Response to the Draft Report of the Pharmaceutical Patents Review conducted by IP Australia April 2013

The Australian Fair Trade and Investment Network (AFTINET)
The Public Health Association of Australia (PHAA)
The Australian Federation of AIDS Organisations (AFAO)
The Asia Pacific Network of People Living with HIV (APN+)
Palliative Care Australia

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Introduction

We commend the Pharmaceutical Patents Review Panel on the Draft Report and welcome the opportunity to make a second submission to the Review. Overall, we endorse the recommendations of the Draft Report, however we also suggest below some areas where the recommendations could be strengthened.

Information about our organisations is included in the Appendix.

International trade agreements and intellectual property

We commend the Review Panel on its recognition of the effects international agreements can have on lengthening patent monopolies, which are not in the public interest. We agree with Draft Finding 3.1 of the Draft Report (Australian Government, 2013) which states that “In their negotiation of international agreements, Australian Governments have lacked strategic intent, been too passive in their IP negotiations, and given insufficient attention to domestic IP interests.”

We endorse Draft Recommendations 3.1 and 3.2, particularly Draft Recommendation 3.2 which states:

“The Government should ensure that future trade negotiations and renegotiations are based on a sound and strategic economic understanding of the costs and benefits to Australia and the world and of the impacts of current and proposed IP provisions, both for Australia and other parties to the negotiations. The Government should strongly resist changes – such as retrospective extensions of patent rights – which are likely to reduce world economic welfare and lead other countries in opposing such measures.” (Australian Government, 2013).

As we outlined in our previous submission to the Review of Pharmaceutical Patents, the U.S. has put forward a set of proposals for extreme intellectual property and pharmaceutical provisions for the Trans Pacific Partnership Agreement (TPP) which go well beyond existing arrangements in the TPP countries and would significantly impede access to affordable medicines in Australia and the other TPP countries.

The Productivity Commission’s 2010 Review of Bilateral and Regional Trade Agreements recommended that the Australian Government should:

- ‘only pursue bilateral and regional trade agreements where they are likely to afford significant net economic benefits’ (Recommendation 1);
- ‘only include IP provisions ‘ in cases where a rigorous economic analysis shows that the provisions would likely generate overall net benefits for the agreement partners’ (Recommendation 4b);
- ‘Commission and publish an independent and transparent assessment of the final text of the agreement, at the conclusion of the negotiations, but before an agreement is signed’ (Recommendation 5c).

However, the Australian Government has made no commitment to undertake economic analysis of the TPP before the agreement is signed by Cabinet.
In the TPP negotiations to date, Australia’s position has been essentially a defensive position, where the starting point has been taken as no changes to existing intellectual property law and no provisions that would compromise the integrity of the Pharmaceutical Benefits Scheme or impede access to generic medicines within Australia. This position is consistent with the 2011 Trade Policy Statement (DFAT, 2011) and, if maintained throughout the negotiations, is likely to result in refusal to accept proposals that would add to the costs of the PBS (Gleeson, Tienhaara & Faunce, 2012). Internal DFAT briefing documents released under a Freedom of Information request by the Pirate Party in April 2013, while heavily redacted, suggest that this position is being maintained in the negotiations to date (DFAT, 2013).

However, our organisations have previously argued in letters to the Prime Minister and Trade Minister (AFAO, MSF, PHAA, Palliative Care Australia, APN+ and AFTINET, 2012a; 2012b) that Australia has an obligation to developing countries in our region to take a leadership role in opposing expansions to intellectual property rights that would impede access to affordable medicines and other health technologies.

The provisions proposed for the TPP by the United States are ‘TRIPS Plus’, that is, they provide much stronger intellectual property rights for pharmaceutical companies than the World Trade Organization’s TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement. They would prevent developing countries from using many of the flexibilities available to them under the TRIPS Agreement and the 2001 Doha Declaration on the TRIPS Agreement and Public Health, to ensure access to affordable medicines.

The leadership role we have argued for would be consistent with Australia’s commitments as a signatory to several international declarations. Clause 71 of the 2011 UN Political Declaration on HIV states that signatories will:

“Commit to remove before 2015, where feasible, obstacles that limit the capacity of low- and middle-income countries to provide affordable and effective HIV prevention and treatment products, diagnostics, medicines and commodities and other pharmaceutical products …”

The UN Political Declaration of the High-level Meeting on the Prevention and Control of Non-communicable Diseases also committed governments to increase “access to affordable, safe, effective and quality medicines and diagnostics and other technologies, including through the full use of trade-related aspects of intellectual property rights (TRIPS) flexibilities” (Clause 45p).

The 2009 Report of the UN Special Rapporteur on the Right to Health stated that “Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health.” The July 2012 Global Commission on HIV and the Law report ‘Risks, Rights & Health’ also made several strongly worded recommendations regarding the inclusion of TRIPS Plus provisions in trade agreements:

Recommendation 6.2: High income countries […] must immediately stop pressuring low- and middle-income countries to adopt or implement TRIPS-plus measures in trade agreements that impede access to life-saving treatment.
Rec 6.2.1 All countries must immediately adopt and observe a global moratorium on the inclusion of any intellectual property provisions in any international treaty that would limit the ability of countries to retain policy options to reduce the cost of HIV-related treatment.

Rec 6.2.2 High income countries must stop seeking to impose more stringent, TRIPS-plus intellectual property obligations on developing country government.

Developing countries are in a weaker bargaining position in the TPP negotiations due to the power imbalances that such trade negotiations involve (Gleeson & Friel, 2013). Internal briefing documents released under FOI show that DFAT is aware that developing countries have particular needs in terms of ensuring access to affordable medicines, however it is not clear how active a role the Australian Government is prepared to take in shaping the TPP negotiations to meet the need of developing countries.

The TPP has the potential to entrench a global intellectual property regime which is increasingly recognized as ineffective in stimulating real innovation (particularly R&D that meets the needs of developing countries) as well as ineffective in providing equitable access to medicines. We believe there is a strong case for the Australian Government to take a more strategic approach to reshaping the negotiations to actively meet the needs of developing countries. Australia should pay particular attention to the recommendations of the report of the World Health Organization’s Consultative Expert Working Group on Research and Development (2012) and consider how the TPP might preserve policy space for, or even actively contribute to, the development of new mechanisms to fund research and development which do not depend on monopoly rights.

**Proposals to reduce patent term extension periods**

We commend the Panel on its recognition of the costs of the current patent term extension arrangements in Australia. We are pleased that the Panel is in the process of estimating the savings that would accrue from reducing the extension of patent terms. These estimates should be publicly released.

We agree that there is no demonstrable link between extension of patent terms and investment in research and development. We support Draft Recommendation 5, Option 5.1 to reduce the patent term extension period and partly replace it with a direct subsidy to support Australian-based pharmaceutical R&D.

The proposal outlined in Option 5.1 is a better policy option compared with the alternative proposal outlined in Option 5.2. There is a general trend towards the expansion of intellectual property rights through bilateral and regional free trade agreements, particularly those in which the US is involved (Lopert & Gleeson, 2013). Aligning patent expiry dates in Australia with those of other competing countries may have short term benefits in terms of reducing patent monopoly periods and generating cost savings to the PBS, but these benefits may be short-lived if the current trend towards increasing IP rights through trade agreements continues. As the Panel notes at other points throughout the Draft Report, arrangements in Australia should not depend on those in other countries.
An even better policy option than both Option 5.1 and 5.2 would be to cease providing patent term extensions (PTE) altogether if the Review Panel’s estimates of savings indicate that it is in the national interest to do so. As we argued in our earlier submission, although AUSFTA Art 17.9.8 has been interpreted as creating an obligation to provide PTE, this is not the only possible interpretation of the text. The AUSFTA text states that PTE must be provided to compensate for delays in the marketing approval process, however since TGA decisions are subject to a statutory timeframe, there are essentially no delays in the marketing approval process in Australia.

**Patent term extension should not be allowed for methods of use and manufacture**

We agree that patent term extensions should not be allowed for methods of use and manufacture (Draft Recommendation 6.1) as this would add significantly to the costs of the PBS and affect access to affordable medicines. Patent term extension, if it is available at all, should also not be permitted for new formulations but only for new molecules, as it was originally intended.

**Evergreening and follow-on patents**

Serious concerns have been raised about the effectiveness of the Raising the Bar Act in preventing evergreening. Strengthening the inventive step threshold should be addressed urgently rather than waiting for a review of the Raising the Bar Act as suggested in Draft Recommendation 7.1.

The prescription shifting described by the Panel on p. 141 of the Draft Report results from the low inventive step threshold, which allows patents to be granted for minor and insignificant variations of drugs, as in the case of desvenlafaxine (which is the active metabolite of venlafaxine and has no improved efficacy or therapeutic outcome over venlafaxine). The solution to this problem is raising the inventive step threshold so that pharmaceuticals which are not truly innovative are not granted patents in the first place, rather than requiring PBAC to ‘have regard to the patent landscape surrounding a pharmaceutical, when forming its recommendation regarding acceptance into the PBS’ (page 141).

We suggest that the Panel examines closely section 3 (particularly s 3(d)) of India’s Patents Act 1970, including the amendments made in 2005. Section 3(d) sets stringent standards for patentability which are highly effective in preventing evergreening. For example, India’s Supreme Court recently upheld the Indian Government’s decision not to grant a patent for Glivec (imatinib mesylate) on the grounds that it is a modified form of an existing drug, which does not demonstrate enhanced efficacy (Lofgren, 2013). High patentability criteria for India have been the cornerstone to delivering affordable ARVs to the world, and that we are now seeing this extended to cancer drugs and other communicable and non-communicable diseases.

**Challenges to patent grants and validity**

We endorse Draft Recommendation 8.1 that “the Government take a more active role in managing the cost to the PBS where a patent relating to a PBS-listed pharmaceutical is successfully challenged in the courts”. We would also support the introduction of a mechanism that provides an incentive to
challenging patents, by “providing the challenger of a patent with a portion of the damages obtained by the Government from an undertaking by the patentee” (Draft Report, p. 158).

We are in favour of increased transparency and agree with the intent of Draft Recommendation 8.2 to introduce a transparent and publicly accessible database of patent information which generic companies can use to easily identify information about patents. Such a database or register should list all patents relevant to all pharmaceutical products, including patents relating to processes or methods of production. However, we have some concerns regarding the possibility that it may be seen as the responsibility of the regulator, the Therapeutic Goods Administration to collect and administer such information. Such a database should be the responsibility of IP Australia rather than the TGA. The TGA’s purpose is to ensure quality, safety and efficacy, and there should be a clear separation between administering the patent system and the marketing approval system.

We are strongly opposed to patent linkage provisions on the grounds that they can cause unacceptable delays to the market entry of generic medicines.

**Data protection**

We are pleased that the Panel has not recommended the extension of the current 5-year data protection period. However, serious consideration should be given to reducing the data protection period or removing it altogether.

We support the Panel’s view (Draft Finding 9.1) that there is no evidence to justify extending data protection for biologics.

We also wish to draw to the Panel’s attention an issue that the Public Health Association of Australia raised in its second submission to the Productivity Commission’s Inquiry into Compulsory Licensing of Patents in March 2013. 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.

Our submission to the Productivity Commission Inquiry recommended that to ensure that data protection will not prevent the effective use of both compulsory licensing and Crown use provisions, the Productivity 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. This issue should also be examined by the Pharmaceutical Patents Review.
References


AFAO, MSF, PHAA, Palliative Care Australia, APN+ and AFTINET (2012b) Trans Pacific Partnership Agreement (TPPA) and access to medicines in developing countries. Letter to the Hon. Dr Craig Emerson (Trade Minister), 17 July 2012.


Appendix: About Our Organisations

Australian Fair Trade and Investment Network (AFTINET)

The Australian Fair Trade and Investment Network (AFTINET) is a national network of 60 community organisations, including unions, public health, church, pensioner, environment, and other community organisations, and many more individuals, supporting fair regulation of trade, consistent with human rights, labour rights and environmental protection. AFTINET welcomes this opportunity to make a submission to the Pharmaceutical Patents Review.

AFTINET supports the development of trading relationships with all countries and recognises the need for regulation of trade through the negotiation of international rules. However trade negotiations take place behind closed doors, and are not subject to public and parliamentary discussion until after the text has been agreed and signed by Cabinet. Public policy issues like the regulation of patents and medicines, which are central to access to medicines and public health, should be decided through democratic processes of public and parliamentary debate, not through trade negotiations. AFTINET promotes these goals through community education, public events, media debate and dialogue with all levels of government.

The Public Health Association of Australia

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 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.

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.

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.

The Australian Federation of AIDS Organisations

The Australian Federation of AIDS Organisations (AFAO) is the national federation for the HIV community response. AFAO’s members are the AIDS Councils in each state and territory; the national association of people with HIV Australia (NAPWHA); the Australian Injecting & Illicit Drug Users League (AIVL); the Anwernekenhe Aboriginal and Torres StraitIslander HIV/AIDS Alliance (ANA); and Scarlet Alliance, Australian Sex Workers Association. AFAO also advocates to AusAID, other global HIV donors and governments and in the Asia Pacific region for resources and political will to fight HIV and to remove laws that enable HIV transmission by criminalising sex workers, gay men, people who inject drugs and people with HIV.

The Asia Pacific Network of People Living with HIV (APN+)

The Asia Pacific Network of People Living with HIV (APN+) with a membership from thirty countries represents the interests and advocates for the needs of all people living with HIV in Asia and the Pacific. In working to improve the lives of people living with HIV in the region APN+ in particular fights for affordable access to treatment for all those people living with HIV who need it and want it, and for their human rights to be upheld.

Palliative Care Australia

Palliative Care Australia (PCA) is the peak national organisation representing all state and territory palliative care organisations, the Australian and New Zealand Society of Palliative Medicine, and the interests and aspirations of all who share the ideal of quality care at the end of life.

Our vision is to achieve quality care at the end of life for all. PCA’s mission is to influence, foster and promote the delivery of quality care at the end of life for all. PCA advocates for equitable, needs based delivery of quality care at the end of life through promotion of the principles of palliative care; development of evidence and needs based service provision models; workforce capacity building; awareness and community capacity building; appropriate funding and resourcing.

Palliative care has been defined by the World Health Organization (WHO) as:
An approach that improves the quality of life of patients and their families facing the problems associated with life threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.