



TPP Transition Periods: Bad Rules Coming Soon in a TPP Country Near You

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Trans-Pacific Partnership (TPP) negotiations concluded in October 2015. Pharmaceutical intellectual property (IP) provisions of the proposed pact have been one of the most contentious issues throughout more than five years of negotiations. Pharmaceutical IP was one of only a few remaining areas that caused the Maui ministerial attempt to reach a deal fail and the Atlanta talks to be extended into double-overtime.¹

Despite fierce resistance from some TPP country negotiators, the published IP chapter² shows that the U.S. Trade Representative (USTR) was successful in including many harmful provisions that, if the deal is enacted, will harm people's health.

The chapter would require all countries eventually to conform to every pharmaceutical patent rule in the TPP, regardless of any individual country's wealth (or lack thereof) or level of development. If adopted, the rules will delay generic and biosimilar competition, making the medicines upon which people depend to stay alive more expensive and, as a consequence, unobtainable.

Forcing expansive pharmaceutical monopoly rules on countries that can scarcely afford high drug prices has not always been U.S. trade policy, and in the past U.S. policymakers have recognized that the needs of developing countries should not always be subordinate to U.S. pharmaceutical industry profits.

On May 10, 2007, democrats in the U.S. House of Representatives came to a compromise with the George W. Bush Administration on the U.S. position regarding access to medicines and IP protections in trade deals with developing countries. Through the May 10 Agreement, as it came to be known, for the first time the U.S. recognized the detrimental impact that the inclusion of stringent IP rules in trade agreements can have on access to medicines in developing countries.³

¹ Public Citizen's Global Access to Medicines Program. (2015). Eleventh Hour TPP Deal on Biotech Drugs Still Harms Access to Medications, May Increase Ire Over TPP in Congress [Press statement]. Retrieved from <http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=5653>

² The TPP IP Chapter is available at <https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text>.

³ Oxfam America. Intellectual property and access to medicine. Retrieved October 8, 2015, from <http://policy-practice.oxfamamerica.org/work/trade/intellectual-property-and-access-to-medicine/>

U.S. trade policy under May 10 made patent linkage⁴ and patent term extensions optional for pharmaceuticals and provided important limitations on data exclusivity rules for developing countries.⁵

From very early on in TPP negotiations, to the ire of health advocates, it became apparent that USTR was abandoning the May 10 Agreement template.⁶ With the recent official release of the TPP IP chapter, for the first time the public can see precisely to what rules negotiators agreed, and, importantly, how far beyond the May 10 Agreement the provisions extend developing country pharmaceutical IP obligations.

May 10 Out; Transition Periods In

An October 2014 leak of the draft IP chapter, published by WikiLeaks,⁷ revealed two competing systems for addressing developing country pharmaceutical IP rules.⁸ One system (henceforth referred to as the development approach), which was ultimately abandoned, provided that some IP provisions would not be required of countries until they reached a certain level of development, defined by an economic indicator.⁹

Addendum II of the 2014 text stood as an alternative to the development approach, requiring countries to conform to all TPP IP rules within a static period of time, regardless of whether they reached a certain development threshold.¹⁰ The 2014 transition periods proposal showed that different countries would be required to implement TPP IP rules at different times, but also that precisely how much time and for which countries longer transitions would be allowed had not been determined at the time of the draft.

⁴ Though the U.S.-Peru FTA does not require patent linkage *per se*, it does require certain administrative rules to be in place.

⁵ Oxfam America. Intellectual property and access to medicine. Retrieved October 8, 2015, from <http://policy-practice.oxfamamerica.org/work/trade/intellectual-property-and-access-to-medicine/>

⁶ Baker, Brook. "US Trade-Enhancing Access to Medicines (Access Window) in its proposed TPP IP text is a sham," available at <http://infojustice.org/resource-library/us-trade-enhancing-access-to-medicines-access-window-in-its-proposed-tpp-ip-text-is-a-sham>

⁷ See <http://www.citizen.org/tpp-ip-wikileaks>

⁸ Public Citizen's Global Access to Medicines Program. Addendum II Transition Periods Proposal for Implementation of Onerous Trans-Pacific Partnership Intellectual Property Rules. (2014, October 16). Retrieved October 8, 2015, from <http://www.citizen.org/documents/tpp-transition-periods.pdf>

⁹ Baker, Brook. "US's Proposed TPP Transition Period for Middle-Income Parties is Fools Gold," available at <http://infojustice.org/archives/31540>

¹⁰ Public Citizen's Global Access to Medicines Program. Addendum II Transition Periods Proposal for Implementation of Onerous Trans-Pacific Partnership Intellectual Property Rules. (2014, October 16). Retrieved October 8, 2015, from <http://www.citizen.org/documents/tpp-transition-periods.pdf>

The final draft of the TPP IP chapter shows that while the development approach was completely abandoned, a version of the transition periods approach was agreed to by the Parties. Transition to implementing pharmaceutical IP rules seems to have been negotiated bilaterally, with the U.S. taking a divide-and-conquer approach. Similar to those in the U.S.-Central American Free Trade Agreement (CAFTA)¹¹, the TPP includes different transition periods depending on the country and the provision (this note only looks at transition periods for pharmaceutical rules; there are other transition periods in this chapter e.g. for copyright and trademark provisions). Furthermore, some countries were given an option to keep current domestic rules in place regarding the implementation of certain rules.

It is vitally important to remember that, with limited exceptions articulated in the endnotes below, all TPP countries – regardless of level of development, poverty or wealth – will be required to adopt the TPP’s pharmaceutical IP rules. The periods are too short to expect that countries will be substantially more able to absorb the rules’ impact than they are today. There is little reason to believe that these rules would actually be good for the people residing in TPP countries, even after the transition periods allowed. Indeed, even in the U.S., where similar rules are already in place, the high prices of medicines – bolstered by TPP-style monopolistic protections – have led to treatment rationing, prescriptions going unfilled and severe budgetary strains.

The table below displays the timetables of each country for adopting each IP provision that impacts access to medicines.

¹¹ Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3). The U.S.-Central American Free Trade Agreement (FTA), The Intellectual Property Provisions; Report of the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3). (2004, March 12). Retrieved October 8, 2015. http://www.cpath.org/sitebuildercontent/sitebuilderfiles/cafta_ip_ifac.pdf

Table of Transition Periods for TPP Pharmaceutical Rules

	Patent Linkage	Marketing Exclusivity (biologics)	Marketing Exclusivity (small molecule)	Extended Exclusivity for New Clinical Information	Patent Term Adjustment (Regulatory Approval)	Patent Term Adjustment (Patent Examination)	UPOV91
Australia							
Brunei	2 years	4 years ⁱ	4 years ⁱ	4 years ⁱ			3 years
Canada							
Chile		No transition period ⁱⁱ	No transition period ⁱⁱ	No transition period ⁱⁱ			
Japan							
Malaysia	4.5 years	5 years ⁱⁱⁱ	No transition period ⁱⁱⁱ	No transition period ⁱⁱⁱ	4.5 years		4 years
Mexico		5 years	5 years	5 years	4.5 years		4 years
New Zealand							3 years ^{iv}
Peru		10 years ^v	No transition period ^v	5 years ^v	No transition period ^{vi}	No transition period ^{vi}	
Singapore							
United States							
Vietnam	3 years	10 years ^{vii}	10 years ^{vii}	10 years ^{vii}	5 years ^{viii}	3 years	

Blank spaces in the chart indicate no transition period. Where “no transition period” is written out, it is only to indicate that there is an endnote relevant to that country and provision.

ⁱ A note attached this provision states “If there are unreasonable delays in Brunei in the initiation of the filing of marketing approval applications for new pharmaceutical products after Brunei implements its obligations under Article 18.50 and Article 18.52 in connection with subparagraphs (a)(iv) and (a)(vi), Brunei may consider adopting measures to incentivize the timely initiation of the filing of these applications with a view to the introduction of new pharmaceutical products in its market.”

ⁱⁱ Annex 18-B Chile provides Chile with the option of maintaining its current system of exemptions for regulatory exclusivity. Currently, Chilean law requires five years of regulatory exclusivity (both data and marketing) for pharmaceutical products with certain limited exceptions. One such exception in Chilean law allows regulatory authorities not to provide exclusivity in the event that a product was approved in another country more than 12 months prior to the application for registration being filed in Chile.

ⁱⁱⁱ Annex 18-C states “Malaysia may, for the purpose of granting protection as specified in Article 18.50.1 and Article 18.50.2 (Protection of Undisclosed Test or Other Data) and Article 18.52.1 (Biologics), require an applicant to commence the process of obtaining marketing approval for pharmaceutical products covered under those Articles within 18 months from the date that the product is first granted marketing approval in any country.” This provides Malaysia the option of not granting regulatory exclusivity to a product if said product was granted marketing approval in any other country more than 18 months prior to applying for marketing approval in Malaysia. Annex 18-C goes on to clarify that regulatory exclusivity periods begin on the date of marketing approval for the product in Malaysia. The flexibility provided to Malaysia as described in the Annex also applies to new clinical information.

^{iv} New Zealand is given the option of within three years either a) acceding to the UPOV (1991) Convention or b) adopting a “*sui generis* plant variety rights system that gives effect to the UPOV 1991.”

^v Annex 18-D adds that if Peru relies on the marketing approval granted by another Party and grants approval within 6 months of the filing of a complete application in Peru, then Peru will be allowed to calculate the length of regulatory exclusivity (for both small-molecule drugs and biologics as well as for new clinical information) starting from the date of marketing approval on which Peruvian marketing approval relied. Further, the Annex articulates that Peru may maintain its current domestic rules regarding the grant of five-year marketing exclusivity for small-molecule and biologic drugs.

^{vi} The TPP’s “Annex to IP Chapter – Peru” requires Peru to commit “to make its best efforts to obtain a waiver from the Andean Community that allows it to adjust its patent term in a way that is consistent with Article 18.46.3 and Article 18.48.2.” In other words, because of potential inconsistency with Andean Community law, Peru will be obligated to seek a waiver. The Annex goes on to state that if Peru fails to achieve such a waiver, Peru will continue to ensure that “it does not discriminate with respect to the availability or enjoyment of patent rights based on the field of technology, the place of invention, and whether products are imported or locally produced,” and thus the treatment of pharmaceutical patents will be no less favorable than treatment of other patents.

^{vii} A note attached to this provision states, “The Parties will consider a justified request from Viet Nam for an extension of the transition period for up to two additional years.”

^{viii} A note attached to this provision states, “For transitions for Article 18.46.3 and Article 18.46.4 (Patent Term Adjustment for Patent Office Delays) for patents claiming pharmaceutical products and agricultural chemical products, the Parties will consider a justified request from Viet Nam for an extension of the transition period for up to one additional year.”