to the draft recommendations and the questions raised at the public hearing.

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au

Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

References

1. Malaysian Directive on Data Exclusivity, issued February 28, 2011 by the Director of Pharmaceutical Services under Regulation 29 of The Control of Drugs and Cosmetic Regulations 1984.
2. Australian Government Department of Health and Ageing. Submission to the Productivity Commission Inquiry into Compulsory Licensing. September 2012. Available at: http://www.pc.gov.au/__data/assets/pdf_file/0003/119928/sub022-patents.pdf
3. Love, J. DG-Enterprise – data exclusivity prevents access to life-saving drugs (in the EU), even in an emergency situation. Knowledge Ecology International. 30 July 2012. Available from: http://keionline.org/node/1510.
4. Letter from the European Commission's Enterprise and Industry Directorate-General to Mr Greg Perry, European Generic Medicines Association, 2006, available from: http://keionline.org/sites/default/files/ec-de-tamiflu.pdf
5. Cox, K. NIH Case: Exclusive rights in regulatory test data are absolute, even where there are drug shortages. Knowledge Ecology International. 31 July 2012. Available from: http://keionline.org/node/1511.

Michael Moore BA, Dip Ed, MPH
Chief Executive Officer
Public Health Association of Australia

Dr Deborah Gleeson
Convenor
Political Economy of Health Special Interest Group, PHAA

4 March 2013

PHAA gratefully acknowledges the assistance of Ruth Townsend, Jessica Taylor and Ruth Lopert with technical issues covered in this submission.

20 Napier Close Deakin ACT Australia, 2600 – PO Box 319 Curtin ACT Australia 2605
T (02) 6285 2373 F (02) 6282 5438 E phaa@phaa.net.au W www.phaa.net.au