

**This Document Contains TPP CONFIDENTIAL Information  
MODIFIED HANDLING AUTHORIZED\***

COVER PAGE

TRANS-PACIFIC PARTNERSHIP

INTELLECTUAL PROPERTY RIGHTS CHAPTER

(Selected Provisions)

SEPTEMBER 2011

Derived From: Classification Guidance  
dated March 4, 2010  
Reason: 1.4(b)  
Declassify on: Four years from entry into  
force of the TPP agreement  
or, if no agreement enters  
into force, four years from  
the close of the negotiations.

\* This document must be protected from unauthorized disclosure, but may be mailed or transmitted over unclassified e-mail or fax, discussed over unsecured phone lines, and stored on unclassified computer systems. It must be stored in a locked or secured building, room, or container.

**CHAPTER [ ]  
INTELLECTUAL PROPERTY RIGHTS**

ARTICLE [X]: 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 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.

**This Document Contains TPP CONFIDENTIAL Information**  
**MODIFIED HANDLING AUTHORIZED\***

**ARTICLE 8: PATENTS**

5. Consistent with paragraph [4] (patent exceptions and limitations), each Party shall permit third persons to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product in that Party, and shall further provide that any product produced under such authority shall not be made, used, or sold in its territory other than for purposes related to generating such information to support an application for meeting marketing approval requirements of that Party. If the Party permits exportation of such a product, the Party shall provide that the product shall only be exported outside its territory for purposes of generating information to support an application for meeting marketing approval requirements of that Party.

6.

- (a) Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable or unnecessary delays.
- (b) Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in the granting of the patent. For purposes of this subparagraph, an unreasonable delay at least shall include a delay in the issuance of the patent of more than four years from the date of filing of the application in the territory of the Party, or two years after a request for examination of the application has been made, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays.
- (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<sup>1</sup> 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.

---

<sup>1</sup> 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.

**This Document Contains TPP CONFIDENTIAL Information**  
**MODIFIED HANDLING AUTHORIZED\***

- (e) In implementing subparagraph 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.<sup>2</sup>
- (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.

**ARTICLE 9: MEASURES RELATING TO CERTAIN REGULATED PRODUCTS**

...

Pharmaceutical Products

Submission of Information of Evidence Concerning the Safety or Efficacy of a New  
Pharmaceutical Product

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.

---

<sup>2</sup> Negotiators 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, such as to assess such implications in jurisdictions where risks may differ from those faced in markets where the product has previously been approved).

**This Document Contains TPP CONFIDENTIAL Information**  
**MODIFIED HANDLING AUTHORIZED\***

- (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 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.

Submission of New Clinical Information or Evidence relating to a Pharmaceutical Product that Includes a Chemical Entity that has been Previously Approved for Marketing in Another Pharmaceutical Product

- (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 form 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 on:

**This Document Contains TPP CONFIDENTIAL Information**  
**MODIFIED HANDLING AUTHORIZED\***

- (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 territory of the Party.

Additional Provisions relating to Pharmaceutical Products

3. Notwithstanding paragraph 2 above, a Party may take measures to protect public health in accordance with:
- (a) the Declaration of the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”);
  - (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and
  - (c) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.
4. A Party that requires or permits an applicant to obtain approval for marketing a new pharmaceutical product in its territory by relying, in whole or in part, on the prior approval of the pharmaceutical product by the regulatory authority in another territory may, as a condition for providing the period of data protection specified in subparagraph 2(b) or 2(d), require an applicant that has submitted an application for marketing approval consistent with said subparagraphs to commence the process of obtaining marketing approval for that pharmaceutical product within [X] years of the date of first marketing approval of the same pharmaceutical product in another Party.
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:<sup>3</sup>
- (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).

---

<sup>3</sup> For greater certainty, the Parties recognize that this paragraph does not imply that the marketing approval authority should make patent validity or infringement determinations.

**This Document Contains TPP CONFIDENTIAL Information**  
**MODIFIED HANDLING AUTHORIZED\***

- (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<sup>4</sup> disputes concerning the validity or infringement of allegedly infringed patents; and
  - (ii) judicial or administrative procedures, including effective provisional measures, to allow for the timely adjudication of disputes concerning the validity or infringement of an allegedly infringed patent.
- (c) if such other person's product has been found to infringe a valid patent identified pursuant to subparagraph (a), provide measures that operate to prohibit the unauthorized marketing of that product prior to the expiration of the patent.
- (d) when a Party delays the grant of marketing approval consistent with subparagraph 5(b)(i), provide an effective reward, consistent with the provisions of this Agreement, for the successful challenge of the validity or applicability of the patent.<sup>5</sup>

6. In implementing subparagraph 5(b)(i), and as a condition for providing the automatic delay of the grant of marketing approval specified in subparagraph 5(b)(i) for a new pharmaceutical product approved consistent with subparagraph 2(b) or 2(d), a Party may require that an applicant that has submitted an application for marketing approval consistent with subparagraph 2(b) or 2(d) to commence the process of obtaining marketing approval for that new pharmaceutical in the Party within [X] years of the date of first marketing approval of the pharmaceutical product in another Party.

7. Where a Party provides for a period of data protection for a pharmaceutical product of more than [5+Y] years pursuant to subparagraph 2(a) or 2(b) of this Article, that Party is not required to implement for that pharmaceutical product subparagraphs 2(c), 2(d) (3-year data protection in connection with submission of new clinical information), 5(b)(i) (automatic delay of marketing approval) or 5(d) of this Article (reward for the successful challenge of the validity or applicability of a patent).

8. Where a Party chooses to apply subparagraph 6(e) of Article 8 and paragraphs 4 and 6 of this Article, the following provisions shall apply:

- (a) a Party shall permit an applicant to commence the process of obtaining marketing approval by providing the regulatory authority of the Party information supporting approval of the new pharmaceutical product in the Party that is available to the person at the time the request is made, such as evidence of the prior approval of the product in another Party. It is understood that, while a Party may impose reasonable additional requirements or deadlines as a condition of authorizing the person to market the

---

<sup>4</sup> Negotiator's Note: As used in Article 9.5(b)(i), "adjudicate" does not mean final adjudication.

<sup>5</sup> 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.

**This Document Contains TPP CONFIDENTIAL Information**  
**MODIFIED HANDLING AUTHORIZED\***

pharmaceutical product in its territory, satisfaction of those additional requirements or deadlines or the granting of approval shall be recognized by the Party as necessarily occurring after the commencement of the marketing approval process within the meaning of subparagraph 6(e) of Article 8 and paragraphs 4 and 6 of this Article; and

- (b) a Party may not refuse to grant approval of a new pharmaceutical product on the basis of a failure of an applicant for marketing approval to satisfy the requirements of subparagraph 6(e) of Article 8, or paragraphs 4 and 6 of this Article.

9. [Placeholder for specific provision applying to biologics].

General Provisions relating to Pharmaceutical Products and Agricultural Chemical Products

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.<sup>6</sup> 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.

11. Subject to paragraph 3 (protection of public health), when a product is subject to a system of marketing approval in the territory of a Party pursuant to paragraph 1 or 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 or 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 or 2.

---

<sup>6</sup> For greater certainty, the Parties understand that the term “pharmaceutical product” as used in this Chapter includes biologic products.