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

Comparative Analysis of the U.S. Intellectual Property Proposal and Malaysian Law[1]

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Patent Law Treaty	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)	Malaysia is not a contracting 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	Section 11. An invention is patentable if it is new, involves an inventive step and is industrially applicable.	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 countries, and is helpful in understanding how the subsequent US-proposed provisions and patent standards would change the laws of Malaysia and other TPPA 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. 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 US proposal would weaken Malaysia’s industrial applicability and inventive step 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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	been obvious to a skilled artisan (or having ordinary skill in the art) at the priority date of claimed invention.		
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.	Section 16. An invention shall be considered industrially applicable if it can be made or used in any kind of industry. *"Industry" is interpreted to include physical activity of a "technical character." Thus, an activity which pertains to the useful or practical arts -- as distinct from the purely intellectual or aesthetic arts -- may meet the requirements of industrial application.*	This provision aims to impose the US patentability test of specific, substantial and credible utility. This 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. 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 8.2*). This enhanced patentability of research tools could create new barriers to entry for future pharmaceutical research and development.
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	Section 14(4). The provisions of subsection 2 [*provisions defining prior art]* shall not exclude the patentability of any substance or composition, comprised in the prior art, for use in a method referred to in paragraph *(d)* of subsection (1) of section 13, if its use in any such method is not comprised in the prior art.	Patents for new forms, uses, and methods of using known medicines can enable patent "evergreening" and, particularly when enhanced therapeutic efficacy is not required, can lead to unwarranted extensions of pharmaceutical monopolies. The U.S. proposal extends patent eligibility to any new form, use or method of using a known product. The current practice in Malaysia is to provide patent protection to first and second/subsequent uses of known products.

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	of the known efficacy of that product.	*This provision provides a legal basis for first medical use, e.g. substance or composition X for use as a treatment for disease Y. These claims, however, are restricted to substances or compositions when presented or packaged for specific uses.* *A claim directed to the second or further medical use of a known therapeutic substance drafted in "Swiss-type format," e.g. use of substance/compound X in the manufacture of a medicine for therapeutic application Z, may also be accepted by the MyIPO.*	However, patent applicants are required to comply with patent claim drafting requirements of the MyIPO and industrial application requirements. The U.S. proposal would provide greater flexibility to pharmaceutical companies in their strategic drafting of patent claims. Rather than claiming Swiss-type use or method claims, pharmaceutical companies could 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, the U.S. proposal would oblige Malaysia to maintain the *status quo* of its patentability requirements. Malaysia would lose the freedom to make independent legislative changes, for example, to provide a statutory presumption against patentability of derivatives such as that found in the India Amended Patent Act (2005) Section 3(d).
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	Section 13. (1) Notwithstanding the fact that they may be inventions within the meaning of section 12, the following shall not be patentable: *(d)* methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body: Provided that this paragraph shall not apply to products used in any such	The TRIPS Agreement allows countries to exclude diagnostic, therapeutic and surgical methods from patentability (Article 27.3). Malaysia expressly excludes treatment by surgery or therapy and diagnostic methods performed on the living human or animal body from patent protection. Nevertheless, the products used therein can be subject to patent protection. However, the MyIPO regards a claim in the form "use of substance X treating disease Y" as a method of treatment – and therefore excludes these

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		methods. *Methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are excluded from patent protection. This exclusion is not applicable to products used in such methods. Therefore, patents may be granted to surgical, therapeutic or diagnostic instruments or apparatus for use in such methods.* *Method of treatment claims may be subject to patent protection provided that they are converted to so-called Swiss type claims and meet industrial application requirements.*	claims from patentability. As explained above, U.S.-proposed Article 8.1 provides patent protection for new uses and method claims. Article 8.2 makes methods of treatment for the human (or animal) body patent eligible subject matter. When read together, these two Articles, in effect, lengthen patent protection for older pharmaceuticals, by facilitating patents for methods of treatment and minor variations on known products. 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 guarantees patent protection for such types of inventions. The TRIPS 27.3 patentability exception is an important flexibility recognized by many countries, for moral and ethical reasons and to avoid hospitals and medical professionals 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.)

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			Adopting the U.S. proposal, without adopting appropriate safeguards, opens up prospects for additional costs imposed on Malaysia'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.
Patent Term Adjustment (For Patent Examination Period)	Article 8.6. (b) Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in the granting of the patent. For purposes of this subparagraph, an unreasonable delay at least shall include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or two years after a request for examination of the application has been made, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays.	Section 35. Subject to subsections (1B) and (1C), the duration of a patent shall be twenty years from the filing date of the application. *The Patent Act contains no provision addressing patent term restoration or adjustment. There is no obligation to grant patent term extensions for perceived "unreasonable delays" in patent examination.*	The US TPPA proposal introduces general patent term adjustments applying to all fields of technology including pharmaceutical products and processes. The US proposal defines unreasonable delay as the later of four years from the date of filing or two years after an examination request. Patent term adjustments allow patent owners to postpone patent expiry. 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 Malaysia.

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Patent Term Adjustment (For Regulatory Review Period)	Article 8.6 (c) Each Party, at the request of the patent owner, shall make available an adjustment of the patent term of a patent which covers a new pharmaceutical product or a patent that covers a method of making or using a pharmaceutical product, to compensate that patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process. (d) In implementing sub-paragraph 6(c), a Party may: (i) limit the applicability of sub-paragraph 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	*No patent term extension is available in Malaysia to compensate for perceived delays in the pharmaceutical regulatory approval process.*	Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. The U.S. proposal would require that Parties make available patent term adjustments 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 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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	in that Party; and (iii) limit the period of the adjustment to no more than 5 years.		
Protection of Test Data Submitted for Marketing 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	*Malaysia's Directive on Data exclusivity issued on February 2011 and is effective from March 2011.* *The Directive is applicable to new drug products containing a new chemical entity and second indications of a registered drug product. (Section 2.1) The application for data exclusivity shall be made within 18 months from the date the product is registered or granted marketing authorisation. (Section 4.2.) The period of data exclusivity is five years for a new drug containing a new chemical entity and three years for a second indication of a registered drug product. (Section 4.5)*	Data exclusivity prevents regulatory authorities from relying on established data regarding drug safety and efficacy to register generic medicines. Data exclusivity delays generic market entry and is inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals. The leaked U.S. TPPA proposal provides data exclusivity for new pharmaceutical products (see Article 9.2 below). In contrast with the Malaysian Directive, the TPPA draft also 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 the in 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 US TPFTA proposal on data exclusivity would limit Malaysia's ability to define national standards for clinical trial data protection that are at once TRIPS-compliant and better safeguard access to medicines. The U.S. may also seek data/market exclusivity for the test data related to biologics (biotech medicines). (See,

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	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		Article 9.9.9 Placeholder for specific provision applying to biologics). This would represent a major change to Malaysian law with potentially dramatic financial consequences.

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	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 new clinical information in the territory of the Party.		
Definition of new pharmaceutical product	Article 9.10 For purposes of this Article, a new pharmaceutical product means a product that does not contain a chemical entity that	*The Legislative Decree 1072 defines new chemical entity as a biologically active fraction, responsible for the pharmacological or physiological action of an active principle that had not been in-*	The TPPA definition includes not only pharmaceutical products but also biologic products. The proposed definition covering biologic products would limit countries' flexibility to define regulatory terms specific to biologic drugs, including potentially in the context of data

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	has been previously approved in the territory of the Party for use in a pharmaceutical product. FN6: For greater certainty, the Parties understand that the term "pharmaceutical product" as used in this Chapter includes biologic products.	*cluded in any drug regulatory registration previously granted in the country at the time of the request for regulatory approval.*	exclusivity.
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	*The Malaysian law contains no provision that links the patent system to 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 US TPPA proposal requires countries to provide a mechanism to identify patents covering an approved pharmaceutical product or its approved method of use. The US draft introduces a notification system for patent holders, an automatic stay of marketing approval and measures to block allegedly infringing products for the duration of 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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	approved method of use; and (ii) provide notice to a patent holder of the identity of another person who intends to market, during the term of the identified patent or patents, a product that is the same as, or similar to, the approved pharmaceutical product referenced in subparagraph 5(a)(i). (b) unless such other person agrees to defer the marketing of the product until after the expiration of an identified patent, ensure that a patent holder may seek, prior to granting of marketing approval to an allegedly infringing product, available remedies by providing: (i) an automatic delay of the grant of marketing approval that remains in place for a period of time designed to ensure sufficient opportunity to adjudicate disputes concerning the validity or infringement of allegedly infringed patents; and (ii) judicial or administrative procedures, including effective		

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	provisional measures, to allow for the timely adjudication of disputes concerning the validity or infringement of an allegedly infringed patent. (c) if such other person's product has been found to infringe a valid patent identified pursuant to subparagraph (a), provide measures that operate to prohibit the unauthorized marketing of that product prior to the expiration of the patent. (d) when a Party delays the grant of marketing approval consistent with subparagraph 5(b)(i), provide an effective reward, consistent with the provisions of this Agreement, for the successful challenge of the validity or applicability of the patent.		
'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	Section 37 1(A) The rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority which regulates the	The TPPA provision provides an exemption, intended to be narrow in scope. The 'bolar' type exemption in the US draft only applies to pharmaceutical products. The Bolar exemption in US law is broader than the US draft. The scope of the exemption covers not only pharmaceutical products but also medical devices. (*Eli*

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	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.	manufacture, use or sale of drugs. *The provision allows for the manufacture, use, sale offer or sale of a patented invention, without the patentee's permission, for uses "reasonably related" to the development and submission of information to the relevant regulatory authority.* *The scope of Malaysia's Bolar exemption is broad and not limited to pharmaceuticals. The term 'patented invention' covers pharmaceutical products and biological products as well as research tools etc.*	*Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402). The scope of the regulatory exemption in Malaysian law is broad, in that it applies to any patented product that requires approval of the authority that regulates the manufacture, use or sale of drugs. The exemption's main objective is to facilitate immediate entry of generic medicines into the market following patent expiration. The U.S. proposal would limit the broad scope of Malaysia's Bolar exemption to pharmaceutical products only, excluding for example biotech products and research tools.
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	*There is no express judicial or administrative presumption of patent validity in Malaysia.* *Any aggrieved party can challenge a patent's validity in Court (Section 56). Invalidity of the patent can be claimed in a declaration of non-infringement proceeding (Section 62/5) or raised as a*	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.

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	claims.	*defence to an infringement action (Section 60).*	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 Patent IP 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.	*In Malaysia, damages are usually awarded on a compensatory (not punitive) basis. Given the broad range of technical and commercial factors involved in patent infringement, an account of profit is rarely chosen. The burden of proof is on the party claiming the damages.*	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. Malaysian courts 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	*In Malaysia, border measures are available for registered trademark goods imported for the purpose of trade. (Trademark Act Part XIVA). An*	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 the customs seizure of generic medicines.[4]

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	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.	*application for infringing or counterfeit goods should be submitted to the Registrar of Trade Marks. The Registrar examines the application and notifies the Royal Malaysian Customs. Customs is then authorised to seize and detain infringing goods. These provisions are not applicable to goods in transit (The Trademark Act, Section 70 D).* Section 70 O. Ex officio Action Any authorised officer may detain or suspend the release of goods, which based on *prima facie* evidence that he or she has acquired, are counterfeit trademark goods. *The Custom officer may act ex-officio to detain or suspend counterfeit trademark goods.*	Special, pre-emptive border measures are most logically applied only to wilful trademark counterfeiting on a commercial scale. The scope of Malaysia's ex officio border measures is appropriate in this regard. The U.S. proposal would broaden this scope to include suspected civil trademark infringement, 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. The U.S. proposal would extend special border measures authority to products exported and in transit through Malaysia -- not only those destined for the Malaysian market.

[4] 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.