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

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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.	Article 29.1. An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention *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.*	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. 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. In the US, the utility test is linked to the written description and enablement

[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.

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			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. 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.
Protection of New Forms, Uses, or Methods of Using Known Products	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.	*The Japanese patent regime provides patent protection to first medical use claims in the form of 'pharmaceutical composition containing substance X'.* *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.* *However, the inventive step test in Japan*	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. 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

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		typically requires a showing of "remarkable effects" beyond those achieved by the optimisation of usage.[3] *Further, the Japanese Patent Office (JPO) requires that patent applications be supported by a representative embodiment or working examples.*[4]	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. 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. (Although applications would still have to meet Japan's inventive step standard.) Additionally, this provision prevents Japan from changing patent standards

[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

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			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	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 29.1. "Any person who has made an invention which is industrially applicable may obtain a patent therefor ..." *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:* 2.1 List of Industrially Inapplicable Inventions … Methods of surgery, therapy or diagnosis of humans have been termed "medical activity" and are normally practiced by medical doctors. *Methods for surgery, therapeutic treatment and diagnosis practiced on humans are excluded from patent protection on the basis that they are not*	The TRIPS Agreement allows countries to exclude diagnostic, therapeutic and surgical methods from patentability (Article 27.3). 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. 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

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		susceptible of industrial application. *However, medical instruments, pharmaceutical substances and methods of producing them are patentable in Japan.*	royalties on the standard of care. Sharing the same humanitarian concerns, the Tokyo High Court[5] highlighted the possible risk to physicians and their patients. 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.) 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

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

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			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. *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.* *The Japanese exemption applies not only to pharmaceutical products but to any kind of patented product including medical devices.*	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]. 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 devices[7].

[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; Telectronics Pacing Systems v. Ventritex 982 F.2d 1520; Chartex Intern. v. M.D. Personal Products 5 F.3d 1505

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	of generating information to support an application for meeting marketing approval requirements of that Party.		

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Patent Term Adjustment (For Patent Examination 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 67.1 The duration of a patent right shall expire after a period of 20 years from the filing date of the patent application. *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.*	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. 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.

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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 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 safely, 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. *In Japan, patent term extensions are available only for patents can only be worked upon regulatory approval.* *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*	Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. The U.S. proposal makes patent term adjustments mandatory for perceived delays during regulatory review. 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). 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)."

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	(iii) limit the period of the adjustment to no more than 5 years.	*patent life of the product has 14 or more years remaining.*	
Protection of test data submitted for market 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 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	*There is no data exclusivity in Japan. Nevertheless, 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, generics 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.* *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.*	Japan's PMS system is intended to serve as a form of pharmacovigilance, whereas US data exclusivity serves the monetary interests of pharmaceutical companies. 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. Data exclusivity provisions are also inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals. 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

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	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 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		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. 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.

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	(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.		
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	*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.*	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. 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

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	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 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		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.

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	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 pursuant to subparagraph (a), provide measures that operate to prohibit the unauthorized marketing of that product prior to the expiration of the patent. (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.		
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	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	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.

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	claim of a patent is presumed valid independently of the validity of the other claims.	exclusive licensee may not be exercised against the adverse party. *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 JPO determine validity or invalidity for all other purposes.*	Judicial or administrative presumptions of patent validity give rise to costly and one-sided court procedures, and make it harder to challenge unwarranted patents. In both the U.S. and Japan, there are two ways to invalidate a patent: before courts or before the patent office (In the United States Patent Office (USPTO), *ex parte* reexamination, *inter partes* review or post-grant review; in the JPO, an invalidation trial). In U.S. patent litigation, a patent claim enjoys 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 to bad patents before courts difficult, and in turn lead to lower patent quality. However, even in the U.S., the same presumption seemingly does not apply

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			to disputes before the USPTO.[8] A "preponderance of the evidence" is enough to invalidate a patent. The U.S. TPP proposal requires an adoption of a presumption of validity even for U.S. administrative proceedings, which may stretch the bounds of U.S. law. 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, there is no presumption of validity or modified evidentiary standard. The JPO does not presume validity either.
Compensation of damages for patent 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	Article 102.1- damages based on the profit earned by the infringer Article 102.3- damages based on the licensing royalty that right holder would have been entitled. Article 105.3. In litigation concerning the	The U.S. draft proposes use of suggested retail price or "other legitimate measure of value" submitted by the right holder. Damages calculated based on retail price strongly favour the interests of rights holders. A suggested retail price

[8] *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008); Yoshinari Oyama, *Standard of Proof for Patent Invalidation in the U.S. and Japan*, 13(1) Chi.-Kent J. Int'l & Comp. L. 25, 41-42 (2012).

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	good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder.	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. *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.* *Japanese Courts have broad discretionary power to calculate the amount of the damages.*	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. 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.