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

Comparative Analysis of the U.S. Intellectual Property Proposal and Peruvian Law

Issue	**US TPPA Proposal**	**Andean Community Decision 486 Common Intellectual Property Regime**	**Analysis**
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.	Article 21. Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent. *The Andean Community provisions regarding patentability of new uses of known products are quite strict. Peru, through Decision 486, places appropriate limits on patentability, which differ considerably from the US practice.* *In 1997, the Peruvian Government passed a presidential decree providing patent protection for second-use of known products. The Peruvian local drug manufacturers filed a complaint with the General Secretariat[1]. The Andean Tribunal of Justice (ATJ) held that second use of known products cannot be subject to patent protection and thus the Peruvian decree was not compliant with the Andean law. The Tribunal directed the Peruvian Patent Office (INDECOPI) to revoke the granted to second-use patents[2]. Since the tribunal decision and in accordance with Andean*	Patents for new forms, uses, and methods of using known medicines can enable patent "ever-greening" and particularly when enhanced efficacy is not required, can lead to unwarranted extensions of pharmaceutical monopolies. Peru's free trade agreement (FTA) with the United States does not require parties to grant patents for new uses or methods of using known products. The U.S. TPPA proposal, however, expressly requires patent protection for any new forms, uses or methods of using a known product. This requirement contradicts Andean law and explicitly undermines limits set by strict standards of patentability in the Andean Community. There is a community-wide refusal to recognize second use patents, which has been subject to fierce criticism by the American pharmaceutical industry and USTR. Under the U.S. proposal, new patents can be granted for minor variations to pharmaceutical substances or methods related to their administration that may not enhance medical care – e.g., changes in formulations, drug dosage regimes, drug delivery, and even packaging systems to aid in the administration

[1] Case 89-AL-2000 (September 21, 2001). Pursuant to the Decree, INDECOPI granted patents for Pfizer's heart medication pyrazolpyrimidinones (Viagra) for its second use -- male impotence.
[2] Resolution 358, Opinion 09-2000 of Government of Peru's non-compliance with Decision 344, Common Industrial Property Regime

		Community Decision 486, claims for second uses of known products are non-patentable in Peru.	of drugs (including their use in therapeutic treatments). When read in conjunction with Article 8.2, eliminating exclusions from patentability (as discussed further below), pharmaceutical companies could freely file patent applications for new uses, new methods of preparation and methods of use or treatment, without being subject to any restrictions. The ATJ position on the issue is strong, in that no appeals/remedies are possible. The U.S. proposal would oblige Peru to go against the supremacy of the Andean Community and fundamentally change patentability requirements of the Andean Community law.
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 20. The following shall not be patentable: d) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.	The TRIPS Agreement allows countries to exclude methods of medical treatment from patentability. This 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. The Peru FTA expressly recognizes this flexibility by stating that nothing in the FTA shall be construed to prevent a Party from excluding inventions from patentability as set out in Articles 27.2 and 27.3 of the TRIPS Agreement (Article 16.9.2). The Andean Community expressly excludes treatment by surgery or therapy and diagnostic methods performed on the living human or animal body from patent protection. Patentability of a new medical effect of known drugs – known as second/subsequent use – also falls within this exclusion.

			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 (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) guarantees availability of patent protection for higher life forms and human biological materials. While the U.S. proposes to bind countries to this 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.)
Industrial Application v. Utility	Article 8.12. Each Party shall provide that a claimed invention is industrially applicable if it has a specific,	Article 19. An invention shall be regarded as industrially applicable when its subject matter may be produced or used in any type of industry; industry being understood as	The Peru FTA includes the same provision (Article 16.9.11). However, the footnote of the provision provides that this paragraph shall be applicable without prejudice to novelty, inventive

	substantial, and credible utility.	that involving any productive activity, including services.	step, and industrial application as patentability conditions determined in Article 16.9.1 as well as exclusions of patentability in Article 16.9.2. The TPPA provision does not provide this explicit clarification. Article 8.12 applies the US patentability test of specific, substantial and credible utility. This test is broad enough to cover inventions without true industrial application. Any invention that has a practical application and that produces useful and specific results satisfies the US 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 (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.
Third-Party 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 42. Within a period of 60 days following the date of publication, any person with a legitimate interest may, one time only, submit valid reasons for contesting the patentability of the invention. *The Andean Community Intellectual Property Regime provides for pre-grant opposition. Standing rules ensure that any third person with a legitimate interest, one time only, can oppose a pending patent*	Pre-grant opposition is a safeguard against patent abuse, improvidently granted patents and unwarranted pharmaceutical monopolies. Pre-grant opposition supports generic competition and access to medicines. The U.S. proposal would eliminate pre-grant opposition in TPPA countries. More information on the U.S. proposal on pre-grant opposition is available at citizen.org/access.[4]

[3] Peru implemented the US FTA through Legislative Decree No. 1075, on June 28, 2008.
[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.

		application with valid reasons for contesting the patentability of the invention. The opposition should be filed within 60 days of publication. *Reckless objections may be sanctioned with a fine of up to fifty (50) UIT (Article 23, Legislative Decree 1075[3]).*	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. Pre-grant opposition helps improve patent quality and the accuracy of patent claims. This process 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 may increase the number of cases before the courts. Costs associated with the patent opposition system could 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 a successful conclusion.
Patent Term Adjustment (For Patent Prosecution 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	Article 32 of the Legislative Decree 1075 of June 2008 The competent Directorate, solely at the request of the party, shall adjust the patent term where an unreasonable delay has occurred in the granting process, except where the patent is for a pharmaceutical product or procedure. *Peruvian law provides patent term adjustment for patent prosecution periods longer than five years from the date of application or three years from the request for a substantive examination. However, the provision excludes pharmaceutical products and pharmaceutical processes.*	The Peru FTA provides that each Party shall provide the means, at the request of the patent owner, to compensate for unreasonable delays in the issuance of a patent, except for a patent for a pharmaceutical product, by restoring the patent term or patent rights (Article 16.9.6(b)). The unreasonable delay is defined as the later of five years from the date of filing or three years after an examination request. The U.S TPPA draft introduces a Peru-FTA plus standard that does not discriminate between fields of technology. The proposed standard would apply to pharmaceutical products and processes, and would evidently override the exception in the Peruvian law and the FTA. The US proposal defines unreasonable delay as the later of four years from the date of filing or two years after an examination request. The

	actions of the patent applicant need not be included in the determination of such delays. (c)		TPPA proposal returns to standards that are in the AUSFTA and Middle East FTAs. 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 Peru.
Patent Term Adjustment (For Regulatory Review Period)	Article 8.6 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	*Peruvian and Andean Community laws contain no provision addressing patent term adjustment to compensate for perceived delays in the regulatory approval process.*	Patent term adjustments (typically called extensions) significantly delay market entry of generic drugs and restrict access to affordable medicines. The Peru FTA provides that each party <u>may</u> make available a restoration of the patent term or patent rights to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process (Article 16.9.6 (c)). The new 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 very similar to those found in the US Patent Act, i.e.

	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.		a one time extension or total extension is limited to no more than 5 years (See, 35 USC 156).
Protection of Test Data Submitted for Marketing 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…. ……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 for granting marketing approval for a new 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…. …….for at least three years	*Peruvian law provides five years of data exclusivity for therapeutic goods containing new chemical entities (Legislative decree 1072, Protection of undisclosed test data or other undisclosed data related to pharmaceutical products).* *The law defines a new chemical entity (NCE) as a biologically active fraction, responsible for the pharmacological or physiological action of an active principle that had not been included in any drug regulatory registration previously granted in the country at the time of the request for regulatory approval.* *Data exclusivity is not provided for method of administration, dosage forms, changes in the pharmaceutical forms or formulations of chemical entities or combinations with other known entities.* *Peruvian law recognizes the first marketing approval for the pharmaceutical product that contains an NCE granted in a country of high sanitary vigilance as defined in the General Health law (Law 29316 of January 2009 amending Legislative Decrees 1072 and 1075). The Legislative Directive 1072 includes important public health safeguards. Data exclusivity provisions do not prevent usage of TRIPS flexibilities such as*	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 Peru FTA provides data exclusivity for "a reasonable period" for pharmaceutical products that utilize a new chemical entity. The Peru FTA requires this information to be undisclosed. The reasonable period is defined as five years from the date on which the Party granted approval to the person that produced the data (Article 16.12.2.b). The leaked U.S. TPPA proposal provides data exclusivity for new pharmaceutical products (see Article 9.2 below). In contrast with the Peru FTA, 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 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.

	from the date of marketing approval based on the new clinical information in the territory of the Party.	*compulsory licenses. The drug regulatory authority may disclose test data to protect public health (Article 4).*	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 change to Peruvian/Andean Community law with potentially dramatic financial consequences.
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 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.	*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 included in any drug regulatory registration previously granted in the country at the time of the request for regulatory approval.*	Contrary to other FTAs, there is no explicit definition of new pharmaceutical product in the Peru FTA. Article 16.10.2 makes reference to a standard FTA definition of new pharmaceutical product and provides that data exclusivity provisions are not applicable to chemical entities that have been previously approved in Peru. 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 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	*The Peruvian law contains no provision that links the patent system to the drug 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 2007 US New Trade Policy made patent linkage optional for countries negotiating trade agreements with the US. Thus, implementation of a patent linkage system is optional in the

	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). (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		Peru-FTA (Article 16.10.4). Legislative Decree 1075 does not implement patent linkage, however it does include several enforcement provisions effectively protecting the legitimate rights of patent holders. Legislative Decree 1075 also includes statutory measures imposing penalties, i.e. sanctions, against a party that knowingly provides the government with false or incomplete information or destroys or alters information relevant to the case (Article 116). The US TPPA proposal changes the deal that had been reached with Peru in the 2007 FTA, and would require countries to implement patent linkage. It is not clear 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.

	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.		
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 explicit judicial or administrative presumption of patent validity in Peruvian law.*	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

	claims.		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 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	Article 243. The following criteria shall be used, among others, to calculate the amount of compensation to be paid for damages: a) the consequential damage and lost profits suffered by the right holder as a result of the infringement; b) the amount of profit obtained by the infringer as a result of the acts of infringement; or, c) based on the commercial value of the infringed right and such contractual licenses as may have already been granted, the price the infringer would have paid for a contractual license *IP damages in the Andean Community are intended to compensate for damages that the right holder has suffered. Article 243 specifies clear rules as to compensation, i.e. the consequential damage and lost profits suffered by the right owner; the amount of profit obtained by the infringer; and the price the infringer would have paid for a contractual license.*	The U.S. TPPA proposal is out of line with Andean Community law. A provision in the Peru FTA requires the Parties' judicial authorities to take into account the value of the legitimate good or service, according to the suggested retail price or other legitimate measure of value submitted by the right holder, It is conceivable that the U.S. TPPA proposal may communicate a stronger preference for the use of retail price, rather than other measures of value submitted by rights holders, when compared to the Peru FTA. Damages calculated based on retail price strongly favour the interests of rights holders. A suggested retail price is a hypothetical price; often greater than actual retail price and considerably greater than the damage suffered by the right holder. Such unrealistic measures of damages empower rights holders in court settlements and discourage defendants from litigating cases where there is uncertainty. 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.

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