



Dangers for Medicine Prices and Local Innovation in the Trans-Pacific Partnership Agreement (TPP): Comparative Analysis of the United States' Intellectual Property Proposal and Japanese Law

Dr. Burcu Kılıç, Mi Kyoeng Kim & Peter Maybarduk
Global Access to Medicines Program
July 2013¹

¹Recommended citation: Kılıç B., Kim M& Maybarduk P.: *Comparative Analysis of the United States' TPP Intellectual Property Proposal and the Japanese Law*, Public Citizen, July , 2013. Available at: www.citizen.org/access.

Windows User 7/17/13 9:22 AM

Deleted:

Windows User 7/16/13 5:30 PM

Deleted: the

Windows User 7/17/13 9:44 AM

Deleted:

Windows User 7/17/13 9:22 AM

Deleted:

	The US TPP IP Chapter Proposal ²	Japanese Patent Act (Act No. 121 of 1959)	Analysis
Industrial Application v. Utility	Art 8.12. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.	<p>Article 29.1. An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention</p> <p><i>Industrial application is a statutory requirement in Japanese law. The term 'industry' includes manufacturing industries, agricultural, fishing and forestry industries, mining industries, commercial industries, and service industries. Being subject to certain limitations, however, the term excludes medical industries –please see below.</i></p>	<p>The TPP provision aims to impose the US test of specific, substantial and credible utility, which is broader than the Japanese standard and broad enough to cover inventions without true industrial application or technical character.</p> <p>Accordingly, any invention that has a practical application and that produces useful and specific results satisfies utility requirements. This standard facilitates the enhanced patentability of medical treatment claims. Industrial application requirements could no longer be asserted as a patent bar against the patentability of such treatments (as discussed below: compare and read in conjunction with articles 8.1 and 8.2). The patentability of medical treatment claims could create new barriers to entry for future pharmaceutical research and development.</p> <p>In the US, the utility test is linked to the written description and enablement</p>

Windows User 7/17/13 1:26 PM

Deleted: , however,

² The September 2011 US-proposed IP Chapter text is available at: <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>, The February 2011 US text is available at: <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>.

	The US TPP IP Chapter Proposal ²	Japanese Patent Act (Act No. 121 of 1959)	Analysis
			<p>requirement. The patent applicant is expected to demonstrate utility in the patent application. The disclosure of the invention should instruct those who read the patent how to use and make the invention and the best mode of practising it.</p> <p>In the Japanese patent regime, best mode disclosure is not a statutory requirement affecting the grant or validity of a patent. However, the Examination Guidelines for Patents requires a patent applicant to describe the best mode of carrying out the invention as a formality.</p>
<p>Protection of New Forms, Uses, or Methods of Using Known Products</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 Japanese patent regime provides patent protection to first medical use claims in the form of 'pharmaceutical composition containing substance X'.</i></p> <p><i>Second medical use claims can also be subject to patent protection. The Japanese Patent office regards such claims as an 'invention of product', e.g. claims for a combination of two or more medicines or dosage regimes.</i></p> <p><i>However, the inventive step test in Japan</i></p>	<p>Patents for new forms, uses, and methods of using known medicines can enable patent 'evergreening' and, particularly when enhanced therapeutic efficacy is not required, can lead to unwarranted extensions of pharmaceutical monopolies.</p> <p>The U.S. proposal provides patent protection to any new form, use or method of using a known product without being subject to any limitations. The Japanese law and practice seem to</p>

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/16/13 5:31 PM
Deleted: P

Windows User 7/16/13 5:31 PM
Deleted: R

Windows User 7/16/13 5:32 PM
Deleted: the

Windows User 7/17/13 1:53 PM
Formatted: No underline

Windows User 7/16/13 5:33 PM
Deleted: .

	The US TPP IP Chapter Proposal ²	Japanese Patent Act (Act No. 121 of 1959)	Analysis
		<p><i>typically requires a showing of "remarkable effects" beyond those achieved by the optimisation of usage.³</i></p> <p><i>Further, the Japanese Patent Office requires that patent applications be supported by a representative embodiment or working examples.⁴</i></p>	<p>be quite liberal as regards claims for first and second medical uses. However, such claims are required to satisfy relatively strict novelty and inventive step requirements. These requirements, in practical terms, set some limits on the patenting of new uses of known medicines.</p> <p>The U.S. proposal would provide greater flexibility to pharmaceutical companies when they draft their patent claims. When read in conjunction with Article 8.2 eliminating exclusions from patentability (as discussed further below) pharmaceutical companies would be able to freely file patent applications for new uses, new methods of preparation and methods of use or treatment without being subject to statutory restrictions. The novelty and inventive step requirements will still be applicable though.</p> <p>Additionally, this provision prevents Japan from changing patent standards</p>

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/16/13 5:33 PM
Deleted: to

Windows User 7/17/13 3:30 PM
Deleted: T

Windows User 7/17/13 3:30 PM
Deleted: the

Windows User 7/17/13 3:30 PM
Deleted: any

³ Examination Guidelines for Patent and Utility Model in Japan, Part VII, Chapter 3 Medicinal Invention, p.8 is available at http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/7_3.pdf

⁴ Id., p.3; Examination Guidelines Part I, Chapter 1 Requirements for Description and Claims, p. 30 is available at http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/1_1.pdf

	The US TPP IP Chapter Proposal ²	Japanese Patent Act (Act No. 121 of 1959)	Analysis
			regarding patentability of new uses and forms. If Japan ever considers it necessary to provide express and detailed statutory presumptions against patentability of derivatives, it would be unable to do so due to its obligations under the TPP.
Exclusions from Patentability	<p>Article 8.2. Each Party shall make patents available for inventions for the following:</p> <p>(a) plants and animals, and (b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals</p>	<p>Article 29.1. "Any person who has made an invention which is industrially applicable may obtain a patent therefor ..."</p> <p><i>The Japanese Patent Act does not list exclusions in Article 29.1. However, The Examination Guidelines for Patent and Utility Models list the following as industrially inapplicable inventions:</i></p> <p>2.1 List of Industrially Inapplicable Inventions</p> <p>Methods of surgery, therapy or diagnosis of humans have been termed "medical activity" and are normally practiced by medical doctors.</p> <p><i>Methods for surgery, therapeutic treatment and diagnosis, practiced on humans are excluded from patent protection on the basis that they are not</i></p>	<p>The TRIPS Agreement allows countries to exclude diagnostic, therapeutic and surgical methods from patentability (Article 27.3).</p> <p>As explained above, Article 8.1 provides patent protection to new uses and method claims. Article 8.2 makes methods of treatment for the human (or animal) body patentable subject matter. Article 8.12 interprets industrial application in a broad sense and seeks specific, substantial and credible utility to satisfy industrial application requirements. When read together, these three Articles, in effect, facilitate patentability of medical activities.</p> <p>The TRIPS 27.3 patentability exception is an important flexibility recognized by many countries, for moral and ethical reasons and to prevent hospitals and medical professionals from paying</p>

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/16/13 5:34 PM
Deleted: While ...t...e Japanese Patent ... [1]

Windows User 7/17/13 3:31 PM
Deleted: The Examination Guidelines for Patent and Utility Models,

Windows User 7/16/13 5:34 PM
Formatted ... [2]

Windows User 7/17/13 3:31 PM
Deleted: Methods of surgery, therapy or diagnosis of humans .

Windows User 7/16/13 5:34 PM
Formatted: Font:Not Italic

Windows User 7/16/13 5:34 PM
Formatted: Font:Not Italic

Windows User 7/17/13 3:31 PM
Deleted: ities

Windows User 7/17/13 5:01 AM
Deleted: .

Windows User 7/17/13 5:01 AM
Deleted: A ...m...thods for surgery, ther ... [3]

	The US TPP IP Chapter Proposal ²	Japanese Patent Act (Act No. 121 of 1959)	Analysis
		<p><i>susceptible of industrial application.</i></p> <p><i>However, medical instruments, pharmaceutical substances and methods of producing them are patentable in Japan.</i></p>	<p>royalties on the standard of care. Sharing the same humanitarian concerns, the Tokyo High Court⁵ highlighted the possible risk to physicians and their patients.</p> <p>While the U.S. proposes to bind countries to its standard through the TPP, 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, the immunity does not apply if the medical activity includes the use of a patented machine, manufacture or composition of matter in violation of such patent.)</p> <p>Adopting the U.S. proposal, without adopting appropriate safeguards, opens up prospects for additional costs imposed on Japan's healthcare system. It is possible that hospitals could be required to obtain licenses for patented treatments that they offer, and doctors could be asked to pay royalties for the</p>

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/17/13 3:32 PM
Deleted: .

Windows User 7/17/13 3:32 PM
Deleted: .

Windows User 7/17/13 8:38 AM
Deleted: Tokyo High Court, 2002, (gyo ke) No. 65

⁵ [Tokyo High Court, Judgment of April 1, 2002, \(gyo-ke\) No.65,](#)

	The US TPP IP Chapter Proposal ²	Japanese Patent Act (Act No. 121 of 1959)	Analysis
			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 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	Article 69.1. A patent right shall not be effective against the working of the patented invention for experimental or research purposes. <i>This statutory experimental use provision is interpreted broadly by the Japanese Supreme Court. The Court held that use of a patented invention for the purpose of obtaining a licence to market the generic equivalent of a patented medicine should be considered within the scope of the statutory research exemption.</i> <i>The Japanese exemption applies not only to pharmaceutical products but to any kind of patented product including medical devices.</i>	Bolar-type regulatory exemptions support non-commercial research uses of patented inventions and help facilitate immediate entry of products into the market following patent expiration. The Bolar exemption serves the public interest in Japan. Article 69 represents a balance established between the interests of the patentee and the general public, which incentivizes the improvement of technology and the development of industry ⁶ . <u>The U.S. proposal for the Bolar exemption does not express the full breadth of the exception in U.S. or Japanese law. While the U.S. proposal applies Bolar to pharmaceutical products, U.S. Supreme Court decisions have made clear that under 35 U.S.C. § 271(e)(1), the U.S. recognizes a broader scope for Bolar, covering, for example, medical devices⁷.</u>

⁶ *Daiichi Pharmaceutical Co., Ltd v. Shiono Chemical K.K., (Tokyo Dist. Ct.)*

⁷ *Eli Lilly and Co. v. Medtronic, Inc., 872 F.2d 402* ; *Teletronics Pacing Systems v. Ventritex 982 F.2d 1520*; *Chartex Intern. v. M.D. Personal Products 5 F.3d 1505*

Windows User 7/17/13 9:21 AM

Deleted: .

Windows User 7/16/13 11:22 PM

Deleted: The

Windows User 7/16/13 11:22 PM

Deleted: the

Windows User 7/16/13 11:32 PM

Deleted: e

Windows User 7/16/13 11:39 PM

Formatted: Don't adjust space between Latin and Asian text, Don't adjust space between Asian text and numbers

Windows User 7/16/13 11:38 PM

Deleted: The Bolar exemption in US law is broader than the US draft. The scope of the US exemption covers not only pharmaceutical products but also medical devices.

Windows User 7/16/13 11:39 PM

Deleted: *Eli Lilly and Co. v. Medtronic, Inc., 872 F.2d 402*.

	The US TPP IP Chapter Proposal ²	Japanese Patent Act (Act No. 121 of 1959)	Analysis
	of generating information to support an application for meeting marketing approval requirements of that Party.		

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/16/13 11:39 PM
Formatted: English (US)

Windows User 7/17/13 9:21 AM
Deleted: .

	The US TPP IP Chapter Proposal ²	Japanese Patent Act (Act No. 121 of 1959)	Analysis
Patent Term Adjustment (For Patent Examination Period)	<p>Article 8.6.</p> <p>(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.</p>	<p>Article 67.1 The duration of a patent right shall expire after a period of 20 years from the filing date of the patent application.</p> <p><i>Japanese Law contains no provision addressing patent term adjustment. There is no obligation to grant patent term extensions for perceived unreasonable delays in patent examination.</i></p>	<p>The US TPP proposal introduces general patent term adjustments applying to all fields of technology including pharmaceutical products and processes. The US proposal defines unreasonable delay as the later of four years from the date of filing or two years after an examination request.</p> <p>Patent term adjustments allow patent owners to postpone patent expiry. This can undermine the balance of interests at work in the patent system. Longer patents keep inventions out of the public domain. This inhibits efforts to build on existing inventions to create new advancements in science, technology and industry. Patent term adjustments increase costs for health systems, and also constrain follow-on innovation.</p>

	The US TPP IP Chapter Proposal	Japanese Patent Act (Act No. 121 of 1959)	Analysis
<p>Patent Term Adjustment (For Regulatory Review Period)</p>	<p>Article 8.6</p> <p>(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.</p> <p>(d) In implementing subparagraph 6(c), a Party may:</p> <p>(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;</p> <p>(ii) require the basis for the adjustment to be the first marketing approval granted to the new pharmaceutical product in that Party; and</p>	<p>Article 67.2 Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safety, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding 5 years.</p> <p><i>In Japan, patent term extensions are available only for patents can only be worked upon regulatory approval.</i></p> <p><i>The product should be the first to obtain marketing approval. Subsequent approvals for the same active ingredient, i.e. a new indication or effect that differs only in dosage form or administration are not eligible for patent term extension. The term of the patent can be extended a maximum 5 years. A product can still be eligible for patent extension even if the</i></p>	<p>Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines.</p> <p>The U.S. proposal makes patent term adjustments mandatory for perceived delays <u>during regulatory review</u>.</p> <p>It would introduce 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).</p> <p>Article 8.6 (d) 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 US Patent Act, i.e., a party may limit extensions to one per pharmaceutical product and/or limit extensions to five years. (See, 35 USC 156)."</p>

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/16/13 11:46 PM
Deleted: in thregulatory

Windows User 7/16/13 11:46 PM
Deleted: approval process

Windows User 7/16/13 11:45 PM
Deleted: The term of the patent may be extended in Japan if the patented invention is unable to be worked because of approval and certification of pharmaceutical products under Pharmaceutical Affairs Law.

Windows User 7/16/13 11:45 PM
Deleted: areavailablefor

	The US TPP IP Chapter Proposal	Japanese Patent Act (Act No. 121 of 1959)	Analysis
	(iii) limit the period of the adjustment to no more than 5 years.	<i>patent life of the product has 14 or more years <u>remaining</u>.</i>	
Protection of test data submitted for market approval	<p>Article 9.2.</p> <p>(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:</p> <p>(i) the safety or efficacy information previously submitted in support of the marketing approval; or</p> <p>(ii) evidence of the existence of the marketing approval,</p> <p>for at least five years from the</p>	<p><i>There is no data exclusivity in Japan. Nevertheless, <u>the Japanese Post Marketing Surveillance (PMS) system, which aims to monitor and confirm the efficacy and safety of, approved new drugs, provides de facto exclusivity to pharmaceutical companies against generic entry, even in some cases after patent expiration. A PMS period is set for most new drug approvals, and until this period is over, generic companies cannot submit their applications for drug approvals. It does not provide for exclusive use of the data, however in practice it delays the market entry of generic drugs.</u></i></p> <p><i>The PMS period is 8 years from the date of marketing approval for active ingredients and 4-6 years from the date of marketing approval for new indications and doses.</i></p>	<p><u>Japan's PMS system is intended to serve as a form of pharmacovigilance, whereas US data exclusivity serves the monetary interests of pharmaceutical companies.</u></p> <p>Data exclusivity delays the market entry of generics and keeps drug prices unnecessarily high by preventing regulatory authorities from relying on established data regarding drug safety and efficacy to register generic medicines.</p> <p>Data exclusivity provisions are also inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals.</p> <p>The leaked U.S. TPP proposal provides data exclusivity for new pharmaceutical products (Article 9.2). This provision provides "at least" five years of data exclusivity for safety and efficacy information submitted in support of marketing approval, which may well be disclosed and in the public domain. The</p>

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/16/13 11:47 PM
Deleted: protection

Windows User 7/16/13 11:47 PM
Deleted: the

Windows User 7/16/13 11:48 PM
Deleted: the

Windows User 7/16/13 11:48 PM
Deleted: of

	The US TPP IP Chapter Proposal	Japanese Patent Act (Act No. 121 of 1959)	Analysis
	<p>date of marketing approval of the new pharmaceutical product in the territory of the Party.</p> <p>...</p> <p>(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:</p> <p>(i) the new clinical information previously submitted in support of the marketing approval; or</p>		<p>draft also introduces “at least three years” additional data exclusivity for submission of new clinical information on new uses or indications for existing pharmaceutical products. Products that are considered to be the same as or similar to the reference product are also excluded from relying on its protected data.</p> <p>The U.S. may also seek data/market exclusivity for the test data related to biologics (biotech medicines). (See, Article 9.9.9 Placeholder for specific provision applying to biologics). Depending on the proposal, this could represent an extension of the exclusive period with potentially dramatic financial consequences for Japan’s health and innovation system.</p>

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/16/13 11:52 PM
Deleted: Adopting the US TPP proposal on data exclusivity would limit Japan’s ability to define national standards for clinical trial data protection that are both TRIPS-compliant and better safeguards for access to affordable medicines.

Windows User 7/16/13 11:53 PM
Deleted: would represent a major extension of the scope of Japanese law

Windows User 7/16/13 11:55 PM
Deleted:

Windows User 7/16/13 11:55 PM
Deleted: for emerging Japanese biotechnological industry

	The US TPP IP Chapter Proposal	Japanese Patent Act (Act No. 121 of 1959)	Analysis
	<p>(ii) evidence of the existence of the marketing approval that was based on the new clinical information,</p> <p>for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party.</p>		
Patent Linkage	<p>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:</p> <p>(a) provide a transparent and effective system to:</p> <p>(i) identify a patent or patents covering an approved</p>	<p><i>Japanese law contains no provision that links the patent system to the marketing approval process. Japanese authorities do not verify patent status when registering generic products.</i></p>	<p>Patent linkage is a regulatory mechanism that links drug marketing approval to patent status. Under patent linkage, even spurious patents may function as barriers to generic drug registration. Patent linkage can facilitate abuse, since the financial benefits to patent holders of deterring generic market entry may outweigh risks of penalties.</p> <p>The US TPP proposal requires countries to provide a mechanism to identify patents covering an approved pharmaceutical product or its approved method of use. The US draft introduces a notification system for patent holders, an automatic stay of marketing approval and measures to block allegedly infringing products for the duration of</p>

	The US TPP IP Chapter Proposal	Japanese Patent Act (Act No. 121 of 1959)	Analysis
	<p>pharmaceutical product or its approved method of use; and</p> <p>(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 similar to, the approved pharmaceutical product referenced in subparagraph 5(a)(i).</p> <p>(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:</p> <p>(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</p> <p>(ii) judicial or administrative procedures, including effective</p>		<p>the patent.</p> <p>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.</p>

Windows User 7/17/13 9:21 AM

Deleted: .

	The US TPP IP Chapter Proposal	Japanese Patent Act (Act No. 121 of 1959)	Analysis
	<p>provisional measures, to allow for the timely adjudication of disputes concerning the validity or infringement of an allegedly infringed patent.</p> <p>(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.</p> <p>(d) 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.</p>		
Judicial and Administrative Presumption of Patent Validity	<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 each</p>	<p>Article 104-3. Where, in litigation concerning the infringement of a patent right or an exclusive license, the said patent is recognized as one that should be invalidated by a trial for patent invalidation, the rights of the patentee or</p>	<p>The TPP 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.</p>

	The US TPP IP Chapter Proposal	Japanese Patent Act (Act No. 121 of 1959)	Analysis
	<p>claim of a patent is presumed valid independently of the validity of the other claims.</p>	<p>exclusive licensee may not be exercised against the adverse party.</p> <p><i>Like the U.S. system, Japan has a dual track system for invalidating a patent. Since the enactment of Article 104-3 in 2005, Japanese courts are empowered to invalidate patents in infringement suits. However, a court's invalidation decision applies only to the parties. Invalidation trials before the Japan Patent Office (JPO) are a way to invalidate a patent in relation to the general public.</i></p>	<p>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>In both the U.S. and Japan, there are two ways to invalidate a patent: challenging a patent's validity before courts or before the Patent Offices (In the USPTO, ex parte reexamination, inter partes review or post-grant review; in the JPO, an invalidation trial).</p> <p>In U.S. patent litigation, a patent claim enjoy a presumption of validity according to 35 U.S.C. § 282. While the statute does not stipulate a standard of proof for overcoming the presumption, U.S. courts have interpreted the statute to mean that the presumption imposes a heavy burden of persuasion, and the presumption can be overcome only by clear and convincing evidence. Such a presumption of validity and the heightened standard of proof make invalidity challenges on bad patents before courts very difficult, and in turn lead to lower patent quality.</p> <p>However, even in the U.S., this presumption only applies to litigation.</p>

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/17/13 9:20 AM
Formatted: Font:Italic

Windows User 7/17/13 9:20 AM
Formatted: Font:Italic

Windows User 7/17/13 9:20 AM
Formatted: Font:Italic

Windows User 7/17/13 9:20 AM
Formatted: Font:Italic

Windows User 7/17/13 9:21 AM

Deleted: .

	The US TPP IP Chapter Proposal	Japanese Patent Act (Act No. 121 of 1959)	Analysis
			<p>The standard of proof is lower at the USPTO. No presumption of patent validity applies at USPTO proceedings. A "preponderance of the evidence" is enough to invalidate a patent.</p> <p>The US-TPP proposal requires an adoption of a presumption of validity even for the U.S. administrative proceedings, which currently do not have a presumption of validity.</p> <p>Japanese courts, like U.S. courts, can invalidate a patent in infringement suits when an invalidity defense is made. Article 104-3 of the Patent Act (2005). However, unlike the U.S. courts, no presumption of validity exists and the Japanese courts can invalidate a patent regardless of whether there is a "clear" reason for invalidity. Also for invalidation trials before the JPO, there is no presumption of validity.</p>
Compensation of damages for patent infringement	<p>Article 12.3. Each party shall provide that</p> <p>b) in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, <i>inter</i></p>	<p>Article 102.1- damages based on the profit earned by the infringer</p> <p>Article 102.3- damages based on the licensing royalty that right holder would have been entitled.</p>	<p>The U.S. draft proposes use of suggested retail price or "other legitimate measure of value" submitted by the right holder.</p> <p>Damages calculated based on retail price strongly favour the interests of</p>

	The US TPP IP Chapter Proposal	Japanese Patent Act (Act No. 121 of 1959)	Analysis
	<p><i>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>Article 105.3. In litigation concerning the infringement of a patent right or exclusive license, where the court has determined that damage actually arose and where it is extremely difficult for the court, due to the nature of the facts, to prove the facts necessary to determine the amount of damage, the court may determine a reasonable amount of damage based on the entire import of oral argument and the result of the examination of evidence.</p> <p><i>Japanese Courts usually calculate the amount of damages suffered by the patent holder based on the amount of the profit earned by the infringer. In cases where it is difficult to determine and prove the infringer's profits, damages are based on the amount of license royalty that patent holder would have been entitled.</i></p> <p><i>Japanese Courts have broad discretionary power to calculate the amount of the damages.</i></p>	<p>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 unrealistic determination of damages, which would empower rights holders in court settlements and discourage defendants from litigating cases where there is uncertainty.</p> <p>Japanese Courts are provided with wide discretionary power to calculate damages and are in a better position to 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>

Windows User 7/17/13 9:21 AM
Deleted: .

Windows User 7/17/13 12:07 AM
Deleted: The

Windows User 7/17/13 12:07 AM
Deleted: The

	The US TPP Transparency Chapter Proposal ⁸	Japan's Drug Pricing System	Analysis
Pharmaceutical Reimbursement System⁹	<p>Paragraph X.3 A Party shall:</p> <p>(c) afford applicants <u>timely and meaningful opportunities to provide comments</u> at relevant points in the decision-making process related to reimbursement for pharmaceutical products or medical devices.</p> <p>(d) ensure that the Party's determination of the reimbursement amount for a pharmaceutical product or medical device has a transparent and verifiable basis consisting of <u>competitive market-derived prices in the</u></p>	<p>In Japan, the prices of drugs are regulated by the government.¹⁰ The Minister of the Ministry of Health, Labour and Welfare (MHLW) sets rates and reimbursement coverage, by consulting with the Central Social Insurance Medical Council (Chuikyo).¹¹ Japan established the National Health Insurance (NHI) Drug Price List ("NHI Price List") and reimburses any drugs listed and every two years reimbursement prices are revised.¹² Unlike the US, Japan's drug pricing system is standardized and sets one fixed price for every drug.¹³</p> <p>When a drug's sale exceeds the original forecast, the drug price is subject to downward repricing for market expansion.¹⁴</p>	

⁸ The June 2011 US-proposed Annex on Transparency Chapter text is available at <http://infojustice.org/download/tpp/tpp-texts/US%20Proposal%20-%20Pharmaceutical%20Pricing%20Provisions.pdf>

⁹ See Oxfam analysis report <http://infojustice.org/download/tpp/tpp-civil-society/Oxfam-Paper-on-the-TPPA-leaked-IP-chapter.pdf>

¹⁰ Japan Pharmaceutical Manufacturers Association (JPMA), *Pharmaceutical Administration and Regulations in Japan*, Chapter 6 Health Insurance Programs and Drug pricing in Japan, p. 202, <http://www.jpma.or.jp/english/parj/pdf/2013.pdf>

¹¹ Gordon G. Liu et al., *Evidence-Based Decision-Making on Medical Technologies in China, Japan, and Singapore*, Volume 12(3), 2009. <http://www.ispor.org/consortiums/asia/ViH/Evidence-Based-Decision-Making-on-Medical-Technologies.pdf>

¹² JPMA, supra note 9, p.202, right column; p.204, right column

¹³ T.R. Reid on Japanese Healthcare, posted on June 8, 2013 <http://nihone.wordpress.com/2013/06/08/t-r-reid-on-japanese-healthcare/>

¹⁴ JPMA, supra note 9, p.203, right column.

	<p><u>Party's territory, or an alternative transparent and verifiable basis</u> consisting of other benchmarks <u>that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue basis.</u></p> <p>(e) Where a Party provides for a determination of the reimbursement amount on a basis other than competitive market-derived prices in that territory, that Party shall permit a manufacturer of the pharmaceutical product or medical device in question, before or after a decision on a reimbursement amount is made, <u>to apply for an increased amount of reimbursement for the product or device</u> based on evidence the manufacturer provides on the product's superior safety, efficacy or quality as compared with comparator products.</p> <p>(g) within a reasonable, specified period, provide</p>	<p>Another method Japanese government employs to contain drug price is reference pricing. For pharmaceuticals, Japan introduced the Foreign Price Adjustment (FPA) Rule in 2002 to reduce reimbursement prices.</p> <p>When the base price of the new drug is higher than the foreign comparator countries' prices in the bracket, the price is adjusted to make the price difference between Japan and those countries smaller.¹⁵ Similarly, for medical devices, MHLW fixes the maximum reimbursement price for medical devices and uses the Foreign Average Price (FAP) rule to reduce reimbursement for devices.</p> <p>In 2010, Japan implemented a new premium system on a trial basis, which minimizes downward price revisions on new drugs.¹⁶ Trial premium pricing scheme applies the six premium rates with ceilings based on innovation, usefulness and market size.</p>	
--	--	--	--

¹⁵ Id.

¹⁶ JPMA, Annex 6 Drug Pricing System in Japan, slide 19

	<p><u>detailed written information to applicants</u> regarding the basis for recommendation or determination relating to their applications for reimbursement of pharmaceutical products or medical devices, including citations to any expert opinions or academic studies upon which the Party has relied.</p> <p>(i) make available <u>an opportunity for independent appeal or review</u> of recommendations or determinations relating to reimbursement for pharmaceutical products or medical devices.</p>		
--	--	--	--

Windows User 7/17/13 9:21 AM
Deleted: .