SUBMISSION OF THE AUSTRALIAN GROUP OF THE INTERNATIONAL ASSOCIATION FOR THE PROTECTION OF INTELLECTUAL PROPERTY (AIPPI) TO THE PHARMACEUTICAL PATENTS REVIEW PANEL

21 January 2013

Introduction
This submission in relation to the Pharmaceutical Patents Review is made by the Australian national group of AIPPI (AIPPI Australia) in response to the Background and Suggested Issues Paper dated November 2012.

About AIPPI and AIPPI Australia
The International Association for the Protection of Intellectual Property, generally known by its French acronym AIPPI, is one of the world's leading international organisations dedicated to the development and improvement of the regimes for the protection of intellectual property.

Established in 1897, AIPPI is a politically neutral, non-profit organisation. It is domiciled in Switzerland and currently has almost 9000 members representing more than 100 countries. The members of AIPPI are people who are actively interested in intellectual property protection on a national or international level. They include lawyers, patent attorneys, trademark agents, judges, academics, scientists and engineers. The members of AIPPI are organised into national groups, with the Australian national group having approximately 90 members.

The objective of AIPPI is to improve and promote the protection of intellectual property on both an international and national basis. It pursues this objective by working for the development, expansion and improvement of international and regional treaties and agreements and also of national laws relating to intellectual property.

AIPPI operates by conducting studies of existing national laws and proposing measures to achieve harmonisation of these laws on an international basis. Proposals generally take the form of resolutions on particular topics that are debated and passed in plenary sessions by members at annual meetings. AIPPI has published over 700 resolutions, which are published in English, French and German and supplied to the World Intellectual Property Organisation, the World Trade Organisation and national and regional intellectual property offices around the world.

While this submission is consistent with the resolutions passed by AIPPI at an international level, it is made by the Australian national group of AIPPI, and not on behalf of the international organisation.

General comments
The Issues Paper states, on page 42, that an evaluation of the efficiency and effectiveness of the pharmaceutical patent extension of term provisions of the Patents Act 1990 (Cth) (Patents Act) will be central to the Review. The Review Panel's terms of reference, and the questions contained in
the Issues Paper, nonetheless encompass a much broader range of issues pertaining to pharmaceutical patents. The implicit premise on which the additional issues are put forward for consideration appears to be that generic competition and the cost to the Australian public of the Pharmaceutical Benefits Scheme may dictate that pharmaceutical patents be treated differently (and potentially less favourably) compared with other patents.

AIPPI Australia notes that only two months have been allowed for public submissions following the release of the Issues Paper on 21 November 2012, with Christmas and New Year falling within that period. Comparatively little time has therefore been allocated to public consultation. In light of the breadth of the range of issues encompassed by the Review, AIPPI Australia submits that any proposed legislative changes deriving from the Review should be subject to further consideration and public consultation, in particular where such changes may diminish existing rights.

Responses to questions stated by the Issues Paper

Question 1: Is the breadth of pharmaceutical patents eligible for an extension of term appropriate?

The current breadth of pharmaceutical patents eligible for an extension of term appears appropriate to meet Australia’s obligations under international agreements, including the Australia-United States Free Trade Agreement (AUSFTA) and World Trade Organisation agreements. It should be noted however, that the breadth of pharmaceutical patents eligible for an extension of term as defined by Section 70 of the Patents Act is inconsistent with the breadth of patents that are eligible for the current “springboarding” provisions provided by Section 119A of the Patents Act. When the patent term extension provisions were first introduced under the current form in 1998, the springboarding provisions were limited to patents that had been granted an extension of term (former Section 78(b) of the Patents Act). The springboarding provisions were amended in 2006 so that such provisions applied to all “pharmaceutical patents” (Section 119A of the Patents Act), regardless of whether they were extended or not.

Indeed, the springboarding provisions encompass “pharmaceutical patents” that may or may not be eligible for a patent term extension. For example, the springboarding provisions according to Section 119A would be inclusive of pharmaceutical patents that define methods or uses of particular pharmaceutical substances. This provides benefits for other parties such as generic pharmaceutical companies when seeking regulatory approval in Australia, over and above any rights they may have had when the current pharmaceutical extension of term provisions were first introduced. As a consequence, it also has the effect of diminishing the value of the patent gained by the innovator. In our view, the breadth of pharmaceutical patents that should be eligible for an extension of term should be extended to at least encompass those patents to which the springboarding provisions of Section 119A would apply, including patents directed to methods of medical treatment or pharmaceutical uses. In that regard, we note that in the US and European jurisdictions, extensions of term for patents for methods of treatment and/or pharmaceutical uses are available.
Question 2: Is the length of the extension of term provided for appropriate?

It should be kept in mind that the pharmaceutical patent term extension provisions were introduced with the aim to provide “fifteen years of effective patent life for pharmaceuticals”.¹ Under the current legislation any extension of term is capped at 5 years. As noted in the current Issues Paper, the average duration for extension appears to be around 3 years and 9 months. Data contained in the submission filed by IPTA² shows that only 53% of patents which were granted a patent term extension achieved 15 years of protection following the date of “first inclusion in the ARTG”.

Consideration should be given therefore to removing the cap of 5 years to ensure that a greater proportion of pharmaceutical patents will be eligible to achieve an effective patent term of 15 years. In order to obtain some balance, it is appreciated that a cap should be in place, however a more realistic cap would be a maximum extension of 8 to 10 years, so that at least there is some defined maximum term of the patent. It should be noted that under the Patents Act 1952 (Cth) it was possible to obtain extensions of up to 10 years based on “inadequate remuneration”.

Question 3: Are the recent amendments to increase the thresholds for the grant of an Australian patent appropriate in the context of pharmaceuticals? If not, why not and what further changes are necessary?

Noting that the higher thresholds for the grant of a patent introduced by the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Cth) (Raising the Bar Act) will not come into effect until April 2013, AIPPI Australia submits that an assessment of their appropriateness or otherwise, both in the pharmaceutical context and more generally, is premature.

Question 4: Do the systems for opposition and re-examination provide appropriate avenues for challenging the granting and validity of a pharmaceutical patent?

As noted on pages 17 through 19 of the Issues Paper, there are multiple mechanisms available to those wishing to challenge the granting or validity of a patent. In some cases, those mechanisms overlap, giving rise to uncertainty for patentees and patent applicants. Further, administrative inefficiencies and expense may arise where the same patent is the subject of simultaneous proceedings in different fora, for example where the patentee sues for infringement of its patent in a court and is met with a request for re-examination of the patent in the Australian Patent Office (the latter is usually stayed).

The potential for such inefficiencies to occur may increase once the amendments made by the Raising the Bar Act, which extend the grounds for re-examination to include all those on which revocation can be sought in a court, come into effect in April 2013.

While AIPPI Australia makes no comment in relation to the relative advantages and disadvantages of each of the mechanisms for challenging the granting or validity of a patent presently available,

² See Submission filed by IPTA.
AIPPI Australia submits that consideration should be given to a system of hierarchy of mechanisms that may reduce the uncertainties and inefficiencies outlined above.

**Question 5: Do interlocutory injunctions, as the law is currently applied, provide appropriate relief in cases involving pharmaceuticals?**

AIPPI Australia notes that in 2011, AIPPI passed Resolution 219 in relation to injunctions in intellectual property cases. Relevantly, by Resolution 219, AIPPI resolved that:

- the criteria to be considered for grant of preliminary injunction should include the following non-exhaustive criteria:
  - (a) a claim of infringement with a reasonable prospect of success on the merits;
  - (b) evidence that the claimed infringing conduct is imminent, ongoing or has already occurred;
  - (c) a reasonable prospect of establishing or defending the validity of the intellectual property rights in suit on the merits; and
  - (d) whether the balance of convenience and/or the concept of proportionality, which can include the risk of irreparable harm, favours the granting of the injunction; and

- the courts should be empowered to impose, as a condition of granting a preliminary injunction, that the claimant provide a bond, security or undertaking to compensate a defendant who has suffered loss by a grant of preliminary injunction which is not upheld on the merits.3

AIPPI Australia submits that Australian law is consistent with those principles. As the law is currently applied, interlocutory injunctions provide appropriate relief in cases involving pharmaceutical patents: ie interlocutory injunctive relief is:

- (a) available; and
- (b) where appropriate, ordered by our Courts,
in respect of allegations of both threatened and actual infringement with the effect of the relief being to maintain the status quo:
- (c) until at least the trial decision; and
- (d) potentially until the end of any appeal period(s); and/or
- (e) if and until final injunctive relief is ordered.

If the interlocutory injunction is found to have been wrongly made, the defendant is protected by being entitled to seek compensation. For this reason, the patent owner provides to the Court the "usual undertaking as to damages."4 In Australia, such undertaking extends to:

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4 Federal Court of Australia Practice Note CM 14:
The “usual undertaking as to damages” if given to the Court in relation to any interlocutory order made by it or any interlocutory undertaking given to it, is an undertaking:
"any person, whether or not a party, adversely affected by the operation of the interlocutory order."

However, as the example in the Issues Paper demonstrates, the claim for compensation under an undertaking as to damages is often a lengthy process and can involve multiple "affected" parties.

As we state in Question 10 (see below), the laws on patent certificates are not appropriate as they are not performing their intended function under the AUSFTA, Article 17.10.4. This has a potentially detrimental impact on the issue of delay because a patent owner who ultimately needs to apply for urgent interlocutory injunctive relief:

(a) does not receive adequate notification of a generics' application for an ARTG registration;
(b) under the Therapeutic Goods Act 1989 (Cth) (TGA), since the AUSFTA was implemented, had its own certification obligations; and
(c) has other statutory obligations which might be unfairly compounded by delay.5

As proposed below, AIPPI Australia recommends that a system be adopted that is closer to the US Abbreviated New Drug Application (ANDA) framework created by the Hatch-Waxman Act.

**Question 6: Is Australian law on contributory infringement appropriate in relation to pharmaceuticals?**

Section 117 of the Patents Act 1990 (Cth) provides for contributory infringement where a supplier supplies or offers to supply means for infringement. This gives rights to a patentee to seek remedies from a person who does not infringe the patent directly, but who supplies another with the means to do so.

AIPPI Australia notes that AIPPI has passed two resolutions relating to contributory infringement.

1. Resolution Q204 ('Liability for contributory infringement of IPRs') adopted in 2008 applies to contributory infringement of intellectual property rights generally.
2. Resolution Q204P ('Liability for contributory infringement of IPRs – certain aspects of patent infringement') adopted in 2010 is specific to patent infringement.

Relevant to this Review:

(a) Resolution Q204 resolved that the basic principles for contributory infringement should include that:

(b) to pay the compensation referred to in (a) to the person there referred to.

5 Federal Court Rules 2011: Part 8.02: Applicant's genuine steps statement

If Part 2 of the Civil Dispute Resolution Act applies to a proceeding, the applicant must, when filing the applicant's originating application, file the applicant's genuine steps statement, in accordance with Form 16.

The applicant's genuine steps statement must comply with section 6 of the Civil Dispute Resolution Act.
• the means supplied or offered by the contributory infringer relate to a substantial element of the subject matter of the protected intellectual property right;
• the means supplied or offered by the contributory infringer are for an infringing use;
• at the time of offering or supply, the suitability and intended use were known to the supplier or obvious under the circumstances.  

(b) Resolution Q204P resolved that:
• It should be a condition for the supply or offering of means to qualify as contributory patent infringement that the means supplied or offered are suitable for committing an act that is a direct patent infringement.
• It should be a condition for the supply or offering of means to qualify as contributory patent infringement that the person supplying or offering such means knows, or it is obvious in the circumstances, that these means are suitable and intended for putting the invention into effect.
• It should be a condition for the supply or offering of means to qualify as contributory infringement that such means relate to a substantial element of the invention; what is a substantial element should be determined on the basis of the ordinary principles of claim construction and patent interpretation.
• The term “substantial element of the invention” is not limited to those elements of the invention by which the invention distinguishes itself from the prior art. An element of a patent claim that contributes directly, through the function it performs in the claimed subject matter, to the result of the invention is a substantial element.
• To the extent that the means supplied or offered are staple commercial products, the supply or offering of such means does not constitute a contributory patent infringement except when the person supplying or offering such means induces the person supplied to commit infringement.

(a) Substantial element

Arguably, section 117 does not comply with Resolution Q204 or Q204P in that it does not require that the means supplied relate to ‘a substantial element’ of the invention. In the laws of other countries cited on page 23 of the Issues Paper, other than Canada, the concept of ‘a substantial element of the invention’ is encompassed in express language.  

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6 AIPPI, Resolution Q204, paragraph 3), see: https://www.aippi.org/download/committees/204/RS204English.pdf.
7 AIPPI, Resolution Q204P, paragraphs 2)-6) inclusive, see: https://www.aippi.org/download/committees/204P/RS204PEnglish.pdf.
8 The US test requires the means to be ‘a material part of the invention’; the UK test requires the means to relate to a core essential element that is not a subordinate part of the claim; the German test requires the means to be suited to cooperate functionally with one or more features of a patent claim to realise the invention; the Japanese test is whether the means is
While Resolution Q204P states that 'what is a substantial element should be determined on the basis of the ordinary principle of claim construction and patent interpretation', Australian case law in this area is scarce. It is assumed that the ordinary principles of claim construction will apply, such that all essential features of the claim must be taken, leading to the outcome that the means supplied would constitute at least one of those essential features. It might also be assumed that the purposive claim construction adopted by Australian courts suggests that there will be some consideration given to the functional aspects of the claim in cases of contributory infringement. However, legislative clarification would provide greater certainty.

(b) **Staple commercial product**

Section 117(2)(b) provides that a reference in section 117(1) to the use of a product is a reference to the use of the product if the supplier had reason to believe that the person would put it to that use in circumstances where the product is not a 'staple commercial product'.

The effect of section 117(2)(b) is that where the product supplied is a staple commercial product, liability for contributory infringement can only realistically arise in the circumstances contemplated by section 117(2)(c), ie use of the product in accordance with any instructions for the use of the product, or any inducement to use the product, given to the person by the supplier or contained in an advertisement published by or with the authority of the supplier. It is difficult to foresee any circumstances where a staple commercial product is capable of only one reasonable use, having regard to its nature or design (section 117(2)(a)).

Section 117 conforms to Resolution Q204P in the approach to staple commercial products, but neither Resolution Q204P nor section 117 clarifies the meaning of 'staple commercial product'. Notwithstanding detailed consideration of this term by the High Court in 2008, the precise meaning remains unsettled. While the High Court provided some guidance in deciding that the timber supplied under a licence by the Northern Territory was a 'staple commercial product', the approach of different members of the High Court was not entirely consistent.

As noted in footnote 32 in the Issues Paper, Crennan J (with Heydon J approving) stated that:

> The phrase "staple commercial product" means a product supplied commercially for various uses. …The relevant enquiry is into whether the supply of the product is commercial and whether the product has various uses.

Hayne J doubted that a product could be a staple commercial product if there was not some market for its sale for various uses. Applying a test which is arguably stricter than that adopted by Crennan and Heydon JJ, Hayne J defined 'staple commercial product' to mean 'an article of commerce that not only can be used in a variety of ways but is also traded for various uses' (emphasis added). Gummow ACJ and Kirby J defined the term to mean 'a product of the kind commonly available in trade or commerce and having more than one reasonable use'.

It can at least be said that the High Court generally adopted a liberal approach to the scope of the phrase. This is consistent with the approach in the US and the UK. While a lack of a consistent meaning may not be problematic when considering common commercial products such as sugar,

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*indispensable for the resolution of the problem by the invention*. Likewise, in Sweden and Denmark, the means must relate to an essential element of the invention.

flour and paper (or timber, as in the Collins case), application to pharmaceutical products is not as straightforward.

In Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (2011) 281 ALR 705, Jagot J found that Apotex's generic version of leflunomide was not a staple commercial product. The evidence in that case demonstrated that leflunomide could be used to treat psoriasis, psoriatic arthritis and rheumatoid arthritis. Arguably, generic leflunomide therefore fulfilled the Collins definition of 'staple commercial product' as articulated by at least some members of the High Court. Central to Jagot J's reasoning was that the 'product' in question was not leflunomide per se, but the specific formulation of Apotex's leflunomide with its particular dosage amount. Adopting the Hayne J approach, Jagot J stated that it could not be said that Apotex's generic leflunomide is a product that not only can be used in a variety of ways but is also traded for use in various ways.

The application of Jagot J's reasoning would seem to disqualify any pharmaceutical product from being considered a staple commercial product. More recently, in granting leave to appeal from the trial judge's findings in Generic Health Pty Ltd v Otsuka Pharmaceutical Co Ltd [2012] STA 412, Katzmann J nevertheless agreed with the trial judge that there was a 'prima facie case' that pharmaceutical products are not staple commercial products for the purposes of section 117(2)(b).

AIPPI Australia submits that the issue of whether a pharmaceutical product is a 'staple commercial product' should not be left to be determined by the evolution of case law. Clarity would better serve the interests of both originators and generic pharmaceutical companies. Accordingly, a legislative solution is desirable.

The equivalent concept in the United States is defined in statute as 'a staple article or commodity of commerce suitable for substantial noninfringing use'.10 In AIPPI Australia's view, it would be appropriate in Australia, and of assistance in determining whether a pharmaceutical product is a 'staple commercial product', for a similar definition to be adopted in Australian legislation.

**Question 7: Are the current timeframes in which infringement proceedings must commence appropriate for pharmaceutical patents?**

In AIPPI Australia's submission, the limitation periods that presently apply are appropriate. AIPPI Australia does not consider there is any reason why claims for infringement of pharmaceutical patents should be subject to any shorter or longer limitation periods than apply to claims for infringement of patents generally.

**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?**

In AIPPI Australia's submission, 'follow-on' patents are not being used to inappropriately extend protection for pharmaceuticals (or indeed for products in any other field of technology), and no changes are needed.

AIPPI Australia notes, as a matter of basic principle, that notwithstanding concerns expressed from time to time regarding 'follow-on' patents, such patents are not a separate class of patents, and are

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10 35 USC §271(c).
not treated any differently under the Patents Act. AIPPI Australia submits that is appropriate.

'Follow-on' patents are subject to the same validity requirements as any other patent, including as to novelty, and as to the increased inventive step standard that will shortly become effective under the Raising the Bar Act.

So-called 'evergreening' cannot occur unless the improvement is itself is patentable. If the improvement meets the criteria for patentability, a patent ought to be granted. AIPPI Australia submits that there is no policy reason why those who develop such improvements should be treated less favourably by the law.

As the Issues Paper notes on page 25, patentable improvements 'can have significant benefits for patients over the original drug'. The case study referred to on page 27 of the Issues Paper (Aktiebolaget Hässle v Alphapharm Pty Limited (2002) 212 CLR 411) is an example where the patentee successfully defended the validity of a patent for an improved formulation in the High Court, including on the ground of inventive step.

The Issues Paper states, on page 27, that '[o]ne technique is to switch consumers to a new, improved variation of the original drug before the original patent expires... [which] can effectively remove, or dramatically reduce' the market for a later generic version of the original. The Issues Paper states further that '[e]ven where the improvement is minor, brand familiarity can play a major role in consumers preferring the new variant of the familiar brand over an unfamiliar generic'.

First, whether or not an improvement is 'minor', in order to be patentable it must meet the requirements of the Patents Act. If it is not patentable, generic competitors are free to replicate it. If it is patentable, it is deserving of protection. Second, the award of a limited monopoly in return for the disclosure of an invention permits the patentee to obtain a return on its investment of time and effort to generate the invention. Having been granted that monopoly, the patentee is, and ought to be, entitled to exploit it for its duration. To the extent a patentee is able to develop reputation and goodwill in its brand during the monopoly period, that reflects an aspect of the benefit conferred on the patentee. In AIPPI Australia’s submission, any attempt to neuter that aspect would be unwarranted, and patent law would in any event be an imprecise tool with which to attempt to do so. Both of these considerations are equally applicable to patents in any field of technology, and not only to pharmaceutical patents.

To the extent a patent might once have served as a barrier to the development of improvements to the patented pharmaceutical by those other than the patentee (and its licensees), that barrier has been removed by changes under the Raising the Bar Act. As noted on pages 26 and 27 of the Issues Paper, those changes have introduced statutory exemptions for infringement for experimental use and for obtaining regulatory approval. The changes thus provide third party researchers with what AIPPI Australia submits is a sufficient footing on which to develop improvements to patented technology during the original monopoly period, and subsequently to bring those improvements to market. By doing so, they provide additional incentive for the patentee itself to continue innovating during the monopoly period.

Question 9: Is the law on data exclusivity appropriate?

The Therapeutic Goods Act 1989 (Cth) provides data exclusivity for products registered on the Australian Register of Therapeutic Goods (ARTG). The 5 year period starts from the marketing approval date. This prevents third parties from relying on the data for registration of their own
generic product and thus can delay entry of a generic medicine onto the ARTG and hence into the marketplace. As the Issues Paper recognises, data exclusivity issues rarely arise in isolation from the patent position and the patent position usually dictates delay of entry into the marketplace. While data exclusivity is an absolute bar for a certain period of time, once that period has expired, an aggressive generic may, notwithstanding patent protection, nonetheless seek ARTG registration. The comparison of data exclusivity periods in various jurisdictions as outlined on page 32 of the Issues Paper shows that Australia has a relatively short data exclusivity period. There is merit in increasing the data exclusivity period in Australia to be more closely aligned with periods available in other jurisdictions as it provides improved consistency for originators and generics operating in the field.

The Australian Government has taken the view that the standard of a granted patent should be increased by enacting the Raising the Bar Act. The changes to the legislation mean that it will be more difficult to obtain a patent and that correspondingly, the validity of granted patents will be less easily challenged. As this increased standard of invention and protection is considered important it makes sense to improve the other forms of protection available also. For this reason, the data exclusivity period should also be lengthened to ensure breadth and strength of protection for worthy inventions.

At present data exclusivity is only available for products that are registered on the ARTG. It is suggested that data exclusivity should also be available for listed medicines. The preparation of information for product listing takes time and incurs cost that should be rewarded by some degree of exclusivity. This is particularly so as listed products will not always be suited to patent protection.

In summary, AIPPI Australia takes the view that the data exclusivity period should be extended to be more closely aligned with other jurisdictions and that data exclusivity should be extended to listed products.

**Question 10: Are the laws on patent certificates appropriate?**

Broadly, the laws on patent certificates are not appropriate as:

(a) there is no meaningful notification to a patent owner of a generics' TGA request for registration of a patented product;

(b) a generic can make its own self-assessment of which certificate it needs to provide to the TGA (and thereby avoid giving notice),

and accordingly are of little practical value.

Our overall conclusion would be that Australia should adopt a system closer to the US ANDA framework, the following basic features of which provide fairness for patent owners and generics:

(a) patents covering registered drugs are listed in a US official publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations – known as the Orange Book (Orange Book). This Book therefore is a system of notification of patents claimed to cover new drugs;
(b) a so-called "Paragraph IV" certificate in which the generic certifies that any Orange Book patents covering its ANDA are either not infringed or are invalid. This certificate is served on the patent owner providing a system of notification following which:

(i) the patent owner has 45 days to issue infringement proceedings; and if so,
(ii) the US Food and Drug Administration stays the approval of the ANDA for 30 months to enable the litigation to be determined;

(c) if the generic is successful, it will enjoy a 180 day exclusivity period over subsequent generics.

This conclusion:

(a) requires further explanation based on the current implementation of AUSFTA, Article 17.10.4; and

(b) is based on the general acknowledgment in the Issues Paper that only a minority of certificates provided by generics state that the patent owner has been given notice.

(a) Notifications under the AUSFTA

AUSFTA, Article 17.10.4\(^\text{11}\) provides for the following generic certificate and the inclusion of a prevention measure (**Notification**): ie

(a) a generic requesting marketing approval to enter the market with a product (or an approved use of a product) during the term of a patent claiming the product (or approved use) shall **notify** the patentee of the request and the identity of any such other person (**Generic Certificate**) (ie not self-determining); and

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\(^{11}\) AUSFTA Article 17.10.4

4. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory:

(a) that Party shall provide measures in its marketing approval process to prevent those other persons from:

(i) marketing a product, where that product is claimed in a patent; or
(ii) marketing a product for an approved use, where that approved use is claimed in a patent,

during the term of that patent, unless by consent or acquiescence of the patent owner; and

(b) if the Party permits a third person to request marketing approval to enter the market with:

(i) a product during the term of a patent identified as claiming the product; or
(ii) a product for an approved use, during the term of a patent identified as claiming that approved use,

the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.
(b) the marketing approval process shall provide measures in its process to prevent generics from marketing a product, where that product (or approved use) is claimed in a patent (Marketing Prevention).

(b) Generics Certificates

The single Generic Certificate requirement was introduced into the TGA by section 26B as two Generic Certificates which operate in practice as shown in Table A below.\(^\text{12}\)

The Issues Paper itself identifies that only a minority of "Second" Certificates are ever provided. Therefore there is no real notification by any generic of its impending registration of a patented product (or approved use) if it "self-assesses" that a patent is "invalid" (generics generally take the view that "valid claim" does not include a claim that they assess to be potentially invalid).

In addition, there does not appear to be any positive obligations to do extensive searches for patents potentially covering a generics product. Often in practice, it is not until after a letter of demand is sent do the generics learn of the number of patents alleged to be infringed.

This means that very often the first time a patentee ever learns that a potentially infringing product is the subject of a marketing approval application is when the generic obtains an ARTG registration. Often this allows only a small window of opportunity to seek undertakings and as necessary obtain Court ordered interlocutory injunctions by establishing all of the necessary elements for an interlocutory injunction.

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\(^\text{12}\) The generics certificate provisions were introduced as section 26B of the TGA which require:

(a) "a certificate to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or

(b) a certificate to the effect that:

(i) a patent has been granted in relation to the therapeutic goods; and

(ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and

(iii) the applicant has given the patentee notice of the application for registration or listing of the therapeutic goods under section 23."

The penalty for giving a false certificate is 100 penalty units (currently $170,000.)
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<tr>
<th>Aware of originator patent</th>
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<tr>
<td>First Certificate</td>
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<tr>
<td>Don’t infringe and/or invalid</td>
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<tr>
<td>No notification required</td>
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<tr>
<td>Patentee certificate</td>
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<tr>
<td>If sued and interlocutory injunction granted, usual rules apply and Government compensation also potentially available</td>
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| Second Certificate        |
| Infringe (valid?)         |
| Notification required     |
| Patentee certificate      |
| If sued and interlocutory injunction granted, usual rules apply and Government and generic compensation also potentially available |

It is AIPPI Australia's view that the "dual" Generic Certificate options do not meet the purposes of the Notification period required under the AUSFTA. Currently, the penalty for providing a false certificate is $170,000 (although an offence, the amount is low compared to a breach of the Patentee's Certificate, as discussed below). The Issues Paper nominates that concerns have been raised about the severity of the penalties given the difficulty in conducting definitive patent searches. The Australian system would benefit from having a publication such as the "Orange Book" which would take away this apparent difficulty in conducting patent searches.

In addition, the Australian Government in implementing changes to the TGA did not adopt a "patent-linkage" system which would grant the patent owner an automatic stay, such as under the ANDA framework. Under AIPPI Australia’s recommended proposal, there is room for such a system to be improved which:

(a) while allowing an automatic stay upon infringement proceedings being issued;

(b) would provide a shortened period for the conduct of the patent litigation (and thus could also address the requirement under the Patentee Certificate of conducting the proceeding "without unreasonable delay").

(c) **Patentee Certificate**

In addition to the Generic Certification System (which is not meeting the notification requirements under the AUSFTA) the Government in implementing changes to the TGA based on the AUSFTA unilaterally introduced a certification process for patent owners\(^\text{13}\) (**Patentee's Certificate**). The Patentee's Certificate requires the owner to certify that any proceedings:

\(^{13}\) See section 26C(3) of the TGA (penalty $10M):

(3) The certificate required by this subsection is a certificate to the effect that the proceedings:
(a) are to be commenced in good faith;
(b) have reasonable prospects of success; and
(c) will be conducted without unreasonable delay.\(^4\)

The Issues Paper recognises that:

(a) the Patentee's Certificate is not similar to the Hatch-Waxman requirements in the US and is based on preventing "linkage evergreening" eg discouraging the commencement of vexatious litigation;
(b) the effectiveness of this provision has been "questioned"; and
(c) vigorous enforcement may "lead to US threats of trade retaliation and the instigation of a dispute under the AUSFTA or the WTO."

In addition, the maximum penalty is $10M for providing:

(a) a false or misleading certificate; or
(b) breaching an undertaking in the certificate.

This is particularly severe in circumstances where an unsuccessful patent owner will already be subject to potential claims under the Court ordered undertaking as to damages or any contractual claims to damages (such as under non-Court ordered undertakings).

(d) Conclusion

The current certificate system is not effective. It does not meet in any way a system close to the ANDA framework, in particular:

(a) the TGA amendments did not include a process to prevent generics from marketing a product, where that product (or approved use) is claimed in a patent as is provided by the ANDA 30 month stay;
(b) there is no meaningful notification obligation on a generic with no effective consequences for non-compliance; importantly, the equivalent in the US requires notification even if the generic believes its product or process is not infringing and/or the claims of the patent are invalid; and
(c) the obligations on a patent owner are onerous and not required under Article 17.10.4 of the AUSFTA.

Question 11: Are the laws on copyright of product information appropriate?

AIPPI Australia understands the issue raised by this question to be whether section 44BA of the Copyright Act 1968 (Cth) should be made retrospective. Since that section was enacted, however, there has been no flood of claims asserting infringement of copyright in product information

\(^{14}\) Certain further obligations under section 26D of the TGA are sometimes required if an application for an interlocutory injunction is claimed.
documents occurring prior to 28 May 2011, suggesting that any such amendment is unnecessary. In AIPPI Australia’s submission, there is no other reason why the section should be amended.