Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement (TPPA): Comparative Analysis of the United States' Intellectual Property Proposal and the law of Brunei Darussalam

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Authors' Note:
Patents Order, 2011 (S57/2011) came into force in Brunei Darussalam on 1 January 2012. It is modelled on the Singapore Patent Act 2005 and provides for an independent system based on self-assessment.

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Patent Law Treaty (2000)	Article 1.5. Each Party shall make all reasonable efforts to ratify or accede to the following agreements by the date of entry into force of the Agreement: (a) Patent Law Treaty (2000);	Brunei Darussalam is not a contracting party to the Patent Law Treaty (PLT). .	The PLT is a treaty of the World Intellectual Property Organization (WIPO). It harmonizes formal procedures involved in national and regional patent applications. The requirements regarding the form of application are quite low. It has been subject to criticism for favoring patent applicants and increasing the burden on national patent offices. The PLT recognizes a presumption of validity on the part of internationally-issued patents and reduces Brunei Darussalam's flexibility to independently evaluate PCT-processed patent applications.
Patentability Requirements	Article 8.1. Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. FN15: For the purposes of this Article, a party may treat the terms "inventive step" and "capable of	Section 13 (1) Subject to subsections (2) and (3), a patentable invention is one that satisfies the following conditions (a) the invention is new; (b) it involves an inventive step; and (c) it is capable of industrial application *Patents Order 2011 introduces a patent self-assessment system[3]. This examination system is formal, but only*	While this provision, which mirrors in part Article 27 of the TRIPS Agreement, would not require TPPA parties to change their laws, it illustrates the differences in patent standards between the negotiating countries, and is helpful in understanding how the subsequent U.S.-proposed provisions and patent standards would change the laws of Brunei Darussalam and other TPPA countries.

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

[3] The examination process is formal and advisory in nature. The Brunei Patent Office (BPO) does not conduct examinations but relies on the examinations conducted by the patent offices of Austria, Denmark and Hungary. Alternatively, the applicant can also submit examination reports obtained for corresponding foreign applications filed in prescribed patent offices: Australia, Canada, European Patent Office, Japan, Republic of Korea' New Zealand, United Kingdom or the United States of America. The applicants can also rely on search results of a corresponding application as well as request for examination to be carried out by the outsourced patent offices. After conducting a formalities examination, BPO issues a certificate of grant and publishes the patent.

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	industrial application" as being synonymous with the terms "non-obvious" and "useful" respectively. In determinations regarding inventive step (or non-obviousness), each Party shall consider whether the claimed invention would have been obvious to a skilled artisan (or having ordinary skill in the art) at the priority date of claimed invention.	*advisory in nature. Patent applications are unlikely to be refused on the basis of failure to meet patentability criteria. After the grant of a patent, third parties can challenge its validity either in a revocation action or infringement proceeding.*	In U.S. law and practice, 'usefulness' is interpreted broadly to cover any application, utility, or an improvement over existing products and/or techniques. "Capable of industrial application" tends to be a more precise concept, leading to higher quality patents. In some cases, treating "capable of industrial application" as synonymous with "useful" can lower patentability standards. Under the TRIPS Agreement and this proposed article, countries may treat the terms as synonymous, but are not required to do so. However, subsequent terms in the U.S. proposal would weaken Brunei Darussalam's industrial applicability standard.
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.	Section 16 (1) Subject to subsection (2), an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture. *The law of Brunei Darussalam is modelled on the Singapore Patent Act 2005. Brunei may decide to what extent it will follow Singapore's patent practices.* *The patent practice in Singapore requires an invention to be capable of being made or used, or able to achieve a concrete end result in any industry.*	The TPPA provision aims to impose the U.S. test of specific, substantial and credible utility, which is broader than the Singapore standard and broad enough to cover inventions without true industrial application. Accordingly, any invention that has a practical application and that produces useful and specific results satisfies utility requirements. This standard enhances the patentability of research tools, such as combinatorial chemistry libraries, cell lines and methods. Industrial application requirements could no longer be asserted as a patent bar against such types of inventions (as discussed below: compare and read in conjunction with articles 8.1 and

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			8.2). This enhanced patentability of research tools 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 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. The U.S. TPPA proposal exports the U.S. utility test to Brunei Darussalam, without including these disclosure requirements.
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.	Section 14 (7) In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art. *The Singaporean patent regime provides patent protection to first and second medical uses of known products*	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. If Brunei Darussalam adopts the Singaporean approach, first and second/subsequent uses of known products would be subject to patent protection providing that the claims are drafted in Swiss-type format. In practical terms, this requirement sets some limits on the patenting of new uses of known medicines. The U.S. proposal would provide greater

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		providing that patent claims are drafted in first and second medical use format. If Brunei Darussalam adopts the same approach, claims directed to a known substance or composition would be subject to patent protection "for use in" a method of treatment by surgery or therapy or of diagnosis, provided that the substance or composition has not been used in any medical method in the prior art, e.g. substance or composition X for use as a medicament for Y (first medical use claims). *The established practice in Singapore is to provide patent protection to the second or further medical uses of known products, provided that they are presented as Swiss-type claims, e.g. Use of substance/compound X for the manufacture of a composition/ medicament for the treatment of X. Accordingly, Swiss-type second use claims may be subject to patent protection in Brunei Darussalam.*	flexibility to pharmaceutical companies when they draft their patent claims. Rather than claiming Swiss-type use or method claims, pharmaceutical companies would be able to freely file patent applications for new uses, new methods of preparation and methods of use or treatment (when read in conjunction with Article 8.2 eliminating exclusions from patentability, as discussed further below) without being subject to any restrictions. Additionally, this provision would prevent Brunei Darussalam from changing patent standards regarding patentability of new uses and forms. If Brunei Darussalam were to find it useful to provide express and detailed statutory presumptions against patentability of derivatives, such as those found in the India Amended Patent Act (2005) Section 3(d), it would be unable to adopt these standards of its own accord due to its obligations under the TPPA.
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	Section 16 (2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application. (3) Subsection (2) will not prevent a	The TRIPS Agreement allows countries to exclude diagnostic, therapeutic and surgical methods from patentability (Article 27.3). Brunei Darussalam allows patents for new uses in some cases, i.e. those drafted in the Swiss-type format. Patents Order, 2011

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	treatment of humans and animals	product consisting of a substance or composition being treated as capable of industrial application merely because it is invented for use in any such method. *Patents Order, 2011 expressly excludes surgical, diagnostic and therapeutic methods of treatment performed on the living human or animal body from patent protection. A method of treatment is not regarded as being capable of industrial application.* *Nevertheless, the products used therein can be subject to patent protection. Second/subsequent use claims in the Swiss-type format, e.g. use of substance X for the treatment of X, can be subject to patent protection.*	explicitly excludes medical method claims from patentability. 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, lengthen patent protection for older pharmaceuticals by facilitating patents for methods of treatment and minor variations on known products. The U.S. proposal would lead to broader pharmaceutical patenting and more low-quality patents in Brunei Darussalam. The new fields of health technology, e.g. biotechnology and genetic science, make extensive use of method claims in their patent applications. Such methods and procedures are usually carried out on the human (or animal) body or are somehow related to treatment of the human (or animal) body. The expansion of patent protection to diagnostic, therapeutic and surgical methods for the treatment of human beings (and animals) makes patent protection available for higher life forms and human biological materials. The TRIPS 27.3 patentability exception is an important flexibility recognized by many

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			countries for moral and ethical reasons, and to prevent hospitals and medical professionals from paying royalties on the standard of care. While the U.S. proposes to bind countries to its standard through the TPPA, it has omitted the essential safeguards and balancing features of its own law. While U.S. law authorizes patents for surgical methods, it also prevents medical practitioners from being sued for patent infringement in the course of medical activity (35 USC 287 (c)). (Nevertheless, other groups including universities, medical education companies, and hospitals can be held liable for involuntary infringement.) Adopting the U.S. proposal, without adopting appropriate safeguards, opens up prospects for additional costs imposed on Brunei Darussalam'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 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	Section 64.2. An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if: (g) it consists of the doing of any thing set out in subsection (1) in relation to	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 TPPA exemption is narrow in scope – it

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	marketing approval of a pharmaceutical product in that Party, and shall further provide that any product produced under such authority shall not be made, used, or sold in its territory other than for purposes related to generating such information to support an application for meeting marketing approval requirements of that Party. If the Party permits exportation of such a product, the Party shall provide that the product shall only be exported outside its territory for purposes of generating information to support an application for meeting marketing approval requirements of that Party.	the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that any thing produced to support the application is not — (i) made, used or sold in Brunei Darussalam; or (ii) exported outside Brunei Darussalam , other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product. *Patents Order, 2011 provides a statutory exemption for acts conducted in pursuance of marketing approval for a pharmaceutical product. However, the scope of the provision is limited to pharmaceutical products and does not apply to medical devices.*	only applies to pharmaceutical products. But the Bolar exemption in U.S. law is broader than those in the U.S. draft or Patents Order, 2011. The scope of the U.S. exemption covers not only pharmaceutical products, but also medical devices. (*Eli Lilly and Co. v. Medtronic, Inc*., 872 F.2d 402).
Patent Term Adjustment (For Patent Examination Period)	Article 8.6. (a) 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	Section 36 (1) A The proprietor of a patent may apply to the Registrar to extend the term of the patent on any of the following grounds: (a) that there was an unreasonable delay by the Registrar in granting the patent; (b) where the patent was granted on the basis of prescribed information relating to a corresponding, application referred to in section 29 (2) (*c*) (ii), that — (i) there was an unreasonable delay in the issue of the corresponding patent; and (ii) the patent office that granted the	Patent term adjustments (typically called extensions) allow patent owners to postpone patent expiry. This further delays market entry of competing generic drugs and restricts access to affordable medicines. The U.S. TPPA proposal is similar to the U.S.-Singapore FTA. Each defines unreasonable delay as the later of four years from the date of filing or two years after an examination request. Brunei, of course, is not a signatory to that agreement,

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	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.	corresponding patent has extended the term of the corresponding patent on the basis of such delay: (2) A delay by the Registrar in granting a patent shall not be treated as an unreasonable delay under subsection (1) (*a*) unless — (a) the interval between the date of filing of the application for the patent and the date of issue of the certificate of grant, excluding any period attributable to an act or omission of the applicant, exceeds 4 years; or (b) the interval between the date on which the applicant — (i) filed a request for a search and examination report in accordance with section 29 (2) (*b*); or (ii) filed a request for an examination report in accordance with section 29 (2) (*c*) (i), (*d*) (i) or (*e*) (i) or (4), and the date of issue of the certificate of grant, excluding any period attributable to an act or omission of the applicant, exceeds 2 years. *Patent term adjustments were introduced to Singapore's law in 2004 as part of the U.S. FTA implementation process. Since Brunei's Patents Order, 2011 is modeled on the Singapore Act 2005, it provides patent term adjustments for perceived unreasonable delays in patent prosecution. A delay is considered unreasonable if (a) it occurs*	and retains the freedom to change its laws and establish a better, pro-access system in the future. Agreeing to the U.S. proposal to the TPPA would lock Brunei in to a costly patent adjustment system, constraining Brunei's ability to make its own rules. Patent term adjustments could also place special burdens on Brunei's emerging patent examination system. The U.S. system has been criticized for demanding examination speed at the expense of quality.

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		during the prosecution process and the interval between filing date and date of issuance exceeds four years and/or (b) it occurs during the search and/or examination process and the interval between the date of the applicant's request for examination and issuance of the patent exceeds two years. *Patent terms can also be extended for perceived unreasonable delays during prosecution of a reference application at a foreign patent office, providing that the foreign patent office has also extended the term of the corresponding patent on the basis of the delay.*	
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.	Section 36 (1) (C) The proprietor of a patent may apply to the Registrar to extend the term of the patent on any of the following grounds: (…) (c) where the subject of the patent includes any substance which is an active ingredient of any pharmaceutical product, that —	The U.S. proposal makes patent term adjustments (extensions) available when drug regulatory review exceeds a certain period.[4] Patent extensions significantly delay market entry and access to affordable medicines. The U.S. proposal is broader than Bruneian law and the Singapore FTA. Brunei limits patent extensions to products with new active ingredients, but the U.S. proposal could make extensions available for new product combinations of old active ingredients and for method or process

[4] Parties are not required to make patent term adjustments available for longer regulatory review periods when a company fails to apply for marketing approval within X years. Please see Article 8.6.(e): "*In implementing subparagraph 6(c), and as a condition for providing the adjustment set forth in subparagraph 6(c) for a new pharmaceutical product approved consistent with Article 9.2(b) or Article 9.2(d), a Party may require an applicant that has submitted an application for marketing approval consistent with Article 9.2(b) or Article 9.2(d) to commence the process of obtaining marketing approval for that new pharmaceutical product in the Party within [X] years of the date of first marketing approval of the same pharmaceutical product in another Party".*

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	(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 years.	(i) there was an unreasonable curtailment of the opportunity to exploit the patent caused by the process of obtaining marketing approval for a pharmaceutical product, being the first pharmaceutical product to obtain marketing approval which uses the substance as an active ingredient; and (ii) the term of the patent has not previously been extended on this ground. *Patents Order, 2011 makes patent term extensions available for patents on pharmaceutical substances -- active ingredients of any pharmaceutical product. The product should be the first using that active ingredient to obtain marketing approval. The patent term must have been curtailed due to a delay in obtaining the required marketing approval, and the term of the patent must not have been previously extended on this ground.* *"Unreasonable curtailment" means marketing approval was obtained after issue of the certificate of grant and the interval between the date of application for marketing approval and date of grant of marketing approval exceeded two years.* *The maximum patent term extension is five years. The Registrar typically*	patents. (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 U.S. 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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		extends the patent term in accordance with the length of the curtailment	
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 date of marketing approval of the new pharmaceutical product in the territory of the Party.	*There is no clear provision on data exclusivity in Brunei Darussalam.*	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.[5][6] The leaked U.S. TPPA 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. Adopting the U.S. TPPA proposal on data

[5] *Judit Rius Sanjuan, James Love and Robert Weissman, Protection of Pharmaceutical Test Data: A Policy Proposal, KEI Research Paper 2006.* http://keionline.org/content/view/86/1.
[6] See also: *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.* http://www.wma.net/en/30publications/10policies/b3/17c.pdf.

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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, for at least three years from the date of marketing approval based on the		exclusivity would limit Brunei Darussalam's ability to define national standards for clinical trial data protection that are both TRIPS-compliant and better safeguards for access to medicines. 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). This would represent a major extension of the scope of Brunei Darussalam law with potentially dramatic financial consequences.

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	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 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).	*There is no clear provision on patent linkage in Brunei Darussalam.* *Patents Order, 2011 does not include any provision linking the patent system to the marketing approval process.*	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 U.S. TPPA proposal requires countries to provide a mechanism to identify patents covering an approved pharmaceutical product or its approved method of use. The U.S. 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 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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	(b) unless such other person agrees to defer the marketing of the product until after the expiration of an identified patent, ensure that a patent holder may seek, prior to granting of marketing approval to an allegedly infringing product, available remedies by providing: (i) an automatic delay of the grant of marketing approval that remains in place for a period of time designed to ensure sufficient opportunity to adjudicate disputes concerning the validity or infringement of allegedly infringed patents; and (ii) judicial or administrative procedures, including effective provisional measures, to allow for the timely adjudication of disputes concerning the validity or infringement of an allegedly infringed patent. (c) if such other person's product has been found to infringe a valid patent identified pursuant to subparagraph (a), provide measures that operate to prohibit the unauthorized marketing of that product prior		

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	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 claim of a patent is presumed valid independently of the validity of the other claims.	*The patent system in Brunei Darussalam is based on self-assessment. A patent is not considered prima facie valid and third parties have a variety of options for challenging patents (see Patents Order, 2011, Section 79). Patent challenges can be put forward as a defense or counterclaim in infringement proceedings.*	The TPPA requires signatory countries to provide for a rebuttable presumption that a patent and each of its claims are independently valid in civil and administrative proceedings. The judicial and administrative presumption of patent validity gives rise to costly and one-sided court procedures, and makes it harder to challenge unwarranted patents. This presumption was only introduced into the U.S. Patents Act in 1952. Since then there has been overwhelming evidence that patent quality is not high enough to justify the continuation of this presumption under U.S. patent law.
Compensation of Damages for	Article 12.3. Each party shall provide that	Section 65 (1) Subject to this Part, civil proceedings may be brought in the court	The U.S. draft proposes use of suggested retail price or other legitimate measure of

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Patent / IP Infringement	(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.	by the proprietor of a patent in respect of any act alleged to infringe the patent and without prejudice to any other jurisdiction of the court in those proceedings a claim may be made for- (…) (c) damages in respect of the infringement; (d) an account of the profits derived by him from the infringement; (2) The court shall not, in respect of the same infringement, both award the proprietor of a patent damages and order that he shall be given an account of the profits. *Patents Order, 2011 assesses damages on a loss of profit basis. In order to avoid double recovery by the claimant, the court awards either damages or an account of profit in infringement cases.*	value submitted by the right holder. Damages calculated based on retail price strongly favour the interests of right 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 right holders in court settlements and discourage defendants from litigating cases where there is uncertainty. The courts of Brunei Darussalam can better balance the competing interests in infringement suits by maintaining the compensatory approach to damages, filtering claims and continuing to determine appropriate calculations for damages case-by-case.
Ex-officio Border Measures	Article 14.4. Each Party shall provide that its competent authorities may initiate border measures *ex officio* with respect to imported, exported, or in-transit merchandise, or merchandise in free trade zones, that is suspected	*Patents Order, 2011 does not include provisions regarding enforcement.* *The Royal Customs and Excise Department enforces border control measures in Brunei* Darussalam*. Copyright Order 1999 and Chapter 98-*	Special border measures that are too broad in scope or fail to include adequate safeguards can lead to customs error or right holder abuse, including customs seizure of generic medicines.[7] Special, pre-emptive border measures are

[7] For further discussion of special border measure standards, see Public Citizen, Comments to the European Commission on Customs Regulation 1383/2003, May 25, 2010, *available at*: http://citizen.org/Page.aspx?pid=3458. *See also* Maybarduk, Peter. 2010. ACTA and Public Health. PIJIP Research Paper No. 9. American University Washington College of Law, Washington, DC.

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	of being counterfeit or confusingly similar trademark goods, or pirated copyright goods.	*Trademarks Act provide border enforcement measures for infringing goods crossing the border upon the request of right holders. (Copyright Order-Section 109 and Chapter 98-Trademarks Part IV).* *Nevertheless, under other grounds and laws, the Customs Department can act ex officio and seize certain articles detrimental to public health and safety, providing that there exists a potential danger to the public or individuals.*	most logically applied only to wilful trademark counterfeiting on a commercial scale. The law of Brunei Darussalam does not specifically authorise ex-officio border measures for suspected civil infringements. The U.S. proposal would specifically authorize ex officio border measures for suspected civil trademark infringements, a standard that does not contribute to public safety but does risk wrongly detaining generic medicines, which may usefully communicate their bioequivalence to consumers through similar packaging.