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## TPP Transition Periods on Pharmaceutical Intellectual Property Rules Bad Rules Coming Soon in a TPP Country Near You

### Introduction

Trans-Pacific Partnership (TPP) negotiations concluded earlier this week in Atlanta. 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.<sup>1</sup>

Despite fierce resistance from some TPP country negotiators, the final version of the IP chapter published today by WikiLeaks<sup>2</sup> 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 finalized 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 expensive for longer and, as a consequence, unobtainable.

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<sup>1</sup> 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>

<sup>2</sup> <https://wikileaks.org/tpp-ip3>

Forcing expansive pharmaceutical monopoly rules on countries that can scarcely afford high medicine 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.<sup>3</sup>

U.S. trade policy under May 10 made patent linkage<sup>4</sup> and patent term extensions optional for pharmaceuticals and provided important limitations on data exclusivity rules for developing countries for the duration of the free trade agreement (FTA).<sup>5</sup>

From very early on in the TPP negotiations, to the ire of health advocates, it became apparent that USTR was abandoning the May 10 Agreement template.<sup>6</sup> With the publication of the concluded version of the TPP IP chapter by WikiLeaks today, 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

The October 2014<sup>7</sup> WikiLeaks released text revealed two competing systems for addressing developing country pharmaceutical IP rules.<sup>8</sup> 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.<sup>9</sup>

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<sup>3</sup> 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/>

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

<sup>5</sup> 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/>

<sup>6</sup> 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>

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

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.<sup>10</sup> 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.

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. Transitions 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)<sup>11</sup>, 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 eg for copyright and trademark provisions). Furthermore, some countries were given an option to keep current domestic rules in place when implementing TPP obligations.

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.

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<sup>8</sup> 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>

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

<sup>10</sup> 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>

<sup>11</sup>The U.S.-Central American Free Trade Agreement (FTA, [https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset\\_upload\\_file934\\_3935.pdf](https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file934_3935.pdf);

**Table of Transition Periods for TPP Pharmaceutical Rules**

	<b>Patent Linkage</b>	<b>Marketing Exclusivity (biologics)</b>	<b>Marketing Exclusivity (small molecule)</b>	<b>Extended Exclusivity for New Clinical Information/combinations</b>	<b>Patent Term Adjustment (Regulatory Approval)</b>	<b>Patent Term Adjustment (Patent Examination)</b>
<b>Australia</b>						
<b>Brunei</b>		No transition period <sup>i</sup>	No transition period <sup>i</sup>	No transition period <sup>i</sup>		
<b>Canada</b>						
<b>Chile</b>		No transition period <sup>ii</sup>	No transition period <sup>ii</sup>	No transition period <sup>ii</sup>		
<b>Japan</b>						
<b>Malaysia</b>	4.5 years	5 years <sup>iii</sup>	No transition period <sup>iii</sup>	No transition period <sup>iii</sup>	4.5 years	
<b>Mexico</b>		5 years	5 years	5 years	4.5 years	
<b>New Zealand</b>						
<b>Peru</b>		10 years <sup>iv</sup>	No transition period <sup>iv</sup>	5 years <sup>iv</sup>	No transition period <sup>v</sup>	No transition period <sup>v</sup>
<b>Singapore</b>						
<b>United States</b>						
<b>Vietnam</b>	3 years	10 years <sup>vi</sup>	10 years <sup>vi</sup>	10 years <sup>vi</sup>	5 years <sup>vii</sup>	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.*

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<sup>i</sup> The TPP's "Annex to IP Chapter 5 – Brunei" states "Brunei may, for the purpose of granting protection as specified in Articles 18.E.16.(1), 18.E.16.(2) and 18.E.20.1, require an applicant to commence the process of obtaining marketing approval for pharmaceutical products covered under these Articles within 18 months from the date the product is first granted marketing approval in any country." This provides Brunei 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 Brunei. The Annex to IP Chapter 5 – Brunei goes on to clarify that regulatory exclusivity periods begin on the date of marketing approval for the product in Brunei. The flexibility provided to Brunei as described in the Annex also applies to new clinical information.

<sup>ii</sup> The TPP's "Annex to IP Chapter 4 – 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 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.

<sup>iii</sup> The TPP's "Annex to IP Chapter 5 – Malaysia" states "Malaysia may, for the purpose of granting protection as specified in Articles 18.E.16.(1), 18.E.16.(2) and 18.E.20.1, require an applicant to commence the process of obtaining marketing approval for pharmaceutical products covered under these Articles within 18 months from the date 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. The Annex to IP Chapter 5 – Malaysia 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.

<sup>iv</sup> The TPP's "Annex to IP Chapter – Peru" 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 medicines and biologics as well as for new clinical information) starting from the date of marketing approval on which Peruvian marketing approval relied..

<sup>v</sup> 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 QQ.E.12.3 and QQ.E.14.2." 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.

<sup>vi</sup> A footnote attached to this provision states, "For those transition periods of 10 years, the Parties will consider up to 2 justified requests from Viet Nam for an extension of the transition period for up to 4 additional years upon each request."

<sup>vii</sup> A footnote attached to this provision states, "For transitions for Article QQE14.2 for pharmaceutical products and agricultural chemical products, the Parties will consider a request from Vietnam for an extension of the transition period for up to one additional year. Parties will give sympathetic consideration to such requests."