Public Health Association
AUSTRALIA

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

Compulsory Licensing of Patents Inquiry
Productivity Commission
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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.

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Summary of Key Issues

Compulsory licensing of patents: the Trans Pacific Partnership free trade agreement could introduce new impediments

PHAA believes that preserving and strengthening Australia's capacity to use compulsory licensing is critically important to ensuring equitable access to affordable medicines for all Australians into the future.

The Productivity Commission Issues Paper has commented on the constraints that international treaty obligations may present to the efficient and effective use of compulsory licensing in Australia. Australia is currently engaged in negotiations for the Trans Pacific Partnership Agreement (TPP), a large regional free trade agreement that presently involves 11 countries around the Pacific Rim, including the United States. The potential implications of the TPP for compulsory licensing in Australia need to be carefully examined.

The Office of the United States Trade Representative is pressing for extremely onerous intellectual property (IP) provisions in the TPP that not only go well beyond the obligations of the TRIPS Agreement, but also exceed 'TRIPs+' IP standards in other free trade agreements to date (1, 2). Negotiating documents are not publicly available. Leaked draft texts from 2011 (3), however, indicate that the US has tabled provisions that would, inter alia, extend the scope of patentability, extend the duration of patents and delay the entry of generic pharmaceuticals to the market (2, 4).

Another key IP provision the US is pursuing involves extending both the duration and scope of protection afforded to pharmaceutical test data at the time of regulatory approval (this is known as 'data protection'). During the period of data protection, data supporting safety or efficacy which has been submitted by the product's manufacturer to regulatory authorities (the Therapeutic Goods Administration in the case of Australia) cannot be relied upon by a generic manufacturer to obtain marketing approval for its product (5, 6).

Leaked documents (3) indicate that the US has sought to include at least five years of data protection for new pharmaceuticals, and an additional three years for new uses of existing products. The current regime in Australia provides for 5 years of protection for new products only; an attempt by the US in the Australia-US Free Trade Agreement to impose the additional 3 years of protection for new uses was not agreed to on the grounds that it would adversely affect access to generic medicines and increase costs to the Pharmaceutical Benefits Scheme.

Furthermore, the US draft provision would preclude the use of *any* data by a generic manufacturer during the period of protection , including data *already in the public domain* (referred to as data exclusivity), because it does not specifically refer to protection being applied only to undisclosed test data (in contrast with the Australia-US Free Trade Agreement which specifies that data protection only applies only to undisclosed data, see Article 17.10.1(a))(2, 6).

To date the leaked texts have also included a placeholder for a future data exclusivity provision applying to biologic drugs, and reports indicate that the US pharmaceutical industry is pressing hard for twelve years of data protection for these (7), a period which currently exceeds that provided for under US law.

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As noted above, Australian law already provides for five years of data protection for new pharmaceuticals, there is no provision for new uses of existing drugs, and no separate provision for therapeutic biologics.

A key issue is that data protection (and data exclusivity) constitute an absolute impediment to the effective use of compulsory licensing of medicines (5, 8, 9). Data protection regimes effectively create monopoly rights that are distinct from – and effective even where – a pharmaceutical product is no longer protected by a patent or when a compulsory license has been issued (8). The patent holders can prevent the marketing of generic equivalents by enforcing data exclusivity even when a compulsory license has been granted.

The current regime of data protection in Australia already precludes effective use of compulsory licensing. Agreeing to adopt the extended data exclusivity provisions sought by the US in the TPP would further prevent Australia from effectively using compulsory licensing to make treatments more available at affordable prices for the Australian Government and consumers.

Recommendations

- **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 use 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.**
- **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.**

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

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References

1. Flynn S, Kaminski M, Baker BK, Koo JH. Public Interest Analysis of the US TPP Proposal for an IP Chapter. Draft Version 1.2, November 14, 2011. Program on Information Justice and Intellectual Property, American University Washington College of Law; 2011. Available from: http://infojustice.org/tpp-analysis-november2011.
2. Lopert R, Gleeson D. The high price of "free" trade: US trade agreements and access to medicines. Journal of Law, Medicine and Ethics (In Press).
3. Trans Pacific Partnership. Intellectual Property Rights Chapter (Selected Provisions). September 2011. Available from: http://www.citizenstrade.org/ctc/wpcontent/uploads/2011/10/TransPacificIP1.pdf.
4. Gleeson DH, Tienhaara KS, Faunce TA. Challenges to Australia's national health policy from trade and investment agreements. MJA, 2012; 196(5): 354-6.
5. World Health Organization Regional Office for South-East Asia. Intellectual Property Rights and Access to Medicines: A South-East Asia Perspective on Global Issues. SEARO, WHO, 2008.
6. Kilic B, Maybarduk P. Comparative Analysis of the United States' TPPA Intellectual Property Proposal and Australian Law (updated March 2012). Washington D. C.: Public Citizen; 2011; Available from: http://www.citizen.org/Australia-TPPA-Chart.
7. Inside U.S. Trade. USTR signals support for longer data protection for biologics in TPP. Inside US Trade 05/27/2011.
8. Sell SK. TRIPS-Plus free trade agreements and access to medicines. Liverpool Law Review, 2007; 28: 41-75.
9. Reid Smith S. Introduction to intellectual property, trade and access to medicines. In: Asia Pacific Network of People Living with HIV/AIDS, editor. Our Health, Our Right: The Roles and Experiences of PLHIV Networks in Securing Access to Generic ARV Medicines in Asia: APN+; 2010.

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