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

Comparative Analysis of the United States' TPFTA Intellectual Property Proposal and Vietnamese Law[1]

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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);	*Although Vietnam participates in the WIPO meetings on the Treaty, Vietnam is not a party to the Patent Law Treaty.*	The Patent Law Treaty (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 favouring patent applicants and increasing the burden on national patent offices.
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 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.	Article 58. An invention shall be protected by mode of grant of invention patent when it satisfies the following conditions: (a) Being novel; (b) Involving an inventive step; (c) Being susceptible of industrial application	While this restatement, which mirrors in part Article 27 of the TRIPS Agreement, would not require TPFTA parties to change their laws, it illustrates the differences in patent standards between the countries, and is helpful in understanding how the subsequent U.S.-proposed provisions and patent standards would change the laws of Vietnam and other TPFTA countries. 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.

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

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			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 Vietnam's industrial applicability and inventive standards.
Industrial Application v. Utility	Article 8.12. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.	Article 62. An invention shall be considered susceptible of industrial application if it is possible to realize mass manufacture or production of products or repeated application of the process that is the subject matter of the invention, and to achieve stable results. ** The invention should be usefully developed and applied in an industrial or commercial context in order to be eligible for patenting in Vietnam.*	This notion of specific, substantial and credible utility is broad enough to cover inventions without true industrial application. Accordingly, any invention that has a practical application and that produces useful and specific results satisfies utility requirements. Under the U.S. proposal standard 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 8.2). This would lower patentability standards.
Protection of New Forms, Uses, or Methods of Using a Known Product	Article 8.1. The Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.	** Vietnamese Law stays silent as to protection of new medical uses or compositions. Nevertheless, Article 4.12 defines "invention" as a technical solution in the form of a product or a process, which is intended to solve a problem by application of laws of nature.* *Since the introduction of the Law on Intellectual Property in 2006, and relying on the definition of invention provided by Article 4.12, the National Intellectual Property Office (NOIP) has rejected all use claims including the first medical use of a*	Vietnamese Law requires an invention to be either a product or process in order to be eligible for patenting. A use or a method claim is not regarded as a product or process and thus does not satisfy the criteria for patentability. Therefore, the NOIP does not provide patent protection to claims for new methods or uses – for example, new medical uses for known, older products. Under the U.S. proposal, patent protection would be extended to new forms, uses, and methods of using a known product. Pharmaceutical companies could then freely file patent applications for new methods of

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		known product and Swiss-type second or subsequent use claims on the basis that they are not eligible for either produce or process patents.	preparation, new formulations and new uses of known substances without being subject to restrictions. When read in conjunction with Article 8.2 (as discussed further below), second or subsequent medical uses may also be subject to patent protection in Vietnam. Patenting of new forms, uses or methods of known products would give rise to patents on minor variations of existing chemical entities, regardless of their impact on therapeutic efficacy, and risks greatly expanding pharmaceutical patenting. This provision stands in contrast to pro-access alternatives such as that found in the India Amended Patent Act (2005), Section 3(d), which has been used to thwart attempts to gain an extra twenty years of patent monopoly protection by making minor changes to existing medicines.
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 59. The following subject matters shall not be protected as inventions: 1. Scientific discoveries or theories, mathematical methods; … 7. Human and animal disease prevention, diagnostic and treatment methods. * *The medical treatment exclusion from patentability applies not only to treatment and diagnostic methods on the human body, but also disease prevention procedures.*	Vietnam excludes diagnostic and treatment methods from patent protection; on the basis that method of treatment claims only produce effects on the human (or animal) body, and not an industrial effect as required by the Vietnamese law (industrial application). This exclusion is also grounded in ethics, i.e. to provide physicians with greater flexibility to treat patients with therapies that best fit their needs. Patentability of a new medical effect of known drugs – known as second/subsequent use – also falls within this exclusion. It is considered a method for treatment of humans in Vietnam.

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		In practice, the NOIP is quite strict about method of treatment claims. The NOIP does not allow patents for method of treatment claims that have been drafted in the form of second use or Swiss-type claims.	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 eligible subject matter for patents. Article 8.12 (as discussed above) 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 assure patent eligibility for second or subsequent use of known products and further restrict generic competition. 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 body or are somehow related to treatment of the human body. The expansion of patent protection to diagnostic, therapeutic and surgical methods for the treatment of human beings help assure patent protection for such types of inventions. Additionally, introduction of patentability for methods of treatment for the human body in Vietnam without any safeguards could impose additional costs on Vietnam'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.

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'Bolar'-type Exemption	Article 8.5. Consistent with paragraph [4] (patent exceptions and limitations), each Party shall permit third persons to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product in that Party, and shall further provide that any product produced under such authority shall not be made, used, or sold in its territory other than for purposes related to generating such information to support an application for meeting marketing approval requirements of that Party. If the Party permits exportation of such a product, the Party shall provide that the product shall only be exported outside its territory for purposes of generating information to support an application for meeting marketing approval requirements of that Party.	Article 125.2 Owners of industrial property objects as well as organizations and individuals granted the right to use or the right to manage geographical indications shall not have the right to prevent others from performing the following acts: a/ Using inventions, industrial designs or layout-designs in service of their personal needs or for non-commercial purposes, or for purpose of evaluation, analysis, research, teaching, testing, trial production or information collection for carrying out procedures of application for licenses for production, importation or circulation of products; *Vietnamese patent law provides broad exemptions allowing for the use of patented inventions for experimental use, research, teaching, testing, trial production or information collection, and to pursue regulatory approval. These exemptions apply to all inventions not only pharmaceutical products.*	Bolar-type exemptions support non-commercial research uses of patented inventions and help facilitate immediate entry of products into the market following patent expiration. Compared to Vietnamese law, the TPFTA exemption is narrow in scope; applying only to regulatory approvals. The Bolar exemption in U.S. law is broader than the provision in the U.S. proposal to the TPFTA. The scope of the exemption in U.S. law covers not only pharmaceutical products but also medical devices. (*Eli Lilly and Co. v. Medtronic, Inc*., 872 F.2d 402). The U.S. TPFTA proposal would limit the broad scope of Vietnam's exemptions to pharmaceutical products only.
Patent Term Adjustment (Extensions 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	Article 93. Invention patents shall each have a validity starting from the grant date and expiring at the end of 20 years after the filing date. * *Vietnamese Law contains no provision addressing patent term restoration or adjustment. There is no obligation to grant patent term extensions for perceived*	The U.S. TPFTA proposal seeks to extend patent terms for perceived "unreasonable delays" during the patent examination period. This provision introduces general patent term adjustments applying to all fields of technology including pharmaceutical products and processes. The U.S. proposal defines unreasonable delay as the later of four years from the date of filing or two years after an

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	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.	*"unreasonable delays" in patent examination.*	examination request. Patent term adjustments allow patent owners to postpone patent expiry. A patent term adjustment that is applicable to pharmaceutical products and processes would further delay market entry of competing generic drugs, restricting access to affordable medicines in Vietnam.
Patent Term Adjustment (Extensions 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 iii. limit the period of the adjustment to no more than 5 years.	* *Vietnamese Law does not provide patent term extension for perceived delays in the regulatory approval process.* *The U.S.-Vietnam Bilateral Trade Agreement (BTA 2001) provides that the term of patent protection may be extended to compensate for delays in the regulatory approval process, but does not oblige Vietnam to provide patent term extensions.*	Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. In contrast to the U.S.-Vietnam BTA, the U.S. proposal to the TPFTA requires that Parties make patent term extensions available for perceived delays in the regulatory approval process. 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 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

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			and/or limit extensions to five years (See, 35 USC 156).
Third-Party Opposition / Pre-grant Opposition	Article 8.7. (…) Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent.	Article 112. As from the date an industrial property registration application is published in the Official Gazette of Industrial Property, until prior to the date of issuance of a decision on grant of a protection title, any third party shall have the right to express opinions to the concerned state management agency in charge of industrial property rights on the grant or refusal to grant a protection title in respect of such application. (…) Article 117/4. Where there appears an objection to the intended grant of a protection title, the relevant industrial property registration application shall be re-examined with regard to the matters against which the objection is made. ** The Vietnamese patent system provides for both pre-grant and post-grant oppositions. During the examination process, any third party can file a written opposition in relation to a grant or refusal of patent rights. The pre-grant oppositions can be filed at any time between publication of the application and its grant.* *Post-grant opposition can be filed in order to invalidate a patent.*	Pre-grant opposition is a safeguard against patent abuse, improvidently granted patents and unwarranted pharmaceutical monopolies. Pre-grant opposition supports appropriate generic competition and access to medicines. The U.S. proposal would eliminate pre-grant opposition in TPFTA counties.[4] Pre-grant opposition allows third parties to formally oppose a patent application by submitting information and analysis to patent examiners, under an adversarial administrative process. This mechanism helps improve patent quality and the accuracy of patent claims and helps to prevent pharmaceutical monopolies based on meritless patents that contribute little to innovation but greatly to price. The absence of pre-grant opposition would make patent examination less informed and would likely increase the number of cases of patent appeals before the courts. Costs associated with the patent opposition system would likely rise. It would create market uncertainty for generics firms, and lead to low-quality patents and unjustified drug monopolies until post-grant challenges could reach successful conclusions.

[4] For further discussion of the U.S. strategy to eliminate patent pre-grant opposition, see Public Citizen, HealthGAP, I-MAK and Third World Network, "Analysis of the Leaked U.S. Paper on Eliminating Patent Pre-Grant Opposition," available at http://www.citizen.org/documents/analysis-of-leaked-US-paper-on-eliminating-pregrant-opposition.pdf.

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Protection of Test Data Submitted for Market Approval / Data Exclusivity	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. … (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	Article 128. 1. Where the law requires applicants for licenses for trading in or circulating pharmaceuticals or agro-chemical products to supply test results or any other data being business secrets obtained by investment of considerable efforts, and where applicants request such data to be kept secret, the competent licensing agency shall be obliged to apply necessary measures so that such data are neither used for unhealthy commercial purposes nor disclosed, except where the disclosure is necessary to protect the public. 2. From the submission of secret data in applications to the competent agency mentioned in Clause 1 of this Article to the end of a 5-year period as from the date the applicants are granted licenses, such agency must not grant licenses to any subsequent applicants in whose applications the said secret data are used without the consent of submitters of such data, except for the cases specified at Point d, Clause 3, Article 125 of this Law. * *Vietnamese law protects the undisclosed data and trade secrets that are products of "remarkable investments." Neither Vietnamese law nor the U.S.-Vietnam BTA provides exclusive control over disclosed data.* *There is no system of automatic test data*	Data exclusivity delays the market entry of generics and keeps drug prices high by preventing regulatory authorities from relying on established data regarding drug safety and efficacy to register generic medicines. Consistent with the TRIPS Agreement, Vietnamese law allows health authorities to rely on disclosed data to register generic medicines. The U.S. TPFTA proposal would eliminate this flexibility. The TRIPS Agreement provides protection for undisclosed test data submitted to drug regulatory authorities for the purposes of obtaining marketing approval against unfair commercial use. Data exclusivity, on the other hand, provides an exclusive right over test data to the originator company and prevents regulatory authorities from relying on test data for approval of generic medicines. The leaked U.S. TPFTA proposal requires 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 the same as or similar to the reference product are also prevented from

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	Party, authorize a third person to market a same or a similar product based on: (i) the new clinical information previously submitted in support of the marketing approval; or (ii) evidence of the existence of the marketing approval that was based on the new clinical information, for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party.	*protection in Vietnam. Pharmaceutical companies are required to specifically request protection while they are applying for marketing approval and submit evidence of the costs of their clinical trials so as to prove that the data was the product of "remarkable investments." The protection only applies to new drugs utilizing new chemical entities and new combinations of known entities.*	relying on its protected data. Data exclusivity provisions are also inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals. The U.S. may seek data/market exclusivity for test data related to biologics (biotech medicines). (See, Article 9.9.9 Placeholder for specific provision applying to biologics). This would represent a major change to Vietnamese law with potentially dramatic consequences.
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	* *Vietnamese law contains no provision that links the patent system to the marketing approval process.* *Vietnam has previously articulated opposition to patent linkage to the European Chamber of Commerce in Vietnam.*[5]	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. TPFTA 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

[5] "Vietnam argues that it is not appropriate to inject patent enforcement procedures into regulatory procedures, and that it is impossible to issue administrative rules or procedures to administrative agencies to enforce patents." Faunce, Thomas Alured and Townsend, Ruth, Trans Pacific Partnership Agreement - Public Health and Medicines Policies (November 7, 2010). NO ORDINARY DEAL - UNMASKING THE TRANS-PACIFIC PARTNERSHIP FREE TRADE AGREEMENT, Ch. 10, pp. 149-162, J. Kelsey, ed., Allen & Unwin, 2010. Available at SSRN: http://ssrn.com/abstract=1704834

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	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 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.		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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Judicial and Administrative Presumption of Patent Validity	Article 10.2. (---) In civil and administrative proceedings involving patents, each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that each claim of a patent is presumed valid independently of the validity of the other claims.	* *There is no explicit judicial or administrative presumption of patent validity in Vietnamese law.* *Parties can claim patent invalidity in post-grant opposition proceedings, or at any time.*	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. The U.S. TPFTA proposal requires each claim of a patent to be presumed valid independently of the validity of the other claims. When read in conjunction with eliminating pre-grant opposition and the provision on patent linkage, this provision threatens the integrity of the Vietnamese patent system and overrides current reform proposals designed to improve the quality of patents. This presumption was only introduced into the U.S. Patents Act in 1952. Since then there has been overwhelming evidence that patent quality is not high enough to justify the continuation of this presumption under U.S. patent law.
Compensation of Damages for IP 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 good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder.	Article 205. Where the plaintiff can prove that an act of infringing upon intellectual property rights has caused material damage to him/her, he/she shall have the right to request the court to decide on the compensation level on one of the following bases: (a) Total material damage calculated in an amount of money plus profit gained by the defendant as a result of an act of infringing upon intellectual property rights where the reduced profit amount of the	The U.S. draft proposes use of suggested retail price or other legitimate measures of value submitted by the rights 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

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		plaintiff has not yet been calculated into such total material damage; (b) The price of the licensing of an intellectual property object with the presumption that the defendant has been licensed by the plaintiff to use that object under a license contract within a scope corresponding to the committed infringing act; (c) Where it is impossible to determine the level of compensation for material damage on the bases specified at Points a and b of this Clause, such compensation level shall be set by the court, depending on the damage extent, but must not exceed VND 500 million. ** The law sets clear standards for calculation of compensatory damages. In practice, Vietnamese courts often calculate damages based on the plaintiff's lost sales or the defendant's profits from the infringing activity.*	settlements and discourage defendants from litigating cases where there is uncertainty.
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 of being counterfeit or confusingly similar trademark goods, or pirated copyright goods.	Article 216. 1. Measures to control intellectual property-related imports and exports include: (a) Suspension of customs procedures for goods suspected of infringing upon intellectual property rights; (b) Inspection and supervision to detect	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.[6] The scope of Vietnam's special border measures provisions is far too broad, implicating patent and civil trademark claims that are

[6] 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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		goods showing signs of intellectual property right infringement. 2. Suspension of customs procedures for goods suspected of infringing upon intellectual property rights means a measure taken at the request of intellectual property right holders in order to collect information and evidence on goods lots in question so that the intellectual property right holders can exercise the right to request the handling of infringing acts and request the application of provisional urgent measures or preventive measures to secure the administrative sanctioning. 3. Inspection and supervision to detect goods showing signs of infringement of intellectual property rights means a measure taken at the request of intellectual property right holders in order to collect information so that they can exercise the right to request the suspension of customs procedures. Article 119. In case of necessity, competent state agencies may apply provisional urgent measures, measures to control intellectual property-related imports and exports, or measures to prevent and secure the administrative sanctioning according to the provisions of this law and other relevant provisions of law. ** In cases of infringement relating to foodstuffs for human and animals, pharmaceuticals, veterinary preparations,*	entirely unrelated to any counterfeiting concerns. It is beyond the competence of customs authorities to assess infringement in such civil intellectual property disputes. Acting on this authority, customs authorities could wrongfully seize generic medicines. Meanwhile, the U.S. proposal would explicitly extend special border measures authority to products in transit through Vietnam – not only those destined for the Vietnamese market or exported from Vietnam. If Vietnam maintained the overly broad scope of its rule, and added actions against in transit goods, the new rule could authorize precisely the sort of wrongful seizures of generic medicines in transit that recently sparked controversy in Europe and complaints by India and Brazil to the World Trade Organization. Special border measures are best applied only to cases of wilful trademark counterfeiting and wilful copyright piracy on a commercial scale.

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		fertilizers, plant protection drugs, plant varieties, livestock and counterfeit goods, custom officers may take administrative actions. *Border control measures in Vietnam are available for all IP protected goods against exports and imports, but evidently not for goods in transit.*	