Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement:

Comparative Analysis of the U.S. Intellectual Property Proposal and Australian Law[1]

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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). *Australian law provides for pre-grant opposition as well as post-grant challenges. Standing rules ensure that any person can formally challenge the validity of a patent at each stage of the prosecution process.* *After the patent office accepts and publishes*	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 counties. More information on the U.S. proposal on pre-grant opposition is available at citizen.org/access.[4] 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. Pre-grant opposition in Australia improves patent quality with minimal interference to well-drafted patent applications.[5] According to data provided by IP Australia, third parties oppose only about 1.5% of accepted

[3] The September US text is *available at*: http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf, The February US text is *available at*: http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf

[4] For 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.

[5] 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 leaked U.S. paper, http://www.citizen.org/documents/Leaked-US-TPPA-paper-on-eliminating-pre-grant-opposition.pdf.

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		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. *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).* *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). However, under the Intellectual Property Laws Amendment -Raising the Bar Bill 2011 (The Bill 2011) which is currently before Parliament, the admissible grounds for challenges would be broadened.*	applications. At the end of opposition proceedings, the patent office most commonly restricts the scope of the claims of the opposed patent.[6] 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.
Protection of New Forms, Uses, or Methods of Using a Known Product	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	*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.*	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. The AUSFTA provides that patents shall be available for any new uses or methods of using a known product

[6] Australia Law Reform Commission Report on Gene Patenting and Human Health, Challenging and Enforcing Patents, IP Australia, Submission P56, 4 November 2003, http://www.alrc.gov.au/publications/9-challenging-and-enforcing-patent-rights/challenges-patent-rights

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	invention does not result in the enhancement of the known efficacy of that product.	*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.* *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*.	(Article 17.9.1). This provision has had limited effect. New uses and methods taking advantage of known properties do not always qualify as a 'new manner of manufacture.' The U.S. TPPA proposal, however, 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 delivery, and even packaging systems to aid in the administration of drugs (including their use in therapeutic treatments).
Exclusions from Patentability	Article 8.2. Each Party shall make patents available for inventions for the following: (a) plants and animals, and (b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals	*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.*	TRIPS 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. 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). While the U.S. proposes to bind countries to this standard through the TPPA, it has omitted the essential

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			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 activity (35 USC 287 (c)). (Nevertheless, other groups including universities, medical education companies, and hospitals can be held liable for involuntary infringement.) 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.
'Bolar'-type Exemption	Article 8.5. Consistent with paragraph [4] (patent exceptions and limitations), each Party shall permit third persons to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product in that Party, and shall further provide that any product produced under such authority shall not be made, used, or sold in its territory other than for purposes related to generating such information to support an	Section 119A The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for: (a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that: (i) are intended for therapeutic use; and (ii) are not medical devices, or therapeutic devices, as (b) defined in the Therapeutic Goods Act 1989; or purposes connected with obtaining similar regulatory approval under a law of a	Bolar-type exemptions support non-commercial research uses of patented inventions and help facilitate immediate entry of products into the market following patent expiration. The AUSFTA provides an exemption allowing generics companies to use patented products solely for purposes of obtaining marketing approval. The exemption does not expressly name medical devices (Article 17.9.6). The exemption in the U.S. TPPA proposal is narrow as well. Indeed, the Bolar exemption in U.S. law is broader than the U.S. proposal to the TPPA. The scope of the exemption in U.S. law covers not only pharmaceutical products but also medical devices. (*Eli Lilly and Co. v. Medtronic, Inc., 872 F.2d 402*).

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	application for meeting marketing approval requirements of that Party. If the Party permits exportation of such a product, the Party shall provide that the product shall only be exported outside its territory for purposes of generating information to support an application for meeting marketing approval requirements of that Party.	foreign country or of a part of a foreign country. *The exemption applies for pharmaceutical patents (which claim a pharmaceutical substance or a method, use or product relating to a pharmaceutical substance) and provides that a pharmaceutical patent is not infringed by exploitation of an invention for the purposes of obtaining regulatory approval in Australia or abroad. However, the exemption is only applicable to goods that are intended for therapeutic use, not medical or therapeutic devices. This exemption is limited in scope; it only permits springboarding on pharmaceutical patents. It has no application in other areas of technology.* *The Bill 2011 recognizes that technologies other than pharmaceuticals may also suffer delays in bringing products to market and expands the existing exemption for pharmaceutical inventions to all technologies.*	This stands in contrast to recent improvements in Australian law. The Patent Bill 2011 includes a broader technology-neutral exemption to facilitate regulatory approval.
Patent Term Adjustment (For Patent Prosecution Period)	Article 8.6. (b) Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in the granting of the patent. For purposes of this subparagraph, an unreasonable delay at least shall include a delay in the issuance of	Section 67. The term of a standard patent is 20 years from the date of the patent. *Australia does not provide patent term adjustment for perceived delays in the patent prosecution period.*	Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. The AUSFTA provides that if there are "unreasonable delays" in a Party's issuance of patents, that Party shall provide the means to adjust the term of the patent (Article 17.9.8.) – meaning push the date of expiry further into the future. Australia maintains that its patent system does not

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	the patent of more than four years from the date of filing of the application in the territory of the Party, or two years after a request for examination of the application has been made, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays.		unreasonably delay patent issuance. The US TPPA proposal challenges Australia's position. It would require Australia to change its law and unconditionally extend patent terms whenever four years pass from the date of filing without a final decision on the patent, or when two years pass after an examination request. It would introduce patent term adjustment for longer patent prosecution periods in Australia for the first time. It would change the deal struck in the AUSFTA.
Patent Term Adjustment (For Regulatory Review Period)	Article 8.6 (c) Each Party, at the request of the patent owner, shall make available an adjustment of the patent term of a patent which covers a new pharmaceutical product or a patent that covers a method of making or using a pharmaceutical product, to compensate that patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process. (d) In implementing subparagraph 6(c), a Party may: i. limit the applicability of subparagraph 6(c) to a single patent term adjustment for each new pharmaceutical product that is being reviewed for marketing approval; ii. require the basis for the adjustment to be the first	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. *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.* *A pharmaceutical substance per se includes compounds, active metabolites, compositions, drug delivery systems etc.*	Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. The TPPA requires that Parties make patent term extensions available for perceived delays in the regulatory approval process. Australian law currently allows extensions on patents for pharmaceutical substances per se. Courts have expanded the range of qualifying substances. The U.S. TPPA proposal introduces patent term adjustments not only for patents covering new pharmaceutical products but also for patents that cover methods of making or using pharmaceutical products (this should be read in conjunction with Article 8.1, which makes patent protection available for new uses, methods and forms of known products). Article 6 provides some flexibility for determining limitations on the period of patent term extensions. These limitations are similar to, though not entirely the same as; those found in the U.S. Patent Act, i.e., a party might limit extensions to one per pharmaceutical product.

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	marketing approval granted to the new pharmaceutical product in that Party; and iii. limit the period of the adjustment to no more than 5 years.		The US TPPA proposal would lead to more patent extensions and would restrict the ability of the Australian legislature to establish appropriate criteria for extensions.
Protection of Test Data Submitted for Marketing Approval	Article 9.2. If a Party requires or permits, as a condition for granting marketing approval for a new pharmaceutical product, the submission of information concerning the safety or efficacy of the product, the origination of which involves a considerable effort, the Party shall not, without the consent of a person previously submitting such safety or efficacy information to obtain marketing approval in the territory of the Party, authorize a third person to market a same or similar product based on: the safety or efficacy information previously submitted in support of the marketing approval; or evidence of the existence of the marketing approval, for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party. …	*Australian law provides five years of protection to therapeutic goods containing new active components (Therapeutic Goods Act 1989, Section 25A).* *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.*	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. Australian law prevents competitors from relying on undisclosed test information to register conventional pharmaceuticals for a maximum five years. Generics producers are free to use disclosed information and available literature. The AUSFTA is arguably Australia law-plus, providing at least five years (Article 17.10.01). The leaked U.S. TPPA proposal requires data exclusivity for new pharmaceutical products. This provision provides "at least" five years of data exclusivity for safety and efficacy information submitted in support of marketing approval, even if it is disclosed and in the public domain. Its scope is considerably broader than the AUSFTA or Australian law, which only protect undisclosed information. The AUSFTA also grants at least three years of additional data exclusivity for new uses or indications for an existing pharmaceutical product (Article 17.10.2). In a last minute political compromise, the AUSFTA allowed Australia and the U.S. to maintain their respective

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	(c) If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of the pharmaceutical product containing the previously approved chemical entity, other than information related to bioequivalency, the Party shall not, without the consent of a person previously submitting such new clinical information to obtain marketing approval in the territory of the Party, authorize a third person to market a same or a similar product based on: 1. the new clinical information previously submitted in support of the marketing approval; or 2. evidence of the existence of the marketing approval that was based on the new clinical information, for at least three years from the date of marketing approval based on the new clinical information in the territory of the		regimes for protection of test data in cases of new uses or indications. The United States insisted on a provision for at least three years of additional data exclusivity protection for submission of new clinical information (Article 17.10.2). But footnote 19 made this provision optional, allowing Australia to maintain its own system of protection which only applies to new active components, and not to submission of new clinical information. The U.S. advances a new proposal in the TPPA designed to guarantee these additional years of data exclusivity for new uses or indications in TPPA countries including Australia. The September 2011 text also introduces "at least three years" additional data exclusivity for submission of new clinical information on new uses or indications for existing pharmaceutical products- again, a very broad scope. The U.S. may 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.

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Patent Linkage	Article 9.5. Where a Party requires or permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence concerning safety or efficacy information for a product that was previously approved, such as evidence of prior marketing approval in another territory, each Party shall: (a) provide a transparent and effective system to: (i) identify a patent or patents covering an approved pharmaceutical product or its approved method of use; and (ii) provide notice to a patent holder of the identity of another person who intends to market, during the term of the identified patent or patents, a product that is the same as, or	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 listing of the therapeutic goods under section 23. *This requirement links drug regulatory approval to patent status—a patent must be determined invalid or expired prior to market approval of a generic drug. But Australian law also includes safeguards against 'linkage evergreening,'[7] by which pharmaceutical companies seek to extend product*	Under patent linkage, even spurious patent claims can serve as barriers to generic drug registration. Controversially, the AUSFTA introduced patent linkage in Australia. The AUSFTA requires Australia to create a procedure whereby patent holders are informed of generics seeking marketing approval, and approval is prevented wherever a competing product is claimed in a patent. Consequently, Australia introduced a system where applicants for marketing approval are required to certify that their product would not infringe a valid patent claim, or that the patent holder has been notified of the application. Australia sought to limit patent holder abuse of the linkage system through statutory measures imposing penalties for vexatious patent litigation. The United States Trade Representative attacked these putative safeguards, making specific reference to the interests of pharmaceutical patent owners.[8] The U.S. TPPA proposal goes further and requires countries to provide a mechanism to identify patents covering an approved pharmaceutical product or its approved method of use. The U.S. draft is more detailed and places an administrative burden on the Australia Therapeutic Goods Administration (TGA). The U.S. proposal introduces a notification system for patent holders, an automatic stay of marketing approval and

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

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

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	similar to, the approved pharmaceutical product referenced in subparagraph 5(a)(i). (b) unless such other person agrees to defer the marketing of the product until after the expiration of an identified patent, ensure that a patent holder may seek, prior to granting of marketing approval to an allegedly infringing product, available remedies by providing: (i) an automatic delay of the grant of marketing approval that remains in place for a period of time designed to ensure sufficient opportunity to adjudicate disputes concerning the validity or infringement of allegedly infringed patents; and (ii) judicial or administrative procedures, including effective provisional measures, to allow for the timely adjudication of disputes concerning the validity or infringement of an allegedly infringed patent. (c) if such other person's product has been found to infringe a valid patent identified	*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.*	measures to block allegedly infringing products for the duration of the patent. It is not clear from the wording of the provision under what conditions a product would be considered "similar to" an approved pharmaceutical product and trigger an obligation to notify a patent holder. This provision could facilitate patent holder harassment of potential competitors. The US seeks to limit or eliminate Australian safeguards against linkage evergreening in the TPPA by introducing remedies for patent holders. These remedies include automatic delay of the grant of marketing approval, as well as judicial or administrative procedures, including effective provisional measures. It is not entirely clear how the U.S. proposal will affect Australia's anti-evergreening measures.

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	pursuant to subparagraph (a), provide measures that operate to prohibit the unauthorized marketing of that product prior to the expiration of the patent. when a Party delays the grant of marketing approval consistent with subparagraph 5(b)(i), provide an effective reward, consistent with the provisions of this Agreement, for the successful challenge of the validity or applicability of the patent.		
Judicial and Administrative Presumption of Patent Validity	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 each claim of a patent is presumed valid independently of the validity of the other claims.	Section 20. Nothing done under this Act or the Patent Cooperation Treaty guarantees the granting of a patent, or that a patent is valid, in Australia or anywhere else. *There is no presumption of patent validity in Australian law.* *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 infringement proceeding.* *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.*	The U.S. TPPA proposed provision is AUSFTA-plus and would require significant changes to Australian law. 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). The U.S. TPPA proposal extends this 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

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		However, Bill 2011 proposes a change to this, requiring the Commissioner to determine whether the patent is valid on the balance of probabilities. In other words, the Bill 2011 would remove any effective presumption of validity that administrative proceedings in Australia may apply.	makes it harder to challenge unwarranted patents. 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.
Compensation of Damages for IP Infringement	Article 12.3. Each party shall provide that b) in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, *inter alia*, 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	Section 122 (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 plaintiff, either damages or an account of profits. *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)).* *In cases of innocent infringement, the infringer may avoid the need to pay damages or account for the profits made (Section 123).*	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. 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). 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. The U.S. TPPA proposal could eliminate this discretion. 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

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			holder may turn out to be inflated or otherwise inaccurate and higher than actual retail prices. This would lead to an unrealistic determination of damages, which would empower rights holders in court settlements and discourage defendants from litigating cases where there is uncertainty. 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.