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

Comparative Analysis of the U.S. Intellectual Property Proposal and Chilean Law

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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 invention does not result in the enhancement of the known efficacy of that product.	Article 37. The following shall not be considered an invention and shall be excluded from the patent protection provided by this Law: (e) The new use, change of form, change of dimensions, change of proportions or change of materials of goods, objects or elements already known and employed for determined purposes. However, the new use of goods, objects or elements can be an invention that can be protected, if said new use solves a technical problem which did not have previously an equivalent solution, and complies with the requirements referred to in Article 32 and it further requires changes in dimensions, proportions or materials of the Article, object or known element to obtain said solution to such technical problem. The claimed new use will have to be proven by means of experimental evidence in the patent application.	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 U.S.-Chile FTA does not require parties to grant patents for new uses, forms, or methods of using of known products. The U.S. TPPA proposal, however, expressly requires patent protection for any new forms, uses or methods of using known products. This undermines the Chilean default rule against new use patents and tests for new use patentability. Under the U.S. proposal, new patents can be granted for minor variations to pharmaceutical substances or methods related to their administration that may not enhance medical care – e.g., changes in formulations, drug dosage regimes, drug delivery, and even packaging systems to aid in the administration of drugs (including

[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] Official Spanish text *available at*: http://www.wipo.int/wipolex/en/text.jsp?file_id=175347. This table lists an unofficial English translation available from the Alessandri Law firm, *at*: www.alessandrilaw.com/legislation/Law-PI-19039.pdf. Please refer to the official Spanish text for clarification.

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		A new use is not an invention per se and Chile's default rule excludes new uses from patentability. But new uses for known products can be patented when they solve a technical problem with no prior equivalent solution and otherwise satisfy patentability requirements. One test may be whether the new use results in a synergistic or remarkable effect.	their use in therapeutic treatments). When read in conjunction with Article 8.2, eliminating exclusions from patentability (as discussed further below), pharmaceutical companies could freely file patent applications for new uses, new methods of preparation and methods of use or treatment, without being subject to any restriction.
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	Article 37. The following will not be considered inventions and will thus be excluded from patent protection: … d) Methods for surgical or therapeutic treatment of the human or animal body, as well as diagnostics methods applied to the human and animal body, except the products destined to put in practice one of these methods. *Chilean law excludes diagnostic, surgical and therapeutic methods for treatment from patent protection. Such methods are not considered inventions. Nevertheless, products that put these methods to use can be subject to patent protection, i.e. surgical, therapeutic or diagnostic instruments or apparatus.*	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 from paying royalties on the standard of care. The U.S.-Chile FTA does not address Chile's right to implement exceptions to patentability for diagnostic, therapeutic and surgical methods. Chilean law expressly excludes surgical, therapeutic and diagnostic methods from patent protection. As explained above, U.S. proposed Article 8.1 provides patent protection for new uses and method claims. Article 8.2 makes methods of treatment for the human (or animal) body patent eligible subject matter. When read together, these two Articles, in effect, lengthen patent protection for older pharmaceuticals, by facilitating

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			patents for methods of treatment and minor variations on known products. The new fields of health technology, e.g. biotechnology and genetic science, make extensive use of method claims in their patent applications. Such methods and procedures are usually carried out on the human (or animal) body or are somehow related to treatment of the human (or animal) body. The expansion of patent protection to diagnostic, therapeutic and surgical methods for the treatment of human beings (and animals) guarantees availability of patent protection for higher life forms and human biological materials. 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 activity (35 USC 287 (c)). (Nevertheless, other groups including universities, medical education companies, and hospitals can be held liable for involuntary infringement.)

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Industrial Application v. Utility	Article 8.12. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.	Article 32. Patents shall be obtained for any inventions, whether products or processes, in all fields of technology, provided that they are novel, have an inventive step and are susceptible of industrial application.[5] Article 36. An invention will be considered to be of industrial application if according to its nature it can be, in principle, produced or used in any type of industry. For these purposes, the term industry will be understood in its broadest sense, including activities such as manufacturing, mining, construction, handicrafts, agriculture, forestry and fishing. *The term industry refers to the practice of any activity that pertains to the applied arts as opposed to the fine arts. An invention should be susceptible of production or use in any industry, must provide a technical solution and as such its contributions as well as the characteristics that describe and differentiate it must be technical.*	This provision aims to impose the US patentability test of specific, substantial and credible utility. This is broad enough to cover inventions without true industrial application. Accordingly, any invention that has a practical application and that produces useful and specific results satisfies utility requirements. This standard enhances the patentability of research tools, such as combinatorial chemistry libraries, cell lines and methods. Industrial application requirements could no longer be asserted as a patent bar against such types of inventions (*as discussed above; compare and read in conjunction with articles 8.1 and 8.2*). This enhanced patentability of research tools could create new barriers to entry for future pharmaceutical research and development.

[5] The unofficial translation by Alessandri law firm read as follows: "Article 32. Patents shall be obtained for any inventions, whether products or procedures, in all fields of technology, provided that they have novelty, inventive level and can be of industrial application."

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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 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.	Article 53 Bis 1. Within six months after the granting of a patent, its holder will be entitled to request a term for Supplementary Protection, as long as there has been an unjustified administrative delay in the granting of the patent and the term for the granting was of over five years from the date of the filing of the application or of three years from the requirement for examination, whichever occurs after. Supplementary protection will only extend for the period proved as unjustified administrative delay. *Patent term extensions were introduced to Chilean law as part of the U.S. FTA implementation process. In case of an "unreasonable" administrative delay in the granting of a patent, Chilean law provides for an extension of the patent term. An unreasonable delay is defined as five years from the date of filing the application or three years after a request for examination of the application has been made, whichever is later. Nevertheless, delays arising from patent opposition or any other judicial remedy or action, periods attributable to national or international entities or agencies for reports or procedures to register patents, and periods attributable to actions of the*	Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. The U.S.-Chile FTA provides patent term extensions for perceived "unreasonable" delays that occur during patent prosecution (Article 17.9.6.) Unreasonable delay is defined as the later of five years from the date of filing or three years after an examination request. The U.S. TPPA proposal introduces a U.S.-Chile FTA-plus standard. The U.S. proposal defines unreasonable delay as the later of four years from the date of filing or two years after an examination request. The TPPA proposal would change the deal struck in the U.S.-Chile FTA and require Chile to change its law and 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. The scope of actions excluded is considerably narrower in the U.S. TPPA proposal than in Chilean law, excluding only periods attributable to actions of the patent applicant.

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		patent owner are not included in the determination of such delays.	
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 marketing approval granted to the new pharmaceutical product in that Party; and	Article 53 Bis 2. Within six months after the granting of a sanitary registration of a pharmaceutical product protected by a patent, its holder will be entitled to request a term for Supplementary Protection for that part of the patent containing the pharmaceutical product, as long as there has been an unjustified administrative delay in the granting of said registration. Supplementary protection may be requested by those holders which sanitary authorization or registration has been granted after a year from the date of the filing of the application. Supplementary protection will only extend for the period proved as unjustified administrative delay by the administrative organ called to decide said registration. *Chilean law provides patent term extensions to compensate the patent owner for perceived delays during the marketing approval process. The extensions apply to patents covering pharmaceutical products. The law does not specify the circumstances that qualify as unjustified delay. However, it explicitly excludes delays arising from opposition or any other judicial remedy or*	Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. The U.S. TPPA proposal would change Chilean law and lead to more patent extensions. The U.S.-Chile FTA introduced patent term extensions to compensate the patent owner for unreasonable curtailment of the patent term as result of the marketing approval process. The U.S. TPPA proposal introduces patent term extensions 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 8.6 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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	iii. limit the period of the adjustment to no more than 5 years.	*action, periods attributable to national or international entities or agencies for reports or procedures to register patents and periods attributable to actions of patent owners.*	
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.	Article 5. Any interested party can file before the Department a notice of opposition to an application for a trademark, patent of invention, utility model, and industrial design, lay-out design or topography of integrated circuits, geographical indication or appellation of origin. The notice of opposition must be filed within 30 days from the date of publication. The above mentioned period will be of 45 days for applications of patents of invention, utility models, and industrial designs, layout-designs or topography of integrated circuits, geographical indications or appellations of origin. *Chilean law provides for pre-grant opposition. Any interested party may oppose the patent application within 45 days of publication in the Official Gazette.*	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.[6] 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. The absence of pre-grant opposition would make patent examination less informed and could increase the number of cases before the courts. Costs associated with the patent opposition system would likely rise. It

[6] 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.

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		The US- Chile Agreement does not include a provision on patent opposition.	would create market uncertainty for generics firms, and contribute to problems of low-quality patents and unjustified drug monopolies until post-grant challenges could reach a successful conclusion.
Protection of Test Data Submitted for Marketing Approval	Article 9.2. (a) 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: (i) the safety or efficacy	*Chilean law provides five years of protection for undisclosed information pertaining to pharmaceutical products which utilize a new chemical entity that has not been previously approved by the competent authority (Article 89). The law defines 'new chemical entity' as an active ingredient, that is, a substance which has one or more pharmacological effect. Data exclusivity is not provided for new therapeutic uses or indications, new dosage forms, methods of administration, forms, formulations or combinations of chemical substances, salts, complexes or crystalline forms (Article 90).* *Article 91 provides several exceptions to the acquisition and maintenance of exclusive rights. These exceptions include circumstances where the owner of the test data has engaged in conduct deemed*	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. The U.S.-Chile FTA provides at least five years exclusive protection to undisclosed data concerning the safety and efficacy of a pharmaceutical product which utilizes a new chemical entity (Article 17.10.01). Footnote 25[7] of the U.S.-Chile FTA allows parties to maintain their respective systems for protection of test data in cases of new uses or indications (Chile does not provide data exclusivity in such cases). USTR continues to complain about Chile's implementation of and exceptions to data exclusivity. The leaked U.S. TPPA proposal requires data exclusivity

[7] U.S.-Chile FTA FN25: Where a Party, on the date of its implementation of the TRIPS Agreement, had in place a system for protecting pharmaceutical or agricultural chemical products not involving new chemical entities from unfair commercial use which conferred a period of protection shorter than that specified in paragraph 1, that Party may retain such system notwithstanding the obligations of paragraph 1.

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	information previously submitted in support of the marketing approval; or (II) 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. … (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	*contrary to free competition, where the pharmaceutical product has not been marketed in Chilean territory within twelve months of the registration or health authorization issued in Chile, or the application is filed in Chile twelve months or more after the same product was first registered or authorized abroad. Other reasons include public health, national security, public non-commercial use, national emergency, or other circumstance of extreme urgency, and compulsory licencing.*	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 U.S.-Chile FTA and Chilean law, which only protect undisclosed information regarding pharmaceutical products utilizing new chemical entities. The U.S. TPPA proposal would introduce data exclusivity for new uses or indications in TPPA countries including Chile. The U.S. September 2011 text would provide for "at least three years" additional data exclusivity for submission of new clinical information on new uses or indications for existing pharmaceutical products. The U.S. may also seek data exclusivity for biologics (biotech medicines). This would represent a major change to Chilean law with potentially dramatic financial consequences.

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	obtain marketing approval in the territory of the Party, authorize a third person to market a same or a similar product based on: (i) the new clinical information previously submitted in support of the marketing approval; or (ii) 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 Party.		

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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	*Resolution 5572 (2004) states that the Institute of Public Health shall publish applications for marketing approval (sanitary permit for a pharmaceutical product) on its website and indicate whether the application corresponds to a new product or a "similar" product (and to which previously registered product it is "similar"). Companies may request to receive the Institute's updates to this list by email. Patent holders can screen these registration applications and, on their own initiative, pursue legal measures including injunctions under Chilean law to block registration.*	Under patent linkage, even spurious patent claims can serve as barriers to generic drug registration. The TPP is U.S.-Chile FTA-plus and would require substantial changes to Chilean law. The U.S.-Chile FTA requires Parties to make the identities of registration applicants available to patent holders. Parties shall not grant marketing approval prior to expiration of the patent term, unless by "consent or acquiescence" of the patent holder (Article 17.10.2(b,c)). Black's Law Dictionary defines "acquiescence" as "tacit or passive acceptance; implied consent to an act … failure to make any objections … binding legal effect is given to silence and inaction." Under the Chilean resolution, patent holders have an opportunity to pursue injunctions and block generic marketing approval after receiving information from the Institute of Public Health regarding "similar" registration applications (which includes the identities of applicants). Logically, if a patent holder does not make use of this opportunity, he or she can be said to have acquiesced to marketing approval. USTR and the Pharmaceutical Research and Manufacturers of America (PhRMA) complain about a lack of patent "linkage" in Chile. But notably, Chilean law seems compliant with the provisions of the U.S.-Chile FTA.

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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		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. proposal is more detailed, would require changes to Chilean law and place an administrative burden on the Chilean Institute of Public Health. It would require a notification system for patent holders, an automatic stay of marketing approval and measures to block allegedly infringing products for the duration of the patent. These provisions risk patent abuse and improvident pharmaceutical monopolies. It is not clear from the wording of the TPPA provision under what conditions a product would be considered "similar to" an approved pharmaceutical product and trigger an obligation to notify a patent holder – or whether "similar" would have the same definition under the TPPA as in Chilean law. This provision could facilitate patent holder harassment of potential competitors.

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	validity or infringement of an allegedly infringed patent. (c) if such other person's product has been found to infringe a valid patent identified 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.		

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'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 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.	Article 49. The patent shall not confer the right to prevent third parties from importing, exporting, manufacturing or producing the subject matter protected by a patent for the purpose of obtaining the registration or health authorization for a pharmaceutical product. The above shall not entitle those products to be marketed without the authorization of the patent owner. *Article 49 provides an exemption for a third party to import, export, and manufacture or produce the subject matter protected by a patent to exploit the invention for the purposes of obtaining a registration or health authorization for a pharmaceutical product. The exemption is limited in scope; it only applies to pharmaceutical products. It has no application in other areas of technology*.	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 U.S.-Chile FTA provides an exemption allowing generics companies to use patented products solely for purposes of obtaining marketing approval or a sanitary permit. The exemption does not expressly name medical devices (Article 17.9.4). The exemption in the U.S. TPPA proposal is narrow as well, failing to expressly name medical devices. 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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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.	*There is no explicit judicial or administrative presumption of patent validity in Chilean law.*	The TPPA requires signatory countries to provide for a rebuttable presumption that a patent and each of its claims are independently valid in civil and administrative proceedings. 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. 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	Article 108. Damages may be determined, at the plaintiff's choice, according to the general rules or according to one of the following rules: a) The profits that the holder would have cease to earn as a consequence of the infringement; b) The profits that the infringer would have earned as a consequence of the violation; or c) The price that the infringer would have paid to the holder of the right for the granting of a license, taking into account the	The US-Chile FTA provides that judicial authorities shall consider, *inter alia*, the legitimate retail value of the infringed goods (Article 17.11.8). Chilean law requires judges to weigh evidence according to rules of sound judgment while determining damages (Article 111). The definition of sound judgment may be interpreted as sufficiently broad to cover legitimate retail value. When compared to the US-Chile FTA, the language in the U.S. TPPA proposal communicates a stronger preference for the use of retail price, and requires the consideration of value as submitted by the right holder.

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		commercial value of the infringed right and contractual licenses that have already been granted. Article 111. The judge shall appreciate evidence in these cases according to rules of sound judgement. *Article 108 establishes three alternatives for determining damages from which the right holder can choose. These remedies include either loss of profits, an account of profits made by the infringing activity, and the fee that the infringer would have paid to the right holder for a license. While calculating the licensing fee, the Court considers the commercial value of the infringed right and contractual licenses that have already been granted. Chilean Law requires the judge to weigh evidence according to rules of sound judgment while determining damages (Article 111).*	Damages calculated based on suggested retail price strongly favour the interests of rights holders. A suggested retail price is a hypothetical price; generally greater than the damages 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 unrealistic determination of damages, which would empower rights holders in court settlements and discourage defendants from litigating cases where there is uncertainty. Chilean 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.