

Comparison of Peru FTA Chapter 16.9, 16.10 and 16.13 – Intellectual Property  
Pharmaceutical-Related Provisions  
CPATH 6-27-07

<b>Old Peru Ch 16</b> <b>(language that has been changed in bold;</b> <b>language repeated elsewhere in <i>italics</i>)</b>	<b>New Peru Ch 16 June 2007</b> <b>(differences in bold type; significant</b> <b>changes within new text also <u>underlined</u>)</b>
<p><b>Article 16.9: Patents</b></p> <p>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. 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.</p> <p>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. Notwithstanding the foregoing, a Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available consistent with paragraph 1. Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection.</p> <p>3. Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.</p> <p>4. Without prejudice to Article 5.A(3) of the Paris Convention, each Party shall provide that a patent may be revoked or nullified only on grounds that would have</p>	<p><b>Article 16.9: Patents</b></p> <p>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. 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.</p> <p>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. Notwithstanding the foregoing, a Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available consistent with paragraph 1. Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection.</p> <p>3. Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.</p> <p>4. Without prejudice to Article 5.A(3) of the Paris Convention, each Party shall provide that a patent may be revoked or nullified a</p>

<p>justified a refusal to grant the patent according to its laws. However, a Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for revoking, nullifying, or holding a patent unenforceable.</p> <p>5. Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product or agricultural chemical product, that Party shall provide that any product produced under such authority shall not be made, used, sold, offered for sale, or imported in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.</p> <p>6.</p> <p>(a) Each Party shall provide the means to and shall, at the request of the patent owner, compensate for unreasonable delays in the issuance of the patent by restoring patent term or patent rights.</p>	<p>refusal to grant the patent according to its laws. However, a Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for revoking, nullifying, or holding a patent unenforceable.</p> <p>5. Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product or agricultural chemical product, that Party shall provide that any product produced under such authority shall not be made, used, sold, offered for sale, or imported in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.</p> <p><b>6. (a) Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays. The Parties shall cooperate and provide assistance to one another to achieve these objectives.</b></p> <p>(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, <b>other than a patent for a pharmaceutical product</b>, by restoring patent term or patent rights. <b>Each Party may 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</b></p>
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Any such restoration shall confer 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.

(b) With respect to any pharmaceutical product that is covered by a patent, each Party shall 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 such restoration shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent.

7. Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure (a) was made or authorized by, or derived from, the patent applicant, and (b) occurred within 12 months prior to the date of filing of the application in the territory of the Party.

8. Each Party shall provide patent applicants with at least one opportunity to make amendments, corrections, and observations in connection with their applications. Each Party shall provide that

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. 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.

(c) With respect to any pharmaceutical product that is covered by a patent, each Party **may** 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.

7. Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure (a) was made or authorized by, or derived from, the patent applicant, and (b) occurred within 12 months prior to the date of filing of the application in the territory of the Party.

8. Each Party shall provide patent applicants with at least one opportunity to make amendments, corrections, and observations in connection with their applications. Each Party shall provide that

<p>no amendment or correction shall introduce new matter into the disclosure of the invention as filed in the original application.</p> <p>9. Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be carried out by a person skilled in the art, without undue experimentation, as of the filing date and may require the applicant to indicate the best mode for carrying out the invention known to the inventor as of the filing date.</p> <p>10. With the aim of ensuring that the claimed invention is sufficiently described, each Party shall provide that a claimed invention is sufficiently supported by its disclosure if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention as of the filing date.</p> <p>11. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.<sup>16</sup></p> <p><sup>16</sup> For greater certainty, this paragraph is without prejudice to paragraphs 1 and 2.</p>	<p>no amendment or correction shall introduce new matter into the disclosure of the invention as filed in the original application.</p> <p>9. Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be carried out by a person skilled in the art, without undue experimentation, as of the filing date and may require the applicant to indicate the best mode for carrying out the invention known to the inventor as of the filing date.</p> <p>10. With the aim of ensuring that the claimed invention is sufficiently described, each Party shall provide that a claimed invention is sufficiently supported by its disclosure if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention as of the filing date.</p> <p>11. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.<sup>16</sup></p> <p><sup>16</sup> For greater certainty, this paragraph is without prejudice to paragraphs 1 and 2.</p>
<p><b>Article 16.10: Measures Related to Certain Regulated Products</b></p> <p>1. (a) If a Party requires or permits, as a condition of granting marketing approval for <b>a new pharmaceutical or new agricultural chemical product</b>, the submission of information concerning safety or efficacy of the product, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the Party, authorize another to</p>	<p><b>Article 16.10: Measures Related to Certain Regulated Products</b></p> <p><i>Agricultural Chemical Products</i></p> <p>1. (a) If a Party requires or permits, as a condition of granting marketing approval for <b>a new agricultural chemical product</b>, the submission of information concerning safety or efficacy of the product, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the Party, authorize another to market a same or a similar product based</p>

<p>market a same or a similar product based on:</p> <p>(i) the safety or efficacy information submitted in support of the marketing approval; or (ii) evidence of the marketing approval,</p> <p>for <b>at least five years for pharmaceutical products and</b> ten years for agricultural chemical products from the date of marketing approval in the territory of the Party.</p> <p>(b) If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical or new agricultural chemical 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 that previously submitted the safety or efficacy information to obtain marketing approval in another territory, authorize another to market a same or a similar product based on:</p> <p style="padding-left: 40px;">(i) the safety or efficacy information submitted in support of the prior marketing approval in the other territory; or (ii) evidence of prior marketing approval in the other territory,</p> <p>for at <b>least five years for pharmaceutical products and</b> ten years for agricultural chemical products from the date of marketing approval of the new product in the territory of the Party. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing</p>	<p>on:</p> <p>(i) the safety or efficacy information submitted in support of the marketing approval; or (ii) evidence of the marketing approval,</p> <p>for at least ten years from the date of marketing approval in the territory of the Party.</p> <p>(b) If a Party requires or permits, in connection with granting marketing approval for a new agricultural chemical 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 that previously submitted the safety or efficacy information to obtain marketing approval in another territory, authorize another to market a same or a similar product based on:</p> <p style="padding-left: 40px;">(i) the safety or efficacy information submitted in support of the prior marketing approval in the other territory; or (ii) evidence of prior marketing approval in the other territory,</p> <p>for at least ten years from the date of marketing approval of the new product in the territory of the Party. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.</p>
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<p>approval in the other territory.</p> <p>(c) For purposes of this Article, <b>a new pharmaceutical product is one that does not contain a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product</b> and a new agricultural chemical product is one that contains a chemical entity that has not been previously approved in the territory of the Party for use in an agricultural chemical product.</p> <p>2. When a product is subject to a system of marketing approval in the territory of a Party pursuant to paragraph 1 and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in paragraph 1.</p> <p><i>[moved in new text to paragraph 5]</i></p>	<p>(c) For purposes of this Article, a new agricultural chemical product is one that contains a chemical entity that has not been previously approved in the territory of the Party for use in an agricultural chemical product.</p> <p><b><i>Pharmaceutical Products</i></b></p> <p>2. (a) <b>If a Party requires, as a condition for approving the marketing of a pharmaceutical product that utilizes a <u>new chemical entity</u>, the submission of <u>undisclosed</u> 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></p> <p>(b) <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</b></p>
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**of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally 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 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.**

**(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.**

**(e) Notwithstanding subparagraphs (a), (b), and (c), a Party may take measures to protect public health in accordance with:**

**(i) the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration");**

**(ii) any waiver of any provision of the**

<p>3. 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,</p>	<p><b>TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and</b></p> <p><b>(iii) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.</b></p> <p><b>3. Each Party shall provide:</b></p> <p><b>(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></p> <p><b>(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</b></p> <p><b>(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.</b></p> <p>4. 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 <b>may implement the provisions of paragraph 3 by:</b></p>
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<p>that Party shall:</p> <p>(a) implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent, unless by consent or acquiescence of the patent owner;<sup>17</sup> and</p> <p>(b) provide 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.</p> <p><i>2. When a product is subject to a system of marketing approval in the territory of a Party pursuant to paragraph 1 and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 in the event that the patent protection terminates on a date earlier than the end of the term of protection</i></p>	<p>(a) implementing measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent, unless by consent or acquiescence of the patent owner;<sup>17</sup> and<sup>17</sup></p> <p>For greater certainty, the Parties recognize that this provision does not imply that the marketing approval authority should make patent validity or infringement determinations.</p> <p>(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;</p> <p>provided that the Party also provides:</p> <p>(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</p> <p>(d) effective rewards for a successful challenge of the validity or applicability of the patent.<sup>18</sup></p> <p><sup>18</sup> 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.</p> <p><i>General Provisions</i></p> <p>5. Subject to paragraph 2(e), when a product is subject to a system of marketing approval in the territory of a Party pursuant to paragraph 1 <b>or</b> 2 and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 <b>or</b> 2 in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in paragraph 1 <b>or</b> 2.</p>
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*specified in paragraph 1.*

[same as #2 above; repeated here for comparison to new version]

**Article 16.13: Understandings Regarding Certain Public Health Measures**

1. The Parties affirm their commitment to the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2).

2. The Parties have reached the following understandings regarding this Chapter.

(a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.

(b) In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively, the "TRIPS/health solution"), this Chapter does not and should not prevent the effective utilization of the TRIPS/health solution.

(c) With respect to the aforementioned

	<p>matters, if an amendment of the TRIPS Agreement enters into force with respect to the Parties and a Party's application of a measure in conformity with that amendment violates this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the amendment.</p>
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CPATH critique of old agreement, 5-25-07:

The PTPA seeks to ensure that the term "new product" that is used in Article 16.10 is not confused with the "novelty" requirement for patentability found in Article 16.9.1 that an invention must be "new."

"ITAC-15 welcomes, as an important clarification of the term "new chemical entity" found in TRIPS Article 39.3, the regulatory-related definition of a "new product" contained in Article 16.10.1(c) as being a product that does not contain a chemical entity that had been previously approved in Peru for use in a pharmaceutical or agricultural chemical product.

<sup>1</sup> The data exclusivity measure, for example, exceeds TRIPS in effectively barring the ability of generic competitors to refer to the clinical trial data used by an originator company in preparing for marketing approval. TRIPS 39.3 states:

"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."

In contrast, the Peru agreement imposes an obligation of "non-reliance" on either the originator's approval or the originator's data package itself for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product in Peru. (Article 16.10.1(a))

In addition, the PTPA explicitly provides protection in cases where regulatory approval is conditioned on the demonstration of prior marketing approval in another territory by requiring the deferral of the date of any marketing approval to third parties not having the consent of the party providing the information in the other territory for a period of at least five years from the date of approval for a pharmaceutical product.