Submission to the Pharmaceutical Patents Review conducted by IP Australia January 2013

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

Contact Dr Patricia Ranald

campaign@aftinet.org.au

ph 0419 695 841

Submission to the Pharmaceutical Patents Review

Introduction

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 Strait Islander 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.

Summary of key issues

Our organisations agree with the point made in the *Pharmaceutical Patents Review Background and Suggested Issues Paper* that patents are a social contract between the inventor and government:

> The government grants an inventor an exclusive, temporary set of legal rights for an invention in exchange for the inventor sharing details of the invention with the public, thereby facilitating further innovation in that field (p.2).

Patent rights are private monopoly rights which need to be regulated judiciously to ensure that public policy goals such as access to affordable medicines are not impeded.

We also agree that medicines are public goods with positive externalities, subject to market failure (p.47) and that government intervention is required to ensure that medicines are affordable to all. The Australian Pharmaceutical Benefits Scheme is based on those principles. Regulation of patents for medicines must therefore ensure that there are limits to the scope and duration of monopoly rights in order to ensure that public health objectives are not impeded.

We note that the *Background and Suggested Issues Paper* recognises that medicine patent owners use a variety of strategies known as 'evergreening' to extend the duration of market monopolies (p.3).

The current system of pharmaceutical patents is unbalanced, and favours pharmaceutical companies which hold patents on medicines. These companies hold patents for the compounds that may ultimately be useful in medicines, and patents for the medicines that are ultimately developed. Through the use of evergreening strategies, they obtain additional patents over these medicines, creating patent 'thickets' and thereby extend patent protection around various aspects of these medicines (such as combination therapies; methods of treatment; new uses and indications; different formulations, e.g. tablets, capsules, liquids; extended release preparations; and dosage regimens). The ease with which pharmaceutical companies obtain these additional patents arises in part from the low inventive step threshold.

Australia's commitments under international trade agreements have also played a role in extending the monopoly rights of patent-holding pharmaceutical companies.

The WTO TRIPS agreement established 20 years as the standard patent period, which was a considerable increase on patent periods in many countries, especially for medicines. This has led to a vast increase in economic benefits for patent holders, at the expense of access to medicines and public health. There is no evidence to suggest that current patent periods are inadequate.

However, pharmaceutical companies are influencing governments to progressively extend their patent rights through bilateral and regional trade agreements, where negotiations are conducted without public scrutiny. Of particular concern are trade agreements involving the United States and the European Union, which have sought increasingly strong intellectual property rights for pharmaceutical companies in successive trade agreements (Sell, 2007, Krikorian and Szymkowiak, 2007).

The Australia-US Free Trade Agreement (AUSFTA) included much stronger intellectual property rights than TRIPS, by expanding the scope of patentability, limiting grounds for revocation of patents, restricting the use of compulsory licensing, reinforcing patent term extension provisions and existing prohibitions on parallel importation and imposing a form of patent linkage. While some of these provisions did not change existing arrangements in Australia (as they were already reflected in Australian law), their inclusion in a trade agreement had the effect of reducing future domestic policy flexibility to modify or remove them (Lopert and Gleeson, 2013).

The Productivity Commission's 2010 *Report on Bilateral and Regional Trade Agreements* concluded:

> 'The Commission is not convinced, however, that the approach adopted by Australia in relation to IP in trade agreements has always been in the best interests of either Australia or (most of) its trading partners. Among other things, there does not appear to have been any economic analysis of the specific provisions in AUSFTA undertaken prior to the finalisation of negotiations, nor incorporated in the government's supporting documentation to the parliament…Subsequent analysis by Commission staff found that the extension of rights to existing patents could result in a large net cost to Australia.
>
> (Productivity Commission, 2010: 263).

Australia is currently involved in negotiations for the Trans-Pacific Partnership Agreement (TPPA) with ten other countries from around the Pacific Rim (Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam). The Office of the United States Trade Representative is pressing for extremely onerous intellectual property (IP) provisions in the TPPA that not only go well beyond the obligations of the TRIPS Agreement, but also exceed 'TRIPS Plus' IP standards in other free trade agreements to date, including the AUSFTA (Lopert and Gleeson, 2013, Flynn *et al*, 2011). Negotiating documents are not publicly available. Leaked draft texts from 2011, 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 (Trans-Pacific Partnership, 2011, Lopert and Gleeson, 2013, Gleeson *et al*, 2012).

The Australian Government should not make commitments in trade agreements that 'lock in' or extend intellectual property rights for pharmaceuticals, thereby reducing domestic flexibility to determine the appropriate balance. We believe that these issues should be deliberated through domestic political processes after transparent public discussion, preparation and discussion of

legislation and democratic parliamentary processes. They should not be determined through confidential trade negotiations where trade-offs between different sectors can be made.

This submission is limited in scope because of limited time and resources. It is therefore confined primarily to addressing those issues which are relevant to current and future trade negotiations.

Responses to the review questions

Question 1:

Is the breadth of pharmaceutical patents eligible for an extension of term appropriate?

The *Pharmaceutical Patents Review Background and Suggested Issues Paper* (p. 4-5) notes that:

> Pharmaceutical extensions of term provisions were first introduced with the *Patents Act 1990* (Cth). Those original provisions were replaced by the current extension of term scheme, which commenced in 1998. The scheme was introduced in recognition that a patent owner is unable to commercially exploit a patent until regulatory approval from the Therapeutic Goods Administration (TGA) is given.
>
> The introduction of the extension of term provisions was estimated to result in an additional cost to the Pharmaceutical Benefits Scheme (PBS) of $6 million in 2001-02, increasing to $160 million in 2005-06, due to delays in the introduction of generic products.
>
> The intended breadth of the provisions is that extensions only be available for patents that include claims to pharmaceutical substances *per se*, but not for new forms of delivery systems or administration regimes.

In principle, we do not support the concept of patent term extension because they are an extension of monopoly rights and result in large costs to the public health system. There is no credible justification for broadening the scope or lengthening the duration of patent term extension.

The purpose of introducing patent term extension (PTE) is argued to be to compensate for delays between the discovery of the molecule and its commercialisation. PTE, if it is provided at all, should therefore only apply to patents disclosing the molecule.

One possible source of delay relates to the time from discovery of the molecule to collation of evidence sufficient to support a marketing approval application. The current PTE extension of five years for patents disclosing the molecule is more than sufficient to compensate for this.

Another potential source of delay is in the marketing approval process. But there is no evidence of any delays in the marketing approval process in Australia. The TGA is an efficient regulator and the statutory timeframe of 255 working days to a decision has only been missed once in the last ten years. The TGA loses 25% of the application fee if the timeframe is exceeded so there is a clear incentive to meet the deadline. Therefore any argument that PTE is needed to compensate for delays in the marketing approval process is entirely spurious.

The *Background and Suggested Issues Paper* states that 'Australia is obliged to retain a system of extensions for pharmaceutical patents under the Australia-United States Free Trade Agreement (AUSFTA).' (p. 4). But while the PTE provision in AUSFTA (Art.17.9.8) has generally 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 in Australia, as noted above, it can be argued that there are no delays in the marketing approval process because it is subject to a statutory timeframe. The Review of Pharmaceutical Patents should include a re-examination of this provision in AUSFTA with a view to re-interpreting its implications.

Leaked negotiating documents for the Trans-Pacific Partnership Agreement show that the United States Trade Representative is seeking for patent term extension to be extended to cover patents for methods of making and using pharmaceutical products (Trans-Pacific Partnership, 2011). This

provision would prevent Australia from acting against ever-greening. It is not in Australia's interests and should not be accepted in the TPPA.

Recommendations for Question 1:

1.1 Patent term extension should be restricted to patents disclosing new molecules. The breadth of pharmaceutical patents eligible for an extension of term should not be extended.

1.2 Patent terms should not be extended to compensate for delays in the marketing approval process as there is no evidence of such delays in Australia.

1.3 The Australian Government should oppose proposals in the Trans-Pacific Partnership Agreement (TPPA) negotiations to extend the scope of patent term extension to cover patents for methods of making and using pharmaceutical products.

Question 2:

Is the length of the extension of term provided for appropriate?

We have responded in part to this in our response to Question 1.

We do not support the concept of patent extensions because they are an extension of monopoly rights. PTE also results in increased costs to the public health system. The *Background and Suggested Issues Paper* notes that 621 patent term extensions have been granted during the period 1991-2012, with an average duration of three years and nine months. Given that patented medicines can be many times more expensive than generic alternatives, the cost of PTE is already a significant burden on the health budget. The Review process, in considering whether PTE of any length is appropriate in the Australian context, should include an economic analysis of the costs of the existing PTE scheme.

The contention that the effective life of pharmaceutical patents is too short to provide the necessary return on investment in new medicines is not supported by evidence. Given that patent term extensions result in delays in the introduction of generic products, with additional costs to the PBS, if there is to be patent term extension, it should be as limited as possible.

As noted above in our response to Question 1, there is no rationale for extending PTE in the Australian context because there is no evidence of delays in the marketing approval process.

Recommendations for Question 2:

2.1 Patent terms should not be extended.

2.2 Economic analysis should be undertaken to determine the costs of the current PTE regime.

2.3 The Australian Government should oppose proposals in the (TPPA) negotiations for expanding the scope and duration of patent term extension.

Question 3:

Are the recent amendments to increase the thresholds for the grant of an Australia patent appropriate in the context of pharmaceuticals? If not, why not and what further changes are necessary?

The thresholds for the grant of an Australian patent should be high in order to limit patent ever-greening and ensure that generics can enter the market in a timely way.

The *Background and Suggested Issues Paper* notes that inventions must satisfy a number of criteria including public disclosure, novelty and inventiveness usefulness (utility) (p. 15). The *Raising the Bar* Act was intended to improve patent standards by raising the threshold for disclosure and inventiveness. However, the threshold remains relatively low. Genuinely inventive patents can still be surrounded by many other more frivolous patents. Furthermore, the *Raising the Bar* Act did not address issues around the adequacy of the assessment of utility.

The current legislation still permits the creation of patent 'thickets' which can extend patent protection around various aspects of medicines which extend monopoly rights. These include combination therapies, methods of treatment, new uses and indications and different formulations e.g. tablets, capsules, liquids; extended release preparations; and dosage regimens. This can result in evergreening of patent protection for periods of up to 50 years.

Recommendation for Question 3:

3.1. The review should re-examine the thresholds for the grant of an Australian patent with a view to strengthening all of the criteria, and preventing the development of patent thickets and evergreening for medicine patents.

Question 4:

Do the systems for opposition and re-examination provide appropriate avenues for challenging the granting and validity of a pharmaceutical patent?

We support the process of public disclosure and pre-grant opposition, which enables public scrutiny of patent applications and a process to reduce spurious applications. Robust pre-grant opposition processes that enable third parties (such as researchers, NGOs, health services and generic companies) to oppose patent applications are vital in reducing the risk of substandard patents and preventing unwarranted patents from being granted (Public Citizen, *et al*, 20011).

The importance of protecting the ability to challenge patent applications before they are granted is demonstrated in the case of anti-retroviral drugs. For example, India's Patent Office rejected 2009 patent applications for the anti-retroviral drugs tenofovir and darunavir due to successful pre-grant opposition by two NGOs. A 2010 patent application for lopinavir/ritonavir was also rejected by the India Patent Office following opposition by three generic companies (Global Commission on HIV and the Law, 2011). This facilitated competition between manufacturers and allowed for much cheaper generic versions of the drugs to be produced.

We support the process of re-examination under the circumstances defined in the *Patents Act*. We support the expansion of the grounds for re-examination to all substantive grounds considered during initial examination.

The US has tabled draft text for the TPPA that would eliminate the process for pre-grant opposition. A comparison of the TPPA provisions with Australian law undertaken by Public Citizen's Global Access to Medicines Campaign concluded that:

> Pre-grant opposition in Australia improves patent quality with minimal interference to well-drafted patent applications. According to data provided by IP Australia, third parties oppose only about 1.5% of accepted applications. At the end of opposition proceedings, the patent office most commonly restricts the scope of the claims of the opposed patent.
>
> Thus, the pre-grant opposition system in Australia provides a relatively inexpensive mechanism for resolving disputes concerning patent validity. The absence of pre-grant opposition would make patent examination less informed and would be likely to increase the number of cases before the courts. Costs associated with the patent opposition system would likely rise. It would create market uncertainty for generics firms, and lead to low-quality patents and unjustified drug monopolies until post-grant challenges could reach a successful conclusion (Kilic and Maybarduk, 2012).

Recommendations for Question 4:

4.1 The process of public disclosure and pre-grant opposition should be retained.

4.2 The grounds for re-examination should include all substantive grounds considered during initial examination.

4.3 The Australian government should oppose proposals in the TPPA negotiations which would result in weakening or removal of pre-grant opposition or patent re-examination.

Question 5:

Do interlocutory injunctions, as the law is currently applied, provide appropriate relief in cases involving pharmaceuticals?

The *Pharmaceutical Patents Review Background and Suggested Issues Paper* (p. 20) notes that:

> Plaintiffs in infringement actions can seek an injunction at an interlocutory hearing to restrain the defendant's allegedly infringing activities until the matter is resolved by the courts.
>
> The plaintiff is often required, as a condition of the court granting an interlocutory injunction, to undertake to pay damages, which the court may order to be paid in the event that the plaintiff is unsuccessful at trial.

The discussion paper gives examples of interlocutory injunctions being obtained by pharmaceutical companies against claimed infringement of patents that the courts subsequently determined to be without foundation. Generic companies were prevented from entering the market, thereby suffering financial disadvantage and the plaintiffs were advantaged. This means that there is an incentive for an originator manufacturer to pursue an interlocutory injunction even where the basis of the claim of infringement is weak or non-existent. This incentive is strong because once an interlocutory injunction is granted, delays in the legal process mean it can be many months – sometimes several years – before the merits of the claim are adjudicated during which time the originator maintains its monopoly.

There is evidence that injunctions seem to be too readily available. An article written from the perspective of those who support the use of interlocutory injunctions cites many examples and boasts that Australia is "the ideal jurisdiction for innovator pharmaceutical companies seeking interlocutory injunctive relief to prevent the launch of competing generic products" (Tyake and Shelton-Agar, 2012).

There are also substantial savings foregone by Government because of delays in the listing of the generics on the Pharmaceutical Benefits Scheme. This is because the listing of the first generic version of a pharmaceutical on the PBS triggers an automatic reduction in the subsidy paid by the government for all versions of the product.

Given that the granting of an injunction can lead to both private losses to the generic company and large costs (savings foregone) to government, they should be granted judiciously only where there is evidence to suggest genuine infringement. The Review should include an analysis of how many interlocutory injunctions have been granted, how many have been shown to be unjustified and what the cost has been to the public health system, with a view to reducing those costs.

Recommendation for Question 5:

5.1 The current process for interlocutory injunctions makes them too readily available, and should be reviewed with a view to reducing delays in the marketing of generic medicines and reducing costs to the public health system.

Question 8:

Are follow-on patents being used to inappropriately extend protection for pharmaceuticals? If so, how? And, if they are, is this sound policy and what changes, if any, are needed?

The *Pharmaceutical Patents Review Background and Suggested Issues Paper* (p. 25-26) notes that:

> Follow-on, secondary or incremental patenting is the practice of patenting further variations and improvements to a patented invention. Australia and many other countries have long provided patents for new uses of known products and new methods of using known products, in accordance with international obligations.
>
> Follow-on patents do not prevent the original patent from expiring and generic versions of the original drug from entering the market. However, there are tactics for making market entry more difficult or less rewarding for the competitor.
>
> A potential form of 'evergreening' is where a patent portfolio is developed by a single company based on an original patented invention and surrounded by follow-on patents. When combined with particular marketing strategies, this can create a 'patent thicket' and hamper generic market entry.
>
> Large numbers of patents covering related inventions increase the costs for competitors to assess their freedom to operate and obtain any necessary licence agreements.

Follow-on or secondary patents can significantly delay the entry of generic drugs to the market. For example, a recent study in the US (Amin and Kesselheim, 2012) found a total of 108 patents associated with the HIV drugs ritonavir and lopinavir/ritonavir, which together were projected to delay generic market entry for at least 12 years beyond the expiry of the first patents and for 39 years beyond the date a patent application was first filed for the base compounds.

We oppose the use of follow-on patents that delay generic market entry and maintain monopoly pricing of medicines. Australian law should be amended to prevent abuse of follow-on patents.

We are opposed to the US proposal in the TPPA for the patenting of new forms of known products, which goes beyond existing Australian law, and encourages ever-greening.

Recommendations for Question 8:

8.1 Follow-on patents delay generic market entry and maintain monopoly pricing of medicines. Australian law should be amended to prevent abuse of follow-on patents.

8.2 The Australian government should oppose proposals in the TPPA negotiations which would result in the patenting of new forms of existing products.

Question 9:

Is the law on data exclusivity appropriate?

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 (Sell, 2007). Currently, Australian law provides five years of data protection for pharmaceutical test data *for new pharmaceutical products* at the time of regulatory approval. 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 (Kilic and Maybarduk, 2012, World Health Organisation, 2008).

The current data protection arrangements are adequate and TRIPS-compliant, and Australia has neither need nor obligation to extend them. In some respects these provisions are already more generous than for example, the US. In Australia data protection is afforded to any combination product in which one or more (but not all) components are new chemical entities. In the US all

components of a product must be new chemical entities (NCEs) for the initial period of 5 years of protection to apply.

A further issue is that data protection constitutes an impediment to the effective use of compulsory licensing of medicines (Sell, 2007, World Health Organisation, 2008, Reid Smith, 2010). A patent holder can prevent the marketing of generic equivalents by enforcing data protection even where a compulsory license has been granted.

The current regime of data protection in Australia already precludes effective use of compulsory licensing (although this has not yet been tested in court). Although compulsory licensing was recently reviewed by the Productivity Commission, and this issue was raised in submissions the report did not deal with this issue.

We oppose any extension of data protection, because it is both unnecessary and anti-competitive, and would delay the entry of more affordable generic drugs.

A key IP provision the US is pursuing in the TPPA involves extending both the duration and scope of data protection. Leaked documents 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 (Trans-Pacific Partnership, 2011). As mentioned above, the current regime in Australia provides for five years of protection for new products only; an attempt by the US in the Australia-US Free Trade Agreement to impose the additional three 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)) (Lopert and Gleeson, 2013, Kilic and Maybarduk, 2012).

Agreeing to adopt the extended data exclusivity provisions sought by the US in the TPPA would further prevent Australia from effectively using compulsory licensing to make treatments more available at affordable prices for the Australian Government and consumers.

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 them (Inside US Trade, 2011).

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

Recommendations for Question 9:

9.1 There should be no extension of data protection.

9.2 There should be a thorough review of the impact of current data protection provisions and their impact on compulsory licensing.

9.3 The Australian government should oppose all proposals for data protection in the TPPA negotiations, including five years of data exclusivity for new pharmaceutical products (which would entrench current arrangements in Australia), an additional three years for new uses of existing products, special provisions for biologic drugs and protection of data which is already in the public domain.

Question 10:

Are the laws on patent certificates appropriate?

The AUSFTA required Australia to introduce a form of patent linkage to prevent the marketing of a generic medicine while the originator is under patent. We are opposed in principle to patent linkage provisions, which can delay market entry of generics.

Patent linkage is not permitted in the EU and is an entirely US-centric phenomenon. Patent rights are private rights and if patent holders feel their rights are being infringed then they can seek redress through existing mechanisms.

Patent linkage is unnecessary and the current patent linkage system in Australia exposes employees of generics companies to criminal penalties if they make an error in a certificate. Unlike the US (where the patent linkage mechanism originated), searching for and identifying all relevant patents is not straightforward in Australia. Moreover, it is not appropriate for regulatory bodies such as the Therapeutic Goods Administration to enforce IP rights as they are irrelevant to the regulatory remit of assessing issues of safety, quality and efficacy.

As noted in the *Background and Suggested Issues Paper*, Australia's Therapeutic Goods Act also includes provisions to prevent 'linkage evergreening'. These provisions were introduced to the AUSFTA implementing legislation after extensive community debate. However, these provisions have not been effectively utilised to date. They should be retained and strengthened to ensure that they are more effective in preventing the inappropriate and vexatious use of interlocutory injunctions and patent litigation to delay the market entry of generic medicines.

The US proposal for patent linkage in the TPPA is far more burdensome than the existing system in Australia. If this proposal were accepted, regulatory authorities would have to actively scan for existing patents, notify patent holders, and delay granting marketing approval until any dispute is settled. This proposal should be opposed.

Recommendations for Question 10:

10.1 The system of patent linkage should be reviewed, as it is not appropriate for regulatory bodies such as the Therapeutic Goods Administration to enforce IP rights, and patent linkage can cause significant delays to market entry of generics.

10.2 The provision in Australia's Therapeutic Goods Act for preventing 'linkage evergreening' should be retained and strengthened.

10.3 The Australian government should oppose proposals in the TPPA negotiations which would result in a more burdensome patent linkage system.

Summary of Recommendations

Recommendations for Question 1:

1.1 Patent term extension should be restricted to patents disclosing new molecules. The breadth of pharmaceutical patents eligible for an extension of term should not be extended.

1.2 Patent terms should not be extended to compensate for delays in the marketing approval process as there is no evidence of such delays in Australia.

1.3 The Australian Government should oppose proposals in the Trans-Pacific Partnership Agreement (TPPA) negotiations to extend patent term extension to cover patents for methods of making and using pharmaceutical products

Recommendations for Question 2:

2.1 Patent terms should not be extended.

2.2 Economic analysis should be undertaken to determine the costs of the current PTE regime.

2.3 The Australian Government should oppose proposals in the (TPPA) negotiations for expanding the scope and duration of patent term extension.

Recommendation for Question 3:

3.1. The review should re-examine the thresholds for the grant of an Australian patent with a view to strengthening all of the criteria, and preventing the development of patent thickets and evergreening for medicine patents.

Recommendations for Question 4:

4.1 The process of public disclosure and pre-grant opposition should be retained.

4.2 The grounds for re-examination should include all substantive grounds considered during initial examination.

4.3 The Australian government should oppose proposals in the TPPA negotiations which would result in weakening or removal of pre-grant opposition or patent re-examination.

Recommendation for Question 5:

5.1 The current process for interlocutory injunctions makes them too readily available, and should be reviewed with a view to reducing delays in the marketing of generic medicines and reducing costs to the public health system.

Recommendations for Question 8:

8.1 Follow-on patents delay generic market entry and maintain monopoly pricing of medicines. Australian law should be amended to prevent abuse of follow-on patents.

8.2 The Australian government should oppose proposals in the TPPA negotiations which would result in the patenting of new forms of existing products.

Recommendations for Question 9:

9.1 There should be no extension of data protection.

9.2 There should be a review of the impact of current data protection provisions and their impact on compulsory licensing.

9.3 The Australian government should oppose all proposals for data exclusivity in the TPPA negotiations, including five years of data exclusivity for new pharmaceutical products (which would entrench current arrangements in Australia), an additional three years for new uses of existing products, special provisions for biologic drugs and protection of data which is already in the public domain.

Recommendations for Question 10:

10.1 The system of patent linkage should be reviewed, as it is not appropriate for regulatory bodies such as the Therapeutic Goods Administration to enforce IP rights, and patent linkage can cause significant delays to market entry of generics.

10.2 The provision in Australia's Therapeutic Goods Act for preventing 'linkage evergreening' should be retained and strengthened.

10.3 The Australian government should oppose proposals in the TPPA negotiations which would result in a more burdensome patent linkage system.

References

Amin T, Kesselheim, AS. (2012) "Secondary patenting of branded pharmaceuticals: A case study of how patents on two HIV drugs could be extended for decades". *Health Affairs*, 31(10):2286-2294.

Flynn S, Kaminski M, Baker BK, Koo JH. (2011) "Public Interest Analysis of the US TPP Proposal for an IP Chapter". Draft Version 1.2, November 14,,. Program on Information Justice and Intellectual Property, American University Washington College of Law; 2011. Available from: http://infojustice.org/tpp-analysis-november2011.

Gleeson DH, Tienhaara KS, Faunce TA. (2012) "Challenges to Australia's national health policy from trade and investment agreements". *Medical Journal of Australia*, 196(5): 354-6.

Global Commission on HIV and the Law. (2011) *Regional Issues Brief: Intellectual Property Rights and Access to Medicines for the Asia-Pacific Regional Dialogue of the Global Commission on HIV and the Law,* 17 February, Thailand.

Inside U.S. Trade. (2011) "USTR signals support for longer data protection for biologics in TPP". *Inside US Trade* 05/27/2011.

Kilic, B, Maybarduk P. (2012). *Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement. Comparative Analysis of the U.S. Intellectual Property Proposal and Australian Law.* Public Citizen. Available from: http://www.citizen.org/documents/Australia-TPPA-chart.pdf

Krikorian GP, Szymkowiak, DM. (2007) "Intellectual property rights in the making: The evolution of intellectual property provisions in US free trade agreements and access to medicines". *The Journal of World Intellectual Property*, 10(5):388-418.

Lopert R, Gleeson D (2013). "The high price of 'free' trade: US trade agreements and access to medicines". *Journal of Law, Medicine and Ethics* (In Press).

Productivity Commission (2010), *Bilateral and Regional Trade Agreements Final Report*, Productivity Commission, Canberra, December.

Public Citizen, Health Gap and Third World Network. "Risks of the Trans-Pacific Free Trade Agreement for Access to Medicines. Briefing Memo: Analysis of the Leaked U.S. Paper on Eliminating Patent Pre-Grant Opposition." (2011) Available from: http://www.citizen.org/documents/analysis-of-leaked-US-paper-on-eliminating-pregrant-opposition.pdf

Reid Smith S. (2010) "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+.

Sell SK. (2007) "TRIPS-Plus free trade agreements and access to medicines". *Liverpool Law Review,*; 28: 41-75.

Trans Pacific Partnership. Intellectual Property Rights Chapter (Selected Provisions). (2011). September Available from: http://www.citizenstrade.org/ctc/wpcontent/uploads/2011/10/TransPacificIP1.pdf.

Tyake N. and Shelton-Agar A. *(*2012) "The land down under of the patent interlocutory injunction". *DLA Piper Life Sciences Spotlight Issue 1,* found at http://www.dlapiper.com/files/Publication/0a8a088e-2d7e-49b8-8d92-170ef7dd621e/Presentation/PublicationAttachment/dec68599-1c4c-42c5-aa8d-28c0d7b1202e/life-sciences-spotlight-issue-1.pdf

World Health Organization Regional Office for South-East Asia. (2008) Intellectual Property Rights and Access to Medicines: *A South-East Asia Perspective on Global Issues*. SEARO, WHO.