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## **Addendum II Transition Periods Proposal for Implementation of Onerous Trans-Pacific Partnership Intellectual Property Rules**

*Addendum II Transition Periods Proposal is inferior to the Addendum I Differential Treatment Proposal, but both would lead to eventual implementation of harmful rules in all TPP countries (and soon)*

### Introduction

The intellectual property (IP) chapter of the Trans-Pacific Partnership (TPP) has been an area of particular contention in the negotiations for several years. The rules proposed in the IP chapter would facilitate high medicine prices by requiring broader, longer and stronger patent protections for pharmaceuticals, delaying the entry of generic drug competition and thus allowing multinational pharmaceutical companies to charge exorbitant monopoly prices for more products and for a longer period of time, putting medicines out of reach for those who need them most.

Because of this, many countries that are party to the negotiations have pushed back against the demands of the Office of the U.S. Trade Representative (USTR) being advanced at the behest of the multinational pharmaceutical industry. The courage of those countries should be commended. Because of the resistance of many negotiating countries to these demands, several harmful provisions included in the initial U.S. proposal have been removed from the negotiating text or have been made less damaging.

### **Despite this, proposals under discussion today would still impede access to medicines.**

Negotiating countries are currently discussing options for mitigating the especially grievous consequences that the TPP IP rules would have on access to medicines in developing countries. However, the rules under consideration in the TPP would harm people everywhere – even in wealthy countries. Additionally, the transition periods being contemplated still would not give much time before even the poorest countries would be required to bring their domestic laws fully into compliance with the TPP's harmful rules, limiting their own people's access to medicines and needlessly straining limited public health resources. This paper will explicate one of the options being considered in the negotiations for the amount of time countries would be given to transition from their current laws to the TPP rules should the agreement come into force.

Transition periods are a subject of much discussion at the negotiations right now, and indeed some of the proposals contemplated may be less harmful than others – for example, basing compliance with the

TPP IP rules on development indicators<sup>1</sup> rather than a static period of time – but even that “differential treatment approach” ultimately would only delay countries’ adoption of harmful rules.

None of this discussion should distract from the point that these rules are detrimental to public health and should be rejected entirely.

#### The Addendum II Transition Periods Proposal

Included as Addendum II to the recently leaked Intellectual Property [Rights] Chapter is a Proposal on Patent Pharmaceuticals Transition Periods. This proposal would enable countries to delay for defined periods of time the implementation of certain aspects of the intellectual property chapter based on a certain category classification. The text does not reveal which country or countries authored the proposal, nor does it show which countries support the proposal or which countries oppose it.

The grounds for placement of countries in one of the three categories in Addendum II are not specified in the text.

Category A includes in the United States, Japan and Singapore, with other countries to be confirmed.

Category B includes Mexico and Brunei, with other countries to be confirmed.

Category C includes only Peru and Vietnam.

Australia, Canada, Chile, Malaysia and New Zealand are not yet categorized in the text.

#### Patent term adjustments for regulatory delays (Article QQ.E.14) & patent linkage (Article QQ.E.17)

For the obligations in the IP chapter related to patent term adjustment due to perceived delays in the regulatory approval process<sup>2</sup> and patent linkage<sup>3</sup>, countries would be allowed the following transition periods to bring their domestic laws into compliance with the chapter:

- Category A countries would have to bring their domestic laws into compliance with the IP chapter within 2 years of entry into force of the agreement.
- Category B countries would have to bring their domestic laws into compliance with the IP chapter within 2 + X<sub>1</sub> years of entry into force of the agreement.

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<sup>1</sup> Even the differential treatment proposal is a step back from the necessary, though insufficient improvements made in the May 10 Agreement. See the February 12, 2014 coalition statement, “USTR’s proposal for the Intellectual Property Chapter of the Trans-Pacific Partnership (TPP) will endanger access to medicines for all,” signed by Public Citizen, Médecins Sans Frontières, Oxfam America, Health GAP, Knowledge Ecology International, Misión Salud, Student Global AIDS Campaign, American Medical Students Association, Universities United for Essential Medicines, IFARMA, Políticas Farmacéuticas CEPFAR and Alianza LAC – Global, available at: <http://www.citizen.org/USTR-IP-proposal-for-TPP-endangers-access-to-medicines-for-all-say-health-advocates>.

<sup>2</sup> Patent term adjustment lengthens drug monopolies by requiring countries to extend patent terms if review at the regulatory authority exceeds a prescribed period, delaying entry of generics into the market.

<sup>3</sup> Patent linkage risks facilitating patent abuse by requiring countries to condition marketing approval on patent status. Under patent linkage, patents, even ones that should not have been granted, block generic market entry.

- Category C countries would have to bring their domestic laws into compliance with the IP chapter within  $2 + X_1 + X_2$  years of entry into force of the agreement.

For example, if  $X_1$  were 3 years, then Mexico, a Category B country, would have 5 years (2+3) to bring its domestic laws into compliance with the IP chapter after entry into force of the agreement. If  $X_1$  were 3 years and  $X_2$  were 5 years, then Vietnam, a Category C country, would have 10 (2+3+5) years to bring its domestic laws into compliance with the IP chapter after entry into force of the agreement.

Data exclusivity (Article QQ.E.16.1(a) and (b) and Article QQ.E.20 and Article QQ.E.22)

Additionally, Addendum II would allow for differing transition periods for bringing domestic laws into compliance with the IP chapter regarding obligations included in the article on pharmaceutical data exclusivity<sup>4</sup> - also claimed as data protection. This section of the addendum requires differing periods of data exclusivity depending both on the category of the country and the amount of time that has passed since the agreement entered into force. The table specifying the required data exclusivity periods in this addendum reads as follows:

	<b>2 years after entry into force of the Agreement</b>	<b>2 years after entry into force of the Agreement + [X<sub>1</sub>] years</b>	<b>2 years after entry into force of the Agreement + [X<sub>1</sub>] years + [X<sub>2</sub>] years</b>
Category A	5 years		
Category B	3 years	5 years	
Category C	0 years	3 years	5 years

By way of illustration, as in the example above, from 2 years after entry into force of the agreement:

- Japan, a Category A country, would be required to supply 5 years of data exclusivity for new chemical entities.
- Brunei, a Category B country, would be required to supply 3 years of data exclusivity for new chemical entities.
- Vietnam, a Category C country, would not be required to supply any period of data exclusivity for new chemical entities.

Likewise, if  $X_1 = 3$  years, then from 5 years (2+3) after entry into force of the agreement:

- Category A countries would be required to supply 5 years of data exclusivity for new chemical entities.
- Category B countries would be required to supply 5 years of data exclusivity for new chemical entities.
- Category C countries would be required to supply 3 years of data exclusivity for new chemical entities.

<sup>4</sup> By providing at least five years of exclusivity for information related to new products and three more in cases of new uses for old medicines, data exclusivity further delays entry of generics into the market.

Finally, if  $X_1 = 3$  years and  $X_2 = 5$  years, then from 10 years ( $2+3+5$ ) after entry into force of the agreement:

- Category A countries would be required to supply 5 years of data exclusivity for new chemical entities.
- Category B countries would be required to supply 5 years of data exclusivity for new chemical entities.
- Category C countries would be required to supply 5 years of data exclusivity for new chemical entities.

Thereby, in a relatively short period of time, all countries will be applying the same stringent data exclusivity rules regardless of level of economic development.

Addendum II also outlines a formula for transition periods concerning parties' biologics exclusivity (data and market exclusivity) obligations. Since the parties have not yet established a period for biologics exclusivity even for the richest countries involved in the negotiations, a placeholder is used ( $\Omega$ ).

	<b>2 years after entry into force of the Agreement</b>	<b>2 years after entry into force of the Agreement + <math>[X_1]</math> years</b>	<b>2 years after entry into force of the Agreement + <math>[X_1]</math> years + <math>[X_2]</math> years</b>
Category A	$[\Omega]$ years		
Category B	$[\Omega-3]$ years	$[\Omega]$ years	
Category C	0 years	$[\Omega-3]$ years	$[\Omega]$ years

For the sake of illustration, these examples will operate under the assumption that  $\Omega = 12$  years, as it has been one period of time for biologics exclusivity reported as being discussed. Under this assumption, from 2 years after entry into force of the agreement:

- Category A countries would be required to supply 12 years of exclusivity for biologics.
- Category B countries would be required to supply 9 years ( $12-3$ ) of exclusivity for biologics.
- Category C countries would not be required to supply any period of exclusivity for biologics.

Under the same assumption that  $\Omega = 12$  as well as the assumption that  $X_1 = 3$ , then 5 years ( $2+3$ ) after entry into force of the agreement:

- Category A countries would be required to supply 12 years of exclusivity for biologics.
- Category B countries would be required to supply 12 years of exclusivity for biologics.
- Category C countries would be required to supply 9 years ( $12-3$ ) of exclusivity for biologics.

Finally, under the assumption that  $\Omega = 12$ , as well as the assumptions that  $X_1 = 3$  and  $X_2 = 5$ , then 10 years ( $2+3+5$ ) after entry into force of the agreement:

- Category A countries would be required to supply 12 years of exclusivity for biologics.
- Category B countries would be required to supply 12 years of exclusivity for biologics.

- Category C countries would be required to supply 12 years of exclusivity for biologics.

Addendum II also defines transition periods regarding parties' obligations related to pharmaceutical products and agricultural chemical products referenced in Article QQ.E.22. The article obliges parties not to alter the term of exclusivity for new chemical entities, biologics, or agricultural chemical products in the event that the patent protection on a given product terminates on a date earlier than the termination of its marketing exclusivity.

Category A countries, Category B countries *and any Category C countries which accede to the agreement later than  $2 + X_1$  years after it enters into force*, would be required to bring their domestic law into compliance with Article QQ.E.22, as outlined above, prior to the period of 2 years after entry into force of the agreement +  $X_1$  years. Countries included in Category C *within  $2 + X_1$  years of the agreement entering into force* would be required to bring their domestic law into compliance with Article QQ.E.22, upon 2 years after entry into force of the agreement +  $X_1$  years.

Operating under the assumption that  $X_1 = 3$  years, then prior to 5 years (2+3) after entry into force of the agreement:

- Countries in either Category A or Category B would be required not to alter the term of data exclusivity for new chemical entities, biologics, or agricultural chemical products in the event that the patent protection on a given product terminates on a date earlier than the termination of its marketing data exclusivity.

Also assuming  $X_1 = 3$  years, countries classified in Category C that accede to the agreement later than 5 years (2+3) after the agreement comes into force would already be required to have their domestic law in compliance with Article QQ.E.22.

Under this same assumption that  $X_1 = 3$  years, then upon 5 years (2+3) after entry into force of the agreement:

- Thereafter, Category C countries which accede to the agreement within the first 5 years (2+3) after it goes into effect, would be required not to alter the term of data exclusivity for new chemical entities, biologics, or agricultural chemical products in the event that the patent protection on a given product terminates on a date earlier than the termination of its marketing data exclusivity.

#### Obligations for Countries Acceding to the TPP After Its Entry into Force

Finally, any country which accedes to the TPP after its entry into force (for example, if Colombia were to accede to the TPP after it had already entered into force for the current 12 negotiating parties), it shall be assigned to a category, but the transition schedules will still date back to the initial entry into force of the agreement.

So, considering a hypothetical situation where the current negotiating parties reach an agreement and the TPP enters into force in July 2016, and Colombia accedes to the TPP agreement in July 2017 and is placed in Category B, it would be:

- Required to bring its domestic law into compliance with obligations in the IP chapter related to patent term adjustment due to perceived delays in the regulatory approval process and patent linkage no later than July 2021 (5 years from the initial entry into the force of the agreement); *not* July 2022 (5 years from Colombia's accession to the agreement).
- Required to provide 3 years of data exclusivity for new chemical entities at the time of its accession and then increase its provision of data exclusivity for new chemical entities to 5 years no later than July 2021 (5 years from the initial entry into the force of the agreement); *not* July 2022 (5 years from Colombia's accession to the agreement).
- Required to provide 9 years of data exclusivity for biologics at the time of its accession and then increase its provision of data exclusivity for biologics to 12 years no later than July 2021 (5 years from the initial entry into the force of the agreement); *not* July 2022 (5 years from Colombia's accession to the agreement).
- Required not to alter the term of data exclusivity for new chemical entities, biologics, or agricultural chemical products in the event that the patent protection on a given product terminates on a date earlier than the termination of its marketing data exclusivity, as specified in Article QQ.E.22 prior to acceding to the agreement.

### Commentary

Addendum II stands as an alternative to Addendum I of the TPP IP chapter. Addendum I would allow for certain countries that do not qualify as “high income,” as defined by the International Bank for Reconstruction and Development, not to alter their domestic laws to comply with certain obligations in the IP chapter. While Addendum II sets specific and static times by which parties to the agreement would be required to bring their laws into compliance, Addendum I would only require countries to implement certain obligations if and when it has maintained a certain development threshold (namely, such a “high income” country status for two consecutive years).

While Public Citizen is opposed to the obligations included in the IP chapter regarding data exclusivity, patent term adjustment and patent linkage (just to name a few), and believes it is inappropriate to set rules on intellectual property in the context of opaque trade negotiations – especially when multinational corporations are given privileged access to negotiating texts and greater opportunities to influence the content of the texts over the public and civil society groups working to advance the public interest – we believe the flexibilities provided in Addendum I would allow for the agreement to be less harmful to access to medicines than those provided in Addendum II.

That being said, access to medicines proponents have raised significant and valid concerns with the type of transition period approach outlined in Addendum I – including the scope of countries covered by

differential treatment and indicators used to determine when a country would cross the threshold and be required to implement the full slate of TPP IP provisions.<sup>5</sup>

Addendum II proponents argue that it would provide greater certainty to brand name pharmaceutical companies, but it would require even the lowest resource countries to adopt stringent policies that would extend patent monopolies and limit access to medicines within 10 years of the TPP entering into force (assuming  $X_1 = 3$  and  $X_2 = 5$ ), regardless of a country's ability to absorb the associated costs. Alternatively, Addendum I at least would assure countries that they need not adopt certain policies unless their economy was relatively better placed to handle this additional strain – even if took longer than 10 years to reach such a level of economic development.

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<sup>5</sup> There is a significant body of analysis on the differential treatment approach. For more information, see Baker, Brook "US's Proposed TPP Transition Period for Middle-Income Parties is Fools Gold," available at <http://infojustice.org/archives/31540> and "Differential Treatment and Developing Country Transition Periods in the IP Chapter of the TPP," available at <http://infojustice.org/archives/31646>, Love, James "The World Bank definition of 'high income' has slipped, in relative terms, compared to high income countries in general" available at <http://www.keionline.org/node/1834>, Palmedo, Mike "In Search of the Least-Bad Threshold for Differential Treatment for TPP Obligations on Intellectual Property and Access to Medicines" available at <http://infojustice.org/archives/32393>, and Balasegaram, Dr. Manica "TPP: Still a Terrible Deal for Poor People's Health" available at [http://www.huffingtonpost.com/dr-manica-balasegaram/tpp-still-a-terrible-deal\\_b\\_5584810.html](http://www.huffingtonpost.com/dr-manica-balasegaram/tpp-still-a-terrible-deal_b_5584810.html).

## Appendix 1: Charts

The following charts provide examples of the schedule of countries' obligations under Addendum II, operating under the assumptions that  $X_1 = 3$  years,  $X_2 = 5$  years, and  $\Omega = 12$  years.

Chart 1: Countries obligations 2 years after entry into force of the agreement

	<b>Patent Term Adjustment &amp; Patent Linkage</b>	<b>Data Exclusivity for New Chemical Entities</b>	<b>Data Exclusivity for Biologics</b>
<b>Japan</b>	Required to have implemented Article QQ.E.14 & Article QQ.E.17	Required to supply 5 years of data exclusivity	Required to supply 12 years of exclusivity
<b>Mexico</b>	Not yet obligated to have implemented Article QQ.E.14 or Article QQ.E.17	Required to supply 3 years of data exclusivity	Required to supply 9 years of exclusivity
<b>Vietnam</b>	Not yet obligated to have implemented Article QQ.E.14 or Article QQ.E.17	Not required to supply any period of data exclusivity	Not required to supply any period of exclusivity
<b>Colombia (Classified under Category B; acceding to the agreement one year after it has entered into force)</b>	Not yet obligated to have implemented Article QQ.E.14 or Article QQ.E.17	Required to supply 3 years of data exclusivity	Required to supply 9 years of exclusivity

Chart 2: Countries obligations 5 years after entry into force of the agreement

	<b>Patent Term Adjustment &amp; Patent Linkage</b>	<b>Data Exclusivity for New Chemical Entities</b>	<b>Data Exclusivity for Biologics</b>
<b>Japan</b>	Required to have implemented Article QQ.E.14 & Article QQ.E.17	Required to supply 5 years of data exclusivity	Required to supply 12 years of exclusivity
<b>Mexico</b>	Required to have implemented Article QQ.E.14 & Article QQ.E.17	Required to supply 5 years of data exclusivity	Required to supply 12 years of exclusivity
<b>Vietnam</b>	Not yet obligated to have implemented Article QQ.E.14 or Article QQ.E.17	Required to supply 3 years of data exclusivity	Required to supply 9 years of exclusivity
<b>Colombia (Classified under Category B; acceding to the agreement one year after it has entered into force)</b>	Required to have implemented Article QQ.E.14 & Article QQ.E.17	Required to supply 5 years of data exclusivity	Required to supply 12 years of exclusivity

Chart 3: Countries obligations 10 years after entry into force of the agreement

	<b>Patent Term Adjustment &amp; Patent Linkage</b>	<b>Data Exclusivity for New Chemical Entities</b>	<b>Data Exclusivity for Biologics</b>
<b>Japan</b>	Required to have implemented Article QQ.E.14 & Article QQ.E.17	Required to supply 5 years of data exclusivity	Required to supply 12 years of exclusivity
<b>Mexico</b>	Required to have implemented Article QQ.E.14 & Article QQ.E.17	Required to supply 5 years of data exclusivity	Required to supply 12 years of exclusivity
<b>Vietnam</b>	Required to have implemented Article QQ.E.14 & Article QQ.E.17	Required to supply 5 years of data exclusivity	Required to supply 12 years of exclusivity
<b>Colombia (Classified under Category B; acceding to the agreement one year after it has entered into force)</b>	Required to have implemented Article QQ.E.14 & Article QQ.E.17	Required to supply 5 years of data exclusivity	Required to supply 12 years of exclusivity

Chart 4: Obligations of countries regarding Article QQ.E.22 – Prohibition of altering the term of data exclusivity in the event of the termination of patent protection

	<b>Upon Entry into Force of the Agreement</b>	<b>5 Years After Entry into Force of the Agreement</b>	<b>Upon Country's Accession to the Agreement</b>
<b>Japan</b>	Required to have implemented obligations under Article QQ.E.22	Required to have implemented obligations under Article QQ.E.22	N/A
<b>Mexico</b>	Required to have implemented obligations under Article QQ.E.22	Required to have implemented obligations under Article QQ.E.22	N/A
<b>Vietnam</b>	Not yet required to have implemented obligations under Article QQ.E.22	Required to have implemented obligations under Article QQ.E.22	N/A
<b>Category C Country Acceding to Agreement Within 5 Years of Agreement Entering into Force</b>	N/A	Required to have implemented obligations under Article QQ.E.22	Not yet required to have implemented obligations under Article QQ.E.22
<b>Category C Country Acceding to Agreement After 5 Years of Agreement Entering into Force</b>	N/A	N/A	Required to have implemented obligations under Article QQ.E.22