

Comparative Analysis of the United States' TPPA Intellectual Property Proposal and Australian Law
Public Citizen, August 29, 2011. Contact: pmaybarduk@citizen.org; bkilic@citizen.org. For more information, see www.citizen.org/access.



Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement:
**Comparative Analysis of the U.S. Intellectual Property Proposal and
Australian Law**

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Issue	US TPPA Proposal	Australia Patent Act 1990	Analysis
Third-Party Opposition	Article 8.7. (...) Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent.	Section 59 The Minister or any other person may, in accordance with the regulations, oppose the grant of a standard patent on one or more of the following grounds, but on no other ground: (a) that the nominated person is either: (i) not entitled to a grant of a patent for the invention; or (ii) entitled to a grant of a patent for the invention but only in conjunction with some other person; (b) that the invention is not a patentable invention; (c) that the specification filed in respect of the complete application does not comply with subsection 40(2) or (3). <i>Australian law provides for pre-grant opposition as well as post-grant challenges. Standing rules ensure that any person can formally challenge the</i>	Pre-grant opposition is a safeguard against patent abuse, improvidently granted patents and unwarranted pharmaceutical monopolies. Pre-grant opposition supports appropriate generic competition and access to medicines. The U.S. proposal would eliminate pre-grant opposition in TPPA countries. More information on the U.S. proposal on pre-grant opposition is available at citizen.org/access . ¹ Pre-grant opposition allows third parties to formally oppose a patent application by submitting information and analysis to patent examiners, under an adversarial administrative process. Pre-grant opposition helps improve patent quality and the accuracy of patent claims. This process helps to prevent pharmaceutical monopolies based on meritless patents that contribute little to innovation but greatly to price.

¹For further discussion of the U.S. strategy to eliminate patent pre-grant opposition, see Public Citizen, HealthGAP, I-MAK and Third World Network, "Analysis of the Leaked U.S. Paper on Eliminating Patent Pre-Grant Opposition," available at <http://www.citizen.org/documents/analysis-of-leaked-US-paper-on-eliminating-pregrant-opposition.pdf>.

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		<p><i>validity of a patent at each stage of the prosecution process.</i></p> <p><i>After the patent office accepts and publishes a patent application, any person may oppose that application within three months. The opposition can only be based on grounds mentioned in Section 59, e.g. lack of novelty or inventive step etc.</i></p> <p><i>A patent may be revoked after its grant. A third party may seek revocation of a patent independently (Section 138) or file as a counter-claim in infringement proceedings (Section 121).</i></p> <p><i>Re-examination provides another means by which third parties can challenge a patent. Re-examination can be requested on grounds of lack of novelty or inventive step (Section 97), although under the Intellectual Property Laws Amendment -Raising the Bar Bill 2011 (The Bill 2011) currently before Parliament, the admissible grounds for challenges would be broadened.</i></p>	<p>The pre-grant opposition system in Australia provides a relatively inexpensive mechanism for resolving disputes concerning patent validity. 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. Pre-grant opposition in Australia improves patent quality with minimal interference to well-drafted patent applications.²</p> <p>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.</p>
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² Australia recently considered whether to abolish its pre-grant opposition system and found that there was no evidence that the system was significantly problematic or subject to abuse. Australia has proposed various ways to streamline the process and make it yet more efficient and more effective. Compare to claims in the U.S. leaked paper, <http://www.citizen.org/documents/Leaked-US-TPPA-paper-on-eliminating-pre-grant-opposition.pdf>.

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<p><i>Protection of New Forms, Uses, or Methods of Using a Known Product</i></p>	<p>Article 8.1. The Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.</p>	<p><i>The Australian Patent Act defines invention as "a manner of manufacture" within the meaning of s.6 of the Statute of Monopolies' in Schedule 1 of the Patents Act. This statute, in turn, refers to "a manner of new manufacture." A patentable invention can be a product, method, system or process.</i></p> <p><i>This preliminary requirement precludes patentability of a new use of a known substance that takes advantage of a known property. Australian case law establishes that such cases do not meet the standards of patentable subject matter.</i></p> <p><i>A patentable invention is required to provide some material advantage in a field of economic endeavour and pertain to the useful arts rather than the fine arts. A new use of a known substance is patentable provided the use takes advantage of a previously unknown property.</i></p>	<p>Patents for new forms, uses, and methods of using known medicines can enable patent "evergreening," and particularly when enhanced efficacy is not required, can lead to unwarranted extensions of pharmaceutical monopolies.</p> <p>The AUSFTA provides that patents shall be available for any new uses or methods of using a known product (Article 17.9.1). This provision had limited effect. New uses and methods taking advantage of known properties do not always qualify as a 'new manner of manufacture.'</p> <p>But the U.S. TPPA proposal expressly requires patent eligibility for new forms -- e.g., a patent on a tablet -- and rejects any enhanced efficacy requirements. This could undermine limits set by Australia's new manner of manufacture test and gut standards of patentability in Australian law. Under the U.S. proposal, new patents can be granted for minor variations to pharmaceutical substances or methods related to their administration that contribute nothing to enhancing medical care -- e.g., changes in formulations, drug dosage regimes, drug</p>
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			delivery, and even packaging systems to aid in the administration of drugs (including their use in therapeutic treatments).
<i>Exclusions from Patentability</i>	<p>Article 8.2. Each Party shall make patents available for inventions for the following:</p> <p>(a) plants and animals, and</p> <p>(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals</p>	<p><i>The Patent Act does not specifically exclude methods of treatment from patentability. The weight of case law supports the patentability of methods of treatment. A new therapeutic effect of a known substance – referred to as second or subsequent use -- is generally eligible for patent protection.</i></p>	<p>The TRIPS Agreement allows countries to exclude methods of medical treatment from patentability. This is an important flexibility recognized by many countries, for moral and ethical reasons and to avoid hospitals and medical professionals paying royalties on the standard of care.</p> <p>In Australia, the patentability of methods of treatment has been hotly debated. Courts have indicated the legislature may exclude these inventions from patentability if it so chooses. If adopted, the U.S. TPPA proposal would tie the hands of the Australian legislature and eliminate a flexibility recognised by the TRIPS Agreement and the AUSFTA (Article 17.9.2).</p> <p>While the U.S. proposes to bind countries to this standard through the TPPA, it has omitted the essential safeguards and balancing features of its own law. While U.S. law authorizes patents for surgical methods, it also prevents medical practitioners from being sued for patent infringement in the course of medical</p>

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			<p>activity (35 USC 287 (c)). (Nevertheless, other groups including universities, medical education companies, and hospitals can be held liable for involuntary infringement.)</p> <p>The absence of such safeguards in Australian law raises concerns among medical practitioners and researchers. Adopting the U.S. proposal, without adopting the corresponding safeguards in U.S. law, opens up prospects for additional costs imposed on Australia's healthcare system. Hospitals might be required to obtain licenses for patented treatments that they offer, and doctors might be asked to pay royalties for the patented diagnostic, therapeutic and surgical methods they use.</p>
<p><i>Patent Term Adjustment (For Patent Prosecution Period)</i></p>	<p>Article 8.6. Placeholder Provision</p>	<p>Section 67. The term of a standard patent is 20 years from the date of the patent.</p> <p><i>Australia does not provide patent term adjustment for perceived delays in the patent prosecution period.</i></p>	<p>Patent term adjustments allow patent owners to push back the date of patent expiry. They delay market entry of competing generic drugs and thus restrict access to affordable medicines.</p> <p>The AUSFTA provides that if there are "unreasonable delays" in a Party's issuance of patents, that Party shall provide a means to adjust the term of the patent (Article 17.9.8.) –</p>

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			<p>meaning push the date of expiry further into the future. Australia maintains that its patent system does not unreasonably delay patent issuance.</p> <p>The U.S. could seek to introduce a new standard or provide a new forum through the TPPA for challenging Australia's position regarding perceived delays in patent prosecution.</p>
<p><i>Patent Term Extension (For Regulatory Review Period)</i></p>	<p>Article 9.4. Placeholder Provision</p>	<p>Section 70 (1) 1) The patentee of a standard patent may apply to the Commissioner for an extension of the term of the patent if the requirements set out in subsections (2), (3) and (4) are satisfied.</p> <p><i>The term of an Australian patent relating to a pharmaceutical substance per se may be extended up to five years beyond the standard patent term. This extension aims to compensate for perceived delays only in the context of drug regulatory approval, and not in patent prosecution.</i></p> <p><i>A pharmaceutical substance per se includes compounds, active metabolites, compositions, drug delivery systems etc.</i></p>	<p>Patent term extensions significantly delay market entry of generic drugs and restrict access to affordable medicines.</p> <p>Australian law currently allows extensions on patents for pharmaceutical substances <i>per se</i>. Courts have expanded the range of qualifying substances.</p> <p>The U.S.-KOREA free trade agreement (KORUS) expressly requires patent extensions for formulations, methods, and improvement patents. The U.S. might propose similar or additional terms in the TPPA, potentially expanding the number of medicines eligible for patent extensions, and/or tying extension</p>

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			standards, which Australian courts or the legislature could otherwise change, to a new international obligation.
<i>Protection of Test Data Submitted for Marketing Approval</i>	Article 9.2. Placeholder provision	<p><i>Australian law provides five years of data exclusivity to therapeutic goods containing new active components (Therapeutic Goods Act 1989, Section 25A).</i></p> <p><i>The law defines active component as a substance that is, or substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods. Data exclusivity is not provided for new dosage forms, routes of administration, indications or combinations with other active ingredients.</i></p>	<p>Data exclusivity prevents regulatory authorities from relying on established data regarding drug safety and efficacy to register generic medicines. Data exclusivity delays generic market entry and is inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals.</p> <p>Australian law limits data exclusivity for conventional pharmaceuticals to a maximum five years. The AUSFTA is arguably Australia law-plus, providing <i>at least</i> five years (Article 17.10.01). No maximum period is defined.</p> <p>The AUSFTA also grants at least three years additional data exclusivity for new uses or indications for an existing pharmaceutical product (Article 17. 10.2). But data exclusivity provisions in Australian law do not apply to such inventions. The U.S. might advance a new proposal in the TPPA designed to guarantee these additional years of data exclusivity for new uses or indications.</p>

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			The U.S. may also seek as many as twelve years exclusivity for biologics (biotech medicines). This would represent a major change to Australian law with potentially dramatic financial consequences.
<i>Patent Linkage</i>	Article 9.3. Placeholder Provision	Therapeutic Act 1989, Section 26B (1) (1) The certificate required under this subsection is either: (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	Under patent linkage, even spurious patent claims can serve as barriers to generic drug registration. Controversially, the AUSFTA introduced patent linkage in Australia. Australia sought to limit its effect through statutory measures imposing penalties for linkage evergreening. The United States Trade Representative attacked these safeguards, making specific reference to the interests of pharmaceutical patent owners. ⁴ This raises a serious concern that the United States may seek to limit or eliminate Australian safeguards against linkage evergreening in the TPPA.

⁴ USTR Robert Zoellick in a letter to Australian Trade Minister Mark Vaile, November 17, 2004.

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		<p>listing of the therapeutic goods under section 23.</p> <p><i>This requirement links drug regulatory approval to patent status. But Australian law also includes safeguards against 'linkage evergreening,'³ by which pharmaceutical companies seek to extend product monopolies. The safeguards, introduced in Section 26C and 26D, include a penalty for evergreening activities and a mechanism for damages to be paid to the government for proven evergreening practices.</i></p>	
<p>Judicial and Administrative Presumption of Patent Validity</p>	<p>Article 10.2. (---) In civil and administrative proceedings involving patents, each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that</p>	<p>Section 20. Nothing done under this Act or the PCT guarantees the granting of a patent, or that a patent is valid, in Australia or anywhere else.</p> <p><i>There is no presumption of patent validity in Australian law.</i></p> <p><i>In practice, Australian Courts tend to effectively re-examine a patent de novo when its validity is questioned, e.g. as a counterclaim in an</i></p>	<p>The U.S. TPPA proposed provision is AUSFTA-plus and would require significant changes to Australian law.</p> <p>The AUSFTA requires parties to provide a rebuttable presumption that a patent is valid in proceedings concerning the grant of provisional measures in relation to enforcement of a patent (Article 17.11.18).</p> <p>The U.S. TPPA proposal extends this</p>

³ See, Faunce T. & Lexcin C.: 'Linkage' pharmaceutical evergreening in Canada and Australia, Aust. New Zealand Health Policy. 2007; 4: 8.

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	<p>each claim of a patent is presumed valid independently of the validity of the other claims.</p>	<p><i>infringement proceeding.</i></p> <p><i>Historically, the Commissioner of Patents in opposition proceedings and in re-examination has revoked acceptance (in opposition) or revoked the patent (in re-examination) if the patent was clearly invalid. However, the Raising the Bar Bill proposes a change to this, requiring the Commissioner to determine whether the patent is valid on the balance of probabilities. In other words, the Raising the Bar bill would remove any effective presumption of validity that administrative proceedings in Australia may apply.</i></p>	<p>presumption to civil and administrative proceedings and requires each claim of a patent to be presumed valid independently of the validity of the other claims. When read in conjunction with eliminating pre-grant opposition and a likely provision on patent linkage, this provision threatens the integrity of the Australian patent system and overrides current reform proposals designed to improve the quality of patents. The judicial and administrative presumption of patent validity gives rise to costly and one-sided court procedures, and makes it harder to challenge unwarranted patents.</p> <p>This presumption was only introduced into the U.S. Patents Act in 1952. Since then there has been overwhelming evidence that patent quality is not high enough to justify the continuation of this presumption under U.S. patent law.</p>
<p>Compensation of Damages for IP Infringement</p>	<p>Article 12.3. Each party shall provide that</p> <p>b) in determining damages for</p>	<p>Section 122</p> <p>(1) The relief which a court may grant for infringement of a patent includes an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the</p>	<p>Unless a strong side letter is included or other understanding reached, the U.S. TPPA proposal is AUSFTA-plus, and would require amending Australian law.</p>

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	<p>infringement of intellectual property rights, its judicial authorities shall consider, <i>inter alia</i>, the value of the infringed good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder</p>	<p>plaintiff, either damages or an account of profits.</p> <p><i>IP damages in Australia are intended to be compensatory. The remedies include either damages or an account of profit made by the infringing activity. An Australian court can order additional damages, which serve a punitive purpose, depending on the flagrancy of the infringement and the need for deterrence (Section 122(1A)).</i></p> <p><i>In cases of innocent infringement, the infringer may avoid the need to pay damages or account for the profits made (Section 123).</i></p>	<p>A provision in the AUSFTA requires the Parties' courts to consider submissions made by a right holder on the value of the infringed good or service, including the suggested retail price (Article 17.11.6).</p> <p>Nevertheless, side Letter 2 of the AUSFTA permits Australia to maintain its current provisions on calculation of damages. Currently, a court is not required to consider such a submission, but has discretion to do so.</p> <p>The U.S. TPPA proposal could eliminate this discretion.</p> <p>Additionally, the language in the U.S. TPPA proposal may communicate a stronger preference for the use of retail price, rather than other measures of value submitted by rights holders, when compared to the AUSFTA. Damages calculated based on retail price strongly favour the interests of rights holders. A suggested retail price is a hypothetical price; generally greater than the damage suffered by the right holder. Further, suggested retail prices submitted by a right holder may turn out to be inflated or otherwise inaccurate and higher than actual retail prices. This would lead to an</p>
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			<p>unrealistic determination of damages, which would empower rights holders in court settlements and discourage defendants from litigating cases where there is uncertainty.</p> <p>Australian courts can better balance the competing interests in infringement suits by maintaining the compensatory approach to damages, filtering claims and continuing to determine appropriate calculations for damages case-by-case.</p>
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