Comparative chart of pharmaceutical patent and data provisions in the TRIPS Agreement, the North American Free Trade Agreement, Free Trade Agreements between Trans-Pacific FTA negotiating countries and the U.S., and the U.S. proposal to the Trans-Pacific FTA

Global Access to Medicines Program
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This chart compares provisions from the following texts:

- the leaked United States proposals to the Trans-Pacific Free Trade Agreement;
- the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights;
- the North American Free Trade Agreement and;
- Free Trade Agreements between the United States and Singapore, Australia, Chile, Peru (the "template" agreements)

These particular provisions were selected because they would jeopardize access to medicines if the leaked U.S. Trans-Pacific FTA proposal is implemented. While this document does not provide analyses of the provisions, comparative legal analyses of the leaked U.S. Trans-Pacific FTA proposal and intellectual property chapters in existing laws of negotiating countries can be found at: http://www.citizen.org/more-about-trans-pacific-FTA.

Comparative chart of pharmaceutical patent and data provisions in the TRIPS Agreement, the North American Free Trade Agreement, Free Trade Agreements between Trans-Pacific FTA negotiating countries and the U.S., and the U.S. proposal to the Trans-Pacific FTA[1]

Item	U.S. TPFTA Proposal	TRIPS Agreement	NAFTA	U.S.-Singapore FTA (2004)	U.S.-Chile FTA (2004	U.S.-Australia FTA[2] (2005)	U.S.-Peru FTA[3] (2006)
Patents for New Forms, Uses, or Methods of Using a Known Product	Art. 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.	*No provision*	*No provision*	*No provision*	*No provision*	Art. 17.9.1. (…) The Parties confirm that patents shall be available for any new uses or methods of using a known product. (…)	*No provision*
Patentability of Diagnostic, Therapeutic, and Surgical Methods	Art. 8.2. Each Party shall make patents available for inventions for the following: (…) (b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.	Art. 27.3 Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals (…)	Art. 1709 3. A Party may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;	Art. 16.7.1. (…) Each Party may exclude inventions from patentability only as defined in Articles 27.2 and 27.3(a) of the TRIPS Agreement.	*No provision*	Art. 17.9.2. Each Party may only exclude from patentability: (…) (b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.	Art. 16.9.2. Nothing in this Chapter 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. (…)
Patent Term Adjustment (For Patent Examination)	Art. 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	*No provision*	*No provision*	Art. 16.7.7. Each Party, at the request of the patent owner, shall extend the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application with the	Art. 17.9.6. Each Party shall provide for the adjustment of the term of a patent, at the request of the patent owner, to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall be understood to include a delay in the issuance of the patent of more than five years from the	Art. 17.9.8. (a) If there are unreasonable delays in a Party's issuance of patents, that Party shall provide the means to, and at the request of a patent owner, shall, adjust the term of the patent to compensate for such delays. An unreasonable delay shall at least include a delay in the issuance of a patent of more than four years from the date of filing of the application in the	Art. 16.9.6. (b) Each Party shall provide the means to and shall, at the request of the patent owner, compensate for unreasonable delays in the issuance of a patent, other than a patent for a pharmaceutical product, by restoring patent term or patent rights. Each Party may[4] provide the means to and may, at the request of the patent owner, compensate for unreasonable delays in the issuance of a patent for a pharmaceutical product by restoring patent term or patent rights. Any restoration under this subparagraph shall confer

[1] See leaked U.S. intellectual property chapter proposal to the Trans-Pacific FTA at: http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf
[2] For a comparative analysis of the Australian law, the AUS-FTA, and the TPPA, please read: Public Citizen, "Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement: Comparative Analysis of the U.S. Intellectual Property Proposal and Australian Law", August 2011. http://cms.citizen.org/documents/Australia-TPPA-chart.pdf
[3] For a comparative analysis of the Peruvian law, the Peru-FTA, and the TPPA, please read: Public Citizen, "Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement: Comparative Analysis of the U.S. Intellectual Property Proposal and Peruvian Law", October 2011. http://www.citizen.org/peru-Trans-Pacific-FTA-chart
[4] In the May 10, 2007 Agreement, Parties agreed to change "shall" to "may", making it optional whether the parties provide patent term adjustments for perceived delays in the patent approval process. —"Congressional Democrats' Concept Statement on Peru & Panama FTA Changes", 10 May 2007. Available at: http://waysandmeans.house.gov/Media/pdf/110/05%2014%2007/05%2014%2007.pdf

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	such delays. (…) (f) Any patent term adjustment under subparagraph 6(b) or subparagraph 6(c) shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions that would otherwise apply to the patent absent any adjustment of the patent term.			Party, or two years after a request for examination of the application has been made, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays.[FN16-13] FN 16-13: Periods attributable to actions of the patent applicant shall include such periods of time taken to file prescribed documents relating to the examination as provided in the laws of the Party.	date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays	Party, or two years after a request for examination of the application has been made, whichever is later. For the purposes of this paragraph, any delays that occur in the issuance of a patent due to periods attributable to actions of the patent applicant or any opposing third person need not be included in the determination of such delay.	all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent. For purposes of this subparagraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays.
Patent Term Adjustment (For Regulatory Review)	Art. 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[FN1] 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. (e) In implementing subparagraph	*No provision*	Art. 1709 12. (…) A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.	Art. 16.8.4. With respect to any pharmaceutical product that is subject to a patent: (a) each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process; (…).	Art. 17.10.2. With respect to pharmaceutical products that are subject to a patent, each Party shall: (a) make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process; (…).	Art. 17.9.8. (…) (b) With respect to a pharmaceutical product[FN17-17] that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process. FN 17-17: For Australia, the term pharmaceutical substance as used in Section 70 of the Patents Act 1990 on the date of entry into force of this Agreement may be treated as synonymous with the term **pharmaceutical**	Art. 16.9.6. (c) With respect to any pharmaceutical product that is covered by a patent, each Party may[5] 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 related to the first commercial marketing of the product in that Party. Any restoration under this subparagraph shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent.

[5] In the May 10, 2007 Agreement, Parties agreed to change “shall” to “may”, making it optional whether the parties provide patent term adjustments for perceived delays in the marketing approval process. — “Congressional Democrats’ Concept Statement on Peru & Panama FTA Changes”, 10 May 2007. Available at: http://waysandmeans.house.gov/Media/pdf/110/05%2014%2007/05%2014%2007.pdf

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	6(c), and as a condition for providing the adjustment set forth in subparagraph 6(c) for a new pharmaceutical product approved consistent with Article 9.2(b) or Article 9.2(d), a Party may require an applicant that has submitted an application for marketing approval consistent with Article 9.2(b) or Article 9.2(d) to commence the process of obtaining marketing approval for that new pharmaceutical product in the Party within [X] years of the date of first marketing approval of the same pharmaceutical product in another Party. FN2 (f) Any patent term adjustment under subparagraph 6(b) or subparagraph 6(c) shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions that would otherwise apply to the patent absent any adjustment of the patent term. FN 1: For greater certainty, **new pharmaceutical product** in subparagraphs 6 (c)-(e) means a product that at least contains a new chemical entity that has not been previously approved as a pharmaceutical product in the territory of the Party. FN2: Negotiator's Note: For purposes of paragraph 6(e) of Article 8 and paragraphs 4 and 6 of Article 9, the length of the [X]-year period should: enhance certainty regarding access to innovative and generic pharmaceutical products for all; provide incentives for innovation; provide incentives for the diffusion of pharmaceutical products within the TPP region; respect commercial considerations; and account for special challenges in developing and commercializing such products throughout the region (e.g., challenges faced by smaller or less experienced applicants, or the time that an applicant may need to assess additional safety or efficacy implications of marketing a					**product** as used in this sub-paragraph.	

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	product, such as to assess such implications in jurisdictions where risks may differ from those faced in markets where the product has previously been approved).						
Elimination of Pre-grant opposition	Art. 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.	*No provision*	*No provision*	Art. 16.7.4. (…) Where such proceedings include opposition proceedings, a Party may not make such proceedings available prior to the grant of the patent.	*No provision*	*No provision*	*No provision*
Utility Satisfies Industrial Application Standard	Art. 8.12. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.	*No provision*	*No provision*	*No provision*	*No provision*	Art. 17.9.13. Each Party shall provide that a claimed invention is useful if it has a specific, substantial, and credible utility.	Art.16.9.11. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility. [FN16] FN 16: For greater certainty, this paragraph is without prejudice to paragraphs 1 [patentability requirements] and 2 [patentability exceptions].

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Data Exclusivity for a New Pharmaceutical Product	Art. 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 a 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. (b) If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical product, the submission of evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the Party shall not, without the consent of a person previously submitting the safety or efficacy information to obtain marketing approval in the other territory, authorize a third person to market a same or similar product based on: (i) the safety or efficacy	*No provision*[6]		Art. 16.8.1. If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, the Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the approval granted to the party submitting such information for a period of at least five years from the date of approval for a pharmaceutical product (…).[16-14] FN16-14: Where a Party, on the date of its implementation of the TRIPS Agreement, had in place a system for protecting pharmaceutical or agricultural chemical products not involving new chemical entities from unfair commercial use that conferred a different form or period of protection shorter than that specified in	Art. 17.10.1. If a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural pharmaceutical product which utilizes a new chemical entity, which product has not been previously approved, to grant a marketing approval or sanitary permit for such product, the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information. A Party shall maintain this prohibition for a period of at least five years from the date of approval for a pharmaceutical product and (…).[FN25] Each Party shall protect such information against disclosure except where necessary to protect the public.	Art. 17.10.1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical product, the submission of undisclosed test or other data concerning safety or efficacy of the product, the Party shall not permit third persons, without the consent of the person who provided the information, to market the same or a similar product on the basis of that information, or the marketing approval granted to the person who submitted such information, for at least five years from the date of marketing approval by the Party. (…) (c) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not	Art. 16.10.2. (a) If a Party requires, as a condition for approving the marketing of a pharmaceutical product that utilizes a new chemical entity, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use. (b) Each Party shall provide that for data subject to subparagraph (a) that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally[7] mean five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and person's efforts and expenditures in producing them. Subject to this provision, there shall be no

[6] Article 39.3 provides for protecting undisclosed test data against unfair commercial use: "Art. 39.3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

[7] According to the "Congressional Democrats' Concept Statement on Peru & Panama FTA Changes", "…where a marketing approval application includes undisclosed test or other data, the FTA would provide for five years of data exclusivity for new chemical entities, taking account of the nature of the data and the person's efforts and expenditures in producing them. However, if a Party relies on marketing approval granted by the United States FDA, and if that Party grants approval within the six months of an application for marketing approval by a person that produced the data, the five-year period begins when the drug was first approved in the United sates (a so-called "concurrent period")." —"Congressional Democrats' Concept Statement on Peru & Panama FTA Changes", 10 May 2007. Available at: http://waysandmeans.house.gov/Media/pdf/110/05%2014%2007/05%2014%2007.pdf

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	information submitted in support of a prior marketing approval in the other territory; or (ii) evidence of the existence of a prior marketing approval in the other territory, for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.			paragraph 1 of Article 16.8, that Party may retain such system notwithstanding the obligations of that paragraph. Art. 16.8.2. If a Party provides a means of granting approval to market a product specified in paragraph 1 on the basis of the grant of an approval for marketing of the same or similar product in another country, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other country for at least five years from the date of approval for a pharmaceutical product (…) in the territory of the Party or in the other country, whichever is later.	FN25: Where a Party, on the date of its implementation of the TRIPS Agreement, had in place a system for protecting pharmaceutical or agricultural chemical products not involving new chemical entities from unfair commercial use which conferred a period of protection shorter than that specified in paragraph 1, that Party may retain such system notwithstanding the obligations of paragraph 1.	permit third persons, without the consent of the person who previously submitted information concerning safety or efficacy, to market the same or a similar product on the basis of evidence of prior marketing approval in another territory, or information concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory, for at least five years and (…) from the date of marketing approval by the Party, or the other territory, whichever is late. FN17-18 (d) For the purposes of this Article, a **new product** is one that does not contain a chemical entity that has been previously approved for marketing in the Party. (e) If any undisclosed information concerning the safety or efficacy of a product submitted to a government entity, or entity acting on behalf of a government, for the purposes of obtaining marketing approval is disclosed by a government entity, or entity acting on behalf of a government, each Party is required to protect such information from unfair commercial use in the manner set forth in this Article.	limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence or bioavailability studies. (c) Where a Party relies on a marketing approval granted by the other Party, and grants approval within six months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

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						FN 17-18: The Parties acknowledge that, at the time of entry into force of this Agreement, neither Party permits third persons, not having the consent of the person that previously submitted information concerning the safety and efficacy of a product in order to obtain marketing approval in another territory, to market a same or similar product in the territory of the Party on the basis of such information or evidence of prior marketing approval in another territory.	

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Data Exclusivity For New Clinical Information Relating to a Pharmaceutical Product with a Chemical Entity That Has Been Previously Approved for Marketing in Another Pharmaceutical Product	Art. 9.2. (c) If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of the pharmaceutical product containing the previously approved chemical entity, other than information related to bioequivalency, the Party shall not, without the consent of a person previously submitting such new clinical information to obtain marketing approval in the territory of the Party, authorize a third person to market a same or a similar product based on: (i) the new clinical information previously submitted in support of the marketing approval; or (ii) evidence of the existence of the marketing approval that was based on the new clinical information, for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party. (d) If a Party requires or permits, in connection with granting marketing approval for a pharmaceutical product of the type specified in subparagraph (c), the submission of evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory, other than evidence of information related to bioequivalency, such as evidence of prior marketing approval based on new clinical information, the Party shall not, without the consent of a person previously submitting such new clinical information to obtain marketing approval in the other territory, authorize a third person to market a same or a similar product based	*No provision*	Art. 1711 5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use. 6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a	*No provision*	*No provision*	Art. 17.10.2. With respect to pharmaceutical products, if a Party requires the submission of: (a) new clinical information (other than information related to bioequivalency) or (b) evidence of prior approval of the product in another territory that requires such new information, which is essential to the approval of a pharmaceutical product, the Party shall not permit third persons not having the consent of the person providing the information to market the same or a similar pharmaceutical product on the basis of the marketing approval granted to a person submitting the information for a period of at least three years from the date of the marketing approval by the Party or the other territory, whichever is later. FN17-19 FN 17-19: As an alternative to this paragraph, where a Party, on the date of entry into force of this Agreement, has in place a system for protecting information submitted in connection with the approval of a pharmaceutical product that utilizes a previously approved chemical component from unfair	Art. 16.10.2. (d) A Party need not apply the provisions of subparagraphs (a), (b), and (c) with respect to a pharmaceutical product that contains a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product.

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	on: (i) the new clinical information submitted in support of a prior marketing approval in the other territory; or (ii) evidence of the existence of a prior marketing approval that was based on the new clinical information in the other territory, for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party.		reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies. 7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.			commercial use, the Party may retain that system, notwithstanding the obligations of this paragraph.	

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Linking Marketing Approval to Patent Status ("Patent Linkage")	Art. 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: [FN3] (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 [FN4] 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	*No provision*	*No provision*	Art. 16.8.4. With respect to any pharmaceutical product that is subject to a patent: (…) (b) the Party shall provide that the patent owner shall be notified of the identity of any third party requesting marketing approval effective during the term of the patent; and (c) the Party shall not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or with the acquiescence of the patent owner.	Art. 17.10.2. With respect to pharmaceutical products that are subject to a patent, each Party shall: (…) (b) make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent; and (c) not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner.	Art. 17.10.4. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory: (a) that Party shall provide measures in its marketing approval process to prevent those other persons from: (i) marketing a product, where that product is claimed in a patent; or (ii) marketing a product for an approved use, where that approved use is claimed in a patent, during the term of that patent, unless by consent or acquiescence of the patent owner; and (b) if the Party permits a third person to request marketing approval to enter the market with: (i) a product during the term of a patent identified as claiming the product; or (ii) a product for an	Art. 16.10.3. Each Party shall provide: (a) procedures, such as judicial or administrative proceedings, and remedies, such as preliminary injunctions or equivalent effective provisional measures, for the expeditious adjudication of disputes concerning the validity or infringement of a patent with respect to patent claims that cover an approved pharmaceutical product or its approved method of use; (b) a transparent system to provide notice to a patent holder that another person is seeking to market an approved pharmaceutical product during the term of a patent covering the product or its approved method of use; and (c) sufficient time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies for an infringing product. Art. 16.10.4.[8] Where a Party 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 evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, the Party may implement the provisions of paragraph 3 by: (a) implementing measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming

[8] According to the "Congressional Democrats' Concept Statement on Peru & Panama FTA Changes", the May 10, 2007 Agreement, "Amend[s] [the] FTA so that there is no "linkage" requirement between drug regulatory agencies and patent issues: in particular, no requirement that the drug regulatory agency withhold approval of a generic until it can certify that no patent would be violated if the generic were marketed."— "Congressional Democrats' Concept Statement on Peru & Panama FTA Changes", 10 May 2007. Available at: http://waysandmeans.house.gov/Media/pdf/110/05%2014%2007/05%2014%2007.pdf

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	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. FN5 FN 3: For greater certainty, the Parties recognize that this paragraph does not imply that the marketing approval authority should make patent validity or infringement determinations. FN 4: [Negotiator's Note: As used in Article 9.5(b)(i), "adjudicate" does not mean final adjudication.] FN 5: A Party may comply with paragraph 5(d) by providing a period of marketing exclusivity in appropriate circumstances to the first such other person or persons to challenge a patent.					approved use, during the term of a patent identified as claiming that approved use, the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.	the product or its approved method of use during the term of that patent, unless by consent or acquiescence of the patent owner; FN17 and (b) providing that the patent owner shall be informed of the identity of any such other person who requests marketing approval to enter the market during the term of a patent identified to the approving authority as covering that product; provided that the Party also provides: (c) an expeditious administrative or judicial procedure in which the person requesting marketing approval can challenge the validity or applicability of the identified patent; and (d) effective rewards for a successful challenge of the validity or applicability of the patent. FN18 FN 17: For greater certainty, the Parties recognize that this provision does not imply that the marketing approval authority should make patent validity or infringement determinations. FN 18: A Party may comply with clause (d) by providing a period of marketing exclusivity for the first applicant to successfully challenge the validity or applicability of the patent.

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Biologics	Art. 9.9 [Placeholder for specific provision applying to biologics].	*No provision*	*No provision*	*No provision*	*No provision*	*No provision*	*No provision*
Definition of a New Pharmaceutical Product	Art. 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] FN 6: For greater certainty, the Parties understand that the term "**pharmaceutical product**" as used in this Chapter includes biologic products.	*No provision*	*No provision*	*No provision*	*No provision*	Art. 17.10.1. (d) For the purposes of this Article, a **new product** is one that does not contain a chemical entity that has been previously approved for marketing in the Party.	*No provision*
Judicial and Administrative Presumption of Patent Validity	Art. 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.	*No provision*	*No provision*	*No provision*	*No provision*	Art. 17.11.18. In proceedings concerning the grant of provisional measures in relation to enforcement of a patent, each Party shall provide for a rebuttable presumption that the patent is valid.	*No provision*
Damages	Art. 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.	Art. 45.1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.	Art. 1715 2. Each Party shall provide that its judicial authorities shall have the authority: (…) (d) to order the infringer of an intellectual property right to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of the infringement where the infringer knew or had reasonable grounds to know that it was engaged in an infringing activity;	Art. 16.9.8. (…) In addition, in determining injury to the right holder, the judicial authorities shall, *inter alia*, consider the value of the infringed-upon good or service, according to the suggested retail price of the legitimate good or service.	Art. 17.11.8. Each Party shall provide that: (…) (b) In determining injury to the right holder, the judicial authorities shall, *inter alia*, consider the legitimate retail value of the infringed goods.	Art. 17.11.6. Each Party shall provide that: (…) (b) in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, *inter alia*, any legitimate measure of the value of the infringed on good or service that the right holder submits, including the suggested retail price.[9]	Art. 16.11.7. (b) Each Party shall provide that: (…) (b) in determining the amount of damages for infringement of intellectual property rights, its judicial authorities shall consider, *inter alia*, the value of the infringed-on good or service, according to the suggested retail price or other legitimate measure of value submitted by the right holder.

[9] Side Letter 2 allows Australia to maintain its current system for compensation damages.

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Ex-Officio Border Measures	Art. 14.4. Each Party shall provide that its competent authorities may initiate border measures *ex officio* [FN22] with respect to imported, exported, or in-transit merchandise, [FN23] or merchandise in free trade zones, that is suspected of being counterfeit or confusingly similar trademark goods, or pirated copyright goods. FN 22: For greater certainty, the parties understand that *ex officio* action does not require a formal complaint from a private party or right holder. FN 23: For purposes of Article 14.4, **in-transit merchandise** means goods under "Customs transit and goods transhipped," as defined in the *International Convention on the Simplification and Harmonization of Customs Procedures* (Kyoto Convention).	*No provision*	Art. 1718 1. Each Party shall, in conformity with this Article, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark goods or pirated copyright goods may take place, to lodge an application in writing with its competent authorities, whether administrative or judicial, for the suspension by the customs administration of the release of such goods into free circulation. No Party shall be obligated to apply such procedures to goods in transit. A Party may permit such an application to be made in respect of goods that involve other infringements of intellectual property rights, provided that the requirements of this Article are met. A Party may also provide for corresponding procedures concerning the suspension by the customs administration of the release of infringing goods destined for exportation from its territory.	Art. 16.9.19. Each Party shall provide that its competent authorities may initiate border measures *ex officio*, without the need for a formal complaint from a private party or right holder. Such measures shall apply to shipments of pirated and counterfeit goods imported into or exported out of a Party's territory, including shipments consigned to a local party. For transshipped goods that are not consigned to a local party, each Party shall, upon request, endeavor to examine such goods. For products transshipped through the territory of a Party destined for the territory of the other Party, the former shall cooperate to provide all available information to the latter Party to enable effective enforcement against shipments of counterfeit or pirated goods.	Art. 17.11.20. Each Party shall provide that the competent authorities are permitted to initiate border measures *ex officio*, without the need for a formal complaint from a person or right holder. Such measures shall be used when there is reason to believe or suspect that goods being imported, destined for export, or moving in transit are counterfeit or pirated. In case of goods in transit, each Party, in conformity with other international agreements subscribed to by it, may provide that *ex officio* authority shall be exercised prior to sealing the container, or other means of conveyance, with the customs seal, as applicable.[32]	Art. 17.11.22. Each Party shall provide that its customs authorities may initiate border measures *ex officio* with respect to imported merchandise suspected of infringing being counterfeit trademark or pirated copyright goods, without the need for a specific formal complaint.	Art. 16.11.23. Each Party shall provide that its competent authorities may initiate border measures *ex officio* with respect to merchandise for importation, exportation, or in transit, without the need for a formal complaint from a private party or right holder. Such measures shall be used when there is reason to believe or suspect that such merchandise is counterfeit or pirated.