Challenges for Health and Innovation Policy in the Trans-Pacific Partnership Agreement (TPP): Comparative Analysis of the United States' Intellectual Property Proposal and Japanese Law

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Patentability of Diagnostic, Therapeutic and Surgical Methods	Article QQ.E.1. 3. Consistent with paragraph 1 each Party shall make patents available for inventions for the following: (b) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals if they cover a method of using a machine, manufacture, or composition of matter * *Japan opposes this provision*	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 susceptible of industrial application.*	Medical procedure patents raise healthcare costs by facilitating pharmaceutical patent evergreening as well as by making health providers, including surgeons, potentially liable for the methods they use to treat patients. Essentially, except for when a surgeon uses her bare hands, surgical methods would be patentable under the U.S. proposal. While U.S. law immunizes certain care providers from infringement liability, the U.S. TPP proposal fails to include these safeguards, risking yet more serious consequences for TPP negotiating countries[3]. The TRIPS Agreement allows countries to exclude diagnostic, therapeutic and surgical methods from patentable subject matter (Article 27.3). Japan generally excludes medical methods from patent eligible subject matter, with some exceptions U.S.-proposed Article QQ.E.1.1 provides patent protection to new uses and method claims. Article QQ.E.1.3 makes methods of treatment for the human (or animal) body patentable. Article QQ.E.10 introduces the broad US test of utility and seeks specific, substantial and credible utility to satisfy usefulness. When read

[2] The Trans-Pacific Partnership (TPP) Intellectual Property Chapter published by WikiLeaks, November 2013, available at http://wikileaks.org/tpp.

[3] For more information, "Medical Procedure Patents In The TPP: A Comparative Perspective On The Highly Unpopular U.S. Proposal", November 2013, available at http://www.citizen.org/documents/MEDICAL%20PROCEDURE%20PATENTS%20IN%20THE%20TPP.pdf

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			together, these three Articles, in effect, provide patent protection for medical activities. The TRIPS 27.3 exception is an important flexibility recognized by many countries, for moral and ethical reasons and to prevent hospitals and medical professionals from paying licensing fees on the standard of care. the only countries in the world - to recognize medical method patents are the United States and Australia[4]. 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 omitted balancing features of its own law. U.S. law authorizes patents for surgical methods, but it also prevents medical practitioners from being sued for patent infringement in the course of medical activity (35 USC 287 (c)). This 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. It does apply if medical activity includes use of an unpatented machine. In other words, in the U.S., each additional use of a

[4] *Ibid.*

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

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			patented machine in the practice of medicine may be subject to the payment of new fees. Determining the extent of change that the U.S. TPP proposal may impose on Japan is complex. For example, Japan excludes methods of using a surgical device inside the human body from patent eligible subject matter. But it allows patents for methods of operating medical devices. The US proposal would most likely require patent subject eligibility of some areas excluded under Japanese law. The elimination of medical activity exclusions could open up prospects for additional costs imposed on Japan's healthcare system. Hospitals and medical practitioners could be required to pay in order to license procedures or methods of treatment that would otherwise be free and in the public domain.
Grace Periods	Article Q.Q.E.2. Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure*: (a) was made or authorized by, or derived from, the patent applicant; and (b) occurred within 12 months prior to the date of filing of the application in the territory of the	Article 30. In the case of an invention which has fallen under any of the items of Article 29 (1) against the will of the person having the right to obtain a patent, such invention shall be deemed not to have fallen under any of the items of Article 29 (1) for the purpose of Article 29 (2) and (2) for the invention claimed in a patent application which has been filed by the said person within six months from the date on which the invention first fell under any of said items.	A grace period is a period of time before the date of filing a patent application during which certain kinds of disclosures would not destroy the novelty of the invention. In other words, under a grace period system, an invention may still be considered new and therefore patentable even if it has been described publicly, for example, in a publication, before the patent application was filed. The grace period system was originally designed as a special relief measure under the first-to-file system. At the international level, there is no harmonization of grace periods. The US TPP proposal provides broad grace periods for

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	Party * *According to footnote 90, Japan is proposing* "A Party shall not be required to disregard information contained in [gazettes related to intellectual properties or] patent applications made available to the public by a patent office unless erroneously published or unless the application was filed without the consent of the inventor or their successor in title by a third party who obtained the information directly or indirectly from the inventor"	*Grace periods in Japan apply to an inventor's own public disclosures (excluding what has become publicly known through the gazettes of invention, utility models, design and trademark) and unauthorized third party disclosures.* *The duration of a grace period is 6 months, which is calculated from the date of filing with the JPO. To invoke a grace period, Japanese law requires applicants to submit a request in writing, along with a proof document to demonstrate exactly which invention was disclosed before the filing.*	any public disclosure that is authorized by or derived from the patent applicant. The duration of the TPP grace period is 12 months, which would double the Japanese period, prolong uncertainty and delay entry of the invention into the public domain. The revision of Japanese Patent Law in 2011 expanded the scope of the grace period. At the time of the revision, discussions took place as to whether to maintain the grace period of 6 months or extend the period to 12 months. It was concluded that international trends should be taken in to account and that it was premature to change the existing grace period. The majority of patent systems do not provide general grace periods.
'Bolar Type' Exemption	Article Q.Q.E.13. *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	Article 69.1. A patent right shall not be effective against the working of the patented invention for experimental or research purposes. *The Japanese Supreme Court has 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*	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].

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

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	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. ** Japan supports this US proposal* *** According to footnote 109, Japan is considering this provision*	*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.*	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]. The Bolar provision of the TPP should be amended to reflect the full breadth of the exemption in Japanese law: applying to any patented product and permitting broad export uses.

[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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US Test of Utility	Art QQ.E.10.* Each Party shall provide that a claimed invention is useful if it has a specific substantial, and credible utility. **According to the footnote 102, Japan is considering this provision.*	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.* *However, the term is subject to certain limitations, and excludes medical industries – please see below.*	Patents shall be available for any invention provided that the invention is new, involves an inventive step, and is capable of industrial application. According to the TRIPS Agreement and proposed Article QQ.E.1 countries may treat the terms "capable of industrial application" and "utility" as being synonymous, but are not required to do so. However, this 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. The patentability of medical treatment claims could create new barriers to entry for future pharmaceutical and medical devices research and development.

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Patent Term Adjustment (For Patent Prosecution Period)	Article QQ.E.XX*. (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. * *Japan opposes this provision*	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 in the context of patent prosecution. There is no obligation to grant patent term extensions for perceived delays in patent examination.*	Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. The US TPP proposal introduces general patent term adjustments for perceived delays in patent prosecution. While Japan offers patent extensions tied to regulatory review periods, conceding extensions for prosecution periods over four years (or two years after an examination request) would be new. 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 QQ.E.14* (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 (iii) limit the period of the adjustment to no more than 5	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 for patents that can only be worked upon regulatory approval. Japan places a series of limitations on the availability of these extensions.* *Extensions are effectively tied to the scope of the regulatory review, rather than the scope of the patent. For example, extensions may be applied to more than one medical indication covered by the same patent if each regulatory review was similarly "delayed." But extensions only protect the specific uses covered by the marketing approval. In other words, an extension related to one product's review period would not automatically allow*	Japan provides patent term extensions for long regulatory review periods, but with several limitations. For example, a patent extended for one product's regulatory review period could not be used to block competition for another product – even if the patent's claims arguably covered both products. This serves the value of limiting extended patent protection to the purpose for which it was granted. The U.S. proposal would not seem to include this particular safeguard. Article QQ.E.14 (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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	years. ** According to footnote 110, Japan is considering this provision*	*patent protection for another product just because both employed the same active ingredient covered by the same patent.*	

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Protection of Test Data Submitted for Marketing Approval	Article QQ.E.16* (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 date of marketing approval of the new pharmaceutical product in the territory of the Party.	*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 re-examination 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 re-examination 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 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. is also seeking 12 years data/market exclusivity for the test data related to biologics (biotech medicines, including most new cancer treatments). (See, Article

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	… (c) If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of the pharmaceutical product containing the previously approved chemical entity, other than information related to bioequivalency, the Party shall not, without the consent of a person previously submitting such new clinical information to obtain marketing approval in the territory of the Party, authorize a third person to market a same or a similar product based on: (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,		QQ.E.20 Placeholder for specific provision applying to biologics). Depending on the term of years, 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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	for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party. * *According to footnote 113, Japan is still considering its position on this provision*		
Patent Linkage	Article QQ.E.17*. 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	Japan does not have a patent linkage system *per se*. However, in principle, the Ministry of Health, Labour and Welfare of Japan (MHLW) does not approve a generic drug for sale as long as the patent right that covers the active ingredients of the original drug is valid. However, MHLW only prevents approval of generic drugs if there is a clear infringement of the patent. The protection does not extend to new indications, dosage or administration regimes.	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. Unlike Japan's current system, this would cover new uses and indications, potentially reducing prospects for generic competition and increasing costs. Under the US proposal, Japan would have to establish a notification system for patent holders and formalize an automatic stay of marketing approval and measures to block allegedly infringing products for the duration of the patent. It is not clear from the wording of the provision under what conditions a product would be considered "similar to" an approved pharmaceutical product and trigger an

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	(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 provisional measures, to allow for the timely adjudication of disputes concerning the validity		obligation to notify a patent holder. This provision could facilitate patent holder harassment of potential competitors.

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	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. ** According to footnote 113, Japan is still considering its position on this provision*		
Judicial and Administrative Presumption of Patent Validity	Article Q.Q.H.2* In civil or administrative patent enforcement proceedings, each Party shall provide for a rebuttable presumption that each claim in a patent	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 previous US TPP proposal required 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 latest version of the proposal does not include

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	substantively examined and granted by the competent authority satisfies the applicable criteria of patentability in the territory of the Party. ** According to footnote 193, Japan is considering this provision*.	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 one-sided court procedures, making it harder to challenge unwarranted patents. In 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[8], 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. Even if the patent office mistakenly issued a patent, the challenger must still overcome the presumption of validity by clear and convincing evidence. However, even in the U.S., the same presumption seemingly does not apply to disputes before the USPTO.[9] A "preponderance of the evidence" is enough to invalidate a patent. The TPP proposal requiring a

[8] Microsoft Corp. v. i4i Ltd., 131 S. Ct. 2238 (2011)

[9] *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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			presumption of validity administrative proceedings 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. 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 QQ.H.4*: 2ter 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. ** The text is no longer bracketed, which might mean that Parties have already agreed on this provision.* Article QQ.H.4.Y	Article 102.1- damages based on the lost profit of right holders. Article 102.2- damages based on the profit earned by the infringer Article 102.3- damages based on reasonable royalties. 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.	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 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. The Article QQ. H.Y provides judicial authorities with broad power to treble any damages awarded. The text offers no limitation on the discretionary enhancement of damages. In the US, enhancement only applies in case of wilful infringement at least a showing of objective recklessness[10].

[10] *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc., No. 10-1510 (Fed. Cir. June 14, 2012)*

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	7** In civil judicial proceedings concerning patent infringement, each Party shall provide that its judicial authorities shall have the authority to increase damages to an amount that is up to three times the amount of the injury found or assessed. ** *Japan opposes this provision*	*Article 102 introduces three methods to calculate the amount of damages suffered by the patent holder:* - *Infringer's sales volume multiplied by the patent holder's profit per unit (as long as the sales volume is within the capability of the patent holder)* - *Infringer's sales volume multiplied by the infringer's profit per unit* - *Infringer's total sales multiplied by the rate of licence fee* *Unless the infringement is wilful or exhibits gross negligence, the Court has discretion to limit damages to an amount equal to a reasonable royalty even if actual damages were higher.* .	Japanese Courts can 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.