Comparative Table of Patent Linkage Provisions in U.S. Free Trade Agreements and the U.S. Proposal to the Trans-Pacific Partnership (TPP) Agreement

Item	U.S. TPP Proposal	U.S.-Singapore FTA (2004)	U.S.-Chile FTA (2004)	U.S.-Australia FTA (2005)	U.S.-Peru FTA (2006)
Obligation ("each Party shall")	**X**	**X**	**X**	**X**	N/A[1]
Provide a system	**X** transparent and effective				**X** transparent
To identify	**X** patents or approved method of use		"make available" the identity of third person	**X** third person	
To notify patent holder …	**X** of identity of third person applying for marketing approval	**X** of identity of third person applying for marketing approval		**X** that there is a request for marketing approval	**X** that another party seeks marketing approval
	of product that is "the same … or similar"				
Automatic delay of marketing approval	**X**	Do not grant marketing approval unless by consent or acquiescence of the patent owner.	Do not grant marketing approval unless by consent or acquiescence of the patent owner.	Provide measures to prevent other persons from marketing products claimed in a patent.	Provide sufficient time and opportunity for patent holder to seek remedies.
Provisional measures	**X**				
Safeguards	**X** Imports U.S.-style measures to deter abuses by patent holders.	*Parties are free to provide their own safeguards.*	*Parties are free to provide their own safeguards.*	*Parties are free to provide their own safeguards – see Australian anti-evergreening measures (Therapeutic Act of 1989, Section 26C and 26D).*	*Parties are free to provide their own safeguards.*

[1]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. Available at: http://waysandmeans.house.gov/Media/pdf/110/05%2014%2007/05%2014%2007.pdf.

Patent Provisions

U.S. proposal to the Trans-Pacific Partnership (TPP) Agreement

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 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.

U.S.-Singapore FTA (2004)

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

U.S.-Chile FTA (2004)

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.

U.S.-Australia FTA (2005)

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 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

U.S.-Peru FTA (2006)

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.[1] 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 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.